Kodiak Sciences Announces Recent Business Highlights and Second Quarter 2024 Financial Results

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PALO ALTO, Calif., Aug. 14, 2024 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), today reported business highlights and financial results for the quarter ended June 30, 2024.

"Our three clinical programs of tarcocimab, KSI-501 and KSI-101 are making strong operational progress," said Victor Perlroth, M.D., Chief Executive Officer of Kodiak Sciences. "The Phase 3 GLOW2 study of tarcocimab in diabetic retinopathy continues to enroll. The Phase 3 DAYBREAK study of tarcocimab and KSI-501 is now actively enrolling patients. DAYBREAK features an innovative study design that includes parallel investigational arms of tarcocimab and KSI-501 against aflibercept in wet AMD, and if successful, could support the marketing authorization applications for both investigational medicines. We have also activated the Phase 1b APEX study of KSI-101 in patients with macular edema secondary to inflammation, and the APEX study is now enrolling patients."

"This past quarter we also strengthened our executive team with the appointment of leaders from both outside and inside our organization," continued Dr. Perlroth. "From outside the organization, we welcomed Dolly Chang, M.D, M.P.H, Ph.D., to the position of Chief Scientific Officer. Dr. Chang joins Kodiak from Genentech, a member of the Roche Group, where she was responsible for Genentech's early-stage ophthalmology pipeline. Dr. Chang brings deep ophthalmology experience in support of Kodiak's early-stage research programs and late-phase Phase 3 programs. From inside the organization, we made new leadership appointments with the promotions of Almas Qudrat, M.Sc., to Chief Quality Officer and Pablo Velazquez-Martin, M.D., to Chief Medical Officer. These two appointments support Kodiak's commercial-facing manufacturing activities including our URSUS facility and our BLA-facing clinical activities including our new set of pivotal studies. We also recognize the on-going maturation of our triplets biopolymer platform with the promotion of Wayne To, M.Phil., to the position of Chief Technology Officer."

"We look forward to sharing ongoing progress of our science and development programs and are planning to host an Investor Day on September 23, 2024, with details to be announced ahead of the event," concluded Dr Perlroth.

Recent Business Highlights

- ***New leadership appointments:***
    - Kodiak welcomed Dolly Chang, M.D., M.P.H., Ph.D. as Chief Scientific Officer. Dr. Chang joins Kodiak from Genentech, where she held positions of increasing responsibility and directed the early-stage research and clinical ophthalmology pipeline
    - Almas Qudrat, M.Sc., was appointed Chief Quality Officer, in recognition of Kodiak's increasing commercial-facing manufacturing activities
    - Wayne To, M.Phil., was appointed Chief Technology Officer to oversee the maturation of our biopolymer derived triplets platform
    - Pablo Velazquez-Martin, M.D., was appointed Chief Medical Officer, in recognition of Kodiak's increasing BLA-facing clinical activities

- ***Tarcocimab pivotal program:*** We previously announced that first patients were treated in the GLOW2 Phase 3 study of tarcocimab in diabetic retinopathy ("DR").

  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 to 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.

  GLOW2 is the second Phase 3 study of tarcocimab in DR in which all patients randomized to investigational therapy will receive tarcocimab on extended, 6-month dosing. The GLOW2 study design mirrors that of the successful GLOW1 Phase 3 study with the benefit of an additional, third monthly loading dose (weeks 0, 4, and 8). We completed site activations for GLOW2 in the second quarter. Accelerated patient screenings and randomizations are ongoing. If successful, GLOW2 could serve as one of the two successful pivotal studies in one foundational indication, diabetic retinopathy, to support the marketing authorization application for tarcocimab.

  We also announced our intention to study tarcocimab as a second investigational arm in the Phase 3 DAYBREAK study to assess its 6-month durability potential, strengthen its competitive position in wet AMD and bolster its regulatory application package. Treatment-naïve wet AMD 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 its

label.

Both GLOW2 and DAYBREAK are being run using tarcocimab's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to balance durability and immediacy. The product vision for tarcocimab in wet AMD is a drug that can be used in any wet AMD patient whether they be in the loading (immediacy) phase or in the maintenance (durability) phase.

Following submission of the study protocol to the FDA in the first quarter of 2024, we began to operationalize the study including site selection in the second quarter of this year.

