



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

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PALO ALTO, Calif., Nov. 13, 2025 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), today reported recent business highlights and financial results for the third quarter ended September 30, 2025.

"Kodiak Sciences has entered a period of strong, sustained momentum driven by compelling clinical data, accelerated execution and growing external enthusiasm...across all three of our late-stage programs," said Victor Perloth, M.D., Chief Executive Officer of Kodiak Sciences.

"Looking ahead, we expect this momentum to continue building as we enter an action-packed 2026 with all three of our Phase 3 assets on track for Phase 3 topline data readouts as well as our first planned BLA filing. On top of our late-stage programs, Kodiak's early-stage pipeline is also advancing with increasing speed and conviction, positioning Kodiak for sustained scientific and pipeline leadership globally," continued Dr. Perloth.

Recent Business Highlights

- **Announced follow-up data through week 20 from the Phase 1b APEX study of KSI-101 in patients with macular edema secondary to inflammation (MESI)**
 - Meaningful vision gains were rapidly achieved as early as week 4 and showed continued improvement in best corrected visual acuity (BCVA) through week 20, with more than half of patients achieving improvement of 3-lines or more on the eye chart (≥ 15 letter gain).
 - $\geq 90\%$ of patients in the top two dose levels achieved and sustained real dryness of the retina, as demonstrated by absence of intraretinal fluid (IRF) as well as subretinal fluid (SRF), key markers of disease activity.
 - The Phase 3 PEAK and PINNACLE studies of KSI-101 are enrolling at a faster-than-expected pace, evaluating the top two dose levels (5 mg and 10 mg) in patients with MESI.
- **Validation from the scientific community for the mechanism of action behind KSI-101**
 - At the recent American Academy of Ophthalmology (AAO) meetings, intraocular interleukin-6 inhibition was shown in Phase 3 clinical trials to deliver a meaningful improvement in vision and anatomy in patients with uveitic macular edema, a key component of MESI. Local IL-6 inhibition also appeared to be well tolerated in these trials.
 - Data appear to highlight a significant opportunity for KSI-101, a potent inhibitor of interleukin-6 that layers on potent inhibition of VEGF, to drive a stronger clinical effect.
- **Completed enrollment in the Phase 3 DAYBREAK study of both tarcocimab and KSI-501 in patients with treatment naive neovascular age-related macular degeneration (wet AMD)**
 - DAYBREAK enrolled approximately 690 subjects, with last visit for the 48-week primary endpoint expected in August 2026.
- **Hosted an investor R&D Day webcast on July 16, 2025, providing a comprehensive overview of Kodiak's three late-phase clinical assets**
 - Presentations by **Dr. Charles Wykoff** and **Dr. Sumit Sharma**, leading retina specialists, shared perspectives on Kodiak's clinical assets.
 - Key highlights included KSI-101: Strong 12-week APEX data; initial addressable market of 150,000+ patients.

Upcoming Catalysts

- **Tarcocimab**
 - Phase 3 GLOW2 diabetic retinopathy study – topline data on track for 1Q 2026
 - Phase 3 DAYBREAK wet AMD study – topline data expected 3Q 2026
- **KSI-501**
 - Phase 3 DAYBREAK wet AMD study – topline data expected 3Q 2026
- **KSI-101 in MESI**
 - Phase 1b APEX study – Week 24 data to be presented by Dr. Sumit Sharma on February 7 at the Angiogenesis, Exudation, and Degeneration 2026 Annual Meeting
 - Phase 3 PEAK study – topline data expected 4Q 2026
 - Phase 3 PINNACLE study – topline data expected 1Q 2027

Third Quarter 2025 Financial Results

Cash Position

Kodiak ended the third quarter of 2025 with \$72.0 million cash and cash equivalents.

Net Loss

Net loss for the third quarter of 2025 was \$61.5 million, or \$1.16 per share on a basic and diluted basis, as compared to a net loss of \$43.9 million, or

\$0.84 per share on a basic and diluted basis, for the third quarter of 2024. Net loss for the third quarter of 2025 included non-cash stock-based compensation expense of \$14.0 million, as compared to \$14.8 million for the third quarter of 2024.

