
**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): August 11, 2021

KALEIDO BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38822
(Commission
File Number)

47-3048279
(IRS Employer
Identification No.)

65 Hayden Avenue Lexington, MA
(Address of principal executive offices)

02421
(Zip Code)

Registrant's telephone number, including area code: **(617) 674-9000**

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 Instruction 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, \$0.001 Par Value	KLDO	NASDAQ Global Select Market

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 Entry into a Material Definitive Agreement.

On August 11, 2021, Kaleido Biosciences, Inc. (the “Company”) announced its financial results for the second quarter ended June 30, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Form 8-K (including Exhibits 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Kaleido Biosciences, Inc., dated August 11, 2021, furnished herewith
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.

KALEIDO BIOSCIENCES, INC.

Date: August 11, 2021

By: /s/ William Duke, Jr.
William Duke, Jr.
Chief Financial Officer
(Principal Financial and Accounting Officer)

--On track to report topline data from a clinical study of KB295 in patients with mild-to-moderate ulcerative colitis by end of third quarter--

--Kaleido and the COPD Foundation to collaborate on the development of KB109 in patients with COPD; plan to initiate Phase 2 clinical study in first quarter 2022--

--Additional data from an observational clinical study of KB109 in patients with mild-to-moderate COVID-19 expected by end of third quarter--

LEXINGTON, MA—August 11, 2021—Kaleido Biosciences, Inc. (Nasdaq: KLDO), a clinical-stage healthcare company with a differentiated, chemistry-driven approach to targeting the microbiome to treat disease and improve human health, today reported financial results for the second quarter ended June 30, 2021.

“We have made considerable progress so far this year across our dynamic and diverse clinical pipeline of novel, targeted Microbiome Metabolic Therapy™ (MMT) candidates. We continue to advance KB295 in patients with mild-to-moderate ulcerative colitis and anticipate reporting topline data from the clinical study by the end of the third quarter,” said Dan Menichella, President and Chief Executive Officer of Kaleido. “This quarter, we also expect to report data from the observational clinical study evaluating COVID-19 symptoms in ‘Long Hauler’ patients that participated in our prior COVID-19 clinical studies.”

Continued Mr. Menichella: “Additionally, we are proud to have announced a strategic collaboration with the COPD Foundation, an organization uniquely qualified to aid us in our mission to improve the lives of patients suffering from COPD. Our KB109 program will be greatly enhanced with support from the COPD Foundation, and we look forward to a productive and mutually beneficial partnership that leverages the strong data from our COVID-19 studies to explore treatment of COPD, the most prevalent chronic respiratory illness, impacting over 250 million people worldwide. While we are prioritizing COPD based on our assessment of the unmet need and commercial opportunity, we will continue to evaluate development opportunities for KB109 in COVID-19 with partners and government agencies.”

Recent Program and Corporate Highlights

- Topline data from the non-IND clinical study of KB295 in patients with mild-to-moderate ulcerative colitis (UC) are expected by the end of the third quarter.
- Additional data from the observational clinical study of KB109 in patients with mild-to-moderate COVID-19 are expected by the end of the third quarter.
- In August, Kaleido announced a collaboration with the COPD Foundation that is on track to initiate a Phase 2 clinical study of KB109 in patients with chronic obstructive pulmonary disease (COPD) in the first quarter of 2022.



Second Quarter Financial Results

Kaleido reported a net loss of \$23.9 million, or \$0.56 per common share, for the second quarter of 2021 compared to \$18.9 million, or \$0.59 per common share, for the same period in 2020. The second quarter net loss includes non-cash stock-based compensation expenses of \$2.4 million, as compared to \$2.8 million in the second quarter of 2020.

Research and development (R&D) expenses were \$17.6 million and \$12.8 million for the three months ended June 30, 2021 and 2020, respectively. The increase was primarily due to an increase in production of material for use in our clinical studies.

General and administrative (G&A) expenses were \$5.8 million and \$5.6 million for the three months ended June 30, 2021 and 2020, respectively. The increase was primarily due to increased facility operating costs that were attributed to general and administrative functions.