The DAYBREAK Phase 3 study is now actively enrolling patients.

- ***KSI-501 clinical program:*** We completed the Phase 1 study of KSI-501 in patients with diabetic macular edema ("DME") in the first quarter of 2024 and shared the study results at the Angiogenesis, Exudation, and Degeneration 2024 Virtual Meeting. The results of the Phase 1 study demonstrated that repeated monthly dosing of KSI-501 was safe and well tolerated and achieved clinically meaningful and sustained visual acuity gains and fluid reductions in patients with diabetic macular edema.

  We announced in the second quarter of 2024 that we intend to advance KSI-501 into the Phase 3 DAYBREAK study to evaluate its efficacy and safety in wet AMD. The DAYBREAK study is a non-inferiority study including 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 four monthly loading doses. Patients randomized to aflibercept will be dosed per its label.

  DAYBREAK will use KSI-501's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to balance durability and immediacy. The objective for KSI-501 in DAYBREAK is to explore the efficacy potential of potent dual inhibition of VEGF and IL-6 in a broad treatment-naïve wet AMD population. 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 the possibility that KSI-501 may be a disease-modifying therapy for retinal vascular diseases.

  The DAYBREAK Phase 3 study is now actively enrolling patients.

- ***KSI-101 clinical program:*** KSI-101 is a novel, potent and high-strength (100 mg/mL) bispecific protein targeting IL-6 and VEGF. With KSI-101, we are seeking to develop an intravitreal biologic therapy whose commercial opportunity sits outside of today's anti-VEGF retinal vascular disease market.

  We held a pre-IND meeting with the FDA in the second quarter of 2024, followed by the IND submission, including the protocol for the Phase 1b APEX study. The APEX study will evaluate KSI-101 in two new cohorts. Cohort 1 is investigating KSI-101 in patients with DME. Cohort 2 is investigating KSI-101 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 2b/3 studies (PEAK and PINNACLE) in MESI. We have activated the APEX study, which is now actively enrolling patients.

  We also plan to explore KSI-101 protein in the pediatric setting where there is high unmet medical need with no approved therapy and, to our knowledge, no locally injected therapies in development. We have submitted KSI-101 requests for (1) rare pediatric disease designation, (2) orphan disease designation, and (3) fast track designation. We are exploring whether, following early indication of adult safety in APEX Cohorts 1 and 2, a third (pivotal) cohort could be run to study KSI-101 in the pediatric setting.

- ***ABC Platform evolution:*** We are working to expand our early research pipeline of duets and triplets built from our modular ABC Platform that embeds diverse active pharmaceutical ingredients ("API") including small molecules, proteins, peptides, macrocycles, and oligonucleotides in the biopolymer backbone to enable high drug antibody ratio ("DAR") medicines with targeted, multi-specific, tailored modulation of biological pathways for ophthalmic and systemic diseases.

- ***Recent scientific presentations:***

  At the Association for Research in Vision and Ophthalmology ("ARVO") 2024 Annual Meeting, we presented a breadth of data on our early- and late-phase retina pipeline. Our presentations included clinical and non-clinical data on our ABC Platform investigational medicines tarcocimab and KSI-501, and we highlighted progress on our duet and triplet platform including discovery and characterization of novel small molecules and biologics.

At the Clinical Trials at the Summit 2024 meeting in the second quarter, we presented on Kodiak's tarcocimab, KSI-501 and KSI-101 programs as well as on the ABC Platform. The presentations highlighted the scientific rationale underlying our ABC Platform medicines, both their ocular durability and, with our new enhanced formulations, the ability to balance both conjugated and unconjugated forms to optimize for durability without compromising immediacy of effect.

- ***A focus on science:*** We have launched a new web page called Scientific Presentations under Our Science on kodiak.com. The new page aggregates scientific presentations and posters we have presented on our preclinical, non-clinical and clinical data at various scientific meetings since 2018 in an easily searchable format. This new web page is intended to serve as a user-friendly tool to help communicate our science.

