# Kodiak Sciences Announces Second Quarter 2022 Financial Results and Recent Business Highlights

August 9, 2022

PALO ALTO, Calif., Aug. 9, 2022 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat high prevalence retinal diseases, today reported business highlights and financial results for the quarter ended June 30, 2022.

"We continue to meaningfully advance the tarcocimab tedromer (KSI-301, tarcocimab) clinical program," said Victor Perlroth, MD, Chief Executive Officer of Kodiak Sciences. "In demonstrating non-inferior visual acuity with a doubling of the treatment interval, we achieved the goal of the BEACON study. A successful outcome in BEACON is one of the pillars of our original development plan, which calls for two successful studies in one indication (GLEAM and GLIMMER in Diabetic Macular Edema) and then individual studies in each of the other indications. Importantly, the BEACON data provide reasons to be optimistic about the potential for GLEAM and GLIMMER to achieve non-inferiority in vision with best in class durability and thus the broader success of our development strategy with tarcocimab. Our suite of Phase 3 pivotal studies is fully enrolled and expected to read out topline data next year. As we learn more from the remaining Phase 3 studies, we look forward to continuing to work with the FDA and global health authorities to bring this medicine to patients."

## Recent Business Highlights

- ***BEACON Phase 3 Pivotal Study of tarcocimab tedromer in Retinal Vein Occlusion Topline Readout:*** We recently announced positive topline results from our Phase 3 pivotal study of tarcocimab tedromer (KSI-301, tarcocimab) in treatment-naïve patients with macular edema due to retinal vein occlusion ("RVO"). The study met its primary efficacy endpoint of non-inferior visual acuity gains at week 24 for subjects dosed every 8 weeks following two monthly loading doses with tarcocimab compared to subjects given aflibercept every 4 weeks. Tarcocimab was safe and well tolerated in the study with no new or unexpected safety signals identified. We intend to include the primary results at week 24 in our anticipated BLA filing to serve as the basis for approval of tarcocimab in RVO.

- ***Update on Tarcocimab tedromer Clinical Program:*** We continued to advance tarcocimab across all ongoing Phase 3 pivotal studies:

    - **GLEAM / GLIMMER:** Our paired Phase 3 studies GLEAM and GLIMMER in diabetic macular edema ("DME") are expected to report topline data in mid-2023 and if successful are designed to serve as the primary basis for a licensing application and potential regulatory approval of tarcocimab.

    - **DAYLIGHT:** Our short-interval Phase 3 study DAYLIGHT in wet age-related macular degeneration (wet "AMD") is expected to report topline results in mid-2023. If successful, we expect DAYLIGHT to contribute data to support approval of tarcocimab in wet AMD.

    - **GLOW**: Our Phase 3 treatment and prevention study GLOW of tarcocimab versus sham in non-proliferative diabetic retinopathy without DME ("NPDR" without "DME") has recently completed enrollment ahead of schedule. The primary endpoint is at one year with topline results expected in the second half of 2023. If successful, we expect GLOW to contribute data to support approval of tarcocimab in NPDR.

- ***Update on Tarcocimab tedromer Regulatory Plan:*** With the suite of Phase 3 studies fully enrolled and anticipated to read out their topline data mid-2023, if successful, we plan to file a single Biologics License Application (BLA) with the data across the program.

- ***Commercial Manufacturing:*** We continued our manufacturing scale up and announced the grand opening of our purpose-built bioconjugation facility with our manufacturing partner Lonza in May 2022. The facility will play a key role in the scaled manufacturing of tarcocimab tedromer to support a potential global commercial launch.

- ***Pipeline Progression:*** We continued progressing our pipeline product candidates KSI-501 and KSI-601. KSI-501 is our dual inhibitor antibody biopolymer conjugate targeting both IL-6 (anti-IL-6 antibody) and VEGF (VEGF-trap) for the treatment of retinal diseases. We are progressing the bioconjugate cGMP manufacturing, non-clinical toxicology and other supporting activities towards an expected IND submission in the second half of 2022.

## Expected Upcoming Events / Milestones

- Full primary results from the BEACON study are expected to be presented by BEACON Study Investigators at upcoming ophthalmology congresses in September 2022.

## Second Quarter 2022 Financial Results
## Cash Position

Kodiak ended the second quarter of 2022 with $597.9 million of cash, cash equivalents and marketable securities. This includes an unrealized loss of $1.9 million on the investment portfolio due to rising interest rates during the quarter.

## Net Loss

The net loss for the second quarter of 2022 was $90.6 million, or $1.74 per share, on both a basic and diluted basis, as compared to a net loss of $55.9 million, or $1.08 per share, on both a basic and diluted basis, for the second quarter of 2021. The net loss for the quarter ended June 30, 2022 included non-cash stock-based compensation of $26.0 million, of which $15.8 million was recorded in the second quarter related to the 2021 Long-Term Performance Incentive Plan.

