Kodiak Sciences Announces Third Quarter 2020 Financial Results and Recent Business Highlights

November 9, 2020

PALO ALTO, Calif., Nov. 9, 2020 /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, 2020.

"We continue our strong execution in this second half of 2020," said Victor Perlroth, MD, Chief Executive Officer of Kodiak. "Our DAZZLE study of KSI-301 in wet age-related macular degeneration has only a handful of patients left to enroll, and we are now enrolling GLEAM and GLIMMER in Diabetic Macular Edema and BEACON in Retinal Vein Occlusion. With over 300 retina specialists, clinical coordinators and staff having participated in our most recent Virtual Investigator Meeting, we are humbled and inspired by the receptivity and enthusiasm of the retina community for KSI-301 and its emerging clinical profile. These accomplishments, powered by our growing Kodiak team, bring us one step closer to a series of top-line data readouts beginning in early 2022. This 2022 Vision will, if successful, enable a single multi-indication BLA filing in 2022."

Recent Business Highlights

- *Upgraded Pivotal Study Program*: We finalized the design of our KSI-301 pivotal study programs in RVO and DME and have launched all three studies. We are currently conducting two Phase 3 studies in DME (GLEAM and GLIMMER) to provide the mutually-confirmatory studies required by FDA for initial demonstration of safety and efficacy, one study in wet AMD (our ongoing DAZZLE study), and one study in RVO (BEACON). Each study protocol design has been optimized based on Phase 1b data and experience and will include the same treatment-naïve patient populations as in the Phase 1b, as well as tighter dosing interval ranging, tighter disease control, and decreased subjectivity for retreatments, and each has high statistical power for non-inferiority (>90%). We also intend to initiate in early 2021 a Phase 3 study of KSI-301 in non-proliferative diabetic retinopathy (GLOW).

- *DAZZLE Study Progress*: We saw robust patient enrollment through the third quarter of 2020 and have completed U.S. patient recruitment into our DAZZLE pivotal study in wet AMD – a potential reflection of the enthusiasm for KSI-301 on the part of clinical investigators and patients. EU patient enrollment commenced in June 2020 and we continue to see robust recruitment. We expect to complete overall DAZZLE study enrollment by year end 2020. With a one-year primary endpoint, we remain on track for a DAZZLE study top-line data readout in early 2022. As of November 4, 2020, over 545 of the planned 550 patients have been enrolled in DAZZLE.

- *GLEAM / GLIMMER and BEACON Study Initiations*: We initiated two Phase 3 studies in DME (GLEAM and GLIMMER) and one Phase 3 study in RVO (BEACON) in the third quarter of 2020. The randomization of treatment-naïve patients into these three studies is a critical step to build the clinical evidence for KSI-301 as a safe, effective and highly durable therapy for patients with retinal diseases. The initiation of the additional Phase 3 studies and the robust patient recruitment into DAZZLE represent strong operational progress towards our 2022 Vision of a single BLA filed for KSI-301 in wet AMD, DME, and RVO in 2022.

- *Continued maturation of Phase 1b Data*: Updated safety and efficacy results from our ongoing Phase 1b trial of KSI-301 in patients with treatment naïve wet AMD, DME, or RVO were presented at the American Society of Retina Specialists 2020 Virtual Annual Meeting in July 2020. We believe the data continue to support the "anti-VEGF Generation 2.0" profile of KSI-301. We intend to continue presenting data updates from the Phase 1b as the study progresses over its full three-year duration.

- *Commercial Manufacturing Progress*: We successfully negotiated a long-term agreement with Lonza for the manufacture of KSI-301. This agreement will provide Kodiak with a custom-built bioconjugation facility with a capacity to supply millions of doses per year. With construction targeted for completion in 2021, the Lonza-Kodiak Ibex facility will provide Kodiak with the facility needed for commercial-scale manufacturing of KSI-301. The timing of this expanded partnership is designed to support Kodiak's BLA submission timeline in 2022, and the scale is designed to support KSI-301's potential to achieve significant market share as a new first-line agent designed to improve outcomes for patients with common and serious retinal vascular diseases.

- *Completed Lease Agreement for Kodiak's New U.S. Headquarters*: We have leased approximately 82,662 square feet located at 1200 Page Mill Road, Palo Alto, California and approximately 72,812 square feet located at 1250 Page Mill Road, Palo Alto, California. These newly leased buildings will serve as Kodiak's U.S. headquarters for office and laboratory space. We also leased approximately 10,750 square feet in Visp, Switzerland, for manufacturing support and supervision.

