

Kodiak Sciences Announces Fourth Quarter and Full Year 2018 Financial Results and Recent Business Highlights

March 28, 2019

PALO ALTO, Calif., March 28, 2019 /PRNewswire/ -- Kodiak Sciences Inc. (Nasdaq: KOD), a clinical-stage biopharmaceutical company specializing in novel therapeutics to treat chronic, high-prevalence retinal diseases, reported business highlights and financial results for the fourth quarter and full year ended December 31, 2018.

"The fourth quarter of 2018 capped an exciting year for Kodiak with the completion of our initial public offering, the completion of our Phase 1a clinical study of KSI-301 demonstrating 12-week safety and durability in patients with Diabetic Macular Edema, and the initiation of our multiple dose Phase 1b clinical study in treatment naïve patients in an expanded set of retinal vascular disease indications," said Victor Perloth, M.D., Chief Executive Officer of Kodiak Sciences. "Our strategy is to develop KSI-301 to be the anti-VEGF of choice for physicians and patients while further deepening our pipeline of development candidates in the major retinal diseases. In 2019, we are focused on expanding our clinical efforts with KSI-301. We expect to complete patient enrollment in our Phase 1b study and present study data at key ophthalmology meetings. We are on track to initiate our global (US and EU) Phase 2 study head-to-head against Eylea in wet AMD. We have submitted pre-IND dossiers to the Chinese Center for Drug Evaluation (CDE), and we are eager to engage on our IND with China regulators as we intend to run our China studies as pivotals designed to meet global ICH standards. This year we also anticipate further advancements in our pipeline of ABC Platform therapeutic candidates. We have progressed KSI-501 into mammalian cell line development, and this bispecific ABC development candidate is demonstrating attractive manufacturing yields. Our goal is to design and develop additional product candidates to prevent and treat leading causes of blindness globally, and we continue to make important strides in this direction."

Recent Business Highlights:

Completion of 12-Week Phase 1a Study of KSI-301 and Presentation at Angiogenesis 2019

In December 2018, we reported final twelve-week data from our Phase 1a single ascending dose clinical study of KSI-301 with sustained responses observed in eight of nine patients after a single dose of KSI-301, measured as improvement from baseline in vision, retinal anatomy, or both. Through the 12-week last visit, single doses of KSI-301 demonstrated 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 in a heavily pre-treated Phase 1 patient population. Data were first presented at the Angiogenesis, Exudation, and Degeneration 2019 medical meeting on February 9, 2019.

Phase 1b Study of KSI-301

We have initiated and continue to recruit into our Phase 1b open-label multiple-dose 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). This study is designed to provide additional understanding of the bioactivity and durability of KSI-301 and to enroll approximately 50 patients. All patients receive three loading doses once a month and then are followed monthly, with further KSI-301 treatment determined by disease-specific retreatment criteria. All patients are planned to be evaluated through 36-weeks. Kodiak expects to present data from the Phase 1b study in the second half of 2019.

Anticipated Milestones in 2019

- Complete patient recruitment into KSI-301 Phase 1b multiple-dose study in patients with wet AMD, DME, and RVO and present study data at key ophthalmology meetings
- Initiate KSI-301 Phase 2 randomized head-to-head study against aflibercept in patients with wet AMD, with all KSI-301 patients receiving every 12-, 16-, or 20-week dosing
- Hold China Pre-IND Meeting and submit China INDs for KSI-301 Phase 2 trials

Fourth Quarter and Full Year 2018 Financial Results:

Cash Position

Kodiak ended 2018 with \$88.3 million of cash and cash equivalents. The Company expects that its existing cash and cash equivalents will be sufficient to fund our projected operations for at least the next twelve months.

Net Loss

The net loss for the fourth quarter of 2018 was \$14.7 million, or \$0.40 per share on both a basic and diluted basis, as compared to a net loss of \$11.6 million, or \$1.52 per share on both a basic and diluted basis, for the fourth quarter of 2017. The net loss for the year ended December 31, 2018 was \$41.4 million, or \$2.77 per share on both a basic and diluted basis, as compared to a net loss of \$27.9 million, or \$3.72 per share on both a basic and diluted basis, for the year ended December 31, 2017.

R&D Expenses

Research and development (R&D) expenses were \$6.9 million for the fourth quarter of 2018, as compared to \$8.8 million for the fourth quarter of 2017. R&D expenses were \$18.8 million for the year ended December 31, 2018, as compared to \$22.0 million for the year ended December 31, 2017.

G&A Expenses

General and administrative (G&A) expenses were \$2.5 million for the fourth quarter of 2018, as compared to \$1.0 million for the fourth quarter of 2017. G&A expenses were \$7.6 million for the year ended December 31, 2018, as compared to \$3.5 million for the year ended December 31, 2017.

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 December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Operating expenses				
Research and development	\$ 6,851	\$ 8,777	\$ 18,793	\$ 22,022
General and administrative	2,506	980	7,581	3,499
Total operating expenses	<u>9,357</u>	<u>9,757</u>	<u>26,374</u>	<u>25,521</u>
Loss from operations	(9,357)	(9,757)	(26,374)	(25,521)
Interest expense	(190)	(778)	(5,519)	(1,185)
Other income (expense), net	364	(1,035)	(4,071)	(1,230)
Loss on extinguishment of debt	(5,479)	-	(5,479)	-
Net loss and comprehensive loss	<u>\$ (14,662)</u>	<u>\$ (11,570)</u>	<u>\$ (41,443)</u>	<u>\$ (27,936)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.40)</u>	<u>\$ (1.52)</u>	<u>\$ (2.77)</u>	<u>\$ (3.72)</u>
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	<u>36,376,234</u>	<u>7,618,592</u>	<u>14,976,515</u>	<u>7,515,336</u>

Kodiak Sciences Inc.

Condensed Consolidated Balance Sheet Data

(Unaudited)

(in thousands)

	December 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 88,254	\$ 1,395
Working capital	85,623	(7,563)
Total assets	92,189	3,244
Accumulated deficit	(110,766)	(69,323)
Total stockholders' equity (deficit)	86,833	(68,738)

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