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 09, 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 2.02 Results of Operations and Financial Condition.

On November 9, 2022, Kodiak Sciences Inc. (the "Company") issued a press release reporting the Company's financial results for the quarter ended September 30, 2022. 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 issued by Kodiak Sciences Inc. dated November 9, 2022
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 9, 2022

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

Kodiak Sciences Announces Third Quarter 2022 Financial Results and Recent Business Highlights

Palo Alto, CA — November 9, 2022 – Kodiak Sciences Inc. (Nasdaq: KOD), a biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat high prevalence retinal diseases, today reported business highlights and financial results for the quarter ended September 30, 2022.

“We continue to execute on our comprehensive pivotal clinical program for tarcocimab tedromer and remain on track to report topline results for all of the ongoing Phase 3 studies in diabetic macular edema, wet age-related macular degeneration and non-proliferative diabetic retinopathy over the next 12 months,” said Victor Perlroth, MD, Chief Executive Officer of Kodiak Sciences. “The retinal vascular disease treatment landscape continues to evolve as new data become available on anti-VEGF therapies from incumbent players. These Phase 3 and commercial anti-VEGF medicines do not appear to be designed with a science of durability and currently are delivering an every 3 to 4-month dosing interval. We remain focused on the vision for tarcocimab, designed from the ground up with a science of durability, to deliver strong efficacy and solid safety while bringing a majority of patients to every 5 and 6-month dosing, which we continue to view as a first-line profile. To this point, in our BEACON study, tarcocimab tedromer is the only anti-VEGF therapy that in clinical trials demonstrated non-inferior vision outcomes in retinal vein occlusion with a doubling of the treatment interval for all patients versus monthly aflibercept. And in our DAZZLE study in patients with wet age-related macular degeneration, although the study demonstrated that a minority of patients may have benefited from treatment with tarcocimab more frequently than every 3 months, the study also indicated that the majority of patients receiving tarcocimab every 5 months could obtain and maintain excellent visual outcomes. If approved, tarcocimab has the potential to provide best in class durability thereby resulting in improved patient outcomes and quality of life.”

Recent Business Highlights

- ***Update on Tarcocimab tedromer Clinical Program:*** We continued to advance our ongoing, fully-enrolled Phase 3 pivotal studies, with four Phase 3 studies on track to read out topline data in 2023:
  - **GLEAM / GLIMMER:** Our paired Phase 3 long-interval (as infrequently as every 6 months) studies GLEAM and GLIMMER in diabetic macular edema (“DME”) are expected to report topline data in mid-2023 and if successful are designed to serve as the primary basis for a licensing application and potential regulatory approval of tarcocimab.
  - **DAYLIGHT:** Our Phase 3 short-interval study DAYLIGHT in wet age-related macular degeneration (wet “AMD”) is expected to report topline results in mid-2023. If successful, we expect DAYLIGHT to contribute data to support approval of tarcocimab in wet AMD.
  - **GLOW:** Our Phase 3 long-interval (every 6 months) treatment and vision loss prevention study GLOW of tarcocimab versus sham in non-proliferative diabetic retinopathy without DME (“NPDR”) is expected to report topline results in the second half of 2023. If successful, we expect GLOW to contribute data to support approval of tarcocimab in NPDR with the potential to be the longest-interval intravitreal therapeutic option in this disease.
  - **BEACON:** The primary (6 month) efficacy and safety results of our successful BEACON study of tarcocimab versus aflibercept in retinal vein occlusion were reported at the 2022 EURetina and AAO scientific congresses.
- ***Commercial Manufacturing:*** We continued our manufacturing scale up activities of tarcocimab tedromer to support a potential commercial launch.
- ***Pipeline Progression:*** We continued progressing our pipeline product candidates, in particular KSI-501. KSI-501 is our dual inhibitor antibody biopolymer conjugate targeting both IL-6 (anti-IL-6 antibody) and VEGF (VEGF-trap) for the treatment of retinal diseases with an inflammatory component, including DME and uveitic macular edema. We believe we are on track to file the IND for KSI-501 in the fourth quarter of 2022 and to begin the Phase 1 clinical study in early 2023.

Third Quarter 2022 Financial Results

Cash Position

Kodiak ended the third quarter of 2022 with $537.4 million of cash, cash equivalents and marketable securities. This includes an unrealized loss of $2.5 million on the investment portfolio due to rising interest rates during the quarter.

Net Loss

The net loss for the third quarter of 2022 was $77.0 million, or $1.47 per share, on both a basic and diluted basis, as compared to a net loss of $67.5 million, or $1.30 per share, on both a basic and diluted basis, for the third quarter of 2021. The net loss for the quarter ended September 30, 2022 included non-cash stock-based compensation of $26.2 million.

