Kodiak Sciences Announces Second Quarter 2021 Financial Results and Recent Business Highlights

August 9, 2021

PALO ALTO, Calif., Aug. 9, 2021 /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 second quarter ended June 30, 2021.

"The Kodiak team continued its strong execution across our clinical, regulatory and pipeline objectives in the second quarter of 2021. DAZZLE, our long-interval wet AMD pivotal study, continues its follow-up phase as patients proceed to their one-year primary endpoint visits and into the second year of the study. BEACON, our RVO pivotal study, is nearly two-thirds enrolled, and enrollment in GLEAM and GLIMMER, our paired long-interval diabetic macular edema pivotal studies, continue on pace globally. In June 2021, we enrolled our first patients in DAYLIGHT, our new short-interval wet AMD study. The KSI-301 anti-VEGF development program is tracking nicely towards top-line data readouts starting in early 2022," said Victor Perlroth, M.D., Chief Executive Officer of Kodiak Sciences. "We also made further strides in bringing KSI-301 to retina patients globally with IND approvals in China, and we expect to enroll our first patients from China in our RVO and DME pivotal studies later this year. In our pipeline, we continue to advance KSI-501, our bispecific anti-VEGF/anti-IL-6 conjugate, towards the clinic, and we are making exciting scientific progress with our new triplets program that combines large-molecules and small-molecules into ABC platform medicines."

Recent Business Highlights

- ***KSI-301 Clinical Program Progress***

  In the second quarter of 2021, we randomized the first patients into our new Phase 3 study in wet AMD (DAYLIGHT). Patient enrollment into GLEAM, GLIMMER, BEACON and DAYLIGHT continues to be on track for completion in the fourth quarter of 2021 or early 2022. Notably, BEACON, our study of KSI-301 in RVO, is nearly two-thirds enrolled and we are extending the study to 18 months to allow participants to continue to receive treatment for a longer period of time. We also plan to begin recruitment in our Phase 3 GLOW study in patients with non-proliferative Diabetic Retinopathy in August 2021. To date, we are pleased with the operational progress in site activation, patient screening and recruitment seen across the clinical program. To date, we continue to observe a low single digit overall rate of missed visits in our pivotal studies despite the continued COVID-19 pandemic.

  Our Phase 2b/3 pivotal study of KSI-301 in patients with wet AMD (DAZZLE) is on track with the last patient's last visit for the primary efficacy endpoint expected in the fourth quarter of 2021 and topline data expected in the first quarter of 2022.

- ***China IND Approval***

  In March 2021, our investigational new drug (IND) applications for KSI-301 in RVO and DME were approved by China's National Medicinal Products Administration (NMPA). The IND approvals allow Kodiak to enroll patients from China into the BEACON and GLIMMER studies; we believe that inclusion of patients from China in these studies could be beneficial for the potential future approval of KSI-301 in China.

- ***KSI-301 International Non-proprietary Name (INN)***

  In May 2021, we selected tarcocimab tedromer as the proposed INN for KSI-301. The INN uniquely describes KSI-301 in all countries and is assigned by the World Health Organization (WHO). The two-part INN is descriptive of our bioconjugate, both the antibody (tarcocimab) and the biopolymer (tedromer).

- ***Royalty Financing Update***

  In December 2019, Kodiak entered into a funding agreement with certain assignees of Baker Bros. Advisors, LP ("BBA") under which BBA agreed to fund up to $225.0 million in exchange for the right to 4.5% royalties on Kodiak's potential future net sales of KSI-301 and certain other products. The royalty was capped at 4.5 times the total amount funded. BBA funded $100.0 million at closing in February 2020, with the remaining $125.0 million to be funded upon receipt of Kodiak's notice that it had satisfied specified product development criteria and making certain certifications to BBA.

  At Kodiak's request, BBA confirmed on July 22, 2021 that, despite Kodiak being in a position to satisfy the product development criteria, the second funding amount would not be paid and the aggregate royalty cap under the Funding Agreement would be reduced from $1,012.5 million to $450.0 million.