## R&D Expenses

Research and development (R&D) expenses were $73.7 million for the second quarter of 2022, as compared to $45.4 million for the second quarter of 2021. The R&D expenses for the second quarter included non-cash stock-based compensation of $14.1 million. The increase in R&D expenses was primarily driven by higher clinical trial costs to support ongoing trials, increased manufacturing activities, as well as higher non-cash stock-based compensation expense.

## G&A Expenses

General and administrative (G&A) expenses were $18.3 million for the second quarter of 2022, as compared to $10.5 million for the second quarter of 2021. The G&A expenses for the second quarter included non-cash stock-based compensation of $11.9 million. The increase in G&A expenses was primarily driven by increased non-cash stock-based compensation expense.

## About tarcocimab tedromer (KSI-301)

Tarcocimab tedromer is an investigational anti-VEGF therapy built on Kodiak's 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's objective with tarcocimab tedromer is to improve outcomes for patients with retinal vascular diseases and to enable earlier treatment and prevention of vision loss for patients with diabetic eye disease. Kodiak is developing tarcocimab to be a new first-line agent which enables a majority of patients to be treated and maintained on an every 5 to 6-month treatment interval and a minority of high need patients to be treated as frequently as monthly. The tarcocimab tedromer clinical program is designed to assess the product's durability, efficacy and safety in wet AMD, DME, RVO and non-proliferative DR (without DME) through clinical studies run in parallel. The Company's GLEAM and GLIMMER pivotal studies in patients with diabetic macular edema, the BEACON pivotal study in patients with retinal vein occlusion, the DAYLIGHT pivotal study in patients with wet AMD, and the GLOW study in patients with NPDR are anticipated to form the basis of the Company's BLA to support potential approval and commercialization in multiple indications. The global tarcocimab tedromer clinical program is being conducted at 150+ study sites in more than 10 countries. Kodiak is developing and owns global rights to tarcocimab tedromer.

## About the BEACON Study

The Phase 3 BEACON study is a global, multi-center, randomized study designed to evaluate the durability, efficacy and safety of tarcocimab tedromer in patients with treatment-naïve macular edema due to retinal vein occlusion, including both branch and central subtypes. Patients are randomized 1:1 to receive tarcocimab 5 mg or aflibercept 2 mg. In the first six months, patients receiving tarcocimab are treated with a proactive, fixed regimen which includes two monthly loading doses followed by treatment every 8 weeks, and patients receiving aflibercept are treated monthly as per its label. In the second six months, patients in both groups will receive treatment on an individualized basis per protocol-specified criteria. Following this, patients can continue to receive tarcocimab tedromer for an additional six months on an individualized basis. The study completed enrollment of 568 patients worldwide in the fourth quarter of 2021 and met its primary efficacy endpoint at six months. Results from the BEACON study are intended to serve as the basis for the potential approval of tarcocimab in RVO. Additional information about the BEACON study (also called Study KS301P103) can be found on www.clinicaltrials.gov under Trial Identifier NCT04592419 (https://clinicaltrials.gov/show/NCT04592419).

## About the GLEAM and GLIMMER Studies

The Phase 3 GLEAM and GLIMMER studies are global, multi-center, randomized pivotal studies designed to evaluate the durability, efficacy and safety of tarcocimab in patients with treatment-naïve diabetic macular edema. In each study, patients are randomized 1:1 to receive either tarcocimab or aflibercept. The tarcocimab arm is treated with a proactive, individualized dosing regimen of every 8-, 12-, 16-, 20- or 24 weeks (utilizing tight dynamic retreatment criteria) after three loading doses. The aflibercept arm is treated with a fixed dosing regimen of every 8-weeks after five monthly loading doses, per its label. Both studies completed enrollment of approximately 450 patients each worldwide in the first quarter of 2022. The primary endpoint for both studies is the average of weeks 60 and 64, and patients will be treated and followed for a total of two years. We expect to announce topline data in mid-2023. If successful, we expect that data from our GLEAM and GLIMMER studies will serve as the primary basis for approval of tarcocimab in our anticipated BLA submission. Additional information about GLEAM (also called Study KS301P104) and GLIMMER (also called Study KS301P105) can be found on www.clinicaltrials.gov under Trial Identifiers NCT04611152 and NCT04603937, respectively (https://clinicaltrials.gov/ct2/show/NCT04611152 and https://clinicaltrials.gov/ct2/show/NCT04603937).

## About the DAYLIGHT Study

The Phase 3 DAYLIGHT study is a global, multi-center, randomized pivotal study designed to evaluate the efficacy and safety of high-frequency tarcocimab in patients with treatment-naïve wet AMD. Patients are randomized to receive either tarcocimab on a monthly dosing regimen or to receive standard-of-care aflibercept on a fixed dosing regimen of every 8-weeks after three monthly loading doses per its label. The primary endpoint is the average of weeks 40, 44 and 48. The DAYLIGHT study is intended to clarify the efficacy of tarcocimab to treat high need patients with wet AMD and, if successful, is intended to serve as the basis for approval in wet AMD with monthly dosing. DAYLIGHT has completed enrollment of approximately 550 patients worldwide and we expect to announce topline data in mid-2023. Additional information about DAYLIGHT (also called Study KS301P107) can

be found on www.clinicaltrials.gov under Trial Identifier NCT04964089 (https://clinicaltrials.gov/show/NCT04964089).

