Kodiak Sciences Announces Recent Business Highlights and Third Quarter 2026 Financial Results

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PALO ALTO, Calif., Nov. 12, 2026 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), today reported recent business highlights and financial results for the third quarter ended September 30, 2026.

"We believe Kodiak stands apart in retina, with three late-stage assets that together give us the opportunity to build a leading retinal medicines company," said Victor Perlroth, M.D., Chief Executive Officer of Kodiak Sciences. "The DAYBREAK results reinforce Zenkuda's potential to become a first-line therapy in wet AMD, combining rapid disease control with a 24-week dosing interval for the majority of patients under strict treat-to-dry and maintain dry criteria reflective of real-world clinical practice. Tabirafusp-ted has delivered a positive Phase 3 readout in wet AMD and is actively enrolling in our Phase 3 ALTO study in diabetic macular edema. And KSI-101 is rapidly approaching its first pivotal readout in macular edema secondary to inflammation, a patient population with severe disease and no approved intravitreal biologic therapy. The breadth of this portfolio creates multiple opportunities to bring new medicines to patients across major retinal diseases."

"Looking ahead, we expect to announce the first Phase 3 KSI-101 results in December and, if successful, plan to file a BLA for KSI-101 in the second quarter of 2027. We are also on track to submit the multi-indication BLA for Zenkuda by year end, supported by five successful Phase 3 studies," continued Dr. Perlroth. "These milestones will bring us closer to our goal of improving vision for patients by providing retina specialists with new treatment options for both retinal vascular and inflammatory diseases."

Recent Business Highlights

Phase 3 DAYBREAK Study — Zenkuda (tarcocimab tedromer) met the primary endpoint

- Zenkuda met the primary endpoint (p-value of 0.0007) demonstrating meaningful vision gains as well as rapid and sustained retinal drying with the majority of patients (54%) on 6-month dosing, establishing a first-line benchmark in wet age-related macular degeneration (wet AMD).
- Zenkuda demonstrated safety consistent with the established safety profile of aflibercept.

Zenkuda — Advancing Toward Biologics License Application (BLA) Submission

- Zenkuda multi-indication biologics license application (BLA) planned for the fourth quarter of 2026 to include five positive Phase 3 studies across wet AMD, diabetic retinopathy and retinal vein occlusion.

Phase 3 DAYBREAK Study — Tabirafusp alfa tedromer (tabirafusp-ted) met the primary endpoint

- Tabirafusp-ted met the vision primary endpoint (p-value of 0.0036) and anatomical key secondary endpoint (p-value of <0.0001).
- Tabirafusp-ted demonstrated safety consistent with the established safety profile of aflibercept.
- Post-hoc analyses to identify which treatment naïve wet AMD patient sub-groups can benefit from IL-6 inhibition are planned. Tabirafusp-ted development program is accelerating in diabetic macular edema and actively enrolling in the ALTO Phase 3 Study.

Phase 3 PEAK Study (KSI-101) – Pivotal Analysis 1 Topline Data Expected December 2026

- Enrollment of the first 300-patient cohort in the PEAK trial supporting Pivotal Analysis 1 has completed and topline results remain on track for a December 2026 release.
- Completion of enrollment in the second pivotal cohort evaluating 600 subjects across the PEAK and PINNACLE studies is expected in the fourth quarter of 2026, with topline clinical data release anticipated in the second quarter of 2027.

Raised net proceeds of $69 million after the third quarter

- Subsequent to September 30, 2026 , Kodiak raised aggregate net proceeds of $69 million from sales of common stock under its at-the-market (ATM) equity offering facility.

Third Quarter 2026 Financial Results

Cash Position

Kodiak ended the third quarter of 2026 with $88.7 million of cash and cash equivalents. We expect that our current cash and cash equivalents will support our current and planned operations into 2027.

Subsequent to September 30, 2026, Kodiak raised aggregate net proceeds of $69 million through sales of common stock under its ATM equity offering facility.

Net Loss

Net loss for the third quarter of 2026 was $66.2 million, or $1.05 per share on a basic and diluted basis, as compared to a net loss of $61.5 million, or $1.16 per share on a basic and diluted basis, for the third quarter of 2025. Net loss for the third quarter of 2026 included non-cash stock-based compensation expense of $12.8 million, as compared to $14.0 million for the third quarter of 2025.