Second Quarter 2024 Financial Results

Cash Position

Kodiak ended the second quarter of 2024 with $219.2 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 second quarter of 2024 was $45.1 million, or $0.86 per share on both a basic and diluted basis, as compared to a net loss of $80.2 million, or $1.53 per share on both a basic and diluted basis, for the second quarter of 2023. The net loss for the quarter ended June 30, 2024 included non-cash stock-based compensation of $18.4 million, as compared to $25.8 million for the quarter ended June 30, 2023.

R&D Expenses

Research and development (R&D) expenses were $32.5 million for the second quarter of 2024, as compared to $67.0 million for the second quarter of 2023. The R&D expenses for the second quarter of 2024 included non-cash stock-based compensation of $8.9 million, as compared to $14.7 million for the second quarter of 2023. The decrease in R&D expenses for the second quarter of 2024, as compared to the same period in 2023, was primarily driven by reduced manufacturing and clinical activities for tarcocimab.

G&A Expenses

General and administrative (G&A) expenses were $15.5 million for the second quarter of 2024, as compared to $17.9 million for the second quarter of 2023. The G&A expenses for the second quarter of 2024 included non-cash stock-based compensation of $9.4 million, as compared to $11.1 million for the second quarter of 2023.

About tarcocimab tedromer (tarcocimab, KSI-301)

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. Kodiak aims to finish the clinical development of tarcocimab to enable marketing authorization application for the retinal vascular diseases of diabetic retinopathy, retinal vein occlusion and wet AMD. We believe tarcocimab can fill an important unmet need in the marketplace for a medicine that can be administered to treatment naïve and treatment experienced patients on a monthly through every 6-month interval, and with the majority of patients able to do well on every 6-month dosing.

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, 100% of tarcocimab treated patients were extended to 6-month dosing. In the BEACON study, in the first 6 months tarcocimab-treated patients were dosed on an every 8-week interval (as opposed to an every 4-week interval for aflibercept) and in the second 6-months nearly half of patients did not require treatment at all, and with both groups achieving overlapping vision outcomes at one year.

Kodiak initiated two additional BLA-facing Phase 3 studies of tarcocimab: the GLOW2 study in diabetic retinopathy and the DAYBREAK study in wet AMD. The GLOW2 study has a similar design as GLOW1 in which all patients randomized to investigational therapy will receive tarcocimab on extended, 6-month dosing. GLOW2 features the benefit of an additional, third monthly loading dose (weeks 0, 4 and 8) to explore even further benefits with tarcocimab in diabetic retinopathy patients. The DAYBREAK study includes tarcocimab in a second investigational arm against active comparator aflibercept. 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 its label. DAYBREAK is designed to assess the 6-month durability potential of tarcocimab, strengthen its competitive position in wet AMD and bolster the regulatory application package for the program. Both GLOW2 and DAYBREAK are being run using tarcocimab's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to balance durability and immediacy. Both GLOW2 and DAYBREAK will use KSI-501's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that balances towards long-interval durability without compromising immediacy. GLOW2 and DAYBREAK are both actively enrolling patients. Additional information about GLOW2 can be found on www.clinicaltrials.gov under Trial Identifier NCT06270836 (https://clinicaltrials.gov/study/NCT06270836).

About KSI-501

KSI-501 is an anti-IL-6, VEGF-trap bispecific antibody biopolymer conjugate 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 multiple disease biologies for differentiated efficacy. A completed Phase 1 multiple ascending dose study demonstrated that repeated monthly dosing of KSI-501 was safe and 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. 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 its label. 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 potent dual inhibition of VEGF and IL-6 in a broad treatment-naïve wet AMD population. 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 are 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. DAYBREAK. DAYBREAK will use KSI-501's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to balance durability and immediacy. The objective for KSI-501 in DAYBREAK is to explore the efficacy potential of potent dual inhibition of VEGF and IL-6 in a broad treatment-naïve wet AMD population. The DAYBREAK study is now actively enrolling patients.

About KSI-101

KSI-101 is the unconjugated protein portion of KSI-501 and is a novel, potent and high strength (100 mg/mL) bispecific protein targeting IL-6 and VEGF. 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 is an important part of our portfolio. We have initiated a dose-finding Phase 1b study APEX. The APEX study will evaluate KSI-101 in two new cohorts. Cohort 1 is investigating KSI-101 in patients with DME. Cohort 2 is investigating KSI-101 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 2b/3 studies (PEAK and PINNACLE) in MESI. APEX study is now actively enrolling patients.

