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 11, 2020

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.)**

2631 Hanover Street 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 May 11, 2020, Kodiak Sciences Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended March 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 May 11, 2020

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: May 11, 2020

By: /s/ Victor Perlroth

Victor Perlroth, M.D.
Chief Executive Officer

Kodiak Sciences Announces First Quarter 2020 Financial Results and Recent Business Highlights

Palo Alto, CA — May 11, 2020 – Kodiak Sciences Inc. (Nasdaq: KOD), a clinical stage biopharmaceutical company specializing in novel therapeutics to treat chronic, high-prevalence retinal diseases, today reported business highlights and financial results for the first quarter ended March 31, 2020.

“I am proud of the dedication and passion of our people who continue to deliver on our mission to help patients with serious retinal diseases as we all navigate the challenges of the COVID-19 pandemic,” said Victor Perlroth, MD, chairman and chief executive officer of Kodiak Sciences. “To date, we are seeing minimal disruption from COVID-19 in our ongoing clinical trials. In DAZZLE, patient missed visit rates are less than 5%, and clinical trial sites continue to enroll new patients. This is a testament to the serious diseases we are attempting to treat and is a vote of confidence from the patients, physicians and study sites partnering with us to advance KSI-301. With over $430 million in cash, cash equivalents and marketable securities at quarter end, and thoughtful management of our spending, we remain on a strong financial footing. We did delay initiation of our next set of KSI-301 pivotal studies by one quarter from June/July to September/October 2020 in order to assess with physicians and our business partners how best to minimize the impact of COVID-19 on clinical trial conduct. But our 2022 Vision towards a BLA filing in the key retinal disease indications remains intact, and we have taken good advantage of this additional time to upgrade our pivotal study plan for KSI-301. We now intend to conduct two phase 3 studies in DME, one study in wet AMD (our ongoing DAZZLE study), one study in RVO, and one study in non-proliferative DR. There are multiple reasons for this shift into two DME studies (and one RVO study) from our earlier plan of two RVO studies (and one DME study). Operationally, we expect faster, simpler and more predictable enrollment in the DME indication and will be able to run the studies in fewer countries and research sites. And further, we prefer to shift resources on the margin into this higher prevalence, higher unmet need disease which remains the leading cause of blindness in working-aged adults in the United States and the EU. Importantly, the data emerging in our phase 1b study remain consistent with our observations shared in February, and we look forward to providing another R&D update in July of this year, either virtually or at the American Society of Retina Specialists meeting. We also recognize the critical role the biopharma industry plays in fighting COVID-19 by developing effective therapies, and we have therefore taken action to explore whether our anti-IL-6/anti-VEGF bispecific protein that is a component of KSI-501 may be an effective therapeutic strategy in patients with severe COVID-19.”

COVID-19 Business Update

Ongoing Clinical Trials

Kodiak remains focused on ensuring safety and data integrity in its ongoing clinical trials. Numerous enhancements have been implemented into our ongoing study execution to help ensure the safety of patients, physicians, study site staff and Kodiak operations team members. Some specific actions we have taken include the use of remote study monitoring, temporarily increasing study site budget overhead rates, providing additional transportation service options for patients to attend study site visits and focusing new patient enrollment at study sites with appropriate backup resource plans in place and where the local COVID-19 situation allows. The company is actively monitoring ongoing clinical trial participation and is engaging proactively with study sites, corporate partners, and regulatory authorities to safeguard study integrity and promptly respond to potential disruptions.

In light of these efforts and the high risk of permanent vision loss presented by the retinal diseases targeted by KSI-301, existing patients continue to participate with few missed visits to date (low- to mid- single digit percentage of missed visits), and new patients continue to be enrolled in our ongoing DAZZLE clinical study. As of May 8, 2020, 245 patients have been enrolled into DAZZLE. The company does not intend to pause screening and enrollment into DAZZLE in the United States but does anticipate slower patient enrollment compared to the 50+ patients per month observed in February and March 2020. Kodiak has issued guidance encouraging study sites to prioritize participation of currently enrolled patients over enrolling new patients, if necessary, for example due to staffing limitations associated with the COVID-19 pandemic. Similarly, in the first quarter of 2020, we activated DAZZLE study sites in the EU, but due to the pandemic, we deferred study patient screening. We expect to begin patient recruitment activities at certain sites in the EU in the second quarter of 2020 as guided by the local COVID-19 situation.

