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

November 9, 2021

PALO ALTO, Calif., Nov. 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 third quarter ended September 30, 2021.

"We are pleased with the operational progress across our pivotal clinical program," said Victor Perlroth, MD, Chief Executive Officer of Kodiak Sciences. "We believe we are on track for a series of KSI-301 topline data readouts beginning in early 2022, with the DAZZLE study in wet AMD expected to read out in the first quarter of 2022 and our BEACON study in retinal vein occlusion shortly thereafter in mid-2022. GLEAM and GLIMMER, our paired long-interval DME studies, are more than two-thirds and three-quarters enrolled, respectively and should complete enrollment in the first quarter of 2022. And DAYLIGHT, our short-interval wet AMD study, is showing robust enrollment and, based on current trends may read out ahead of GLEAM and GLIMMER. In the third quarter, we also began recruitment in GLOW, our study evaluating every six-month dosing of KSI-301 for preventing sight-threatening complications in diabetic retinopathy patients."

KSI-301 Clinical Program Highlights

We are engaged in a broad development program for KSI-301 with concurrent late-stage development activities across all of the major disease indications for which intravitreal anti-VEGF therapies are used and have made considerable progress in advancing the KSI-301 pivotal study program over this past quarter. We expect to include the results of all our pivotal clinical trials in wet AMD, DME and RVO in a single initial BLA. The ambitious program for KSI-301 reflects our conviction in KSI-301 (and our ABC Platform) and seeks labeling at launch that is supportive of a broad range of individualized dosing intervals, from every 4-week dosing up to once every 20-week dosing for wet AMD patients; from every 4-week dosing up to once every 24-week dosing for DME patients; and from every 4-week dosing up to once every 8-week dosing for RVO patients.

- ***DAZZLE – Phase 2b/3 Study in Patients with Treatment-Naïve Wet Age-Related Macular Degeneration (Wet AMD)***

  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.

  We initiated the DAZZLE pivotal study in October 2019 and completed enrollment in November 2020 with over 550 patients enrolled globally. We expect the last patient's primary endpoint visit to occur in the fourth quarter of 2021 and to announce topline data in the first quarter of 2022.

- ***BEACON – Phase 3 Study in Patients with Treatment-Naïve Retinal Vein Occlusion (RVO)***

  We began enrolling patients into BEACON in the third quarter of 2020. With over 475 patients randomized, we believe we are on track to complete enrollment into BEACON before the end of this year. Based on the 24-week primary endpoint for BEACON, we expect to announce topline data in mid-2022.

- ***GLEAM / GLIMMER – Paired Phase 3 Studies in Patients with Treatment-Naïve Diabetic Macular Edema (DME)***

  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 a total of two years.

  We initiated GLEAM and GLIMMER in the third quarter of 2020. Continued elevated COVID-19 transmission rates globally have impacted enrollment rates for patients with treatment naïve DME. With GLEAM more than two-thirds enrolled and GLIMMER more than three-quarters enrolled, we expect to complete enrollment in the first quarter of 2022.

- ***DAYLIGHT – Phase 3 Study in Patients with Treatment-Naïve Wet AMD***

  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 40 weeks, and the study is being planned and executed to allow for inclusion of its results in the initial BLA for KSI-301.

  In June 2021, we randomized the first patients into DAYLIGHT. Study enrollment has been strong with recruitment now underway both in the US and EU. Additional global study sites will be activated through the fourth quarter of 2021, and we believe we can complete enrollment in the first half of 2022.

- ***GLOW – Phase 3 Study in Patients with Non-Proliferative Diabetic Retinopathy without DME***

  We began screening patients into GLOW in the second quarter of 2021 and randomized the first patients in September. We are not planning for this study and indication to be included in our initial BLA filing given our expectations for a longer recruitment timeframe. We are excited to be recruiting patients in this chronic, more preventive disease indication and believe KSI-301 can be a new longest-interval therapeutic option for

patients with diabetic retinopathy.

