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

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PALO ALTO, Calif., Nov. 12, 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 third quarter ended September 30, 2019.

"During the third quarter and into the early fourth quarter, we presented promising safety, efficacy, and durability data from the clinical study of our novel anti-VEGF antibody biopolymer conjugate KSI-301 in retinal diseases and showed for the first time that it is possible for many patients to go for as long as four to six months before retreatment with an intravitreally-injected biologic," said Victor Perlroth, M.D., Chief Executive Officer of Kodiak Sciences. "KSI-301 continues to demonstrate a meaningfully differentiated durability profile across all the diseases under study: wet age-related macular degeneration (wet AMD), diabetic macular edema (DME), and retinal vein occlusion (RVO). We began enrollment in DAZZLE, our pivotal study of KSI-301 in patients with treatment-naïve wet AMD. We completed an End of Phase 2 meeting with FDA, where we confirmed that an approval for KSI-301 in wet AMD, DME, and RVO could potentially be achieved with a total of only four pivotal trials. This allows us to further accelerate the clinical development of KSI-301 and bring DME and diabetic retinopathy (DR) into our 2022 Vision. We look forward to discussing these recent business highlights and also reviewing the latest safety, efficacy, and durability data from our ongoing Phase 1b trial at today's teleconference."

Recent Business Highlights:

- Initiated recruitment in our pivotal 'DAZZLE' clinical trial of KSI-301 in patients with treatment naïve wet AMD;
- Presented promising clinical safety, efficacy, and durability data from the ongoing Phase 1b study of KSI-301 at the American Academy of Ophthalmology Annual Meeting Retina Subspecialty Day;
- Announced an accelerated development and registration strategy for KSI-301;
- Completed a Type B (End of Phase 2 or EOP) meeting with the FDA where we discussed and agreed on:
    - The recommended clinical, non-clinical, and manufacturing activities to support the licensure of KSI-301, and
    - The order and number of clinical studies required to support an initial Biologics License Application (BLA) in RVO and supplemental BLAs (sBLA) in wet AMD, DME, and DR; and
- Provided clarity on a capital efficient "2022 Vision" towards an initial FDA approval of KSI-301 in 2022 for RVO and supplemental BLA submissions in 2022 for wet AMD, DME and potentially DR without DME.

Based on the emerging clinical data as well as our productive EOP meeting with FDA, we are accelerating the clinical development of KSI-301, with the goal of demonstrating a meaningfully-differentiated durability profile in each of wet AMD, RVO, DME, and DR, as compared to currently-marketed medicines and those known to be in clinical development.

Additional details around the accelerated clinical development strategy for KSI-301, the FDA EOP meeting, and the latest clinical data from the ongoing Phase 1b study can also be found in the Company's third quarter 2019 Quarterly Report on Form 10-Q to be filed with the SEC on November 12, 2019.

Conference Call and Webcast
Kodiak will host a business highlights conference call and webcast today at 2:00 p.m. Pacific Time. The call may be accessed by dialing 786-789-4797 and providing the passcode 5902695. The live webcast with synchronized slides will be available on the "Investors & Media" section of Kodiak's website at http://ir.kodiak.com/ and will remain available for replay following the event.

Third Quarter 2019 Financial Results and Financial Guidance

Cash Position

Kodiak ended the third quarter of 2019 with $60.6 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 third quarter of 2019 was $12.4 million, or $0.33 per share on both a basic and diluted basis, as compared to a net loss of $10.5 million, or $1.33 per share on both a basic and diluted basis, for the third quarter of 2018.

R&D Expenses

Research and development (R&D) expenses were $10.1 million for the third quarter of 2019, as compared to $4.7 million for the third quarter of 2018.

G&A Expenses

General and administrative (G&A) expenses were $2.6 million for the third quarter of 2019, as compared to $1.7 million for the third quarter of 2018.

About KSI-301

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

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 study is expected to enroll at least 368 patients worldwide. 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™ 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, and we are expanding our early research pipeline to include ABC Platform based triplet inhibitors for multifactorial retinal diseases such as dry AMD and the neurodegenerative aspects of glaucoma. 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, but are not limited to, statements regarding our platform technology and potential therapies, future development plans including "2022 Vision," clinical and regulatory objectives and the timing thereof, anticipated design of planned clinical trials, including the order and number of clinical studies required to support a potential approval for KSI-301 in wet AMD, DME, RVO and DR, expectations regarding the potential efficacy and commercial potential of our product candidates, including KSI-301 and its ability to reduce treatment burden and improve vision outcomes, the anticipated presentation of data, the results of our research and development efforts, our ability to advance our product candidates into later stages of development and the sufficiency of our cash, cash equivalents and marketable securities. 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 from the Phase 1b 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; 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 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,	
	2019	2018	2019	2018
Operating expenses				
Research and development	$ 10,115	$ 4,709	$ 24,676	$ 11,942
General and administrative	2,617	1,671	8,330	5,075
Total operating expenses	12,732	6,380	33,006	17,017
Loss from operations	(12,732)	(6,380)	(33,006)	(17,017)
Interest income	354	—	1,265	—
Interest expense	(2)	(1,982)	(8)	(5,329)
Other income (expense), net	—	(2,090)	—	(4,435)

Net loss	$ (12,380)	$ (10,452)	$ (31,749)	$ (26,781)
Net loss per common share, basic and diluted	$ (0.33)	$ 1.33	$ (0.85)	$ (3.45)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	37,330,066	7,851,560	37,291,328	7,764,888

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

	September 30, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 60,604	$ 88,254
Working capital	$ 53,743	$ 85,623
Total assets	$ 68,916	$ 92,189
Accumulated deficit	$ (142,515)	$ (110,766)
Total stockholders' equity	$ 59,691	$ 86,833

View original content:http://www.prnewswire.com/news-releases/kodiak-sciences-announces-third-quarter-2019-financial-results-and-recent-business-highlights-300956210.html

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