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): August 10, 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 August 10, 2020, Kodiak Sciences Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended June 30, 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 August 10, 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: August 10, 2020

By: /s/ Victor Perlroth

Victor Perlroth, M.D.
Chief Executive Officer

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

Palo Alto, CA — August 10, 2020 – 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 second quarter ended June 30, 2020.

“We have made strong progress across the entire company this quarter— clinical, manufacturing, research and corporate. I am very proud of how our growing Kodiak community has continued to execute in the midst of the ongoing global pandemic,” said Victor Perlroth, MD, Chief Executive Officer of Kodiak. “There is a high unmet need for a new foundational therapy in the diseases we are exploring with KSI-301, namely wet age-related macular degeneration (wet AMD), diabetic macular edema (DME) and retinal vein occlusion (RVO). With strong physician and patient enthusiasm for KSI-301 and its emerging durability profile, enrollment has been brisk in our DAZZLE wet AMD pivotal study, and we successfully began recruitment in Europe in the second quarter. US enrollment in DAZZLE is near its conclusion. Building on the strong Phase 1b data that well-characterize KSI-301 in treatment-naïve patients and show the potential for many patients to achieve every five- or six-month dosing, we have conviction in the designs of our pivotal studies in DME and RVO and are focused on initiating recruitment. Our ambitious KSI-301 development plan which we call our ‘2022 Vision’ will, if successful, enable a single multi-indication BLA filing in 2022 and commercialization in 2023. We remain on track for achieving our vision from a timeline perspective and from a data perspective as well, with the 44-week KSI-301 Phase 1b results recently presented at ASRS continuing to demonstrate differentiated treatment durability alongside standard-of-care level safety and efficacy. As competing programs-in-development continue to present their own on-going safety, efficacy and durability data, we see the real possibility emerging for KSI-301 to achieve our aspirational goal as the ‘product for everyone’ with retinal vascular diseases. At the same time, we are making strides towards Kodiak as a global center of excellence for high-science retinal medicines development, with our growing pipeline of bispecific and triplet inhibitors built on our ABC Platform continuing to advance. Given the growing prevalence of sight-threatening diseases and the demographics of aging and diabetes globally, Kodiak’s ten-plus years of focus and dedication to retina is allowing us to begin accelerating our impact. With all these efforts in progress and a strong cash runway from our equity and royalty financings, we enter the third quarter with a growing and resilient team who continue to step-in daily for patients. We applaud their passion and look forward to continued execution in this second half of 2020.”

Recent Business Highlights:

Optimized Pivotal Study Program

We have finalized the design of our pivotal study program. We intend to conduct two Phase 3 studies in DME (GLEAM and GLIMMER) to provide the mutually confirmatory studies required by FDA for initial demonstration of safety and efficacy, one study in wet AMD (our ongoing DAZZLE study), one study in RVO (BEACON), and one study in non-proliferative diabetic retinopathy without DME (GLOW). Each study protocol design has been optimized based on Phase 1b data and experience and will include the same patient populations, tighter dosing interval ranging, tighter disease control, decreased subjectivity and high statistical power for non-inferiority.

DAZZLE Study Progress

Recruitment into our DAZZLE pivotal study in wet AMD was robust. As of July 30, 2020, over 375 patients have been enrolled in DAZZLE. The impact of the pandemic on patient retention and missed visits has been minimal, with few missed visits to date. EU patient enrollment commenced in June 2020. 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 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 American Society of Retina Specialists (ASRS) 2020 Virtual Annual Meeting in July 2020. We believe the data continue to support the differentiated “anti-VEGF Generation 2.0” profile of KSI-301.

Commercial Manufacturing Progress

We 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. With construction targeted for completion in 2021, the Lonza-Kodiak Ibex facility will provide Kodiak with the facility needed for commercial-scale manufacturing of KSI-301. The timing of this expanded partnership is designed to support Kodiak’s targeted BLA submission timeline in 2022, and the scale is designed to support KSI-301’s potential to achieve significant market share, if approved, as a new first-line agent designed to improve outcomes for patients with common and serious retinal vascular diseases.

