

**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 27, 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 8.01 Other Events.

On August 27, 2021 the Company received a Warning Letter from the U.S. Food and Drug Administration (FDA) for failure to submit an investigational new drug application (IND) prior to conducting two clinical studies, K031 and K032, of the Company's MMT KB109 in subjects with COVID-19. The Warning Letter followed receipt of a Form FDA 483 that was provided to the Company in March 2021 at the conclusion of a clinical inspection. The Form FDA 483 and Warning Letter were each based on a single observation that the Company failed to submit an IND for the conduct of these studies; there were no findings related to the conduct or oversight of these studies or the data that was generated. The Company is coordinating with the FDA and intends to continue with its plans to submit an IND for KB109 in support of future clinical research.

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: September 3, 2021

By: /s/ Daniel L. Menichella
Daniel L. Menichella
President and Chief Executive Officer
(Principal Executive Officer)