

Kodiak Sciences Announces Second Quarter 2019 Financial Results and Recent Business Highlights

August 14, 2019

PALO ALTO, Calif., Aug. 14, 2019 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a clinical stage biopharmaceutical company specializing in novel therapeutics to treat chronic, high-prevalence retinal diseases, today reported business highlights and financial results for the second quarter ended June 30, 2019.

"During the second quarter, we expanded enrollment in our Phase 1b study of KSI-301 across all three major retinal vascular disease indications of wet AMD, diabetic macular edema, and retinal vein occlusion. Last month we presented interim safety and efficacy results on the podium at the American Society of Retina Specialists (ASRS) 2019 Annual Meeting. Across all three diseases under study, we observed strong improvements in vision and retinal anatomy and encouraging signs of disease modification," said Victor Perlroth, M.D., Chief Executive Officer of Kodiak Sciences. "Additionally, this quarter we look forward to initiating our pivotal Phase 2 DAZZLE study of KSI-301 head-to-head versus aflibercept in patients with treatment-naïve wet AMD, with all patients randomized to KSI-301 on an every 12-week or longer dosing regimen after three monthly loading doses. We are excited by the growing body of promising safety and efficacy data on KSI-301, the opportunities to present evolving durability data at upcoming ophthalmology meetings, and our expanding set of clinical studies with the molecule."

Recent Business Highlights:

Positive Data from Ongoing Phase 1b Study of KSI-301 Presented at ASRS 2019 Meeting

The first data from the ongoing Phase 1b study of KSI-301 in patients with anti-VEGF treatment-naïve neovascular (wet) age-related macular degeneration (AMD), diabetic macular edema (DME), and macular edema due to retinal vein occlusion (RVO) were presented at the American Society of Retina Specialists (ASRS) 2019 Annual Meeting. Across all three diseases under study, strong improvements in vision and retinal anatomy were observed over 12 weeks. The efficacy data presented at ASRS include outcomes from 35 patients in the study who had reached the week 12 visit. In the study, patients are being treated with three monthly doses of either 2.5 mg or 5 mg KSI-301 and followed for 7 months thereafter, with additional treatments according to protocol-specified retreatment criteria. As of the July 24, 2019 ASRS presentation's data cut-off date, a total of 77 patients were enrolled in the Phase 1b study. Further, more than 200 injections with KSI-301 have been given to date across the Phase 1a and Phase 1b program with no intraocular inflammation or ocular serious adverse events reported. Based on the positive data observed to date, Kodiak is planning for supplemental cohorts to explore additional scientific questions relevant to KSI-301 and its use for the treatment of retinal diseases.

Presentation of 12-Week Phase 1a Study of KSI-301 at ARVO 2019 Annual Meeting

Data presentations at the Association for Research in Vision and Ophthalmology (ARVO) 2019 Annual Meeting highlighted the final 12-week results of the Phase 1a clinical study of KSI-301 with sustained responses observed after a single dose of KSI-301, measured as improvement from baseline in vision, retinal anatomy, or both. Through the 12-week last visit, there were no dose-limiting toxicities, no drug-related adverse events, and no signs of intraocular inflammation. Rapid high-magnitude and durable treatment responses were seen at all dose levels tested.

Expected Upcoming Milestones in 2019

- Initiate KSI-301 pivotal phase 2 DAZZLE randomized head-to-head study against aflibercept in treatment-naïve patients with wet AMD with all KSI-301 patients on a 12-week or longer dose regimen. For additional details about the study, please see <https://clinicaltrials.gov/ct2/show/NCT04049266>
- Present additional Phase 1b data at the European Society of Retina Specialists EURETINA Annual Meeting (September), the Annual Meeting of the Retina Society (September), and the American Academy of Ophthalmology (AAO) Annual Meeting (October)

Second Quarter 2019 Financial Results and Financial Guidance

Cash Position

Kodiak ended the second quarter of 2019 with \$68.1 million of cash, cash equivalents and marketable securities. The Company expects that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations at least through the first half of 2020.

Net Loss

The net loss for the second quarter of 2019 was \$11.4 million, or \$0.31 per share on both a basic and diluted basis, as compared to a net loss of \$7.4 million, or \$0.96 per share on both a basic and diluted basis, for the second quarter of 2018.

R&D Expenses

Research and development (R&D) expenses were \$8.8 million for the second quarter of 2019, as compared to \$3.6 million for the second quarter of 2018.

G&A Expenses

General and administrative (G&A) expenses were \$3.0 million for the second quarter of 2019, as compared to \$1.5 million for the second quarter of 2018.

About KSI-301

KSI-301 is an investigational therapy built on the Company's 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. KSI-301 is being developed and is fully owned globally by Kodiak Sciences Inc.

About Kodiak Sciences Inc.

Kodiak™ is a clinical-stage biopharmaceutical company specializing in novel therapeutics to treat chronic, 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. Our ABC Platform™ merges 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 and diabetic eye diseases. 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. Kodiak is based in Palo Alto, CA. For more information, 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 our platform technology and potential therapies, future development plans, clinical and regulatory objectives and the timing thereof, expectations regarding the sufficiency of cash, cash equivalents and marketable securities to fund operations at least through the first half of 2020, anticipated design of planned clinical trials, expectations regarding the potential efficacy and commercial potential of our product candidates, including KSI-301, 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. Statements that are not historical fact are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that involve risks, uncertainties and other factors that may cause actual results, events or developments to be materially different from those expressed or implied by such forward-looking statements. These risks and uncertainties, many of which are beyond our control, include, but are not limited to: clinical trials may not demonstrate safety and efficacy of any of our product candidates; our assumptions regarding our planned expenditures and sufficiency of our cash to fund operations may be incorrect; our efforts to advance the clinical development of additional product candidates may not be successful; any of our product candidates may fail in development; the preliminary safety, efficacy and durability data for our KSI-301 product candidate from the Phase 1 study will not continue or persist; cessation or delay of any of the ongoing clinical studies and/or our development of KSI-301 may occur; 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; 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," "ABC Platform" and the Kodiak logo are registered trademarks or trademarks of Kodiak Sciences Inc. in various jurisdictions.

Kodiak Sciences Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Operating expenses				
Research and development	\$ 8,838	\$ 3,591	\$ 14,561	\$ 7,233
General and administrative	2,976	1,499	5,713	3,404
Total operating expenses	11,814	5,090	20,274	10,637
Loss from operations	(11,814)	(5,090)	(20,274)	(10,637)
Interest income	431	76	911	124
Interest expense	(2)	(1,877)	(6)	(3,347)
Other income (expense), net	—	(518)	-	(2,469)
Net loss	\$ (11,385)	\$ (7,409)	\$ (19,369)	\$ (16,329)
Net loss per common share, basic and diluted	\$ (0.31)	\$ (0.96)	\$ (0.52)	\$ (2.11)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	37,294,853	7,757,081	37,271,638	7,720,967

Kodiak Sciences Inc.

Condensed Consolidated Balance Sheet Data

(Unaudited)

(in thousands)

	June 30, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	\$ 68,101	\$ 88,254
Working capital	\$ 64,278	\$ 85,623
Total assets	\$ 78,275	\$ 92,189
Accumulated deficit	\$ (130,135)	\$ (110,766)
Total stockholders' equity	\$ 70,019	\$ 86,833

View original content: <http://www.prnewswire.com/news-releases/kodiak-sciences-announces-second-quarter-2019-financial-results-and-recent-business-highlights-300901237.html>

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