R&D Expenses

Research and development ("R&D") expenses were \$50.5 million for the third quarter of 2025, as compared to \$31.9 million for the third quarter of 2024. R&D expenses for the third quarter of 2025 included non-cash stock-based compensation expense of \$7.2 million, as compared to \$6.3 million for the third quarter of 2024. The increase in R&D expenses in the third quarter of 2025 was primarily driven by increased clinical activities related to our active DAYBREAK and PEAK/PINNACLE studies and increased manufacturing activities across our Phase 3 programs.

G&A Expenses

General and administrative ("G&A") expenses were \$11.9 million for the third quarter of 2025, as compared to \$14.8 million for the third quarter of 2024. G&A expenses for the third quarter of 2025 included non-cash stock-based compensation expense of \$6.9 million, as compared to \$8.5 million for the third quarter of 2024. Additionally, sublease income from one of our corporate office buildings helped offset G&A expenses in the third quarter of 2025.

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. In the DAYLIGHT study, tarcocimab demonstrated non-inferior efficacy results and compelling safety and tolerability on a once monthly dosing interval.

Tarcocimab is currently being studied in two Phase 3 clinical trials, the GLOW2 study in DR and the DAYBREAK study in wet AMD. Both studies have completed enrollment. 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 study 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 tedomer 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 durability potential, strengthen its competitive position in wet AMD and bolster the possible regulatory application package for the program. DAYBREAK was designed to showcase the potential for tarcocimab to be a mainstay biologic for VEGF-driven retinal vascular diseases with both a strong efficacy/immediacy (driven by its enhanced formulation) and a 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 has completed enrollment. 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 IL-6 and VEGF inhibition in a broad treatment-naïve wet AMD population. DAYBREAK has completed enrollment. 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. We are developing KSI-101 for patients with macular edema (retinal fluid) secondary to inflammation (MESI). MESI is a heterogeneous group of diseases that clinically present with macular edema and visual impairment which are caused by a common pathophysiology of inflammation and blood retinal barrier disruption. The clinical presentation of retinal fluid and visual impairment is a mainstay in these patients, irrespective of the location of the inflammation inside of the eye (anterior, intermediate, posterior or all intraocular compartments) or the specific etiology (defined autoimmune associated, idiopathic, post-procedural, or inflammatory choroidal neovascularization).

Currently there are no available intravitreal biologic therapies addressing the spectrum of MESI diseases. We believe that MESI represents a new market segment separate from the established anti-VEGF market.

We have completed enrollment 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"). APEX demonstrated that KSI-101 provides meaningful visual and anatomical gains in both DME and MESI and that KSI-101 is well tolerated. Meaningful treatment responses were seen in the MESI population, irrespective of the location of inflammation and specific MESI etiology, opening up the potential for KSI-101 to become a unifying treatment for this patient population.

Based on APEX, the top two dose levels tested were selected to advance into the Phase 3 program. The PEAK and PINNACLE Phase 3 studies are actively enrolling MESI subjects at the 5 mg and 10 mg dose levels versus sham.

About PEAK and PINNACLE

The PEAK and PINNACLE studies are superiority studies evaluating two dose levels of KSI-101 (5 mg and 10 mg) compared to sham treatment in patients with MESI. PEAK and PINNACLE are identical in study design with key differences in patient population. PEAK includes patients with more severe disease (moderate to severe macular edema and vision impairment) and PINNACLE includes patients with milder disease (mild macular edema and any vision impairment), as well as patients with moderate to severe macular edema with good vision. Together, PEAK and PINNACLE are designed to enroll complementary patient populations and to cover a wide spectrum of MESI patients.

Patients randomized to the KSI-101 treatment arms will receive fixed monthly dosing for 6 doses (from Day 1 to Week 20), with subsequent individualized dosing (up to monthly dosing) for 6 additional visits (Week 24 to Week 44). Patients in the sham arm will receive monthly sham dosing for 6 doses followed by sham PRN.