Expected Upcoming Events/Milestones

- Initiate pivotal Phase 3 randomized study of every 24-week KSI-301 in non-proliferative diabetic retinopathy patients (the GLOW study)
- Complete patient enrollment in Retinal Vein Occlusion (BEACON), Diabetic Macular Edema (GLEAM and GLIMMER) and wet AMD (DAYLIGHT) pivotal clinical studies
- Complete wet AMD DAZZLE pivotal clinical study last patient last visit for primary endpoint
- Announce topline data for DAZZLE expected in the first quarter of 2022

Second Quarter 2021 Financial Results

Cash Position

Kodiak ended the second quarter of 2021 with $880.9 million of cash and cash equivalents.

Net Loss

The net loss for the second quarter of 2021 was $55.9 million, or $1.08 per share on both a basic and diluted basis, as compared to a net loss of $26.0 million, or $0.58 per share on both a basic and diluted basis, for the second quarter of 2020.

R&D Expenses

Research and development (R&D) expenses were $45.4 million for the second quarter of 2021, as compared to $20.6 million for the second quarter of 2020. The increase in R&D expenses was primarily driven by higher clinical trial costs for KSI-301, as well as higher payroll and stock-based compensation expense.

G&A Expenses

General and administrative (G&A) expenses were $10.5 million for the second quarter of 2021, as compared to $6.2 million for the second quarter of 2020. The increase in G&A expenses was primarily driven by higher payroll and stock-based compensation expenses.

About KSI-301

KSI-301 is an investigational anti-VEGF therapy built on the Kodiak's Antibody Biopolymer Conjugate (ABC) Platform and is designed to maintain potent and effective drug levels in ocular tissues for longer than existing agents. Kodiak's objective with KSI-301 is to develop a new first-line agent 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. The KSI-301 Clinical Program is designed to assess KSI-301'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 Phase 2b/3 DAZZLE pivotal study in patients with treatment-naïve wet AMD was initiated in October 2019 and completed enrollment in November 2020, and Kodiak initiated the Phase 3 GLEAM, GLIMMER and BEACON pivotal studies of KSI-301 in diabetic macular edema and retinal vein occlusion in September 2020. The Company initiated the Phase 3 DAYLIGHT pivotal study of monthly KSI-301 in wet AMD patients in June 2021. These pivotal studies are anticipated to form the basis of the Company's initial BLA to support potential approval and commercialization in multiple indications and with a full range of labeled and reimbursable dosing frequencies in each indication. An additional Phase 3 pivotal study in patients with non-proliferative diabetic retinopathy (the GLOW study) is also expected to be initiated in summer 2021. The global KSI-301 clinical program is being conducted at 150+ study sites in more than 10 countries. Kodiak Sciences Inc. is developing KSI-301 and owns global rights to KSI-301.

About the DAZZLE Study

The Phase 2b/3 DAZZLE study is a global, multi-center, randomized pivotal study designed to evaluate the durability efficacy and safety of KSI-301 in patients with treatment-naïve wet AMD. Patients are randomized to receive either KSI-301 on an individualized dosing regimen as infrequently as every five months and no more often than every three months or to receive aflibercept on its labeled every eight-week dosing regimen, each after three monthly initiating doses. The study has enrolled over 550 patients worldwide. The primary endpoint is at one year, and the Last Patient Last Visit (LPLV) for the primary endpoint is expected to occur in the fourth quarter of 2021. Each patient will be treated and followed for two years. Additional information about DAZZLE (also called Study KSI-CL-102) can be found on www.clinicaltrials.gov under Trial Identifier NCT04049266 (https://clinicaltrials.gov/show/NCT04049266).

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 KSI-301 in patients with treatment-naïve diabetic macular edema (DME). In each study, patients are randomized to receive either intravitreal KSI-301 on an individualized dosing regimen every eight to 24 weeks after only three loading doses or intravitreal aflibercept every eight weeks after five loading doses per its label. Each study is expected to enroll approximately 450 patients worldwide. The primary endpoint for both studies is at one year, and patients will be treated and followed for two years. 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 BEACON Study

