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): March 01, 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 March 1, 2022, Kodiak Sciences Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter and year ended December 31, 2021. A copy of the Company's press release is attached hereto as Exhibit 99.1. The information in this Form 8-K and the attached exhibit are furnished to, but not filed with, the Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Pursuant to the rules and regulations of the Securities and Exchange Commission, the attached exhibit is deemed to have been furnished to, but not filed with, the Securities and Exchange Commission:

Exhibit Number	Description
99.1	Press Release issued by Kodiak Sciences Inc. dated March 1, 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: March 1, 2022

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

Exhibit 99.1

Kodiak Sciences Announces Fourth Quarter and Full Year 2021 Financial Results and Recent Business Highlights

Palo Alto, CA — March 1, 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 fourth quarter ended December 31, 2021.

“Although our Phase 2b/3 pivotal study in wet AMD did not meet its primary efficacy endpoint, we believe the data served as important validation for KSI-301 and our ABC platform in its ability to extend dosing in a compelling manner for nearly 60% of wet AMD patients and doing so safely, which to our knowledge no other intravitreal anti-VEGF therapy has demonstrated to date,” said Victor Perlroth, MD, Chief Executive Officer of Kodiak Sciences. “We do take away important learnings from this initial study, in particular that some patients may benefit from more frequent dosing. The designs of our other ongoing Phase 3 studies have more proactive dosing and therefore we believe less risk of undertreatment. We intend to continue advancing our ongoing pivotal studies of KSI-301 in all of the major retinal vascular disorders for which intravitreal anti-VEGF therapies are currently used, namely our Phase 3 pivotal study BEACON in retinal vein occlusion (“RVO”), our paired Phase 3 studies GLEAM/GLIMMER in diabetic macular edema (“DME”), our Phase 3 short-interval study DAYLIGHT in wet AMD, and our Phase 3 pivotal study GLOW in non-proliferative diabetic retinopathy without DME (“NPDR” without DME). Our BEACON study is expected to have the primary endpoint visit completed in all patients this coming June, with top-line data anticipated to follow shortly thereafter. For our DAYLIGHT study as well as our GLEAM and GLIMMER studies, we expect top-line data in 2023. We remain committed to bringing potentially the longest-interval intravitreal anti-VEGF therapy to patients with retinal vascular diseases and, despite our disappointment in not having met the primary endpoint in our Phase 2b/3 study, I believe we are one step closer to achieving that goal.”

Recent Business Highlights

- ***KSI-301 Phase 2b/3 Pivotal Study in Wet AMD Top-line Data:*** We recently announced top-line data from our Phase 2b/3 pivotal study of KSI-301 in patients with treatment-naïve wet AMD. The study did not meet its primary efficacy endpoint of non-inferior visual acuity gains for subjects dosed on extended regimens every 12, 16, or 20 weeks with KSI-301 compared to subjects given aflibercept every 8 weeks. Year 1 data showed 59% of patients in the KSI-301 arm achieved 5-month dosing with visual acuity gains and anatomic improvements comparable to the overall aflibercept group. KSI-301 was safe and well tolerated in the study, with no new safety signals identified.
- ***Continued Progress in Ongoing KSI-301 Pivotal Program:*** We completed enrollment of over 550 patients worldwide in 2021 for our pivotal study BEACON in RVO and expect to announce top-line data in the third quarter of 2022. Our paired Phase 3 studies GLEAM/GLIMMER in DME have completed enrollment of approximately 450 patients each worldwide. Our short-interval Phase 3 study DAYLIGHT in wet AMD randomized the first patient in June 2021 and recruitment continues in both the U.S. and EU. We expect to complete enrollment in the first half of 2022. We began screening patients into GLOW, our Phase 3 study in NPDR, in 2Q 2021 and randomized the first patients in September 2021. Our belief in the potential of KSI-301 (and our ABC Platform) to extend treatment intervals and improve patient outcomes in retinal vascular diseases remains, and we are encouraged by the promising safety profile KSI-301 demonstrated. We are pleased with the continued operational progress across our pivotal program and plan to continue advancing our pivotal program towards an initial BLA with a label that is supportive of a range of indications and dosing intervals.
- ***Commercial Manufacturing:*** We continued making substantial progress in our commercial manufacturing capabilities in collaboration with our partner Lonza. Our custom-built commercial scale bioconjugation facility is scheduled for mechanical completion in the first half of 2022.
- ***Pipeline Progression:*** We continued advancing our pipeline product candidates KSI-501 and KSI-601. KSI-501 is our dual inhibitor antibody biopolymer conjugate targeting both VEGF and IL-6 for the treatment of retinal diseases with an inflammatory component. KSI-501 is being progressed towards an IND submission in 2022. KSI-601 is targeting the multifactorial nature of dry AMD, and we continued development on KSI-601 and the triplet platform towards an IND.

