

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

May 15, 2019

PALO ALTO, Calif., May 15, 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 first quarter ended March 31, 2019.

"This year, a major focus of the company is to build our voice in the scientific, clinical and investor communities. In the first quarter, we were pleased to present the science of our ABC Platform and the early clinical data of KSI-301 on the podium for the first time at a major ophthalmology meeting," said Victor Periroth, M.D., Chief Executive Officer of Kodiak Sciences. "We continue to enroll well in our Phase 1b multiple-dose study of KSI-301 in patients with wet AMD, diabetic macular edema, and retinal vein occlusion. We are pleased with the emerging clinical data which show bioactivity in all three diseases and no intraocular inflammation or drug-related adverse events to date. Based on strong investigator interest, we are expanding the Phase 1b study from 50 to 90 patients balanced across the three indications. We look forward to presenting data from the Phase 1b study on the podium at upcoming major medical meetings in the second half of 2019. At the same time, our team is focused on initiating recruitment in our global Phase 2 study of KSI-301 in wet AMD. We also held a successful pre-IND meeting with China's Center for Drug Evaluation."

Recent Business Highlights:

Presentation of 12-Week Phase 1a Study of KSI-301 at Angiogenesis and ARVO 2019 Annual Meetings

Data presentations at the Angiogenesis 2019 Meeting and the ARVO 2019 Meeting highlighted the final twelve-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.

Expanding Enrollment in Phase 1b Study of KSI-301

The Phase 1b open-label multiple-dose study of KSI-301 continues to recruit well 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). Based on strong investigator support, we have elected to increase the targeted number of patients from 50 to 90 with approximately ten additional patients in each of wet AMD and DME and twenty in RVO. This study is designed to provide additional scientific and clinical understanding of the safety, bioactivity and durability of KSI-301 in retinal vascular disease. All patients receive three loading doses once a month and are then followed monthly with further KSI-301 treatments determined by disease-specific retreatment criteria. All patients will be evaluated through 36-weeks. To date, we have not observed signs of intraocular inflammation in the multiple dose setting with more than 75 doses administered in total. Kodiak expects to present data from the Phase 1b study in the second half of 2019.

Held Pre-IND Meeting for KSI-301 with China's Center for Drug Evaluation (CDE)

The Kodiak team held a successful pre-IND meeting with China's CDE. Based on the discussion and advice received, Kodiak currently expects to submit one or more INDs for confirmatory (pivotal) studies of KSI-301 in China in the second half of 2019. These studies are being designed and planned as dual-use studies to support China and global regulatory requirements.

Manufacturing Platforms

Kodiak continues to expand its chemical and biologics manufacturing capabilities and leadership in anticipation of expanded manufacturing for KSI-301, KSI-501 and our pipeline. Laurent Ducry, PhD, has joined as Vice President, Biologics Development and Manufacturing, after a successful 19-year career at Lonza where he led the bioconjugates business of Lonza including large scale commercial supply of marketed antibody drug conjugate products.

Expected Upcoming Milestones in 2019:

- Initiate KSI-301 Phase 2 randomized head-to-head study against aflibercept in patients with wet AMD, testing a potential leading wet AMD profile of all KSI-301 patients on a 12-week, 16-week or 20-week dosing regimen.
- Complete expanded recruitment into KSI-301 Phase 1b multiple-dose study in patients with wet AMD, DME, and RVO.
- Present Phase 1b data in the second half of 2019, including podium presentations at the American Society of Retina Specialists (ASRS) and American Academy of Ophthalmology (AAO) meetings.
- File one or more INDs in China for KSI-301.

First Quarter 2019 Financial Results and Financial Guidance:

Cash Position

Kodiak ended the first quarter of 2019 with \$81.1 million of cash and cash equivalents and marketable securities. The Company expects that its existing cash and cash equivalents and marketable securities will be sufficient to fund projected operations for at least the next twelve months.

Net Loss

The net loss for the first quarter of 2019 was \$8.0 million, or \$0.21 per share on both a basic and diluted basis, as compared to a net loss of \$8.9 million, or \$1.16 per share on both a basic and diluted basis, for the first quarter of 2018.

R&D Expenses

Research and development (R&D) expenses were \$5.7 million for the first quarter of 2019, as compared to \$3.6 million for the first quarter of 2018.

G&A Expenses

General and administrative (G&A) expenses were \$2.7 million for the first quarter of 2019, as compared to \$1.9 million for the first quarter of 2018.

About Kodiak Sciences Inc.

Kodiak™ is a clinical-stage biopharmaceutical company specializing in novel therapeutics to treat chronic, high-prevalence retinal diseases. Our ABC Platform™ merges the fields of antibody-based and chemistry-based therapies and is at the core of Kodiak's discovery engine. In addition to its lead product candidate, KSI-301, a novel anti-VEGF antibody biopolymer conjugate in clinical development for the treatment of age-related macular degeneration and diabetic retinopathy, 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 such as wet AMD and diabetic retinopathy. 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 to fund operations for at least the next 12 months, expectations regarding the potential efficacy and commercial potential of our product candidates, the anticipated presentation of data at upcoming conferences, 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; as well as the other risks identified in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and we undertake 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	
	March 31,	
	2019	2018
Operating expenses		
Research and development	\$ 5,723	\$ 3,642
General and administrative	2,737	1,905
Total operating expenses	8,460	5,547
Loss from operations	(8,460)	(5,547)
Interest income	480	48
Interest expense	(4)	(1,470)
Other income (expense), net	—	(1,951)
Net loss	\$ (7,984)	\$ (8,920)
Net loss per common share, basic and diluted	\$ (0.21)	\$ (1.16)
Weighted-average common shares outstanding used computing net loss per common share, basic and diluted	37,248,165	7,684,045

Kodiak Sciences Inc.

Condensed Consolidated Balance Sheet Data

(Unaudited)

(in thousands)

	March 31, 2019	December 31, 2018
Cash and cash equivalents and marketable securities	\$ 81,075	\$ 88,254
Working capital	\$ 78,504	\$ 85,623
Total assets	\$ 87,077	\$ 92,189
Accumulated deficit	\$ (118,750)	\$ (110,766)
Total stockholders' equity	\$ 80,095	\$ 86,833

SOURCE Kodiak Sciences Inc.

John Borgeson, Senior Vice President and Chief Financial Officer, Tel (650) 281-0850, ir@kodiak.com