R&D Expenses

Research and development (R&D) expenses were $61.7 million for the third quarter of 2022, as compared to $56.0 million for the third quarter of 2021. The R&D expenses for the third quarter of 2022 included non-cash stock-based compensation of $14.9 million. The increase in R&D expenses was primarily driven by higher non-cash stock-based compensation.

G&A Expenses

General and administrative (G&A) expenses were $17.8 million for the third quarter of 2022, as compared to $11.5 million for the third quarter of 2021. The G&A expenses for the third quarter of 2022 included non-cash stock-based compensation of $11.2 million. The increase in G&A expenses was primarily driven by increased non-cash stock-based compensation.

About tarcocimab tedromer (KSI-301)
Tarcocimab tedromer is an investigational anti-VEGF therapy built on Kodiak's Antibody Biopolymer Conjugate (ABC) Platform and is designed to maintain potent and effective drug levels in ocular tissues for longer than existing available agents. Kodiak's objective with tarcocimab tedromer is to develop a new first-line agent to improve outcomes for patients with retinal vascular diseases and to enable earlier treatment and prevention of vision loss for patients with diabetic eye disease. The tarcocimab tedromer clinical program is designed to assess the product's durability, efficacy and safety in wet AMD, DME, RVO and non-proliferative DR (without DME) through clinical studies run in parallel. The Company's GLEAM and GLIMMER studies in patients with diabetic macular edema, the BEACON study in patients with retinal vein occlusion, the DAYLIGHT study in patients with wet AMD, and the GLOW study in patients with NPDR are anticipated to form the basis of the Company's BLA to support potential approval and commercialization in multiple indications. The global tarcocimab tedromer clinical program is being conducted at 150+ study sites in more than 10 countries. Kodiak is developing and owns global rights to tarcocimab tedromer.

About the BEACON Study
The Phase 3 BEACON study is a global, multi-center, randomized study designed to evaluate the durability, efficacy and safety of tarcocimab tedromer in 568 patients with treatment-naïve macular edema due to retinal vein occlusion, including both branch and central subtypes. Patients are randomized 1:1 to receive tarcocimab 5 mg or aflibercept 2 mg. In the first six months, all patients receiving tarcocimab were treated with two monthly loading doses followed by treatment every 8 weeks, and patients receiving aflibercept were treated monthly as per its label. In the BEACON study, tarcocimab tedromer dosed every two months met the primary endpoint of non-inferior visual acuity gains compared to aflibercept dosed every month. Tarcocimab is the first anti-VEGF therapy that in clinical trials demonstrated non-inferiority in visual acuity gains while doubling the treatment interval in patients with RVO. In the study, tarcocimab was well tolerated with a low rate of intraocular inflammation and no new or unexpected safety signals. Results from the BEACON study are intended to serve as the basis for the potential approval of tarcocimab in RVO. In the second six months, patients in both groups will receive treatment on an individualized basis per protocol-specified criteria. Additional information about the BEACON study (also called Study KS301P103) can be found on www.clinicaltrials.gov under Trial Identifier NCT04592419 (https://clinicaltrials.gov/show/NCT04592419).

About the GLEAM and GLIMMER Studies
The Phase 3 GLEAM and GLIMMER studies are global, multi-center, randomized pivotal studies designed to evaluate the durability, efficacy and safety of tarcocimab in patients with treatment-naïve diabetic macular edema. In each study, patients are randomized 1:1 to receive either tarcocimab or aflibercept. The tarcocimab arm is treated with a proactive, individualized dosing regimen of every 8-, 12-, 16-, 20- or 24 weeks (utilizing tight dynamic retreatment criteria) after three loading doses. The aflibercept arm is treated with a fixed dosing regimen of every 8-weeks after five monthly loading doses, per its label. Both studies completed enrollment of approximately 450 patients each worldwide in the first half of 2022. The primary endpoint for both studies is at year one, and patients will be treated and followed for a total of two years. We expect to announce topline data in mid-2023. If successful, we expect that data from our GLEAM and GLIMMER studies will serve as the primary basis for approval of tarcocimab in our anticipated BLA submission. Additional information about GLEAM (also called Study KS301P104) and GLIMMER (also called Study KS301P105) can be found on www.clinicaltrials.gov under Trial Identifiers NCT04611152 and NCT04603937, respectively (https://clinicaltrials.gov/ct2/show/NCT04611152 and https://clinicaltrials.gov/ct2/show/NCT04603937).

