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): May 10, 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 May 10, 2022, Kodiak Sciences Inc. (the "Company") issued a press release reporting the Company's financial results for the quarter ended March 31, 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 May 10, 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: May 10, 2022

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

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

Palo Alto, CA — May 10, 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 March 31, 2022.

“We learned in February that our Phase 2b/3 study in wet AMD did not meet its primary endpoint,” said Victor Perlroth, MD, Chief Executive Officer of Kodiak Sciences. “We have continued to analyze the data from this study and continue to believe that our two primary observations were correct: (a) not allowing treatment more frequent than every 12 weeks (q12w) was a fundamental flaw in the study design and resulted in critical undertreatment in a minority of patients, and (b) the durability with nearly 60% of KSI-301 patients sustained on every five-month dosing while achieving excellent visual and anatomic outcomes is real and represents an important advance in the field. The learnings from this initial study are enabling us to improve the probability of success of the ongoing KSI-301 Phase 3 program, with the anticipation of four Phase 3 study readouts in 2022 and 2023. We remain optimistic that KSI-301 can demonstrate best-in-class durability and meaningfully improve outcomes for patients with common retinal diseases.”

Recent Business Highlights

- ***KSI-301 Clinical Program:*** As part of the learnings from our initial Phase 2b/3 study in wet AMD, we are implementing changes to our ongoing Phase 3 studies of KSI-301 including changes in the DME program that we believe will mitigate the potential risk of undertreatment in high-need patients and improve the probability of success of these studies. Our regulatory strategy remains intact, and we intend to include data from the BEACON, GLEAM, GLIMMER and DAYLIGHT studies in a single initial BLA, if successful, and would seek labeling at launch that is supportive of a range of indications and dosing intervals.
    - BEACON – Phase 3 Study in Patients with Treatment-Naïve Retinal Vein Occlusion (RVO)

      The BEACON study design remains unchanged and compares four doses of KSI-301 versus six doses of aflibercept over the 6-month duration to the primary endpoint. The last patient visit for the 24-week primary endpoint is expected in June 2022, and we expect to announce top-line data in August 2022.
    - DAYLIGHT – Phase 3 Study in Patients with Treatment-Naïve Wet AMD

      The DAYLIGHT study will further clarify the efficacy of KSI-301 in treating high-need patients with wet AMD and, if successful, is intended to serve as the basis for approval in wet AMD with monthly dosing. Consistent with this intent to serve as a registrational study worldwide, we are extending the length of this study by eight weeks to 48 weeks with the primary endpoint, mean change in BCVA from baseline, measured at the average of weeks 40, 44 and 48. DAYLIGHT has completed enrollment of approximately 550 patients worldwide, and we expect to announce top-line data in mid-2023.
    - GLEAM and GLIMMER – Paired Phase 3 Studies in Patients with Treatment-Naïve Diabetic Macular Edema (DME)

      We have modified the study protocols to decrease the risk of undertreatment in high need patients by 1) triggering retreatment earlier in disease reactivation, 2) triggering retreatment in the presence of persistent disease, and 3) removing subjectivity in the application of the criteria. We are also extending the primary endpoint by twelve weeks to allow two full cycles of every 24-week dosing for patients receiving KSI-301, so that the durability, efficacy, and safety of the longer dosing intervals can be more fully evaluated. The primary endpoint for both studies is the average of weeks 60 and 64, and patients will continue to be treated and followed for a total of two years. We expect to announce top-line 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 KSI-301 in our anticipated BLA submission.
- ***Commercial Manufacturing:*** We continued our manufacturing scale up and in March 2022 achieved mechanical completion of our purpose-built bioconjugation facility in Visp, Switzerland.
- ***Pipeline Progression:*** We continued progressing our pipeline product candidates KSI-501 and KSI-601. 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 progressing the bioconjugate cGMP manufacturing, non-clinical toxicology and other supporting activities towards expected IND submission in 2H 2022.

Expected Upcoming Events/Milestones

- Announce top-line data for BEACON, Phase 3 pivotal study of KSI-301 in RVO, in 3Q 2022
- Complete enrollment for GLOW, Phase 3 pivotal study of KSI-301 in non-proliferative diabetic retinopathy (NPDR), in 3Q 2022
- Submit IND for KSI-501, a novel bispecific antibody biopolymer conjugate, in 2H 2022

First Quarter 2022 Financial Results

Cash Position

Kodiak ended the first quarter of 2022 with $671.7 million of cash and cash equivalents.

Net Loss

The net loss for the first quarter of 2022 was $95.7 million, or $1.83 per share, on both a basic and diluted basis, as compared to a net loss of $50.4 million, or $0.98 per share, on both a basic and diluted basis, for the first quarter of 2021. The net loss for the quarter ended March 31, 2022 included non-cash stock-based compensation of $28.1 million, of which $16.0 million was recorded in the first quarter related to the 2021 Long-Term Performance Incentive Plan.

R&D Expenses

Research and development (R&D) expenses were $76.2 million for the first quarter of 2022, as compared to $40.3 million for the first quarter of 2021. The R&D expenses for the first quarter included non-cash stock-based compensation of $16.0 million. The increase in R&D expenses was primarily driven by higher clinical trial costs to support ongoing trials, increased manufacturing activities, as well as higher non-cash stock-based compensation expense.

G&A Expenses

General and administrative (G&A) expenses were $19.6 million for the first quarter of 2022, as compared to $10.2 million for the first quarter of 2021. The G&A expenses for the first quarter included non-cash stock-based compensation of $12.1 million. The increase in G&A expenses was primarily driven by increased non-cash stock-based compensation expense.