R&D Expenses

Research and development (R&D) expenses were $58.3 million for the third quarter of 2026, as compared to $50.5 million for the third quarter of 2025. R&D expenses for the third quarter of 2026 included non-cash stock-based compensation expense of $6.7 million, as compared to $7.2 million for the third quarter of 2025. The increase in R&D expenses in the third quarter of 2026 was primarily driven by increased clinical activities related to our active PEAK/PINNACLE and ALTO studies and increased manufacturing activities to support our Phase 3 programs.

G&A Expenses

General and administrative (G&A) expenses were $8.8 million for the third quarter of 2026, as compared to $11.9 million for the third quarter of 2025. G&A expenses for the third quarter of 2026 included non-cash stock-based compensation expense of $6.1 million, as compared to $6.9 million for the third quarter of 2025. The remaining decrease in G&A expenses was primarily driven by a non-cash non-recurring gain recognized upon termination of one of our Palo Alto, California building leases, in exchange for which we received an option to lease a separate building on the same campus with certain lease incentives.

About Zenkuda™(tarcocimab tedromer)

Zenkuda is an anti-vascular endothelial growth factor ("VEGF") biopharmaceutical built on Kodiak's proprietary ABC platform for intravitreal administration. Zenkuda has a mean ocular half-life in humans of 20 days, approximately three times longer than approved anti-VEGF therapies and is designed to maintain potent and effective drug levels in ocular tissues for longer. Zenkuda is being developed as a mainstay intravitreal biologic monotherapy that provides rapid initial effect and real-world durability, driven by the ABC platform and Kodiak's 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, and severe patients).

Zenkuda has completed five successful Phase 3 pivotal studies: the Phase 3 DAYBREAK and DAYLIGHT studies in wet age-related macular degeneration ("wet AMD"), the Phase 3 GLOW1 and GLOW2 studies in diabetic retinopathy ("DR") and the Phase 3 BEACON study in retinal vein occlusion ("RVO"). In the DAYBREAK study, Zenkuda met the primary endpoint (p-value of 0.0007) demonstrating meaningful vision gains as well as rapid and sustained retinal drying with the majority of patients (54%) on 6-month dosing, establishing a first-line benchmark in wet AMD. In the GLOW1 and GLOW2 studies, Zenkuda successfully treated DR patients and prevented disease progression with 100% of patients on extended 6-month dosing at Year 1. In the BEACON study, during the first 6 months, Zenkuda-treated patients were dosed at 8-week intervals (as opposed to 4-week intervals for aflibercept). In the second 6 months, identical retreatment criteria were used for the Zenkuda and aflibercept arms, and nearly half of Zenkuda patients did not require any treatment while achieving similar vision and anatomical outcomes as the aflibercept group at one year. We are planning to submit a three-indication (wet AMD, DR, and RVO) biologics license application ("BLA") for Zenkuda in the fourth quarter of 2026.

About DAYBREAK (and Zenkuda)

The Phase 3 DAYBREAK study was a non-inferiority study evaluating parallel investigational arms of Zenkuda and KSI-501 against active comparator aflibercept. Patients randomized to Zenkuda received individualized dosing every 4 to 24 weeks on an as needed basis following four monthly loading doses. Patients randomized to aflibercept were dosed per label. The individualized dosing of Zenkuda was determined by a treat-to-dry and maintain dry proactive approach using the presence of retinal fluid as a disease activity marker, which resembles retina specialists' practice and optimizes each patient's treatment, instead of using a combination of central subfield thickness and vision loss. Specific objectives for Zenkuda in DAYBREAK were (1) to assess safety, (2) to meet the primary endpoint of non-inferiority of best corrected visual acuity, (3) to explore the strength of fluid control and vision gain through the loading phase, and (4) to demonstrate a differentiated, real-world durability profile. General objectives for Zenkuda in DAYBREAK were to 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 Zenkuda 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). The Phase 3 DAYBREAK study met the one-year primary endpoint of non-inferiority of best corrected visual acuity in September 2026. In the ongoing second year of the DAYBREAK study, patients will continue to receive treatment to further assess Zenkuda's differentiated profile.

About Tabirafusp-ted (KSI-501)

Tabirafusp-ted is an 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. Tabirafusp-ted 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.