In the interest of monitoring the progress and impact of the COVID-19 pandemic, we delayed the initiation of the next set of KSI-301 pivotal studies for DME and RVO into September/October 2020 versus the previously planned June/July 2020 timeframe. We are still evaluating whether we can initiate the NPDR (without DME) study on the same timeframe and are expecting a one to two quarter additional delay for the NPDR study start, due to the pandemic resulting in deferral of diagnosis or follow-up in the NPDR patient population who have overall lower disease severity than patients with wAMD, DME and RVO.

Drug Supply

Kodiak’s supply chain and manufacturing activities remain intact, and the company does not currently anticipate disruptions to its supply of KSI-301 due to the COVID-19 pandemic.

Kodiak Business Operations

We have taken steps in line with guidance from the U.S. Centers for Disease Control and Prevention, or CDC, and the State of California to protect the health and safety of our employees and the community. In particular, the Company has implemented remote work arrangements for non-essential employees since March 17, 2020.

KSI-501 Program Acceleration

Our bispecific conjugate KSI-501 inhibits both interleukin 6, or IL-6, and Vascular Endothelial Growth Factor, or VEGF. IL-6 blockade is being explored as a novel therapeutic strategy in patients with severe COVID-19 disease. VEGF is a potent inducer of vascular permeability and edema which play a pathological role in COVID-19 driven lung dysfunction. OG2072, the bispecific fusion protein used to build our ophthalmology product candidate KSI-501, binds with high affinity to both of its targets simultaneously (IL-6 and VEGF) and shows synergistic inhibition of these mechanisms of action in vitro. We are advancing by six months the GMP manufacturing for OG2072 which may enable an assessment of systemically administered OG2072 protein in patients with worsening COVID-19 disease. Ancillary benefits of this acceleration include the use of GMP material for KSI-501 toxicology program and a more predictable IND submission and First in Human timeline for bioconjugate KSI-501 in 2021 in patients with retinal vascular diseases featuring an inflammatory component.

Additional Recent Business Highlights:

Closing of Royalty Funding Agreement

On December 1, 2019, we announced the sale of future royalties on KSI-301 for $225.0 million to Baker Bros. Advisors. Under the terms of the agreement, Baker Bros. Advisors purchased a capped 4.5% royalty on net sales of KSI-301 to be paid upon marketing approval. On February 4, 2020, we closed the funding agreement and received the first $100.0 million payment.

DAZZLE Study Update

Through most of the first quarter, recruitment into our DAZZLE pivotal study in wet AMD was very robust – a reflection of the enthusiasm for KSI-301 on the part of clinical investigators and patients. As of May 8, 245 patients have been enrolled in DAZZLE. As noted above, we slowed U.S. enrollment beginning in March 2020 due to the COVID-19 pandemic. Existing patients continue to participate with few missed visits to date, and new patients continue to be enrolled in DAZZLE. As of late April 2020, the number of weekly new patient screenings and enrollment at DAZZLE sites in the US is increasing. The Independent Data Monitoring Committee responsible for safeguarding the interests of DAZZLE study participants, assessing safety during the trial, and monitoring overall study conduct met in early May 2020 and recommended that DAZZLE should continue without modification.

Phase 1b Data Presentation

Updated safety and efficacy results from our ongoing Phase 1b trial of KSI-301 in patients with treatment naïve wet AMD, DME, or RVO were presented at the Angiogenesis, Exudation, and Degeneration Annual Meeting in February 2020. We believe the data continue to support the highly differentiated “anti-VEGF Generation 2.0” profile of KSI-301. We intend to continue presenting data updates from Phase 1b throughout 2020, and if meetings or congresses are canceled due to COVID-19, we anticipate one or more virtual R&D webinars where new data will be presented. We anticipate providing an R&D update together with the American Society of Retina meeting in July 2020.