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.

Kodiak's lead investigational medicine, tarcocimab, is a novel anti-VEGF antibody biopolymer conjugate under development for the treatment of high prevalence retinal vascular diseases including diabetic retinopathy, the leading cause of blindness in working-age patients in the developed world, and wet age-related macular degeneration, the leading cause of blindness in elderly patients in the developed world. Tarcocimab is currently being studied in two Phase 3 clinical trials, GLOW2 in patients with diabetic retinopathy and DAYBREAK in patients with wet AMD. Both studies are actively enrolling patients.

KSI-501 is our second investigational medicine, a first-in-class anti-IL-6, VEGF-trap bispecific antibody biopolymer conjugate designed to inhibit both IL-6 mediated inflammation and VEGF-mediated angiogenesis and vascular permeability. KSI-501 is being developed for the treatment of high prevalence retinal vascular diseases to address the unmet needs of extended durability and targeting multiple disease biologies for differentiated efficacy. Phase 1b data for KSI-501 was presented in February 2024, and the Phase 3 DAYBREAK study of KSI-501 in wet AMD is actively enrolling patients.

KSI-101, our third product candidate, is a novel anti-IL-6, VEGF-trap bispecific protein, the unconjugated protein portion of KSI-501. Kodiak is developing KSI-101 for the treatment of retinal inflammatory diseases, as currently there are no available intravitreal biologic therapies addressing the spectrum of inflammatory conditions of the retina. The Phase 1b APEX study of KSI-101 is actively enrolling patients.

Kodiak has worked to expand its early research pipeline of duet and triplet inhibitors that embed small molecules and other active pharmaceutical ingredients ("APIs") in the biopolymer backbone to enable high drug-antibody ratio ("DAR") medicines. The diverse APIs are designed to be released over time to achieve targeted, multi-specific and tailored modulation of biological pathways. The unique combination of high DAR and tailored therapeutic benefit offers potential for broad application to multifactorial ophthalmic and systemic diseases.

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

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 for DAYBREAK to support marketing authorization applications for tarcocimab and KSI-501; Kodiak's increasing commercial-facing manufacturing activities; Kodiak's increasing BLA-facing clinical activities; the maturation of our biopolymer derived triplets platform; the potential for GLOW2 to serve as one of the two successful pivotal studies in diabetic retinopathy to support a marketing authorization application for tarcocimab; the prospects and potential benefits of the product candidates in our pipeline, including tarcocimab, KSI-501, and KSI-101; the timing of activation and completion of our planned and ongoing studies; the potential success of our ongoing studies; and our guidance on our 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 the results of our ongoing 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 Biologics License Application (BLA) submission for wet AMD, RVO and NPDR; 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, 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 a new formulation of tarcocimab,

KSI-501 or other ABC Platform derived molecules may not provide the benefits expected; our research and development efforts and our ability to advance our product candidates into later stages of development may fail; the risk that KSI-501 may not inhibit VEGF and IL-6 or have an impact on the treatment of patients as expected; 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™, 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
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses				
Research and development	$ 32,514	$ 66,961	$ 62,445	$ 123,481
General and administrative	15,469	17,871	31,593	35,966
Total operating expenses	47,983	84,832	94,038	159,447
Loss from operations	(47,983)	(84,832)	(94,038)	(159,447)
Interest income	2,954	4,683	6,307	8,300
Interest expense	—	(4)	—	(8)
Other income (expense), net	(88)	(35)	(425)	187
Net loss	$ (45,117)	$ (80,188)	$ (88,156)	$ (150,968)
Net loss per common share, basic and diluted	$ (0.86)	$ (1.53)	$ (1.68)	$ (2.88)
Weighted-average shares of common stock outstanding used in computing net loss per common share, basic and diluted	52,554,215	52,378,729	52,532,337	52,358,279

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

	June 30, 2024	**December 31, 2023**
Cash and cash equivalents	$ 219,225	$ 285,507
Working capital	$ 203,425	$ 247,580
Total assets	$ 401,578	$ 479,372
Accumulated deficit	$ (1,240,687)	$ (1,152,531)
Total stockholders' equity	$ 214,506	$ 265,781

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