To date, we are pleased with the continued operational progress across our pivotal program. We believe we are on track for a series of KSI-301 topline data readouts beginning in early 2022 with DAZZLE in the first quarter of 2022, BEACON in mid-2022 and then DAYLIGHT and GLEAM/GLIMMER tracking towards early 2023.

Expected Upcoming Events/Milestones

- Announce topline data for DAZZLE, pivotal study of KSI-301 in wet AMD (long-interval dosing), 1Q 2022.
- Announce topline data for BEACON, pivotal study of KSI-301 in RVO, mid-2022.
- Complete enrollment in GLEAM and GLIMMER, pivotal studies of KSI-301 in DME (long-interval dosing), 1Q 2022.
- Complete enrollment in DAYLIGHT, pivotal study of KSI-301 in wet AMD (short-interval dosing), 1H 2022

Third Quarter 2021 Financial Results

Cash Position

Kodiak ended the third quarter of 2021 with $799.2 million of cash and cash equivalents.

Net Loss

The net loss for the third quarter of 2021 was $67.5 million, or $1.30 per share on both a basic and diluted basis, as compared to a net loss of $36.1 million, or $0.80 per share on both a basic and diluted basis, for the third quarter of 2020.

R&D Expenses

Research and development (R&D) expenses were $56.0 million for the third quarter of 2021, as compared to $29.3 million for the third quarter of 2020. The increase in R&D expenses was primarily driven by higher clinical trial and manufacturing costs for KSI-301 as well as increased headcount and stock-based compensation expense.

G&A Expenses

General and administrative (G&A) expenses were $11.5 million for the third quarter of 2021, as compared to $7.4 million for the third quarter of 2020. The increase in G&A expenses was primarily driven by increased headcount 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. The Phase 3 pivotal study in patients with non-proliferative diabetic retinopathy (the GLOW study) was initiated in August 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 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 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 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 the GLOW Study

The Phase 3 GLOW study is a global, multi-center, randomized pivotal study designed to evaluate the efficacy and safety of KSI-301 in patients with treatment-naïve, moderately severe to severe non-proliferative diabetic retinopathy (NPDR). Patients are randomized to receive either KSI-301 on a once every six-month dosing regimen after three monthly initiating doses or to receive sham injection. The study is expected to enroll approximately 240 patients worldwide. The primary endpoint is at one year and patients will be treated and followed for two years. 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, Kodiak is 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's 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, Kodiak's bispecific anti-IL-6/VEGF biopolymer conjugate for the treatment of neovascular retinal diseases with an inflammatory component, and Kodiak is expanding its 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 a single BLA submission in wet AMD, DME and RVO; the sufficiency of our cash, cash equivalents and marketable securities to fund our operations; our platform technology and potential therapies; future development plans; the potential for KSI-301 to obtain a broad product label and reduce barriers to reimbursement; planned KSI-301 dosing regimens; 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 (including any announcement of topline data) 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses				
Research and development	$ 56,002	$ 29,306	$ 141,743	$ 70,033
General and administrative	11,533	7,357	32,259	19,132
Total operating expenses	67,535	36,663	174,002	89,165
Loss from operations	(67,535)	(36,663)	(174,002)	(89,165)
Interest income	40	645	270	2,551
Interest expense	(6)	(6)	(17)	(19)
Other income (expense), net	(25)	(98)	(76)	120
Net loss	$ (67,526)	$ (36,122)	$ (173,825)	$ (86,513)
Net loss per common share, basic and diluted	$ (1.30)	$ (0.80)	$ (3.36)	$ (1.92)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	51,875,315	45,119,885	51,722,611	44,972,085

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

	September 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 799,247	$ 968,974
Working capital	$ 751,110	$ 940,583
Total assets	$ 958,206	$ 1,067,347
Accumulated deficit	$ (465,052)	$ (291,227)
Total stockholders' equity	$ 726,320	$ 860,751

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