Further Extension of the Phase 1b Study

Based on positive feedback from investigators and a desire to continue to generate long-term safety and efficacy outcomes data with KSI-301, we are amending the Phase 1b program to include an additional 18 months of treatment and follow-up per patient, for a total of up to 36 months.

Pivotal Study Program Design

Following our communications with FDA at the time of our end of phase 2 meeting as well as subsequent communications, we have further upgraded our pivotal study program and now intend to conduct two Phase 3 studies in DME to provide the mutually-confirmatory studies required by FDA for initial demonstration of safety and efficacy, one Phase 2/3 study in wAMD (our ongoing DAZZLE study), one Phase 3 study in RVO, and one Phase 3 study in NPDR without DME. By conducting our paired studies in DME, we are able to generate additional data on the safety, efficacy and durability of KSI-301 in this area of high unmet need and commercial opportunity, while also narrowing the number of sites and countries required for successful enrollment of the entire pivotal program. We expect a majority of research sites to be located in the U.S. with contributions from EU countries and China. Given that we are currently seeing continued new patient enrollment and low missed visit rates in our DAZZLE wAMD pivotal study in the US despite the ongoing COVID-19 pandemic, we believe refocusing the KSI-301 program helps minimize uncertainty with respect to clinical trial conduct during and through the COVID-19 pandemic and towards our “2022 Vision.” Additional specific reasons for running paired DME pivotals (and one RVO pivotal) include: fewer countries and sites needed for two DME studies versus two RVO studies (avoiding the cost and logistical burdens of opening and supporting clinical trial sites that would only participate in RVO studies); better oversight of operational execution (essentially all sites can concurrently enroll treatment naïve patients in wAMD, DME and RVO); lower probability of disruption; higher unmet need in DME versus RVO; marginal, if any, increase in overall trial execution costs; and the potential for similar timelines for two DME versus two RVO pivotals. On top of these operational considerations, we remain pleased with the DME clinical data we are seeing in the Phase 1b study and want to align greater clinical data generation in DME given the larger number of diabetic patients and higher unmet need and market opportunity as compared to that of RVO.

Charles Bancroft Appointed to Board of Directors

Charles Bancroft, formerly Chief Financial Officer of Bristol Myers Squibb (BMS), joined Kodiak’s Board of Directors as chair of our audit committee and member of our nominating and governance committee in April 2020. Charles recently retired from a successful

career at BMS where he held a number of leadership roles in commercial, strategy and finance. Charles brings financial and management experience that will be vital to Kodiak as the company continues to scale and build its manufacturing and commercial capabilities.

Kodiak and Kodiak Sciences Trademarks Registered to Kodiak Sciences

The company received full registration of their trademarks “Kodiak” and “Kodiak Sciences” from the U.S. Patent and Trademark Office for the exclusive use of Kodiak Sciences Inc. and its subsidiaries. Obtaining exclusive trademark rights over “Kodiak” and “Kodiak Sciences” strengthens recognition of Kodiak as a leader in the research and development of medicines to treat and prevent retinal diseases.

Expected Upcoming Events/Milestones in 2020

- Host conference call and webcast to review recent business highlights
- Initiate two KSI-301 pivotal Phase 3 randomized head-to-head studies against aflibercept in treatment naïve Diabetic Macular Edema (DME) patients
- Initiate KSI-301 pivotal Phase 3 randomized head-to-head study against aflibercept in treatment naïve branch Retinal Vein Occlusion (BRVO) and central Retinal Vein Occlusion (CRVO) patients
- Initiate KSI-301 pivotal Phase 3 randomized study against sham in non-proliferative Diabetic Retinopathy (NPDR) without DME patients
- Present additional Phase 1b data updates throughout 2020 at major medical meetings and/or company organized virtual events with next update planned for July 2020

First Quarter 2020 Financial Results

Cash Position

Kodiak ended the first quarter of 2020 with $430.4 million of cash, cash equivalents and marketable securities. Based on the company's current cash position, Kodiak estimates having sufficient funds to execute on current operating plans into 2022.

Net Loss

The net loss for the first quarter of 2020 was $24.4 million, or $0.54 per share on both a basic and diluted basis, as compared to a net loss of $8.0 million, or $0.21 per share on both a basic and diluted basis, for the first quarter of 2019.

