

Kodiak Sciences Announces Fourth Quarter and Full Year 2019 Financial Results and Recent Business Highlights

March 16, 2020

PALO ALTO, Calif., March 16, 2020 /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 fourth quarter and full year ended December 31, 2019.

"We made tremendous progress this past year toward our goal of developing a next generation platform for retinal medicines," said Victor Perloth, MD, CEO of Kodiak Sciences. "We remain very pleased with the emerging clinical profile of KSI-301, our first product candidate built on our ABC Platform. We continue to see impressive safety, efficacy and durability data across our active clinical studies. We initiated our first pivotal clinical study (DAZZLE) assessing KSI-301 in wet age-related macular degeneration (wet AMD) patients. We held a productive End-of-Phase 2 meeting with the FDA in which we reached agreement on an innovative clinical plan for registration. We secured substantive resources to fund accelerated clinical, manufacturing, and commercial plans for KSI-301. We look forward to initiating four more pivotal studies for KSI-301 later this year. We remain focused on achieving our 2022 Vision of filing a BLA in wet AMD, Diabetic Macular Edema (DME), and Retinal Vein Occlusion (RVO) in 2022."

In 2019 and into the first quarter of 2020, highlights of our activities included:

- Initiation of enrollment and on-going recruitment in our pivotal DAZZLE clinical trial of KSI-301 in patients with treatment naïve wet AMD. As of March 6, 2020, more than 175 patients have been enrolled in the study randomized 1:1 between KSI-301 and Eylea;
- Completion of recruitment into our ongoing Phase 1b study of KSI-301 in 121 treatment-naïve patients with wet AMD, DME and RVO;
- Presentation of promising on-going clinical safety, efficacy and durability data at the American Society of Retina Specialists 2019 Annual Meeting, the Macula Society 2019 Annual Meeting, the American Academy of Ophthalmology 2019 Annual Meeting Retina Subspecialty Day, and the Angiogenesis, Exudation, and Degeneration 2020 Annual Meeting;
- Completion of a Type B (End of Phase 2 or EOP) meeting with FDA where we discussed and agreed on:
 - Certain recommended clinical, non-clinical, and manufacturing activities to support the potential licensure of KSI-301, and
 - The order and number of potential clinical studies required to support a BLA in wet AMD, DME, RVO and diabetic retinopathy (DR);
- Announcement of an accelerated registration strategy for KSI-301 which includes: (i) running our pivotal clinical studies in the major retinal vascular disease indications in parallel (rather than in series), and (ii) initiating BLA and pre-commercial manufacturing validation and scale-up activities;
- Expansion of our Board of Directors with the appointment of Taiyin Yang, Ph.D., Executive Vice President, Pharmaceutical Development and Manufacturing of Gilead, who brings expertise and experience in the relevant pre-commercial areas of clinical and commercial manufacturing, quality and supply chain operations;
- Entry into a royalty funding agreement in which we sold a capped, pre-payable 4.5% royalty on future net sales of KSI-301 in exchange for \$225.0 million in committed development funding payable to us, of which \$100.0 million was paid to us in February 2020, with the remaining \$125.0 million to be paid to us following the achievement of certain clinical trial enrollment milestones; and
- Closing of a \$317.4 million follow-on offering of our common stock.

Cash Position

Kodiak ended 2019 with \$348.2 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 our projected operations for at least the next twelve months.

Net Loss

The net loss for the fourth quarter of 2019 was \$15.6 million, or \$0.40 per share on both a basic and diluted basis, as compared to a net loss of \$14.7 million, or \$0.40 per share on both a basic and diluted basis, for the fourth quarter of 2018. The net loss for the year ended December 31, 2019 was \$47.4 million, or \$1.25 per share on both a basic and diluted basis, as compared to a net loss of \$41.4 million, or \$2.77 per share on both a basic and

diluted basis, for the year ended December 31, 2018.

R&D Expenses

Research and development (R&D) expenses were \$12.8 million for the fourth quarter of 2019, as compared to \$6.9 million for the fourth quarter of 2018. R&D expenses were \$37.5 million for the year ended December 31, 2019, as compared to \$18.8 million for the year ended December 31, 2018.

G&A Expenses

General and administrative (G&A) expenses were \$3.4 million for the fourth quarter of 2019, as compared to \$2.5 million for the fourth quarter of 2018. G&A expenses were \$11.7 million for the year ended December 31, 2019, as compared to \$7.6 million for the year ended December 31, 2018.

About KSI-301

KSI-301 is an investigational anti-VEGF therapy built on the Company's Antibody Biopolymer Conjugate, or 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 DAZZLE pivotal study in patients with treatment-naïve wet AMD was initiated in October 2019. Kodiak plans to initiate additional pivotal studies of KSI-301 in 2020 in diabetic macular edema, retinal vein occlusion and diabetic retinopathy. These studies are anticipated to form the basis of the Company's BLA to support potential approval and commercialization.

About the DAZZLE Study

The DAZZLE study (also called Study KSI-CL-102) is a global, multi-center, randomized study designed to evaluate the safety and efficacy 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 standard-care aflibercept on its every eight-week dosing regimen, each after three monthly initiating doses. The primary endpoint is at one year and each patient will be treated and followed for two years. Additional information about DAZZLE can be found on www.clinicaltrials.gov under Trial Identifier NCT04049266 (<https://clinicaltrials.gov/show/NCT04049266>).

About Kodiak Sciences Inc.

Kodiak (Nasdaq: KOD) is a clinical stage biopharmaceutical company specializing in novel therapeutics to treat chronic, 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, a leading cause of blindness in elderly patients, and diabetic eye diseases, a leading cause of blindness in working-age patients. 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 BLA submission in wet AMD, DME, RVO and diabetic retinopathy; the sufficiency of our cash, cash equivalents and marketable securities; our receipt of the remaining amounts under our royalty funding agreement; our platform technology and potential therapies; future development plans; 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; 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; 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 December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Operating expenses				
Research and development	\$ 12,830	\$ 6,851	\$ 37,506	\$ 18,793
General and administrative	3,354	2,506	11,684	7,581
Total operating expenses	<u>16,184</u>	<u>9,357</u>	<u>49,190</u>	<u>26,374</u>
Loss from operations	(16,184)	(9,357)	(49,190)	(26,374)
Interest income	498	431	1,568	617
Interest expense	—	(190)	(8)	(5,519)
Other income (expense), net	70	(67)	265	(4,688)
Loss on extinguishment of debt	—	(5,479)	—	(5,479)
Net loss	<u>\$ (15,616)</u>	<u>\$ (14,662)</u>	<u>\$ (47,365)</u>	<u>\$ (41,443)</u>
Net loss per common share, basic and diluted	<u>\$ (0.40)</u>	<u>\$ (0.40)</u>	<u>\$ (1.25)</u>	<u>\$ (2.77)</u>
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	<u>39,522,146</u>	<u>36,376,234</u>	<u>37,853,616</u>	<u>14,976,515</u>

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

	December 31, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	\$ 348,177	\$ 88,254
Working capital	\$ 327,519	\$ 85,623
Total assets	\$ 358,866	\$ 92,189
Accumulated deficit	\$ (158,131)	\$ (110,766)
Total stockholders' equity	\$ 345,359	\$ 86,833

View original content: <http://www.prnewswire.com/news-releases/kodiak-sciences-announces-fourth-quarter-and-full-year-2019-financial-results-and-recent-business-highlights-301024517.html>

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