Expected Upcoming Events/Milestones

- Complete enrollment in DAZZLE pivotal Phase 2b/3 randomized head-to-head study of KSI-301 against aflibercept in treatment naïve wet macular degeneration patients by year-end 2020
- Presentation on KSI-301 and Kodiak's ABC Platform at Late Breaking Developments Part II of American Academy of Ophthalmology (AAO) 2020 Virtual Annual Meeting in November 2020
- Presentation of KSI-301 one-year data from Phase 1b study in wet AMD, DME and RVO cohorts at Angiogenesis, Exudation, and Degeneration 2021 – Virtual Edition meeting in February 2021
- Initiate pivotal Phase 3 randomized study of KSI-301 in non-proliferative diabetic retinopathy patients (the GLOW study) in early 2021

Third Quarter 2020 Financial Results

Cash Position

Kodiak ended the third quarter of 2020 with $380.5 million of cash, cash equivalents and marketable securities. Based on the company's current cash position, Kodiak estimates having sufficient funds to execute on current operating plans into 2022.

Net Loss

The net loss for the third quarter of 2020 was $36.1 million, or $0.80 per share on both a basic and diluted basis, as compared to a net loss of $12.4 million, or $0.33 per share on both a basic and diluted basis, for the third quarter of 2019.

R&D Expenses

Research and development (R&D) expenses were $29.3 million for the third quarter of 2020, as compared to $10.1 million for the third quarter of 2019.

G&A Expenses

General and administrative (G&A) expenses were $7.4 million for the third quarter of 2020, as compared to $2.6 million for the third quarter of 2019.

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 Company's Phase 2b/3 DAZZLE pivotal study in patients with treatment-naïve wet AMD was initiated in October 2019, 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. These studies are anticipated to form the basis of the Company's initial BLA to support potential approval and commercialization. An additional pivotal study in patients with non-proliferative diabetic retinopathy is planned. Kodiak Sciences Inc. is developing KSI-301 and owns global rights to KSI-301.

About the GLEAM and GLIMMER Studies in DME

The Phase 3 GLEAM and GLIMMER studies are global, multi-center, randomized studies designed to evaluate the efficacy, durability 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 the change from baseline in best-corrected vision at one year, and patients will be treated and followed for two years. Additional information about the GLEAM study (also called Study KS301P104) and the GLIMMER study (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 in RVO

The Phase 3 BEACON study is a global, multi-center, randomized study designed to evaluate the efficacy, durability 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. The study is expected to enroll approximately 550 patients worldwide. The primary endpoint is the change from baseline in best-corrected vision at six months, and patients will be treated and followed for one year. 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 DAZZLE Study in Wet AMD

The Phase 2b/3 DAZZLE study is a global, multi-center, randomized study designed to evaluate the efficacy, durability 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 is expected to enroll approximately 550 patients worldwide. The primary endpoint is at one year and 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 KSI-301 Clinical Program

The KSI-301 Clinical Program is designed to assess KSI-301's safety, efficacy and durability in wet AMD, DME, RVO and non-proliferative DR (without DME) through clinical studies run in parallel. We are conducting two Phase 3 studies in DME (the GLEAM and GLIMMER studies) to provide the mutually confirmatory studies required by FDA for initial demonstration of safety and efficacy. We also are conducting one study in wet AMD (our

ongoing DAZZLE study) and one study in RVO (the BEACON study) to support approval in these indications. We intend to file this package together in a single BLA in 2022. We also plan to run an additional study in patients with non-proliferative DR without DME (the GLOW study). We expect that the global KSI-301 clinical program will be conducted at 150+ study sites in more than 10 countries.

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 in 2022; the sufficiency of our cash, cash equivalents and marketable securities to fund our operations into 2022; our platform technology and potential therapies; future development plans, including our ability to initiate the GLOW study in early 2021 and present top-line data readout in DAZZLE in early 2022; the ability of the Lonza-Kodiak Ibex facility to provide commercial-scale manufacturing of KSI-301; 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," "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,	
	2020	2019	2020	2019
Operating expenses				
Research and development	$ 29,306	$ 10,115	$ 70,033	$ 24,676
General and administrative	7,357	2,617	19,132	8,330
Total operating expenses	36,663	12,732	89,165	33,006
Loss from operations	(36,663)	(12,732)	(89,165)	(33,006)
Interest income	645	277	2,551	1,070
Interest expense	(6)	(2)	(19)	(8)
Other income (expense), net	(98)	77	120	195
Net loss	$ (36,122)	$ (12,380)	$ (86,513)	$ (31,749)
Net loss per common share, basic and diluted	$ (0.80)	$ (0.33)	$ (1.92)	$ (0.85)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	45,119,885	37,330,066	44,972,085	37,291,328

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

	September 30, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	$ 380,450	$ 348,177
Working capital	$ 359,240	$ 327,519
Total assets	$ 480,736	$ 358,866
Accumulated deficit	$ (244,644)	$ (158,131)
Total stockholders' equity	$ 281,780	$ 345,359

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