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 14, 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 2.02 Results of Operations and Financial Condition.

On November 14, 2023, Kodiak Sciences Inc. (the "Company") published a press release reporting the Company's financial results for the quarter ended September 30, 2023 and business highlights. A copy of the Company's press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2. of Form 8-K, the information contained or incorporated herein, including the press release filed as Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release published by Kodiak Sciences Inc. dated November 14, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 14, 2023

By: /s/ Victor Perlroth

Victor Perlroth, M.D.
Chief Executive Officer

Exhibit 99.1

Kodiak Sciences Announces Third Quarter 2023 Financial Results and Recent Business Highlights

Palo Alto, CA — November 14, 2023 – Kodiak Sciences Inc. (Nasdaq: KOD), today reported business highlights and financial results for the quarter ended September 30, 2023.

“We have three retinal disease prospects in our pipeline: two molecules built with our antibody biopolymer conjugate platform (ABC Platform), (1) tarcocimab ABC, an anti-VEGF bioconjugate, (2) KSI-501 ABC, a bispecific anti-IL-6 and anti-VEGF bioconjugate, as well as (3) KSI-501 P, a bispecific anti-IL-6 and anti-VEGF protein (not conjugated) which is not part of the ABC Platform. We believe this pipeline of three promising retina candidates, combined with our learnings from running six tarcocimab phase 3 pivotal studies, positions the Company well for the future,” said Dr. Victor Perlroth, CEO of Kodiak.

“We recently announced our plan to reboot the tarcocimab program following strong data in both our GLOW diabetic retinopathy study and our one-year head-to-head BEACON retinal vein occlusion (RVO) study. We believe tarcocimab with its 6-month durability profile could be a differentiated, value-add medicine for patients and providers,” continued Dr. Perlroth. “We also believe that our extensive clinical experience to date with tarcocimab should allow us to design and run one additional pivotal study that, if successful, can serve as the basis for a single Biologics License Application (BLA) for macular edema following retinal vein occlusion (RVO), wet age-related macular degeneration (wAMD) and non-proliferative diabetic retinopathy (NPDR). We look forward to sharing the emerging details around our portfolio development plan and timing.” concluded Dr Perlroth.

Recent Business Highlights

- ***Tarcocimab pivotal program:*** We unmasked our GLOW phase 3 study of tarcocimab in patients with moderately severe and severe diabetic retinopathy. GLOW met its primary endpoint 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). GLOW also met all key secondary endpoints, including 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% in the sham group (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.
- ***KSI-501 clinical program:*** Our Phase 1 study of KSI-501 ABC has completed its enrollment and dosing phases, and patient data are continuing to be collected. Clinical data are expected to be presented in the first quarter of 2024 at an upcoming scientific meeting. We also announced our intention to develop both (1) the KSI-501 ABC bioconjugate in an enhanced formulation containing a mix of free (unconjugated) protein together with bioconjugated protein and (2) the KSI-501 P unconjugated protein. The KSI-501 program may represent a new category of retinal medicine with applicability both to inflammatory diseases of the retina as well as the existing high prevalence diseases of the retina such as DME and wAMD.

Third Quarter 2023 Financial Results

Cash Position

Kodiak ended the third quarter of 2023 with $345.7 million of cash and cash equivalents.

Net Loss

The net loss for the third quarter of 2023 was $50.0 million, or $0.95 per share on both a basic and diluted basis, as compared to a net loss of $77.0 million, or $1.47 per share on both a basic and diluted basis, for the third quarter of 2022. The net loss for the quarter ended September 30, 2023 included non-cash stock-based compensation of $13.9 million, as compared to $26.2 million for the quarter ended September 30, 2022.

R&D Expenses

Research and development (R&D) expenses were $36.2 million for the third quarter of 2023, as compared to $61.7 million for the third quarter of 2022. The R&D expenses for the third quarter of 2023 included non-cash stock-based compensation of $2.7 million, as compared to $14.9 million for the third quarter of 2022. The decrease in R&D expenses for the third quarter of 2023 was primarily driven by reduction in expense during the pause of tarcocimab development and equity award forfeitures related to the 2021 Long-Term Performance Incentive Plan.

