
**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 4, 2020

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.

On August 4, 2020, Kaleido Biosciences, Inc. (the “Company”) announced its financial results for the second quarter ended June 30, 2020. 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 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 4, 2020, 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 4, 2020

By: /s/ Michael Bonney
Michael Bonney
Executive Chair
(Principal Executive Officer)

Kaleido Biosciences Reports Second Quarter 2020 Financial Results and Provides Corporate Update

- COVID-19 Clinical Development Program Topline Data Readout of Multi-Center Study Expected in Q4 2020 -
- Plan to Initiate New Clinical Study in Ulcerative Colitis in Q3 2020 -

LEXINGTON, Mass., August 4, 2020 – Kaleido Biosciences, Inc. (Nasdaq: KLDO), a clinical-stage healthcare company with a chemistry-driven approach to targeting the microbiome to treat disease and improve human health, today announced financial results for the second quarter 2020 and provided a corporate update.

“We have made several important advancements across critical areas of the business, including initiating two clinical studies in our COVID-19 program and strengthening our financial foundation by extending our cash runway into the second half of 2021,” said Michael Bonney, Executive Chair of Kaleido. “We anticipate top-line data from the 350-patient, multi-center COVID-19 study in the fourth quarter. We also continue to make progress on our preclinical programs and look forward to reporting data in the fourth quarter from our immuno-oncology, cardiometabolic and liver disease programs.”

Company Highlights

- Initiated two non-IND clinical studies that are part of the ongoing COVID-19 clinical development program evaluating KB109 when added to Supportive Self-Care in outpatients with mild-to-moderate COVID-19 disease: clinical study K031 is a multi-center study of approximately 350 patients and clinical study K032, in collaboration with Massachusetts General Hospital, aims to include approximately 50 patients.
- Completed a \$35.6 million offering of common stock.

Anticipated Milestones

- Clinical and *ex vivo* data from KB174, being developed for the treatment of hepatic encephalopathy (HE), to be featured in poster presentations during The Digital International Liver Congress™ (EASL 2020) August 27-29, 2020.
- Topline data from the multi-center (K031) clinical study of KB109 in patients with mild-to-moderate COVID-19 disease expected in Q4 2020 and top-line data from the study with Massachusetts General Hospital (K032) are expected in the first quarter of 2021. A patient may be enrolled in the study if an initial positive COVID-19 test result is received and the patient remains symptomatic.
- Initiating a clinical study in Q3 2020 evaluating KB295 in approximately 30 patients with mild-to-moderate ulcerative colitis (UC). Topline results are expected in mid-2021.



- Preclinical data from the immuno-oncology, cardiometabolic and liver diseases programs expected in Q4 2020.
- Topline data from Phase 2 clinical trial (UNLOCKED) of KB195 in patients with UCD inadequately controlled on standard of care in second half 2021.

Second Quarter 2020 Financial Results

For the second quarter 2020, Kaleido reported a net loss of \$18.9 million, or \$0.59 per common share, compared to \$24.6 million, or \$0.83 per common share, for the second quarter 2019. The 2020 second quarter net loss includes non-cash stock-based compensation expenses of \$2.8 million, as compared to \$2.4 million in the second quarter of 2019.

Research and development (R&D) expenses were \$12.8 million for the second quarter 2020, compared to \$18.8 million for the second quarter 2019. The second quarter decrease in R&D, as compared to the second quarter of 2019, was primarily driven by decreased external development, manufacturing, and research costs.

General and administrative (G&A) expenses were \$5.6 million for the second quarter 2020, compared to \$6.2 million for the second quarter of 2019. The second quarter 2020 decrease in G&A, as compared to the second quarter of 2019, was primarily due to decreased personnel-related costs, partially offset by increased facility-related expenses.

As of June 30, 2020, the Company reported cash and cash equivalents of \$71.0 million and has cash runway into the second half of 2021.

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, as amended, including, without limitation, statements regarding the therapeutic potential of our MMT candidates, the timing of initiation, completion and reporting of results of our clinical and preclinical studies, our anticipated cash runway and our strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those related to the breadth of our pipeline of product candidates, the strength of our proprietary product platform, the efficiency of our discovery and development approach, the clinical development and safety profile of our MMT candidates and their therapeutic potential, whether and when, if at all, our MMT candidates will receive approval from the U.S. Food and Drug Administration and for which, if any, indications, competition from other biotechnology companies, and other risks identified in our SEC filings, including our most recent Form 10-K, and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.



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,	
	2020	2019	2020	2019
Income:				
Collaboration revenue	\$ 250	\$ —	\$ 250	\$ —
Operating expenses:				
Research and development	12,833	18,775	25,970	33,957
General and administrative	5,559	6,181	11,476	11,614
Total operating expenses	18,392	24,956	37,446	45,571
Loss from Operations	(18,142)	(24,956)	(37,196)	(45,571)
Other (expense) income	(780)	317	(1,277)	713
Net loss	\$ (18,922)	\$ (24,639)	\$ (38,473)	\$ (44,858)
Net loss per share—basic and diluted	\$ (0.59)	\$ (0.83)	\$ (1.24)	\$ 2.10
Weighted-average common shares outstanding used in net loss—basic and diluted	31,880,672	29,667,221	31,106,977	21,361,749

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

	June 30, 2020	December 31, 2019
Assets:		
Cash and cash equivalents	\$ 71,032	\$ 71,241
Other assets	15,947	11,065
Total assets	\$ 86,979	\$ 82,306
Liabilities and stockholders' equity		
Liabilities	\$ 35,657	\$ 33,423
Stockholders' equity (deficit)	51,322	48,883
Total liabilities and stockholders' equity	\$ 86,979	\$ 82,306



Contacts

Kaleido Biosciences
William Duke, Jr.
Chief Financial Officer
617-890-5772
william.duke@kaleido.com

Investors

Lee M. Stern
Solebury Trout
646-378-2922
lstern@soleburytrout.com

Media

Joshua R. Mansbach
Solebury Trout
646-378-2964
jmansbach@troutgroup.com