The Phase 3 BEACON study is a global, multi-center, randomized study designed to evaluate the durability, efficacy and safety of KSI-301 in patients with treatment-naïve macular edema due to retinal vein occlusion (RVO), including both branch and central subtypes. Patients are randomized to receive either intravitreal KSI-301 every eight weeks after only two loading doses or monthly intravitreal aflibercept per its label, for the first six months. 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 KSI-301 for an additional six months on an individualized basis. The study is expected to enroll approximately 550 patients worldwide. The primary endpoint is at six months, and patients will be treated and followed for 18 months. 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 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 KSI-301 in patients with treatment-naïve wet AMD. Patients are randomized to receive either KSI-301 on a monthly dosing regimen or to receive standard-of-care aflibercept. The study is expected to enroll approximately 500 patients worldwide. The primary endpoint is at ten months, and the study is being planned and executed to allow for inclusion of its results in the initial BLA for KSI-301 along with the DAZZLE, BEACON, GLEAM and GLIMMER studies. The intent of this pivotal study is to broaden KSI-301's potential product labeling, explore the potential for improved treatment outcomes in certain patients with intensive anti-VEGF treatment, and eliminate possible barriers to market access and insurance reimbursement that have impeded or complicated the commercial uptake of other anti-VEGF medications in the past. We believe that pursuing a broad product label will provide physicians with the flexibility, agency, and reimbursement confidence required to consider KSI-301 treatment for all their patients. 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 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, KSI-301, is a novel anti-VEGF antibody biopolymer conjugate being developed for the treatment of retinal vascular diseases including 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 including KSI-501, our bispecific anti-IL-6/VEGF biopolymer conjugate for the treatment of neovascular retinal diseases with an inflammatory component, and 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 the potential licensure of KSI-301 and a single BLA submission in wet AMD, DME, RVO and diabetic retinopathy; the sufficiency of our cash, cash equivalents and marketable securities to fund our operations; our platform technology and potential therapies; future development plans, including our ability to begin recruitment in our Phase 3 GLOW study in patients with non-proliferative Diabetic Retinopathy in August 2021; the potential for KSI-301 to obtain a broad product label and reduce barriers to reimbursement; the potential for KSI-301 to offer best-in-class dosing regimens; the potential for KSI-301 to be approved in China; our ability to complete patient enrollment in clinical studies; clinical and regulatory objectives and the timing thereof, anticipated design of planned clinical trials, expectations regarding the potential efficacy and commercial potential of our product candidates; and the anticipated presentation of data; the results of our research and development efforts and our ability to advance our product candidates into later stages of development. 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 preliminary safety, efficacy and durability data for our KSI-301 product candidate will not continue or persist; cessation or delay of any of the ongoing clinical studies and/or our development of KSI-301 may occur, including as a result of the ongoing COVID-19 pandemic; future potential regulatory milestones of KSI-301, including those related to current and planned clinical studies may be insufficient to support regulatory submissions or approval; anticipated presentation of data at upcoming conferences may not occur; our research and development efforts and our ability to advance our product candidates into later stages of development may fail; any one or more of our product candidates may not be successfully developed, approved or commercialized; adverse conditions in the general domestic and global economic markets, including the COVID-19 pandemic, which may significantly impact our business and operations, including out of our headquarters in the San Francisco Bay Area and 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-Q, 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 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,	
	2021	2020	2021	2020
Operating expenses				
Research and development	$ 45,404	$ 20,557	$ 85,741	$ 40,727
General and administrative	10,505	6,222	20,726	11,775
Total operating expenses	55,909	26,779	106,467	52,502
Loss from operations	(55,909)	(26,779)	(106,467)	(52,502)
Interest income	81	698	230	1,906

Interest expense	(5)	(6)	(11)	(13)
Other income (expense), net	(19)	88	(51)	218
Net loss	$ (55,852)	$ (25,999)	$ (106,299)	$ (50,391)
Net loss per common share, basic and diluted	$ (1.08)	$ (0.58)	$ (2.06)	$ (1.12)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	51,573,894	44,969,795	51,644,946	44,897,269

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

	June 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 880,870	$ 968,974
Working capital	$ 843,312	$ 940,583
Total assets	$ 997,601	$ 1,067,347
Accumulated deficit	$ (397,526)	$ (291,227)
Total stockholders' equity	$ 779,427	$ 860,751

View original content:https://www.prnewswire.com/news-releases/kodiak-sciences-announces-second-quarter-2021-financial-results-and-recent-business-highlights-301351445.html

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