As of June 30, 2021, the Company reported cash and cash equivalents of \$72.0 million and has cash runway into the second quarter of 2022.

About Microbiome Metabolic Therapies (MMT™)

Kaleido's Microbiome Metabolic Therapies, or MMTs, are designed to drive the function and distribution of the microbiome's existing microbes in order to decrease or increase the production of metabolites, or to advantage or disadvantage certain bacteria in the microbiome community. The Company's initial MMT candidates are targeted, synthetic glycans that are orally administered, have limited systemic exposure, and are selectively metabolized by enzymes in the microbiome. Kaleido utilizes its discovery and development platform to study MMTs in microbiome samples to rapidly advance MMT candidates rapidly into clinical studies in healthy subjects and patients. These human clinical studies are conducted under regulations supporting research with food, evaluating safety, tolerability and potential markers of effect. For MMT candidates that are further developed as therapeutics, the Company conducts clinical trials under an Investigational New Drug (IND) or regulatory equivalent outside the U.S., and in Phase 2 or later development.

About Kaleido Biosciences

Kaleido Biosciences is a clinical-stage healthcare company with a differentiated, chemistry-driven approach to targeting the microbiome to treat disease and improve human health. The Company has built a proprietary product platform to enable the rapid and cost-efficient discovery and development of novel Microbiome Metabolic Therapies (MMT™). MMTs are designed to modulate the metabolic output and profile of the microbiome by driving the function and distribution of the gut's existing microbes. Kaleido is advancing a broad pipeline of MMT candidates with the potential to address a variety of diseases and conditions with significant unmet patient needs. To learn more, visit <https://kaleido.com/>.



Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the timing of initiation, completion and reporting of results of clinical studies, and our anticipated regulatory filings, strategy, business plans and focus. The use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify such forward-looking statements. All such 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 fluctuations in our stock price, changes in market conditions and satisfaction of customary closing conditions related to the public offering and those risks more fully discussed in the section entitled "Risk Factors" in Kaleido's annual report on Form 10-K for the fiscal year ended December 31, 2020, which is available at www.sec.gov, as well as discussions of potential risks, uncertainties, and other important factors in Kaleido's subsequent filings with the Securities and Exchange Commission. Any forward-looking statements represent Kaleido's views only as of today and should not be relied upon as representing its views as of any subsequent date. All information in this press release is as of the date of the release, and Kaleido undertakes no duty to update this information unless required by law.



Kaleido Biosciences, Inc. and Subsidiaries
Condensed Consolidated Statement of Operations (Unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Collaboration revenue	\$ 211	\$ 250	\$ 508	\$ 250
Operating expenses:				
Research and development	17,633	12,833	34,818	25,970
General and administrative	5,785	5,559	11,245	11,476
Total operating expenses	23,418	18,392	46,063	37,446
Loss from Operations	(23,207)	(18,142)	(45,555)	(37,196)
Other (expense) income	(682)	(780)	(1,376)	(1,277)
Net loss	\$ (23,889)	\$ (18,922)	\$ (46,931)	\$ (38,473)
Net loss per share—basic and diluted	\$ (0.56)	\$ (0.59)	\$ (1.14)	\$ (1.24)
Weighted-average common shares outstanding—basic and diluted	42,538,563	31,880,672	41,123,435	31,106,977

Kaleido Biosciences, Inc. and Subsidiaries
Condensed Consolidated Balance Sheet Data (Unaudited)
(in thousands)

	June 30, 2021	December 31, 2020
Assets:		
Cash and cash equivalents	\$ 71,979	\$ 46,222
Other assets	12,311	13,122
Total assets	\$ 84,290	\$ 59,344
Liabilities and stockholders' equity		
Liabilities	\$ 34,024	\$ 38,848
Stockholders' equity	50,266	20,496
Total liabilities and stockholders' equity	\$ 84,290	\$ 59,344

Contacts:

Kaleido Biosciences

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Investors and Media

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