G&A Expenses

General and administrative (G&A) expenses were $18.3 million for the third quarter of 2023, as compared to $17.8 million for the third quarter of 2022. The G&A expenses included non-cash stock-based compensation of $11.2 million for both periods.

About GLOW

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 non-proliferative diabetic retinopathy ("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. The primary endpoint is at one year. Outcomes include changes in diabetic retinopathy severity, measured on a standardized photographic grading scale, and the proportion of tarcocimab treated patients who developed a sight threatening complication due to diabetic retinopathy. Additional information about GLOW (also called Study KS301P106) can be found on www.clinicaltrials.gov under Trial Identifier NCT05066230 (https://clinicaltrials.gov/show/NCT05066230).

About Kodiak Sciences Inc.

Kodiak (Nasdaq: KOD) is a biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat 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 antibody biopolymer conjugate platform, or ABC Platform™, is at the core of Kodiak's discovery engine. Kodiak's first investigational medicine, tarcocimab tedromer, is a novel anti-VEGF antibody biopolymer conjugate explored for the treatment of retinal vascular diseases. Kodiak's second clinical program, KSI-501, built from a first-in-class bispecific protein targeting both IL-6 (anti-IL-6 antibody) and VEGF (VEGF-trap), is intended to treat both orphan and high prevalence retinal diseases. Kodiak is based in Palo Alto, CA. For more information, please 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: the potential benefits of KSI-501, including that it may represent a new category of retinal medicine with applicability both to inflammatory diseases of the retina as well as the existing high prevalence diseases of the retina such as DME and wAMD; the prospects of the candidates in our pipeline, including tarcocimab ABC, KSI-501 ABC, as well as KSI-501 P; our ability to apply our clinical experience with tarcocimab to allow us to design and run one additional pivotal study, and the potential success of such study; our ability to file a single BLA together for macular edema following RVO, wAMD and NPDR; tarcocimab's differentiated durability profile; the potential for Kodiak's ABC Platform and tarcocimab to be important innovations for patients; the expected enhancements and benefits of a new formulation; tailored clinical development plan to KSI-501 based on the learnings from the tarcocimab clinical program and the ABC platform itself; and planned expansion of our research pipeline. 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 cessation or delay of any of the on-going clinical studies and our development of tarcocimab or KSI-501 may occur; the risk that the BEACON and/or GLOW results may not provide the evidence, insights or benefits as anticipated; 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 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; future potential regulatory milestones of tarcocimab or KSI-501, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; the risk that a new formulation of tarcocimab, KSI-501 or other ABC Platform derived molecules may not provide the benefits expected; 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; any one or more of our product candidates may not be successfully developed, approved or commercialized; our manufacturing facilities may not operate as expected; 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.

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,	
	2023	2022	2023	2022
Operating expenses				
Research and development	$ 36,188	$ 61,676	$ 159,669	$ 211,597
General and administrative	18,312	17,802	54,278	55,716
Total operating expenses	54,500	79,478	213,947	267,313
Loss from operations	(54,500)	(79,478)	(213,947)	(267,313)
Interest income	4,536	2,484	12,836	4,054
Interest expense	(5)	(4)	(13)	(14)
Other income (expense), net	(38)	(40)	149	(102)
Net loss	$ (50,007)	$ (77,038)	$ (200,975)	$ (263,375)
Net loss per common share, basic and diluted	$ (0.95)	$ (1.47)	$ (3.84)	$ (5.04)
Weighted-average shares of common stock outstanding used in computing net loss per common share, basic and diluted	52,455,620	52,288,257	52,391,083	52,227,072

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

	September 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 345,668	$ 478,933
Working capital	$ 280,153	$ 433,509
Total assets	$ 547,652	$ 666,628
Accumulated deficit	$ (1,093,015)	$ (892,040)
Total stockholders' equity	$ 302,417	$ 436,167

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