

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): February 23, 2022

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.)

1200 Page Mill Rd
Palo Alto, California
(Address of Principal Executive Offices)

94304
(Zip Code)

Registrant's Telephone Number, Including Area Code: 650 281-0850

(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:

- 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))

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

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.

Item 2.02 Results of Operations and Financial Condition.

Kodiak Sciences Inc. (the “Company”) expects that, as of December 31, 2021, its cash and cash equivalents were approximately \$731.5 million.

Item 8.01 Other Events.

On February 23, 2022, the Company announced top-line results from its randomized, double-masked, active comparator-controlled Phase 2b/3 clinical trial evaluating the efficacy, durability and safety of KSI-301, a novel antibody biopolymer conjugate, in treatment-naïve subjects with neovascular (wet) age-related macular degeneration.

The trial randomized 559 participants, approximately 80% of whom were enrolled in the United States. The study had two treatment arms: KSI-301 5mg on a flexible long-interval regimen and aflibercept 2mg on a fixed short-interval regimen. In the study, three monthly loading doses were administered to all subjects at 0-, 4- and 8-weeks. Subjects on aflibercept were then treated at fixed 2-month intervals. Subjects on KSI-301 were assessed starting 3 months after the completion of the loading phase (i.e., beginning at 20 weeks) and, based on predefined disease activity criteria, were treated every 3-, 4-, or 5-months, thus patients in the KSI-301 group could not receive dosing more frequently than every 3 months at any point in the study after the loading phase. The primary endpoint of the study was the average change in best-corrected visual acuity (BCVA) score (a measure of the best vision a person can achieve when reading letters on an eye chart, including with correction such as glasses) from baseline at year 1. For the assessment of the primary efficacy endpoint, KSI-301 patients in all three groups (dosed every 3-, 4- or 5-months) were pooled together and their BCVA was compared as a group to the aflibercept group (dosed every 2 months).

The results show that KSI-301 did not meet the primary efficacy endpoint of showing non-inferior visual acuity gains for subjects dosed on extended regimens compared to aflibercept given every eight weeks.

A pre-specified secondary analysis at year 1 assessing durability showed 59% of patients in the KSI-301 arm achieved five-month dosing with visual acuity gains and anatomic improvements comparable to the overall aflibercept group.

KSI-301 was generally safe and well tolerated in the study, with no new safety signals identified. Intraocular inflammation occurred in a low single-digit percent of KSI-301 patients (3.2%), as compared to 0.0% of patients treated with aflibercept. In all cases reported in the Company’s study, the clinical finding of inflammation resolved, and no cases of intraocular inflammation with vascular occlusions were observed.

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 thereunto duly authorized.

KODIAK SCIENCES INC.

Date: February 23, 2022

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