Completed Lease Agreement for Kodiak’s New Corporate Headquarters

We have leased approximately 82,662 square feet located at 1200 Page Mill Road, Palo Alto, California and approximately 72,812 square feet located at 1250 Page Mill Road, Palo Alto, California. These newly leased buildings will serve as Kodiak’s corporate headquarters for office and laboratory space. We also leased approximately 10,750 square feet at Rottenstrasse 5 in Visp, Switzerland, for manufacturing support and supervision.

Expected Upcoming Events/Milestones in 2020

- Initiate two pivotal Phase 3 randomized head-to-head studies of KSI-301 against aflibercept in treatment naïve Diabetic Macular Edema patients (GLEAM and GLIMMER)
- Initiate one pivotal Phase 3 randomized head-to-head study of KSI-301 against aflibercept in treatment naïve Retinal Vein Occlusion patients (BEACON)
- (Potential) Initiate one pivotal Phase 3 randomized study of KSI-301 against sham in non-proliferative Diabetic Retinopathy without DME patients (GLOW)
- (Potential) Complete enrollment in DAZZLE pivotal Phase 2b/3 randomized head-to-head study of KSI-301 against aflibercept in treatment naïve wet macular degeneration patients.

Second Quarter 2020 Financial Results

Cash Position

Kodiak ended the second quarter of 2020 with $417.1 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 second quarter of 2020 was $26.0 million, or $0.58 per share on both a basic and diluted basis, as compared to a net loss of $11.4 million, or $0.31 per share on both a basic and diluted basis, for the second quarter of 2019.

R&D Expenses

Research and development (R&D) expenses were $20.6 million for the second quarter of 2020, as compared to $8.8 million for the second quarter of 2019.

G&A Expenses

General and administrative (G&A) expenses were $6.2 million for the second quarter of 2020, as compared to $3.0 million for the second quarter of 2019.

About KSI-301

KSI-301 is an investigational anti-VEGF therapy built on the Company'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 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 intend to conduct two Phase 3 studies in DME (the GLEAM and GLIMMER studies) to provide the mutually confirmatory studies required by FDA for initial demonstration of safety and efficacy. We also intend to conduct one study in wet AMD (our ongoing DAZZLE study) and one study in RVO (the BEACON study) 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 (the GLOW study) which depending on data readiness may be combined either into the single initial BLA or may be filed as a supplemental BLA. We expect that the global KSI-301 clinical program will be conducted at 150+ study sites in more than 10 countries.

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, 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 to fund our operations into 2020; our platform technology and potential therapies; future development plans, including our ability to initiate the GLEAM, GLIMMER, BEACON and GLOW studies in 2020 and complete enrollment in in DAZZLE in 2020; 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; 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-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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses				
Research and development	$ 20,557	$ 8,838	$ 40,727	$ 14,561
General and administrative	6,222	2,976	11,775	5,713
Total operating expenses	26,779	11,814	52,502	20,274
Loss from operations	(26,779)	(11,814)	(52,502)	(20,274)
Interest income	698	331	1,906	793
Interest expense	(6)	(2)	(13)	(6)
Other income (expense), net	88	100	218	118
Net loss	$ (25,999)	$ (11,385)	$ (50,391)	$ (19,369)
Net loss per common share, basic and diluted	$ (0.58)	$ (0.31)	$ (1.12)	$ (0.52)
Weighted-average common shares outstanding used in computing net loss per common share, basic and diluted	44,969,795	37,294,853	44,897,269	37,271,638

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

	June 30, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	$ 417,134	$ 348,177
Working capital	$ 400,245	$ 327,519
Total assets	$ 429,368	$ 358,866
Accumulated deficit	$ (208,522)	$ (158,131)
Total stockholders' equity	$ 309,197	$ 345,359

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