About the DAYLIGHT Study
The Phase 3 DAYLIGHT study is a global, multi-center, randomized pivotal study designed to evaluate the efficacy and safety of high-frequency tarcocimab in patients with treatment-naïve wet AMD. Patients are randomized to receive either tarcocimab on a monthly dosing regimen or to receive standard-of-care aflibercept on a fixed dosing regimen of every 8-weeks after three monthly loading doses per its label. The primary endpoint is at one year. The DAYLIGHT study is intended to clarify the efficacy of tarcocimab to treat high need patients with wet AMD and, if successful, is intended to serve as the basis for approval in wet AMD with monthly dosing. DAYLIGHT has completed enrollment of approximately 550 patients worldwide and we expect to announce topline data in mid-2023. Additional information about DAYLIGHT (also called Study KS301P107) can be found on www.clinicaltrials.gov under Trial Identifier NCT04964089 (https://clinicaltrials.gov/show/NCT04964089).

About the GLOW Study
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 approximately 240 patients with treatment-naïve, 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 and patients will be treated and followed for two years. Outcomes include changes in diabetic retinopathy severity, measured on a standardized photographic grading scale, and the rate of development of sight-threatening complications due to diabetic retinopathy. We believe tarcocimab tedromer has the potential to be the longest-interval intravitreal therapeutic option for patients with diabetic retinopathy. GLOW has completed enrollment of approximately 240 patients in August 2022, and we expect to announce topline data in the second half of 2023. 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. Founded in 2009, 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 ABC Platform™ uses molecular engineering to merge the fields of antibody-based and chemistry-based therapies and is at the core of Kodiak's discovery engine. Kodiak's lead product candidate, tarcocimab tedromer, is a novel anti-VEGF antibody biopolymer conjugate being developed for the treatment of retinal vascular diseases including wet age-related macular degeneration, the leading cause of blindness in elderly patients in the developed world, and diabetic eye diseases, the leading cause of blindness in working-age patients in the developed world. Kodiak has leveraged its ABC Platform to build a pipeline of product candidates in various stages of development. KSI-501 is our dual inhibitor antibody biopolymer conjugate targeting both VEGF (VEGF-trap) and IL-6 (anti-IL-6 antibody) for the treatment of retinal diseases. We are expanding our early research pipeline to include ABC Platform based triplet inhibitors for multifactorial retinal diseases such as dry AMD and glaucoma. 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 regulatory developments and strategy, including plans to seek and potentially obtain regulatory approval, expected timing of data from studies and submission of INDs, the bases on which regulatory approval may be sought, and contribution of data to support approval of tarcocimab; anticipated benefits of anti-VEGF therapies from third parties; the potential for tarcocimab to deliver strong efficacy and solid safety while bringing a majority of patients to every 5 and 6-month dosing; and expectations regarding commercial manufacturing capabilities. 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 preliminary safety, efficacy and durability data for our tarcocimab tedromer product candidate may not continue or persist; the risk that tarcocimab tedromer may not have the anti-VEGF effect or impact on the treatment of patients as expected; cessation or delay of any of the ongoing clinical studies and/or our development of tarcocimab tedromer may occur, including as a result of the ongoing COVID-19 pandemic; the risk that our ABC Platform may not extend treatment intervals in retinal disorders as anticipated, or at all; future potential regulatory milestones of tarcocimab tedromer, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; adverse economic conditions may significantly impact our business and operations, including our clinical trial sites, and those of our manufacturers, contract research organizations or other 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,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 61,676	$ 56,002	$ 211,597	$ 141,743
General and administrative	17,802	11,533	55,716	32,259
Total operating expenses	79,478	67,535	267,313	174,002
Loss from operations	(79,478)	(67,535)	(267,313)	(174,002)
Interest income	2,028	40	3,239	270
Interest expense	(4)	(6)	(14)	(17)
Other income (expense), net	416	(25)	713	(76)
Net loss	$ (77,038)	$ (67,526)	$ (263,375)	$ (173,825)
Net loss per common share, basic and diluted	$ (1.47)	$ (1.30)	$ (5.04)	$ (3.36)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	52,288,257	51,875,315	52,227,072	51,722,611

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

	September 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 537,395	$ 731,510
Working capital	$ 479,062	$ 670,128
Total assets	$ 723,988	$ 904,220
Accumulated deficit	$ (821,592)	$ (558,217)
Total stockholders' equity	$ 479,529	$ 663,320

Kodiak Contact:
John Borgeson
Chief Financial Officer
Tel (650) 281-0850
ir@kodiak.com