Kaleido Biosciences Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update

March 2, 2020

- Results from three clinical studies in 2019 support Phase 2 development program in urea cycle disorders (UCD) and advancement of hepatic encephalopathy program into next clinical study

- Top-line data expected in Q4 2020 from Phase 2 trial of KB195 in patients with UCD and from multi-drug resistant pathogens clinical study of KB109

LEXINGTON, Mass., March 02, 2020 (GLOBE NEWSWIRE) -- Kaleido Biosciences, Inc. (Nasdaq: KLDO), a clinical-stage healthcare company with a chemistry-driven approach to leveraging the microbiome organ to treat disease and improve human health, today announced financial results for the fourth quarter and full year ended December 31, 2019, and provided a corporate update.

“2019 was a transformational year for Kaleido as we validated our platform with patient clinical data, advanced our pipeline, continued to build our library of Microbiome Metabolic Therapies (MMT™), and completed our Initial Public Offering,” saidAlison Lawton, President and Chief Executive Officer of Kaleido. “We initiated five clinical studies with three MMTs, including our first Phase 2 trial, and the results we reported from the three completed studies support our development programs for KB195 in urea cycle disorders and KB174 in hepatic encephalopathy. We also established collaborations with leaders at the forefront of microbiome research.”

Ms. Lawton continued, “We enter 2020 with strong momentum as we aim to deliver key data sets later this year, first from our Phase 2 trial in patients with UCD and then our multi-drug resistant pathogens clinical study with KB109. We also anticipate reporting *in vivo* findings from our programs in immuno-oncology and cardiometabolic and liver diseases before year end. Importantly, through efficient resource management during Q4 2019 and into 2020, we now anticipate that we have sufficient cash to extend our runway into Q1 2021.”

Recent Highlights

- Announced positive top-line results from a proof of concept clinical study of KB174 in patients with well-compensated cirrhosis and plans to advance the program into a clinical study in patients with hepatic encephalopathy (HE) in the second half of 2020.
- Multiple abstracts relating to KB174 and Kaleido’s MMT development program for HE have been accepted for presentation during The International Liver Congress™, the Annual Meeting of theEuropean Association for the Study of the Liver (EASL), April 15-19, 2020, and Digestive Disease Week® (DDW), May 2-5, 2020.
- Announced a collaboration with Janssen to explore the potential for MMTs to promote healthy function of the gut microbiome and effects on childhood-onset of atopic, immune and metabolic conditions.

Anticipated Milestones

- Top-line data expected in Q4 2020 from:
  - Phase 2 clinical trial (UNLOCKED) of KB195 in patients with UCD inadequately controlled on standard of care; and
  - Clinical study of KB109 (VITORA) in patients colonized with multi-drug resistant pathogens.
- *In vivo* findings from ongoing programs in immuno-oncology and cardiometabolic and liver diseases also expected in Q4 2020.

Fourth Quarter and Full Year 2019 Financial Results

For the full year 2019, Kaleido reported a net loss of $86.3 million, or $3.36 per common share, compared to $61.7 million, or $12.09 per common share, for the prior year. Kaleido reported a net loss of $19.5 million, or $0.65 per common share, for the fourth quarter of 2019 compared to $21.2 million, or $3.81 per common share, for the same period in 2018. Related to the measures announced in October 2019 to focus resources on pipeline programs and extend cash runway, headcount was reduced by approximately 25 percent and the fourth quarter net loss figure was inclusive of a one-time severance charge of $1.2 million. Additionally, the 2019 fourth quarter net loss includes non-cash stock-based compensation expenses of $2.2 million, as compared to $2.4 million in the fourth quarter of 2018. The full year 2019 net loss included non-cash stock-based compensation expenses of $10.1 million, as compared to $7.0 million in 2018.

Research and development (R&D) expenses were $14.1 million for the three months ended December 31, 2019 and $64.2 million for the full year ended December 31, 2019, compared to $15.2 million for the three months ended December 31, 2018 and $42.1 million for the full year ended December 31, 2018. The 2019 full year increase in R&D was primarily driven based on increases in direct costs related to the KB195 program, R&D headcount, external manufacturing and research costs, and consulting fees.

General and administrative (G&A) expenses were $4.9 million for the three months ended December 31, 2019 and $22.4 million for the full year ended December 31, 2019, compared to $5.6 million for the three months ended December 31, 2018 and $18.6 million for the full year ended December 31, 2018. The 2019 full year increase in G&A was primarily due to increased facility-related expenses. The fourth quarter 2019 decrease in G&A, as compared to the fourth quarter of 2018, was primarily due to reduced personnel-related costs.

As of December 31, 2019, the Company reported cash and cash equivalents of $71.2 million. Kaleido expects that its cash and cash equivalents will

enable it to fund its planned operating expenses and capital expenditure requirements into the first quarter 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 organ'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 glycans that are orally administered, have limited systemic exposure, and are selectively metabolized by enzymes in the microbiome. Kaleido utilizes its human-centric discovery and development platform to study MMTs in microbiome samples in an *ex vivo* setting, followed by advancing 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 leveraging 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 initiation, completion and reporting of results of our clinical and in vivo 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 form 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 December 31,		Twelve Months Ended December 31,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 14,087	$ 15,208	$ 64,232	$ 42,062
General and administrative	4,886	5,597	22,428	18,621
Total operating expenses	**18,973**	**20,805**	**86,660**	**60,683**
Loss from Operations	(18,973)	(20,805)	(86,660)	(60,683)
Other (expense) income	(537)	(425)	329	(1,061)
Net loss	**$ (19,510)**	**$ (21,230)**	**$ (86,331)**	**$ (61,744)**
Net loss per share—basic and diluted	$ (0.65)	$ (3.77)	$ (3.36)	$ (12.09)
Weighted-average common shares outstanding used in net loss—basic and diluted	30,091,773	5,630,883	25,703,269	5,108,147

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

	December 31, 2019	**December 31, 2018**
Assets:		
Cash and cash equivalents	$ 71,241	$ 76,086
Other assets	11,065	9,239

Total assets	**$ 82,306**	**$ 85,325**
Liabilities and stockholders' equity (deficit)		
Liabilities	$ 33,423	$ 28,343
Preferred stock	-	153,226
Stockholders' equity (deficit)	48,883	(96,244)
Total liabilities and stockholders' equity (deficit)	**$ 82,306**	**$ 85,325**

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Source: Kaleido Biosciences