

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 15, 2019

KODIAK SCIENCES INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38682

(Commission File Number)

27-0476525
(IRS Employer
Identification No.)

2631 Hanover Street
Palo Alto, CA
(Address of Principal Executive Offices)

94304
(Zip Code)

Registrant's telephone number, including area code: (650) 281-0850

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001	KOD	The Nasdaq Stock Market LLC

Item 2.02. Results of Operations and Financial Condition

On May 15, 2019, Kodiak Sciences Inc. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended March 31, 2019. A copy of the Company’s press release is attached hereto as Exhibit 99.1. The information in this Form 8-K and the attached exhibit are furnished to, but not filed with, the Securities and Exchange Commission.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Pursuant to the rules and regulations of the Securities and Exchange Commission, the attached exhibit is deemed to have been furnished to, but not filed with, the Securities and Exchange Commission:

Exhibit

Number	Description
99.1	Press Release issued by Kodiak Sciences Inc. dated May 15, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KODIAK SCIENCES INC.

Date: May 15, 2019

By: _____ /s/ Victor Perloth
Victor Perloth, M.D.
Chief Executive Officer

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

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 Perloth, 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 in 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

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