UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 1, 2021

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 Road Palo Alto, CA	**94304**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 281-0850

Not Applicable
(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 (see General Instructions A.2. below):

☐ 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, 2021, Kodiak Sciences Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter and year ended December 31, 2020. 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, 2021
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 hereunto duly authorized.

KODIAK SCIENCES INC.

Date: March 1, 2021

By: /s/ Victor Perlroth

Victor Perlroth, M.D.
Chief Executive Officer

Exhibit 99.1

Kodiak Sciences Announces Fourth Quarter and Full Year 2020 Financial Results and Recent Business Highlights

Palo Alto, CA — March 1, 2021 – 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, 2020.

“Our Phase 1b data show two in every three patients are on a 6-month or longer treatment free interval at Year 1 in each of the three major retinal vascular diseases after only three loading doses”, said Victor Perlroth, MD, Chief Executive Officer of Kodiak. “Importantly, the durability profile of KSI-301 is tied to strong efficacy improvements in all three diseases at Year 1. The treatment naïve wet AMD patients in our study achieved 20/40 vision on average at Year 1 and DME and RVO patients achieved 20/32 vision on average. We also are pleased with the retinal anatomic effects of KSI-301 observed through one year of treatment, with robust retinal drying seen across all three diseases being studied. The safety profile of KSI-301 continues to be very encouraging. The initiation of our Phase 3 studies in DME (GLEAM and GLIMMER) and RVO (BEACON) and the timely completion of patient recruitment into our pivotal wet AMD study (DAZZLE) are meaningful operational milestones on our path towards multiple top-line clinical study readouts planned for 2022. The journey of today’s retinal vascular disease patients inspires us to accelerate and lean into the hard work of developing novel medicines for tomorrow. Our accomplishments in 2020 are motivating, and we are excited to continue our story into 2021.”

Recent Business Highlights

- ***Presentation of Year 1 KSI-301 Phase 1b Study Data:*** Year 1 durability, efficacy and safety data from our ongoing Phase 1b study of KSI-301 in patients with treatment naïve wet AMD, DME or RVO were presented at the Angiogenesis, Exudation, and Degeneration 2021 – Virtual Edition meeting in February 2021. The data show 2 in every 3 patients are on a 6-month or longer treatment-free interval at Year 1 in each of the 3 major retinal vascular diseases after only 3 loading doses. Robust vision gains (particularly notable in the context of very good baseline vision) and robust retinal drying (when baseline anatomical characteristics are considered) were seen across all three diseases being studied. An encouraging safety profile continues to be observed.

- ***Continuing KSI-301 Pivotal Program Progress:*** We completed global patient recruitment into our pivotal wet AMD Phase 2b/3 study (DAZZLE) in November 2020. With a one-year primary endpoint, we remain on track for DAZZLE primary endpoint last patient last visit in late 2021 and topline results in early 2022.

  In the third quarter of 2020, we initiated two Phase 3 studies in DME (GLEAM and GLIMMER) and one Phase 3 study in RVO (BEACON). The randomization of treatment-naïve patients into these three studies is a critical step to build the clinical evidence for KSI-301 as a highly durable, effective, and safe therapy for patients with retinal diseases. The initiation of the DME and RVO Phase 3 studies and the robust patient recruitment into DAZZLE represent strong operational progress towards our 2022 Vision of a single BLA filed for KSI-301 in wet AMD, DME and RVO in 2022. In addition to the initiation of recruitment in the US, clinical trial applications for BEACON, GLEAM and GLIMMER have been submitted and approved in countries across the EU and recruitment is underway globally. To date, we are pleased with progress in site activation, patient screening and recruitment in these studies. We believe we are also on track to begin recruitment of the GLOW study in patients with non-proliferative Diabetic Retinopathy without DME in the first half of 2021.

- ***Completion of Follow-on Equity Offering:*** On November 20, 2020, we completed a follow-on equity offering and issued and sold 5,972,222 shares of the Company’s common stock, which included the full exercise of the underwriters’ option to purchase additional shares, at a price of $108.00 per share, resulting in net proceeds to us of $612.0 million, after underwriting discounts and commissions and offering expenses payable by us.

  Our current cash, cash equivalents and marketable securities provide the resources for us to advance the KSI-301 program towards achieving our “2022 Vision” and also to advance our pipeline of drug candidates including KSI-501 and our triplet inhibitor drug candidates.

- ***Commercial Manufacturing:*** We successfully negotiated a long-term agreement with Lonza for the manufacture of KSI-301. This agreement will provide Kodiak with a custom-built bioconjugation facility with a capacity to supply millions of doses per year. The Lonza-Kodiak Ibex Dedicate facility will provide Kodiak with the capacity needed for commercial-scale manufacturing of KSI-301. The scale of manufacturing is designed to support KSI-301’s potential to achieve significant market share as a new first-line agent designed to improve outcomes for patients with common and serious retinal vascular diseases.

Expected Upcoming Events/Milestones

- Initiate pivotal Phase 3 randomized study of KSI-301 in non-proliferative diabetic retinopathy patients (the GLOW study)
- Complete patient enrollment in DME (GLEAM and GLIMMER) and RVO (BEACON) studies
- DAZZLE wet AMD last patient last visit for primary endpoint
- Submit IND for KSI-501, a novel bispecific antibody biopolymer conjugate

Fourth Quarter and Full Year 2020 Financial Results

Cash Position

Kodiak ended 2020 with $969.0 million of cash, cash equivalents and marketable securities, including the $612.0 million net proceeds from our recent financing.

