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): August 08, 2022

Kodiak Sciences Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38682**	**27-0476525**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1200 Page Mill Rd **Palo Alto, California**	**94304**
(Address of Principal Executive Offices)	**(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 8.01 Other Events.

On August 8, 2022, Kodiak Sciences Inc. announced that its BEACON Phase 3 study of tarcocimab tedromer (KSI-301; tarcocimab), its novel antibody biopolymer conjugate, met the primary endpoint of non-inferior change from baseline in visual acuity at week 24 compared to aflibercept in patients with macular edema due to retinal vein occlusion. Tarcocimab also demonstrated robust anatomic responses and a favorable safety profile. After two initial monthly loading doses, tarcocimab was dosed every two months compared to consistent monthly dosing for aflibercept.

The BEACON study is a randomized, double-masked, multicenter, active comparator-controlled Phase 3 clinical trial in treatment naïve patients with vision loss and macular edema due to retinal vein occlusion, including both branch (BRVO) and central (CRVO) subtypes. This condition occurs when a branch or central draining vein of the retina becomes blocked, for example due to chronic hypertension, and the retina becomes swollen as a result. The study randomized 568 participants (438 BRVO, 130 CRVO) from 11 countries 1:1 into two treatment arms: tarcocimab tedromer 5 mg on a fixed every-8-week dosing regimen following 2 monthly loading doses and aflibercept 2 mg on a fixed every 4-week dosing regimen per its label.

The primary efficacy endpoint of the study was 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, from baseline at week 24. In the first 24 weeks of the study, patients randomized to tarcocimab received a total of 4 doses compared with 6 doses received by patients randomized to aflibercept.

The non-inferiority margin for the comparison to aflibercept at week 24 was established at 4.5 eye chart letters based on pretrial regulatory feedback and precedent. Under the study's prespecified statistical analysis plan and hierarchical testing strategy for control of type 1 error, non-inferiority of tarcocimab to aflibercept was first demonstrated in patients with branch RVO, with a statistically significant p-value of 0.0004, and then also demonstrated with a statistically significant p-value of 0.0243 in the overall RVO population (branch and central types combined). Tarcocimab tedromer was safe and well tolerated in the study, with no new safety signals identified. A low rate of intraocular inflammation was observed in both groups (1.4% vs 0.4% for tarcocimab and aflibercept, respectively) with no vasculitis or retinal arterial occlusion events reported in any patient.

Full primary results from the BEACON study are expected to be presented by BEACON Study Investigators at upcoming ophthalmology congresses in September 2022.

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: August 8, 2022

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