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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
**Pursuant to Section 13 OR 15(d)**  
**of The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **May 2, 2019**

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**KALEIDO BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

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**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)

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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))

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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<b>Common Stock, \$0.001 Par Value</b>	<b>KLDO</b>	<b>NASDAQ Global Select Market</b>

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**Item 2.02. Results of Operations and Financial Condition.**

On May 2, 2019, Kaleido Biosciences, Inc. announced its financial results for the first quarter ended March 31, 2019. 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 Exhibit 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	<a href="#">Press Release issued by Kaleido Biosciences, Inc., dated May 2, 2019, furnished herewith</a>





## Kaleido Biosciences Reports First Quarter 2019 Financial Results and Provides Corporate Update

**LEXINGTON, Mass., May 2, 2019** – Kaleido Biosciences, Inc. (Nasdaq: KLDO), a clinical-stage healthcare company with a differentiated, chemistry-driven approach to leveraging the potential of the microbiome organ to treat disease and improve human health, today announced financial results for the first quarter ended March 31, 2019, and provided a corporate update.

“The first quarter of 2019 was historic for Kaleido. During the four years since our inception, we built a library of over 1,000 Microbiome Metabolic Therapy (MMT™) candidates, completed seven non-IND human clinical studies, and established a pipeline with five programs spanning multiple disease areas. This rapid advancement of our platform and portfolio culminated with our Initial Public Offering and the initiation of our first human studies in two different target patient populations in the first quarter,” said Alison Lawton, President and Chief Executive Officer of Kaleido. “I am exceptionally proud of our talented and hard-working team, and we are grateful to everyone who has supported us along the way, including investigators, clinical study participants and investors. Looking ahead, we anticipate additional important milestones during 2019, including the initiation of our Phase 2 clinical trial under our cleared IND for KB195 in patients with urea cycle disorders (UCD) – as well as data from non-IND clinical studies we recently initiated for KB195 in UCD patients and KB174 in patients with cirrhosis.”

### Recent Highlights

- Completed Initial Public Offering of common stock, raising gross proceeds of \$75 million
- Commenced trading on The Nasdaq Global Select Market on February 28, 2019, under the ticker symbol KLDO
- Initiated dosing in three non-Investigational New Drug (non-IND) human clinical studies:
  - KB195 in patients with UCD
  - KB174 in patients with cirrhosis
  - KB174 in healthy subjects to explore dosing
- Presented *ex vivo* and clinical study data highlighting Kaleido’s hyperammonemia programs and its proprietary product platform at three clinical and scientific conferences:
  - The International Liver Congress™ 2019, the Annual Meeting of the European Association for the Study of Liver (EASL)
  - Society for Inherited Metabolic Disorders (SIMD) 41<sup>st</sup> Annual Meeting
  - Keystone Symposia Meeting, Microbiome: Chemical Mechanisms and Biological Consequences
- Expanded the leadership team with appointment of Johan van Hylckama Vlieg Ph.D. as Chief Scientific Officer and Clare Fisher as Chief Business Officer

## Anticipated Key Milestones

- Initiation of Phase 2 clinical trial of KB195 in patients with UCD (Q2 2019)
- Data from non-IND clinical study of KB195 in patients with UCD (Q4 2019)
- Data from non-IND clinical study of KB174 in patients with cirrhosis (Q4 2019)
- Data from non-IND clinical study of KB174 in healthy subjects to explore dosing (Q4 2019)

## First Quarter 2019 Financial Results

For the first quarter ended March 31, 2019, Kaleido reported a net loss of approximately \$20.2 million, or \$1.56 per share, basic and diluted, compared to a net loss for the quarter ended March 31, 2018 of \$10.8 million, or \$2.27 per share, basic and diluted.

Total operating expenses for the quarter ended March 31, 2019 were \$20.6 million compared to \$10.2 million for the quarter ended March 31, 2018.

Research and development expenses for the quarter ended March 31, 2019 were \$15.2 million, compared to \$7.5 million for the quarter ended March 31, 2018. The increase in expense for the quarter was driven by an increase in external manufacturing and research costs to support the production of study material used in preclinical studies, non-IND human clinical studies, and clinical trials and clinical research organizations costs associated with MMT candidates for 2019.

General and administrative expenses were \$5.4 million for the quarter ended March 31, 2019, compared to \$2.7 million for the quarter ended March 31, 2018. The increase in general and administrative expenses for the year was driven by increased professional services and employee-related costs as the Company continues to increase its headcount and expand its infrastructure to support its growth.

Total operating expenses for the quarter ended March 31, 2019 include non-cash stock-based compensation expense of \$2.5 million compared to \$0.2 million of non-cash stock-based compensation expense for the quarter ended March 31, 2018.

Cash and cash equivalents were \$121.3 million as of March 31, 2019.

## About Kaleido Biosciences

Kaleido Biosciences is a clinical-stage healthcare company with a differentiated, chemistry-driven approach to leveraging the potential of the microbiome organ to treat disease and improve human health. The Company has built a human-centric 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 organ'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 our clinical studies and receipt of data from the same 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 final prospectus for our initial public offering, 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. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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

	Three Months Ended March 31,	
	2019	2018
<b>Operating expenses:</b>		
Research and development	\$ 15,182	\$ 7,546
General and administrative	5,433	2,670
<b>Total operating expenses</b>	<b>20,615</b>	<b>10,216</b>
Loss from Operations	(20,615)	(10,216)
Other (expense) income	396	(544)
<b>Net loss</b>	<b>\$ (20,219)</b>	<b>\$ (10,760)</b>
Net loss per share attributable to common shareholders—basic and diluted	\$ (1.56)	\$ (2.27)
Weighted-average common shares outstanding used in net loss per share attributable to common shareholders—basic and diluted	12,963,994	4,743,824

**Kaleido Biosciences, Inc.**  
**Condensed Consolidated Balance Sheet Data (unaudited)**  
**(in thousands)**

	<b>March 31,</b>	<b>December 31,</b>
	<b>2019</b>	<b>2018</b>
<b>Assets:</b>		
Cash and cash equivalents	\$ 121,340	\$ 76,086
Other assets	9,928	9,239
<b>Total assets</b>	<b>\$ 131,268</b>	<b>\$ 85,325</b>
<b>Liabilities and stockholders' (deficit) equity</b>		
Liabilities	\$ 24,132	\$ 28,343
Preferred stock	-	153,226
Stockholders' (deficit) equity	107,136	(96,244)
<b>Total liabilities and stockholders' equity</b>	<b>\$ 131,268</b>	<b>\$ 85,325</b>

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