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): November 06, 2023

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 November 6, 2023, Kodiak announced that its Phase 3 GLOW superiority study evaluating tarcocimab tedromer 5 mg in moderately severe to severe non-proliferative diabetic retinopathy (NPDR) met its one-year primary endpoint.

The Phase 3 GLOW study is a global, multi-center, randomized pivotal superiority study designed to evaluate the efficacy and safety of tarcocimab tedromer in treatment-naïve patients with moderately severe to severe NPDR. Patients are randomized to receive either tarcocimab every six months after initiating doses given at baseline, 8 weeks and 20 weeks into the study, or to receive sham injections. At one year, GLOW met its primary endpoint of the proportion of patients with at least a 2-step improvement on the Diabetic Retinopathy Severity Scale (DRSS) score, a grading system measuring the degree of retinopathy. Tarcocimab achieved a 29-fold increased response rate ratio, with 41.1% of evaluable patients on tarcocimab demonstrating at least 2-step improvement versus 1.4% of evaluable patients in the sham group (p less than 0.0001). Visual acuity and retinal anatomy were improved and stable with tarcocimab on its extended-dosing intervals. At one year, GLOW also met its key secondary endpoint of greater reductions in the proportion of patients developing sight-threatening complications (such as diabetic macular edema and proliferative diabetic retinopathy), versus sham, demonstrating an 89% decreased risk, achieving 21.0% versus 2.3% (p less than 0.0001). Tarcocimab also showed a 95% risk reduction in the development of DME, versus sham, from 13.7% on sham versus 0.7% on tarcocimab.

After the occurrence of a sight-threatening complication, all subjects were rescued with open-label tarcocimab, where subjects received two loading doses once monthly followed by continued every 12-week dosing. In patients developing sight-threatening complications, the initial visual acuity decrease and retinal anatomy worsening were both rapidly controlled and then stabilized with every 12-week dosing of tarcocimab.

The rates of serious ocular adverse events and intraocular inflammation in patients treated with tarcocimab and sham were similar in both groups.

Kodiak paused further development of tarcocimab after its GLEAM and GLIMMER studies in diabetic macular edema did not meet their primary endpoint. Kodiak intends to resume the tarcocimab tedromer development program. Following dialogue with the U.S. FDA, Kodiak also intends to conduct one additional pivotal study with an enhanced formulation of tarcocimab, after which, depending on the results of the additional study, Kodiak intends to pursue a single BLA submission for wet age-related macular degeneration, macular edema due to retinal vein occlusion and NDPR.

Forward-Looking Statements

This report 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: Kodiak’s plans to resume development of tarcocimab tedromer, conduct an additional pivotal study and potentially submit a single BLA for wAMD, RVO and NPDR; the pathway for a single potential BLA submission for approval of tarcocimab for RVO, wAMD and NPDR on the basis of the BEACON, DAYLIGHT and GLOW plus one additional pivotal trial; and expectations and plans for the development of KSI-501. 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," "could," "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 risk that the BEACON and/or GLOW results may not provide the evidence, insights or benefits as anticipated; the risk that the results of the tarcocimab Phase 3 studies plus one additional pivotal study may not be sufficient to support a single BLA submission for wAMD, RVO and NPDR; the risk that a BLA may not be accepted by, or receive approval from, the FDA or foreign regulatory agencies when expected, or at all; the risk that cessation, modification or delay of any of the ongoing clinical studies and our development of tarcocimab and/or KSI-501 may occur; the risk that safety, efficacy and durability data observed in our product candidates in current or prior studies may not continue or persist; the risk that our research and development efforts and our ability to advance our product candidates into later stages of development may fail; the risk that KSI-501 may not inhibit VEGF and IL-6 or have an impact on the treatment of patients as expected; the risk that 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, which may significantly impact our business and operations, including our clinical trial sites, as well as the business or operations of our manufacturers, contract research organizations or other third parties with whom we conduct business; 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-K, 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.

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: November 6 , 2023

By: /s/ Victor Perlroth

Victor Perlroth, M.D.
Chief Executive Officer