## About the GLOW Study

The Phase 3 GLOW study is a global, multi-center, randomized pivotal superiority study designed to evaluate the efficacy and safety of tarcocimab tedromer in approximately 240 patients with treatment-naïve, moderately severe to severe non-proliferative diabetic retinopathy (NPDR). Patients are randomized to receive either tarcocimab every six months after initiating doses given at baseline, 8 weeks and 20 weeks into the study, or to receive sham injections. The primary endpoint is at one year and patients will be treated and followed for two years. Outcomes include changes in diabetic retinopathy severity, measured on a standardized photographic grading scale, and the rate of development of sight-threatening complications due to diabetic retinopathy. We believe tarcocimab tedromer has the potential to be the longest-interval intravitreal therapeutic option for patients with diabetic retinopathy. GLOW has completed enrollment of approximately 240 patients in August 2022. Additional information about GLOW (also called Study KS301P106) can be found on www.clinicaltrials.gov under Trial Identifier NCT05066230 (https://clinicaltrials.gov/show/NCT05066230).

## About Kodiak Sciences Inc.

Kodiak (Nasdaq: KOD) is a biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat high prevalence retinal diseases. Founded in 2009, 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 antibody-based and chemistry-based therapies and is at the core of Kodiak's discovery engine. Kodiak's lead product candidate, tarcocimab tedromer, is a novel anti-VEGF antibody biopolymer conjugate being developed for the treatment of retinal vascular diseases including wet age-related macular degeneration, the leading cause of blindness in elderly patients in the developed world, and diabetic eye diseases, the leading cause of blindness in working-age patients in the developed world. Kodiak has leveraged its ABC Platform to build a pipeline of product candidates in various stages of development. KSI-501 is our dual inhibitor antibody biopolymer conjugate targeting both VEGF (VEGF-trap) and IL-6 (anti-IL-6 antibody) for the treatment of retinal diseases. We are expanding our early research pipeline to include ABC Platform based triplet inhibitors for multifactorial retinal diseases such as dry AMD and glaucoma. Kodiak is based in Palo Alto, CA. 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 regulatory developments and strategy, including plans to obtain regulatory approval, expected timing of data from studies and submission of INDs, the bases on which regulatory approval may be sought, and contribution of data to support approval of tarcocimab; timing of upcoming presentations; and expectations regarding commercial manufacturing capabilities, including the potential of the bioconjugation facility to scale manufacturing to support a potential product launch. 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. These risks and uncertainties include, but are not limited to, the risk that preliminary safety, efficacy and durability data for our tarcocimab tedromer product candidate may not continue or persist; the risk that tarcocimab tedromer may not have the anti-VEGF effect or impact on the treatment of RVO expected; cessation or delay of any of the ongoing clinical studies and/or our development of tarcocimab tedromer may occur, including as a result of the ongoing COVID-19 pandemic; the risk that our ABC Platform may not extend treatment intervals in retinal disorders as anticipated, or at all; future potential regulatory milestones of tarcocimab tedromer, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; adverse economic conditions may significantly impact our business and operations, including our clinical trial sites, and those of our manufacturers, contract research organizations or other 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**
**(Unaudited)**
**(in thousands, except share and per share amounts)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Operating expenses | | | | |
| Research and development | $ 73,744 | $ 45,404 | $ 149,921 | $ 85,741 |
| General and administrative | 18,324 | 10,505 | 37,914 | 20,726 |
| Total operating expenses | 92,068 | 55,909 | 187,835 | 106,467 |
| Loss from operations | (92,068) | (55,909) | (187,835) | (106,467) |
| Interest income | 1,135 | 81 | 1,211 | 230 |
| Interest expense | (5) | (5) | (10) | (11) |
| Other income (expense), net | 310 | (19) | 297 | (51) |
| Net loss | $ (90,628) | $ (55,852) | $ (186,337) | $ (106,299) |
| Net loss per common share, basic and diluted | $ (1.74) | $ (1.08) | $ (3.57) | $ (2.06) |

| | | | | |
|---|---|---|---|---|
| Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted | 52,218,773 | 51,573,894 | 52,195,972 | 51,644,946 |

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

| | June 30, 2022 | December 31, 2021 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 597,876 | $ 731,510 |
| Working capital | $ 534,536 | $ 670,128 |
| Total assets | $ 781,905 | $ 904,220 |
| Accumulated deficit | $ (744,554) | $ (558,217) |
| Total stockholders' equity | $ 530,931 | $ 663,320 |

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