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): November 01, 2021

KALEIDO BIOSCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38822**	**47-3048279**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

65 Hayden Avenue **Lexington, Massachusetts**	**02421**
(Address of Principal Executive Offices)	**(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:

☐ 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 November 1, 2021, Kaleido Biosciences, Inc. (the "Company") announced its financial results for the third quarter ended September 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:

Exhibit No.	Description
99.1	Press Release issued by Kaleido Biosciences, Inc., dated November 1, 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 thereunto duly authorized.

KALEIDO BIOSCIENCES, INC.

Date: November 1, 2021

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

Exhibit 99.1

Kaleido Biosciences Reports Third Quarter 2021 Financial Results

--Achieved primary objective of safety and tolerability in clinical study evaluating KB295 in mild-to-moderate ulcerative colitis; meaningful reduction observed in key biomarkers correlated with disease activity and inflammation--

--Remain on track to initiate Phase 2 clinical trials of KB109 in COPD and KB295 in UC in first half 2022--

LEXINGTON, Mass.—November 1, 2021—Kaleido Biosciences, Inc. (Nasdaq: KLDO), a clinical-stage biotech company with a differentiated, small-molecule approach to treating inflammatory conditions and diseases by selectively targeting the resident microbiome to restore gut-immune homeostasis, today reported financial results for the third quarter ended September 30, 2021.

“This has been a productive quarter for Kaleido, highlighted by the reporting of positive data from our first-in-human study in mild-to-moderate ulcerative colitis paving a clear path forward to advance KB295 into a Phase 2 clinical trial under an IND next year,” said Dan Menichella, President and Chief Executive Officer of Kaleido. “Additionally, we are continuing to work closely with our partners at the COPD Foundation and remain on track to initiate a Phase 2 trial of KB109 in COPD in the first half of 2022. We are excited to initiate clinical trial in these two indications next year and look forward to demonstrating the immunomodulatory effect of our unique, microbiome metabolic therapies.”

Recent Program and Corporate Highlights

- In October, Kaleido announced the primary objective of safety and tolerability in the non IND/CTA K030 study evaluating KB295 in mild-to-moderate ulcerative colitis (UC) was achieved. Findings from the study revealed KB295 was well tolerated across subjects, including those taking 5-ASA medications and/or biologics, and no product-emergent serious adverse events were reported. In addition, subjects receiving KB295 experienced a reduction in three biomarkers known to be associated with UC disease activity, fecal calprotectin (FCP), fecal lactoferrin, and FimH. These results, together with pre-clinical data from *ex vivo* studies, support the Company’s plans to initiate a phase 2 trial, under an Investigational New Drug (IND) application and Clinical Trial Application (CTA), of KB295 in mild-to-moderate UC in the first half of 2022.

- The Company remains on track to initiate a Phase 2 clinical trial of KB109 in patients with chronic obstructive pulmonary disease (COPD) in the first half of 2022, in collaboration with the COPD Foundation.

Third Quarter Financial Results

Kaleido reported a net loss of $23.1 million, or $0.54 per common share, for the third quarter of 2021 compared to $23.1 million, or $0.65 per common share, for the same period in 2020. The third quarter net loss includes non-cash stock-based compensation expenses of $2.0 million, as compared to $4.4 million for the same period of 2020.

Research and development (R&D) expenses were $17.4 million and $15.7 million for the three months ended September 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 $5.1 million and $7.2 million for the three months ended September 30, 2021 and 2020, respectively. The decrease was primarily due to the modification of the vesting provision of stock options and restricted stock units related to the resignation of our former CEO in July 2020.

As of September 30, 2021, the Company reported cash and cash equivalents of $55.7 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 into clinical studies in healthy subjects and patients. These human clinical studies may be conducted under regulations supporting research with food, evaluating safety and tolerability and impact on the microbiome. For MMT candidates that are developed as therapeutics, the Company currently conducts and will conduct clinical trials under an Investigational New Drug (IND) or regulatory equivalent outside the U.S., often in Phase 2 or later development.

About Kaleido Biosciences

Kaleido Biosciences is a clinical-stage biotech company with a differentiated, small-molecule approach to treating inflammatory conditions and diseases by selectively targeting the resident microbiome to restore gut-immune homeostasis. 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 clinical study plans and timelines, plans and timing for regulatory filings, and the Company's business 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, regulatory agencies will approve our IND application or clinical trial applications for KB295 or KB109, whether and when, if at all, our MMT candidates will receive approval from the U.S. Food and Drug Administration or other regulatory agencies 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Collaboration revenue	$ 104	$ 482	$ 612	$ 732
Operating expenses:				
Research and development	17,411	15,659	52,229	41,629
General and administrative	5,106	7,201	16,351	18,677
Total operating expenses	22,517	22,860	68,580	60,306
Loss from Operations	(22,413)	(22,378)	(67,968)	(59,574)
Other (expense) income, net	(672)	(753)	(2,048)	(2,030)
Net loss	$ (23,085)	$ (23,131)	$ (70,016)	$ (61,604)
Net loss per share—basic and diluted	$ (0.54)	$ (0.65)	$ (1.68)	$ (1.89)
Weighted-average common shares outstanding—basic and diluted	42,577,570	35,554,128	41,613,473	32,605,592

Kaleido Biosciences, Inc. and Subsidiaries

Condensed Consolidated Balance Sheet Data (Unaudited)

(in thousands)

	September 30, 2021	December 31, 2020
Assets:		
Cash and cash equivalents	$ 55,657	$ 46,222
Other assets	12,147	13,122
Total assets	$ 67,804	$ 59,344
Liabilities and stockholders' equity		
Liabilities	$ 38,604	$ 38,848
Stockholders' equity	29,200	20,496
Total liabilities and stockholders' equity	$ 67,804	$ 59,344

Contacts:

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