Kodiak Sciences Announces Second Quarter 2023 Financial Results and Recent Business Highlights

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PALO ALTO, Calif., Aug. 14, 2023 /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, 2023.

"We experienced a significant setback with the recently announced topline data for our Phase 3 GLEAM and GLIMMER studies in diabetic macular edema patients," said Victor Perlroth, MD, Chief Executive Officer of Kodiak Sciences. "Tarcocimab demonstrated what we see as industry-leading durability together with solid potency, but an unexpected increased rate of cataracts appears to have been the main driver to missing the primary efficacy endpoint in both studies. In our concurrent DAYLIGHT study in age-related macular degeneration where we dosed patients on a high-exposure regimen of 12 monthly doses of tarcocimab, fewer tarcocimab treated patients had a finding of cataract than did aflibercept treated patients. Notwithstanding the negative primary results in GLEAM and GLIMMER, we have two positive Phase 3 studies with tarcocimab: the BEACON study in patients with retinal vein occlusion and the DAYLIGHT study in patients with wet AMD. Following the recent presentation of the GLEAM and GLIMMER data at the American Society of Retina Specialists (ASRS) annual meeting, we have heard encouraging feedback from the retina community that tarcocimab's 6-month durability profile might be compelling and important for many patients, especially in pseudophakic patients who have already had cataract surgery and make up as many as 40% of anti-VEGF treated patients. While Kodiak has made the business decision to wind down ongoing studies of tarcocimab as previously communicated, we are still evaluating a variety of future options for the tarcocimab program.

"We have also communicated that Kodiak will be advancing the KSI-501 clinical program," continued Dr. Perlroth. "We are fortunate to have the active KSI-501 clinical program in our pipeline. KSI-501 is a first-in-class anti-IL-6 and anti-VEGF bispecific molecule, and we have completed enrollment of the multiple dose escalation Phase 1 study. The obvious question is why are we confident in advancing KSI-501 if it is based on the same platform as tarcocimab, and the answer is multiple. First, KSI-501 has the potential for both better anti-VEGF potency as it is a VEGF-trap as well as enhanced efficacy due to its dual mechanism of action, as compared to tarcocimab. Second, we believe we can deliver a tailored clinical development plan based on the learnings from the tarcocimab clinical program and the ABC platform itself. Third, we may explore an accelerated development pathway through orphan and/or breakthrough therapy designation applications with KSI-501. And fourth, we are planning to explore development of KSI-501 in its two therapeutic forms, both as its unconjugated protein which is itself a novel bispecific protein and as its bioconjugate form. We believe that exploring both therapeutic forms may result in a higher probability of success of the program and also provide us with a better understanding of the ABC platform."

Recent Business Highlights

- ***Tarcocimab pivotal program:*** We recently announced that our Phase 3 GLEAM and GLIMMER studies of tarcocimab in diabetic macular edema (DME) did not meet their primary efficacy endpoints of non-inferior visual acuity gains for tarcocimab dosed every 8 to 24 weeks after 3 monthly loading doses compared to aflibercept given every 8 weeks after 5 monthly loading doses. Tarcocimab demonstrated strong durability with half of tarcocimab treated patients achieving every 24-week dosing at the primary endpoint. An unexpected increase in cataract adverse events was reported over time in the tarcocimab arms of both GLEAM and GLIMMER and contributed meaningfully to the failure of each study. We also announced that the Phase 3 DAYLIGHT study of tarcocimab in wet age-related macular degeneration (wet AMD) did meet the primary efficacy endpoint of non-inferior visual acuity gains for tarcocimab dosed monthly compared to aflibercept dosed every 8 weeks following 3 monthly loading doses. No imbalance in cataracts was observed between the tarcocimab arm and the aflibercept arm in this study. In light of these clinical trial outcomes, we have made the business decision to wind down on-going clinical studies of tarcocimab.
- ***KSI-501 clinical program:*** Our Phase 1 study of KSI-501 has completed enrollment of patients across all dose levels. KSI-501 is our first-in-class bispecific investigational medicine designed to inhibit both IL-6-mediated immune inflammation and VEGF-mediated angiogenesis and vascular permeability. The Phase 1 study is an open-label, multiple ascending dose study to evaluate ocular and systemic safety, to establish a maximum tolerated dose and to explore bioactivity of KSI-501, initially in patients with DME. We are planning to explore development of KSI-501 both as (i) its unconjugated protein which is itself a novel bispecific anti-IL-6 antibody / anti-VEGF trap fusion protein and (ii) its bioconjugate form.

Second Quarter 2023 Financial Results

Cash Position

Kodiak ended the second quarter of 2023 with $378.7 million of cash and cash equivalents.

Net Loss

The net loss for the second quarter of 2023 was $80.2 million, or $1.53 per share on both a basic and diluted basis, as compared to a net loss of $90.6 million, or $1.74 per share on both a basic and diluted basis, for the second quarter of 2022. The net loss for the quarter ended June 30, 2023 included non-cash stock-based compensation of $25.8 million, as compared to $26.0 million for the quarter ended June 30, 2022.

R&D Expenses

Research and development (R&D) expenses were $67.0 million for the second quarter of 2023, as compared to $73.7 million for the second quarter of 2022. The R&D expenses for the second quarter of 2023 included non-cash stock-based compensation of $14.7 million, as compared to $14.1 million

for the second quarter of 2022. The decrease in R&D expenses for the second quarter of 2023 was primarily driven by the maturation of the tarcocimab clinical program and the timing of manufacturing activities.

G&A Expenses

General and administrative (G&A) expenses were $17.9 million for the second quarter of 2023, as compared to $18.3 million for the second quarter of 2022. The G&A expenses for the second quarter of 2023 included non-cash stock-based compensation of $11.1 million, as compared to $11.9 million for the second quarter of 2022.

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. 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. 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: the potential benefits of KSI-501, including its potential to be a first-in-class bispecific investigational medicine inhibiting both VEGF and IL-6; our ability to apply tailored clinical development plan to KSI-501 based on the learnings from the tarcocimab clinical program and the ABC platform itself; expectations regarding our ability to seek an accelerated development pathway through orphan and/or breakthrough therapy designation applications with KSI-501; planned expansion of our research pipeline; and potential future options for the tarcocimab program. 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 cessation or delay of any of the ongoing clinical studies and our development of KSI-501 may occur; future potential regulatory milestones of tarcocimab or KSI-501, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; 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
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses				
Research and development	$ 66,961	$ 73,744	$ 123,481	$ 149,921
General and administrative	17,871	18,324	35,966	37,914
Total operating expenses	84,832	92,068	159,447	187,835
Loss from operations	(84,832)	(92,068)	(159,447)	(187,835)
Interest income	4,683	1,494	8,300	1,570
Interest expense	(4)	(5)	(8)	(10)
Other income (expense), net	(35)	(49)	187	(62)
Net loss	$ (80,188)	$ (90,628)	$ (150,968)	$ (186,337)
Net loss per common share, basic and diluted	$ (1.53)	$ (1.74)	$ (2.88)	$ (3.57)
Weighted-average shares of common stock outstanding used in computing net loss per common share, basic and diluted	52,378,729	52,218,773	52,358,279	52,195,972

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

	June 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 378,670	$ 478,933
Working capital	$ 312,717	$ 433,509
Total assets	$ 589,659	$ 666,628
Accumulated deficit	$ (1,043,008)	$ (892,040)
Total stockholders' equity	$ 338,478	$ 436,167

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