Net Loss

The net loss for the fourth quarter of 2020 was $46.6 million, or $0.97 per share on both a basic and diluted basis, as compared to a net loss of $15.6 million, or $0.40 per share on both a basic and diluted basis, for the fourth quarter of 2019. The net loss for the year ended December 31, 2020 was $133.1 million, or $2.91 per share on both a basic and diluted basis, as compared to a net loss of $47.4 million, or $1.25 per share on both a basic and diluted basis, for the year ended December 31, 2019.

R&D Expenses

Research and development (R&D) expenses were $37.4 million for the fourth quarter of 2020, as compared to $12.8 million for the fourth quarter of 2019. R&D expenses were $107.4 million for the year ended December 31, 2020, as compared to $37.5 million for the year ended December 31, 2019. The increase in R&D expenses was primarily driven by higher clinical trial costs to support ongoing trials, higher payroll and stock-based compensation expenses, as well as increased manufacturing activities.

G&A Expenses

General and administrative (G&A) expenses were $9.5 million for the fourth quarter of 2020, as compared to $3.4 million for the fourth quarter of 2019. G&A expenses were $28.6 million for the year ended December 31, 2020, as compared to $11.7 million for the year ended December 31, 2019. The increase in G&A expenses was primarily driven by higher payroll and stock-based compensation expenses.

About KSI-301

KSI-301 is an investigational anti-VEGF therapy built on the Kodiak's Antibody Biopolymer Conjugate (ABC) Platform and is designed to maintain potent and effective drug levels in ocular tissues for longer than existing 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 Phase 2b/3 DAZZLE pivotal study in patients with treatment-naïve wet AMD was initiated in October 2019 and completed enrollment in November 2020, and Kodiak initiated the Phase 3 GLEAM, GLIMMER and BEACON pivotal studies of KSI-301 in diabetic macular edema and retinal vein occlusion in September 2020. These studies are anticipated to form the basis of the Company's initial BLA to support potential approval and commercialization. An additional pivotal study in patients with non-proliferative diabetic retinopathy (the GLOW study) is planned. We expect that the global KSI-301 clinical program will be conducted at 150+ study sites in more than 10 countries. Kodiak Sciences Inc. is developing KSI-301 and owns global rights to KSI-301.

About the DAZZLE Study

The Phase 2b/3 DAZZLE study is a global, multi-center, randomized study designed to evaluate the durability efficacy and safety of KSI-301 in patients with treatment-naïve wet AMD. Patients are randomized to receive either KSI-301 on an individualized dosing regimen as infrequently as every five months and no more often than every three months or to receive aflibercept on its labeled every eight-week dosing regimen, each after three monthly initiating doses. The study has enrolled over 550 patients worldwide. The primary endpoint is at one year, and each patient will be treated and followed for two years. Additional information about DAZZLE (also called Study KSI-CL-102) can be found on www.clinicaltrials.gov under Trial Identifier NCT04049266 (https://clinicaltrials.gov/show/NCT04049266).

About the GLEAM and GLIMMER Studies

The Phase 3 GLEAM and GLIMMER studies are global, multi-center, randomized 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 to receive either intravitreal KSI-301 on an individualized dosing regimen every eight to 24 weeks after only three loading doses or intravitreal aflibercept every eight weeks after five loading doses per its label. Each study is expected to enroll approximately 450 patients worldwide. The primary endpoint for both studies is at one year, and patients will be treated and followed for two years. 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 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 to receive either intravitreal KSI-301 every eight weeks after only two loading doses or monthly intravitreal aflibercept per its label, for the first six months. In the second six months, patients in both groups will receive treatment on an individualized basis per protocol-specified criteria. The study is expected to enroll approximately 550 patients worldwide. The primary

endpoint is at six months, and patients will be treated and followed for one year. 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 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 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 licensure of KSI-301 and a single BLA submission in wet AMD, DME, RVO and diabetic retinopathy in 2022; the sufficiency of our cash, cash equivalents and marketable securities to fund our operations; our platform technology and potential therapies; future development plans, including our ability to initiate the GLOW study in the first half of 2021 and present top-line data readout in DAZZLE in 2022; the ability of the Lonza-Kodiak Ibex facility to provide commercial-scale manufacturing of KSI-301; clinical and regulatory objectives and the timing thereof, anticipated design of planned clinical trials, expectations regarding the potential efficacy and commercial potential of our product candidates; and the anticipated presentation of data; 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," "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 preliminary safety, efficacy and durability data for our KSI-301 product candidate will not continue or persist; 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; 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; anticipated presentation of data at upcoming conferences may not occur; 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; adverse conditions in the general domestic and global economic markets, including the COVID-19 pandemic, which may significantly impact our business and operations, including out of our headquarters in the San Francisco Bay Area and 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-Q, 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 December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Operating expenses				
Research and development	$ 37,356	$ 12,830	$ 107,389	$ 37,506
General and administrative	9,486	3,354	28,618	11,684
Total operating expenses	46,842	16,184	136,007	49,190
Loss from operations	(46,842)	(16,184)	(136,007)	(49,190)
Interest income	351	498	2,902	1,568
Interest expense	(6)	—	(25)	(8)
Other income (expense), net	(86)	70	34	265
Net loss	$ (46,583)	$ (15,616)	$ (133,096)	$ (47,365)
Net loss per common share, basic and diluted	$ (0.97)	$ (0.40)	$ (2.91)	$ (1.25)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	48,034,290	39,522,146	45,741,845	37,853,616

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

	December 31, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	$ 968,974	$ 348,177
Working capital	$ 940,583	$ 327,519
Total assets	$ 1,067,347	$ 358,866
Accumulated deficit	$ (291,227)	$ (158,131)
Total stockholders' equity	$ 860,751	$ 345,359

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