R&D Expenses

Research and development (R&D) expenses were $20.2 million for the first quarter of 2020, as compared to $5.7 million for the first quarter of 2019. Research and development expenses included $3.4 million in stock-based compensation expense for the first quarter of 2020.

G&A Expenses

General and administrative (G&A) expenses were $5.6 million for the first quarter of 2020, as compared to $2.7 million for the first quarter of 2019. General and administrative expenses included $2.6 million in stock-based compensation expense for the first quarter of 2020.

About KSI-301

KSI-301 is an investigational anti-VEGF therapy built on the Company's Antibody Biopolymer Conjugate, or 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 Company's DAZZLE pivotal study in patients with treatment-naïve wet AMD was initiated in October 2019. Kodiak plans to initiate additional pivotal studies of KSI-301 in 2020 in diabetic macular edema, retinal vein occlusion and diabetic retinopathy. These studies are anticipated to form the basis of the Company's initial BLA to support potential approval and commercialization. Kodiak Sciences Inc. is developing KSI-301 and owns rights to KSI-301 in key geographies including the US, EU, China and other major countries.

About the DAZZLE Study

The DAZZLE study (also called Study KSI-CL-102) is a global, multi-center, randomized study designed to evaluate the safety and efficacy 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 standard-care aflibercept on its every eight-week dosing regimen, each after three monthly initiating doses. The primary endpoint is at one year and each patient will be treated and followed for two years. Additional information about DAZZLE can be found on www.clinicaltrials.gov under Trial Identifier NCT04049266 (https://clinicaltrials.gov/show/NCT04049266).

About the KSI-301 Clinical Program

The KSI-301 Clinical Program is designed to assess KSI-301's safety, efficacy and durability in wet AMD, DME, RVO and non-proliferative DR (without DME) through clinical studies run in parallel. We have agreed on the order and number of clinical studies required to support the licensure of KSI-301 in wet AMD, DME, RVO and non-proliferative DR at an end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA). We confirmed that two clinical studies conducted in a single indication are expected by FDA to demonstrate the initial safety and efficacy of KSI-301. One clinical study each in the additional disease indications, if successful, can be used to support approval in the additional indications. We intend to conduct two Phase 3 studies in DME to provide the mutually confirmatory studies required by FDA for initial demonstration of safety and efficacy. We also intend to conduct one study in wAMD (our ongoing DAZZLE study) and one study in RVO to support approval of these additional indications. We intend to file this package together in a single BLA in 2022. We also plan to run an additional study in patients with non-proliferative DR without DME which depending on data readiness may be combined either into the single initial BLA or may be filed as a supplemental BLA. We estimate that the global KSI-301 clinical program will be conducted at 100+ study sites in more than 10 countries.

About Kodiak Sciences Inc.

Kodiak (Nasdaq: KOD) is a clinical stage biopharmaceutical company developing novel therapeutics to treat chronic, 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, a leading cause of blindness in elderly patients, and diabetic eye diseases, a leading cause of blindness in working-age patients. 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 BLA submission in wet AMD, DME, RVO and diabetic retinopathy; the sufficiency of our cash, cash equivalents and marketable securities; our platform technology and potential therapies; future development plans; 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; 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; and the impact of the COVID-19 pandemic on our operations, clinical studies and the global economy. 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 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-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 March 31,	
	2020	**2019**
Operating expenses		
Research and development	$ 20,170	$ 5,723
General and administrative	5,553	2,737
Total operating expenses	25,723	8,460
Loss from operations	(25,723)	(8,460)
Interest income	1,208	462
Interest expense	(7)	(4)
Other income (expense), net	130	18
Net loss	$ (24,392)	$ (7,984)
Net loss per common share, basic and diluted	$ (0.54)	$ (0.21)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	44,824,587	37,248,165

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

	March 31, 2020	**December 31, 2019**
Cash, cash equivalents and marketable securities	$ 430,393	$ 348,177
Working capital	$ 410,973	$ 327,519
Total assets	$ 443,042	$ 358,866
Accumulated deficit	$ (182,523)	$ (158,131)
Total stockholders' equity	$ 327,687	$ 345,359

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