
**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): March 3, 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.

On March 3, 2021, Kaleido Biosciences, Inc. (the “Company”) announced its financial results for the year ended December 31, 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 March 3, 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: March 3, 2021

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

Kaleido Biosciences Reports Fourth Quarter and Full Year 2020 Financial Results

Topline data from two ongoing COVID-19 studies with KB109 expected in Q1 2021

KB295 study in patients with ulcerative colitis remains on track with topline data anticipated mid-year 2021

LEXINGTON, MA—March 3, 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 fourth quarter and full year ended December 31, 2020.

“In 2020, our Company achieved several important financial and clinical milestones that have positioned us for a productive and busy year ahead. Supported by our recently completed financing, we are beginning the year with a strong cash position, enabling continued growth and expansion of our broad, Microbiome Metabolic Therapies (MMT™)-based pipeline,” said Dan Menichella, President and Chief Executive Officer of Kaleido. “Recently we reported positive interim results from K031, one of two ongoing non-IND controlled clinical studies of KB109 evaluating outpatients with mild-to-moderate COVID-19 disease. Results demonstrated favorable safety and tolerability as well as evidence of clinical benefit for subjects reporting one or more comorbidities. We look forward to reporting data from both of our KB109 studies in the first quarter of 2021, including the full study population in the K031 study as well as topline results from the K032 study.”

Continued Mr. Menichella: “While our immediate priority remains advancing KB109 in COVID-19, we continue to make strong progress across our entire pipeline of novel, targeted, MMT therapies. We are currently enrolling patients in our recently initiated study of KB295 for the treatment of mild-to-moderate ulcerative colitis with topline data targeted for mid-year and continue to advance our Phase 2 clinical trial with KB195 in patients with urea cycle disorder. We are also looking forward to advancing our preclinical programs, particularly in immuno-oncology, cardiometabolic and liver diseases, and around an existing partnership with Janssen to deepen our understanding of how MMTs could potentially play a role in the prevention of childhood-onset atopic and immune conditions.”

Recent Program and Corporate Highlights

- Interim analysis (n=176) from a controlled non-IND clinical study of KB109 in patients with mild-to-moderate COVID-19 demonstrates favorable safety and tolerability, and provides strong signal of clinical benefit for subjects reporting one or more comorbidities
- In February, Kaleido closed a public offering with gross proceeds of approximately \$69.4 million, before deducting underwriting discounts and commissions and other offering expenses

Anticipated Near-Term Milestones

- Topline data from full study population (n=350) from a non-IND clinical study of KB109 in patients with mild-to-moderate COVID-19 as well as results from a second similar study expected in Q1 2021
- Topline data from a non-IND clinical study of KB295 in patients with mild-to-moderate ulcerative colitis (UC) expected in mid-2021

Fourth Quarter and Full Year 2020 Financial Results

Kaleido reported a net loss of \$20.0 million, or \$0.56 per common share, for the fourth quarter of 2020 compared to \$19.5 million, or \$0.65 per common share, for the same period in 2019. For the full year 2020, Kaleido reported a net loss of \$81.6 million, or \$2.44 per common share, compared to \$86.3 million, or \$3.36 per common share, for the prior year. The 2020 fourth quarter net loss includes non-cash stock-based compensation expenses of \$2.8 million, as compared to \$2.2 million in the fourth quarter of 2019. The full year 2020 net loss included non-cash stock-based compensation expenses of \$12.7 million, as compared to \$10.1 million in 2019.

Research and development (R&D) expenses were \$14.3 million and \$14.1 million for the three months ended December 31, 2020 and 2019, respectively. R&D expenses were \$56.0 million and \$64.2 million for the year ended December 31, 2020 and 2019, respectively. The full year decrease was primarily due to reduced headcount in our R&D function and less spend with external support for our clinical studies with external CROs and external CMOs and preclinical and clinical development activities. These decreases were partially offset by increased professional and consulting spend related to our studies and increased operating costs related to our facility expansion.

General and administrative (G&A) expenses were \$5.2 million and \$4.9 million for the three months ended December 31, 2020 and 2019, respectively. G&A expenses were \$23.9 million and \$22.4 million for the year ended December 31, 2020 and 2019, respectively. The full year increase 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 and increased operating costs related to our facility expansion. These increases were partially offset by reduced headcount in our G&A functions.

As of December 31, 2020, the Company reported cash and cash equivalents of \$46.2 million. Following the close of the February 2021 public offering, the Company has cash runway into the first 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 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 December 31, | | Year Ended December 31, | |
|--|------------------------------------|--------------------|----------------------------|--------------------|
| | 2020 | 2019 | 2020 | 2019 |
| Revenue: | | | | |
| Collaboration revenue | \$ 243 | \$ — | \$ 975 | \$ — |
| Operating expenses: | | | | |
| Research and development | 14,338 | 14,087 | 55,967 | 64,232 |
| General and administrative | 5,205 | 4,886 | 23,882 | 22,428 |
| Total operating expenses | 19,543 | 18,973 | 79,849 | 86,660 |
| Loss from Operations | (19,300) | (18,973) | (78,874) | (86,660) |
| Other (expense) income | (713) | (537) | (2,745) | 329 |
| Net loss | \$ (20,013) | \$ (19,510) | \$ (81,619) | \$ (86,331) |
| Net loss per share—basic and diluted | \$ (0.56) | \$ (0.65) | \$ (2.44) | \$ (3.36) |
| Weighted-average common shares outstanding—basic and diluted | 35,981,830 | 30,091,773 | 33,450,213 | 25,703,269 |

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

| | December 31, 2020 | December 31, 2019 |
|---|-------------------|-------------------|
| Assets: | | |
| Cash and cash equivalents | \$ 46,222 | \$ 71,241 |
| Other assets | 13,122 | 11,065 |
| Total assets | \$ 59,344 | \$ 82,306 |
| Liabilities and stockholders' equity | | |
| Liabilities | \$ 38,848 | \$ 33,423 |
| Stockholders' equity | 20,496 | 48,883 |
| Total liabilities and stockholders' equity | \$ 59,344 | \$ 82,306 |



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