The primary and key secondary endpoints will be evaluated at Week 24. PEAK and PINNACLE are now actively enrolling patients. Additional information about PEAK and PINNACLE can be found on www.clinicaltrials.gov under Trial Identifiers NCT06990399 and NCT06996080, respectively (<https://clinicaltrials.gov/study/NCT06990399>; <https://clinicaltrials.gov/study/NCT06996080>).

About Kodiak Sciences Inc.

Kodiak Sciences (Nasdaq: KOD) is a precommercial retina focused biotechnology company committed to researching, developing and commercializing transformative therapeutics. 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 late-stage clinical programs. Tarcocimab and KSI-501 are being explored in two BLA-facing Phase 3 studies in the retinal vascular diseases, targeting the \$15 billion anti-VEGF marketplace, with topline data readouts expected in 1Q 2026 and 3Q 2026. KSI-101 is a bispecific protein being explored in two Phase 3 studies in Macular Edema Secondary to Inflammation (MESI), with topline data readouts expected in 4Q 2026 (PEAK) and 1Q 2027 (PINNACLE).

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: timing of topline data; timing of upcoming studies; planned regulatory submissions; the potential for Kodiak to achieve sustained scientific and pipeline leadership; the potential benefits of and market opportunities for tarcocimab, KSI-501 and KSI-101; maximizing the probability of meeting the primary endpoint of DAYBREAK and demonstrating additional efficacy benefits of tarcocimab; 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; the ultimate objective of tarcocimab to provide a flexible 1-month through 6-month label for all patients with retinal vascular disease; and tarcocimab's potential to achieve strong efficacy both in treating existing disease and preventing vision threatening complications and disease progression. 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 risks and uncertainties that could cause actual results to differ materially and adversely from those in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the risk that cessation, modification or delay of any of the ongoing 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; the risk that any one or more of our product candidates may not be successfully developed, approved or commercialized; our manufacturing facilities may not operate as expected; the risk that adverse economic conditions may significantly impact our business and operations, including our clinical trial sites, and those of our manufacturers, contract research organizations or others with whom we conduct business; the risk that sufficient capital may not be available as expected, or at all, to complete the development of any products; as well as the other risks identified in our filings with the Securities and Exchange Commission (SEC). 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 sections entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2024, our subsequent Quarterly Reports in Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the SEC. 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 Sciences Inc.

Condensed Consolidated Statements of Operations (unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development	\$ 50,476	\$ 31,878	\$ 136,880	\$ 94,323
General and administrative	11,876	14,754	40,055	46,347
Total operating expenses	<u>62,352</u>	<u>46,632</u>	<u>176,935</u>	<u>140,670</u>
Loss from operations	(62,352)	(46,632)	(176,935)	(140,670)
Interest income	917	2,711	3,760	9,018
Other expense, net	(22)	(25)	(56)	(450)
Net loss and comprehensive loss	<u>\$ (61,457)</u>	<u>\$ (43,946)</u>	<u>\$ (173,231)</u>	<u>\$ (132,102)</u>
Net loss per share, basic and diluted	<u>\$ (1.16)</u>	<u>\$ (0.84)</u>	<u>\$ (3.28)</u>	<u>\$ (2.51)</u>
Weighted-average shares outstanding, basic and diluted	<u>52,859,308</u>	<u>52,616,183</u>	<u>52,795,343</u>	<u>52,560,489</u>

Kodiak Sciences Inc.

Condensed Consolidated Balance Sheet Data (unaudited)

(in thousands)

	September 30, 2025	December 31, 2024
Cash and cash equivalents	\$ 72,038	\$ 168,074
Working capital	33,299	146,363
Total assets	218,069	335,578
Accumulated deficit	(1,501,969)	(1,328,738)
Total stockholders' equity	23,692	150,288

 View original content: <https://www.prnewswire.com/news-releases/kodiak-sciences-announces-recent-business-highlights-and-third-quarter-2025-financial-results-302615021.html>

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