We advanced tabirafusp-ted into the registrational Phase 3 DAYBREAK study to evaluate its efficacy and safety in wet AMD. DAYBREAK used tabirafusp-ted's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to balance immediacy and durability. In the DAYBREAK study, tabirafusp-ted met the vision primary endpoint (p-value of 0.0036) and anatomical key secondary endpoint (p-value of <0.0001). Kodiak has also advanced tabirafusp-ted into the registrational Phase 3 ALTO study designed to explore the superiority of bispecific tabirafusp-ted (anti-VEGF, anti-IL-6) versus monospecific aflibercept (anti-VEGF) in patients with diabetic macular edema ("DME"). The ALTO study is now enrolling patients.

About DAYBREAK (and tabirafusp-ted)

The DAYBREAK study was a non-inferiority study evaluating parallel investigational arms of KSI-501 and Zenkuda against active comparator aflibercept. Patients randomized to KSI-501 received fixed every 8-week dosing with additional individualized dosing (up to monthly dosing) on an as needed basis after four monthly loading doses. Patients randomized to aflibercept were dosed per label. Using the same treat-to-dry and maintain dry approach as Zenkuda, coupled with fixed intensive proactive dosing, the goal was to maximize both the probability of meeting the primary endpoint as well as the probability of demonstrating additional efficacy benefits. The primary endpoint was 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 was to explore the efficacy potential of bispecific IL-6 and VEGF

inhibition in a broad treatment-naïve wet AMD population. The Phase 3 DAYBREAK study met the one-year primary endpoint of non-inferiority of best corrected visual acuity in September 2026. The ongoing second year of the DAYBREAK study will further assess the long-term efficacy profile of tabirafusp-ted and explore whether dual inhibition of IL-6 and VEGF can deliver additional benefits for specific patient groups within the study's broad treatment-naïve wet AMD population.

About ALTO

The ALTO Study is a global, multicenter, randomized, double-masked, active comparator-controlled Phase 3 study evaluating the efficacy and safety of intravitreal tabirafusp-ted 5 mg compared with intravitreal aflibercept 2 mg in patients with visual impairment secondary to center-involved DME. Approximately 910 patients, treatment-naïve or previously treated, will be randomized 5:3:5 to one of three arms: (A) tabirafusp-ted 5 mg every 8 weeks, with monthly assessment for additional individualized dosing, following six monthly loading doses; (B) tabirafusp-ted 5 mg on an individualized regimen of every 4 to 24 weeks, following six monthly loading doses; and (C) aflibercept 2 mg every 8 weeks, following five monthly loading doses.

The primary endpoint is non-inferiority of the mean change in best-corrected visual acuity from baseline to the average of Week 48 and Week 52. The key secondary endpoint is the proportion of patients improving two or more steps on the DRSS from baseline at Week 48. Additional secondary and exploratory endpoints evaluate visual function, retinal anatomy, treatment burden and durability, and safety.

The ALTO study will include a second year of treatment and follow-up to explore tabirafusp-ted's potential to deliver sustained visual and anatomical benefits with fixed (Arm A) or extended (Arm B) treatment intervals. By combining inhibition of VEGF and IL-6 with the durability of the ABC platform, tabirafusp-ted aims to raise the standard of care for patients with DME through improved vision, fluid control, and reduced treatment burden.

About KSI-101

KSI-101 is a novel, potent and high strength (100 mg/mL) antibody-based therapy with a bispecific mechanism of action targeting both 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. Existing therapies remain limited by side effects and tolerability, underscoring the need for safer and more effective treatment options. MESI represents a new macular edema market segment separate from the established anti-VEGF market.

Data from our dose-finding Phase 1b APEX study demonstrated robust anatomical and visual responses across MESI patients. More than half of patients achieved ≥15-letter gains in best corrected visual acuity, with additional benefit at higher dose levels. Rapid vision improvements and anatomical response were observed with 10-letter gains by Week 4 in top dose groups and OCT CST <325 microns achieved as early as Week 1 in top dose groups. Continued anatomical improvement was observed over time with >90% resolution of intraretinal ("IRF") and subretinal fluid ("SRF") by Week 8 and 20/25 Snellen visual acuity by Week 20. In top dose groups, ≥90% achieved complete absence of IRF and SRF, indicating retinal dryness and normalization of retinal architecture. KSI-101 also continued to be well tolerated with a favorable safety profile. The top two dose levels in APEX have been advanced into the Phase 3 pivotal studies, PEAK and PINNACLE. Enrollment of the first 300-patient cohort in the PEAK trial supporting Pivotal Analysis 1 has completed and topline results remain on track for a December 2026 release. Completion of enrollment in the second pivotal cohort evaluating 600 subjects across the PEAK and PINNACLE studies is expected in the fourth quarter of 2026, with topline clinical data release anticipated in the second quarter of 2027.