Expected Upcoming Events/Milestones

- Announce top-line data for BEACON, Phase 3 pivotal study of KSI-301 in RVO, 3Q 2022
- Complete enrollment in DAYLIGHT, short-interval pivotal study of KSI-301 in wet AMD, 1H 2022
- Mechanical completion of the Lonza-Kodiak Ibex Dedicate facility in 1H 2022
- Submit IND for KSI-501, a novel bispecific antibody biopolymer conjugate

Fourth Quarter and Full Year 2021 Financial Results

Cash Position

Kodiak ended the fourth quarter of 2021 with $731.5 million of cash and cash equivalents.

Net Loss

The net loss for the fourth quarter of 2021 was $93.2 million, or $1.79 per share on both a basic and diluted basis, as compared to a net loss of $46.6 million, or $0.97 per share on both a basic and diluted basis, for the fourth quarter of 2020. The net loss for the year ended December 31, 2021 was $267.0 million, or $5.16 per share on both a basic and diluted basis, as compared to a net loss of $133.1 million, or $2.91 per share on both a basic and diluted basis, for the year ended December 31, 2020. The net loss for the fourth quarter and for the year ended December 31, 2021 included non-cash stock-based compensation of $28.0 million and $61.4 million, respectively, of which $14.2 million was recorded in the fourth quarter related to the 2021 Long-Term Performance Incentive Plan (“LTPIP”).

R&D Expenses

Research and development (R&D) expenses were $75.6 million for the fourth quarter of 2021, as compared to $37.4 million for the fourth quarter of 2020. R&D expenses were $217.3 million for the year ended December 31, 2021, as compared to $107.4 million for the year ended December 31, 2020. The R&D expenses for the fourth quarter and for the year ended December 31, 2021 included non-cash stock-based compensation of $15.6 million and $33.2 million, respectively, of which $8.3 million was recorded in the fourth quarter related to the LTPIP. 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 $17.5 million for the fourth quarter of 2021, as compared to $9.5 million for the fourth quarter of 2020. G&A expenses were $49.7 million for the year ended December 31, 2021, as compared to $28.6 million for the year ended December 31, 2020. The G&A expenses for the fourth quarter and for the year ended December 31, 2021 included non-cash stock-based compensation of $12.4 million and $28.1 million, respectively, of which $5.9 million was recorded in the fourth quarter related to the LTPIP. The increase in G&A expenses was primarily driven by increased headcount and 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 (RVO), 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 4-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 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 mid-June 2022. We expect to announce top-line data in the third quarter of 2022. 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. The study is expected to enroll approximately 500 patients worldwide. The primary endpoint is at ten months, and the study is being planned and executed to allow for inclusion of its results in the initial BLA for KSI-301. The intent of this pivotal study is to broaden KSI-301’s potential product labeling, explore the potential for improved treatment outcomes in certain patients with intensive anti-VEGF treatment, and eliminate possible barriers to market access and insurance reimbursement that have impeded or complicated the commercial uptake of other anti-VEGF medications in the past. We believe that pursuing a broad product label will provide physicians with the flexibility, agency, and reimbursement confidence required to consider KSI-301 treatment for all their patients. 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 (DME). 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 regimen of 8-week dosing after five monthly loading doses, per its label. Both studies have completed enrollment of approximately 450 patients each worldwide. The primary endpoint for both studies is at one year, and patients will be treated and followed for a total of two years. We expect to announce top-line data in the first half of 2023. 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 monthly initiating doses or to receive sham injection. The study is expected to enroll approximately 240 patients worldwide. The primary endpoint is at one year and patients will be treated and followed for two years. 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 including KSI-501, our bispecific anti-IL-6/VEGF biopolymer conjugate for the treatment of neovascular retinal diseases with an inflammatory component, and 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 and the timing thereof, anticipated design and benefits of planned clinical trials, and the anticipated presentation of data; potential for a single BLA submission in wet AMD, DME and RVO; 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; and the results of our research and development efforts and our ability to advance our product candidates into later stages of development. 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 December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Operating expenses				
Research and development	$ 75,597	$ 37,356	$ 217,340	$ 107,389
General and administrative	17,452	9,486	49,711	28,618
Total operating expenses	93,049	46,842	267,051	136,007
Loss from operations	(93,049)	(46,842)	(267,051)	(136,007)
Interest income	28	351	298	2,902
Interest expense	(5)	(6)	(22)	(25)
Other income (expense), net	(139)	(86)	(215)	34
Net loss	$ (93,165)	$ (46,583)	$ (266,990)	$ (133,096)
Net loss per common share, basic and diluted	$ (1.79)	$ (0.97)	$ (5.16)	$ (2.91)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	51,988,910	48,034,290	51,788,918	45,741,845

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

	December 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 731,510	$ 968,974
Working capital	$ 670,128	$ 940,583
Total assets	$ 904,220	$ 1,067,347
Accumulated deficit	$ (558,217)	$ (291,227)
Total stockholders' equity	$ 663,320	$ 860,751

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