About KSI-301

KSI-301 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 KSI-301 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 KSI-301 clinical program is designed to assess KSI-301'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 pivotal studies in patients with diabetic macular edema, the BEACON pivotal study in patients with retinal vein occlusion and the DAYLIGHT pivotal study in patients with wet AMD are anticipated to form the basis of the Company's initial BLA to support potential approval and commercialization in multiple indications. An additional Phase 3 pivotal study, GLOW, in patients with non-proliferative diabetic retinopathy is also underway. The global KSI-301 clinical program is being conducted at 150+ study sites in more than 10 countries. Kodiak is developing KSI-301 and owns global rights to KSI-301.

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 KSI-301 in patients with treatment-naïve macular edema due to retinal vein occlusion, including both branch and central subtypes. Patients are randomized 1:1 to a KSI-301 arm or an aflibercept arm. In the first six months, the KSI-301 arm is treated with a proactive, fixed regimen which includes two monthly loading doses and then every 8-week treatment (including treatment four weeks prior to the 24-week primary endpoint). In the first six months, the aflibercept arm is treated with a fixed monthly regimen, per its label. In the second six months, patients in both groups will receive treatment on an individualized basis per protocol-specified criteria. Following this, patients can continue to receive KSI-301 for an additional six months on an individualized basis. The study completed enrollment of over 550 patients worldwide in the fourth quarter of 2021. The primary endpoint is at six months, and patients will be treated and followed for 18 months. The last patient visit for the 24-week primary endpoint is expected in June 2022, and we expect to announce top-line data in August 2022. If successful, data from the BEACON study are intended to serve as the basis for approval in RVO. 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 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 KSI-301 in patients with treatment-naïve wet AMD. Patients are randomized to receive either KSI-301 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 DAYLIGHT study is intended to clarify the efficacy of KSI-301 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. Consistent with this intent to serve as an approval study, we are extending the length of DAYLIGHT, specifically extending the primary endpoint to the average of weeks 40, 44 and 48. DAYLIGHT has completed enrollment of approximately 550 patients worldwide, and we expect to announce top-line 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 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 KSI-301 in patients with treatment-naïve diabetic macular edema. In each study, patients are randomized 1:1 to receive either KSI-301 or aflibercept. The KSI-301 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 quarter of 2022. The primary endpoint for both studies is the average of weeks 60 and 64, and patients will be treated and followed for a total of two years. We expect to announce top-line 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 KSI-301 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 GLOW Study
The Phase 3 GLOW study is a global, multi-center, randomized pivotal study designed to evaluate the efficacy and safety of KSI-301 in patients with treatment-naïve, moderately severe to severe non-proliferative diabetic retinopathy (NPDR). Patients are randomized to receive either KSI-301 on a once every six-month dosing regimen after three initiating doses 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 randomized the first patients into GLOW in September 2021 and expect to complete enrollment of approximately 240 patients worldwide in 2022. We believe KSI-301 has the potential to be a longest-interval therapeutic option for patients with diabetic retinopathy. If successful, we intend to include the results of the GLOW study in a supplemental BLA following our planned initial BLA submission. 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, KSI-301, 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 the potential of our ABC Platform to significantly extend treatment intervals in retinal disorders in a safe and convenient manner, the anti-VEGF effect of KSI-301, the expected advances for treatment of wet AMD represented by KSI-301, the anticipated safety profile for KSI-301, future development plans, including clinical objectives or milestones and the timing thereof or the evaluation of durability, efficacy, and safety of dosing interval, anticipated design and benefits of planned clinical trials, and the anticipated announcement or presentation of data; potential for a single BLA submission in wet AMD, DME and RVO or other approval (or basis thereof); the timing for enrollment in our studies; the timing of submission of an IND for KSI-501; the potential for our products to obtain a product label in multiple indications and with a full range of labeled and reimbursable dosing frequencies in each indication; expectations regarding commercial manufacturing capabilities; the results of our research and development efforts and our ability to advance our product candidates into later stages of development; our observations about the data from our Phase 2b/3 study in wet AMD; the impact of changes to our ongoing Phase 3 studies of KSI-301 to mitigate the potential risk of undertreatment. 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 KSI-301 product candidate may not continue or persist; the risk that KSI-301 may not have the anti-VEGF effect or impact on the treatment of wet AMD expected; cessation or delay of any of the ongoing clinical studies and/or our development of KSI-301 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 KSI-301, including those related to current and planned clinical studies, may be insufficient to support regulatory submissions or approval; our research and development efforts and our ability to advance our product candidates into later stages of development may fail; any one or more of our product candidates may not be successfully developed, approved or commercialized; manufacturing facilities may not be completed when expected, or at all; adverse conditions in the general domestic and global economic markets, including the COVID-19 pandemic, 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®, Kodiak Sciences®, ABC™, ABC Platform™ and the Kodiak logo are registered trademarks or trademarks of Kodiak Sciences Inc. in various global jurisdictions.

Kodiak Sciences Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses		
Research and development	$ 76,177	$ 40,337
General and administrative	19,590	10,221
Total operating expenses	95,767	50,558
Loss from operations	(95,767)	(50,558)
Interest income	76	149
Interest expense	(5)	(6)
Other income (expense), net	(13)	(32)
Net loss	$ (95,709)	$ (50,447)
Net loss per common share, basic and diluted	$ (1.83)	$ (0.98)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	52,172,918	51,573,909

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

	March 31, 2022	**December 31, 2021**
Cash and cash equivalents	$ 671,727	$ 731,510
Working capital	$ 605,853	$ 670,128
Total assets	$ 850,288	$ 904,220
Accumulated deficit	$ (653,926)	$ (558,217)
Total stockholders' equity	$ 597,384	$ 663,320

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