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. We have completed enrollment of the first 300-patient pivotal cohort in the PEAK trial, supporting Pivotal Analysis 1, with topline clinical data from the 24-week primary endpoint on track for a December 2026 release. Completion of enrollment in the second pivotal cohort, evaluating 600 patients across the PEAK and PINNACLE studies, is expected in the fourth quarter of 2026, with topline clinical data release anticipated in the second quarter of 2027.

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. We are developing a portfolio of three late-stage clinical programs. Zenkuda (tarcocimab tedromer) has a BLA-ready profile in wet AMD, diabetic retinopathy, and retinal vein occlusion. KSI-501 is being evaluated in wet AMD and diabetic macular edema. Zenkuda and KSI-501 target the $15 billion anti-VEGF market across retinal vascular diseases. KSI-101 is a bispecific protein being explored in two BLA-facing Phase 3 studies in Macular Edema Secondary to Inflammation (MESI). Topline data for Pivotal Analysis 1 (PEAK) are expected in December 2026 and Pivotal Analysis 2 (PEAK+PINNACLE) in 2Q 2027.

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Forward-Looking Statements

This press 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: Kodiak's planned BLA submission for Zenkuda by year-end and for KS-101 in the second quarter of 2027; expectations regarding ongoing second-year treatment, follow-up and analyses in the DAYBREAK Phase 3 study for both Zenkuda and KSI-501; the status of enrollment in, and expectations regarding the timing of topline data readouts from, the PEAK and PINNACLE Phase 3 studies; and the status of enrollment in, and expectations regarding the ALTO study. 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 "anticipate," "believe," "could," "expect," "intend," "may," "plan," "pursue," "should," "will," "would," 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. These risks and uncertainties include, but are not limited to the risk that: the completed Phase 3 studies for Zenkuda may not be sufficient to support a BLA submission or approval in wet AMD, DR, or RVO; a BLA for Zenkuda or any other product candidate may not be accepted by, or receive approval from, the FDA or foreign regulatory agencies when expected, or at all; cessation, modification, or delay of any ongoing clinical studies and Kodiak's development of Zenkuda, KSI-501, KSI-101, or any other product candidate may occur; safety, efficacy, and durability data observed in Kodiak's product candidates in current or prior studies may not continue or persist; KSI-501 may not inhibit VEGF and IL-6 or have an impact on the treatment of patients as expected; the PEAK Phase 3 study for KSI-101 may not achieve its primary endpoint or may not do so on the anticipated timeline; any one or more of Kodiak's product candidates may not be successfully developed, approved, or commercialized; sufficient capital may not be available as expected, or at all, to complete the development of any products; our financial condition raises substantial doubt about our ability to continue as a going concern; adverse conditions in the U.S. and global economic markets may significantly impact Kodiak's business and operations, including its clinical trial sites, as well as the business or operations of its manufacturers, contract research organizations, or other third parties with whom Kodiak conducts business; as well as the other risks identified in the section entitled "Risk Factors" in Kodiak's Annual Report on Form 10-K for the year ended December 31, 2025, as well as discussions of potential risks, uncertainties, and other important factors in Kodiak's subsequent filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and Kodiak undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise. 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,	
	2026	2025	2026	2025
Operating expenses				
Research and development	$ 58,304	$ 50,476	$ 162,934	$ 136,880
General and administrative	8,794	11,876	30,779	40,055
Total operating expenses	67,098	62,352	193,713	176,935
Loss from operations	(67,098)	(62,352)	(193,713)	(176,935)
Interest income	899	917	3,795	3,760
Other income (expense), net	(24)	(22)	(106)	(56)
Net loss and comprehensive loss	$ (66,223)	$ (61,457)	$ (190,024)	$ (173,231)
Net loss per share, basic and diluted	$ (1.05)	$ (1.16)	$ (3.04)	$ (3.28)
Weighted-average shares outstanding, basic and diluted	62,960,644	52,859,308	62,486,988	52,795,343

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

	September 30, 2026	December 31, 2025
Cash and cash equivalents	$ 88,678	$ 209,862
Working capital	38,146	169,283
Total assets	209,413	351,533
Accumulated deficit	(1,748,729)	(1,558,705)
Total stockholders' equity	12,572	157,383

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