April 16, 2018

Mateon Therapeutics Provides Business Update and Reports 2017 Financial Results

SOUTH SAN FRANCISCO, Calif., April 16, 2018 (GLOBE NEWSWIRE) -- Mateon Therapeutics, Inc. (OTCQX:MATN), a biopharmaceutical company developing investigational drugs for the treatment of orphan oncology indications, today provided a business update and announced 2017 financial results.

Business Update

Earlier today, Mateon announced the raise of additional capital in a private placement transaction with accredited investors. In addition to general corporate purposes, the additional capital will be prioritized towards the advancement of the company's two drug development programs:

- Using OXi4503 as a treatment for relapsed refractory acute myeloid leukemia
- Using CA4P as an immuno-oncology agent as a treatment for advanced melanoma

Both of the company's clinical development programs have potential to generate additional new clinical data before the end of 2018, with new data from OXi4503 in acute myeloid leukemia (AML) expected before initial data from CA4P as an immuno-oncology agent. The company plans to continue to pursue corporate collaboration opportunities with larger pharmaceutical companies for both of these programs.

The following provides an overview of the company's two drug development programs:

OXi4503 as a treatment for AML

Mateon has an on-going clinical trial in which its investigational drug OXi4503 is being tested as a new treatment for relapsed/refractory AML and myelodysplastic syndromes (MDS). In this clinical trial, we have completed five ascending dose cohorts using OXi4503 in combination with cytarabine, but subsequently paused enrollment due to lack of sufficient funds. Following the financing announced earlier today, the trial is again opening for patient enrollment. Newly enrolled patients will enter into the trial's sixth cohort (12.2 mg/m^2 of OXi4503; a 25% greater dose than the most recently completed 5th cohort). In the completed fifth cohort, we observed two complete remissions (50%) after one cycle of treatment with 9.76 mg/m^2 of OXi4503, and did not observe any dose-limiting toxicities. Among the first four cohorts (lower doses of OXi4503 ranging from 3.75 to 7.81 mg/m^2), we observed three complete remissions (18%), each occurring after two cycles of treatment. Because of these promising data, we are planning to enroll a higher number of patients into the sixth cohort in order to better evaluate the potential efficacy of OXi4503. Initial data from the sixth cohort is expected this summer.

CA4P as an Immuno-Oncology Agent

CA4P in combination with immuno-oncology agents is a promising investigational new treatment regimen for patients with advanced cancer who have failed standard therapies. This combination regimen, when studied in animal models of different cancer types, has been shown to increase tumor associated immune responses, tumor regressions, and overall survival compared to immuno-oncology agents alone. While there exist a number of new FDA-approved immuno-oncology agents which have significantly improved treatment options for patients with advanced cancer, unfortunately relatively few of these patients achieve a durable clinical response after treatment with these agents alone. New drugs which enhance the efficacy of these drugs, such as CA4P has been shown to do in animals, are greatly needed.

The mechanism-of-action of CA4P appears to be both unique and promising. CA4P causes rapid and widespread ischemic necrosis of the tumor shortly after infusion. This potent and tumor-specific type of necrosis in turn causes a potent and tumor-specific immune response. Animal models, for example, show that CA4P in combination with an immuno-oncology agent significantly enhances the number and activity of cancer-fighting T-cells within tumors compared to the immuno-oncology agent alone. In these animal models, these cancer-fighting T-cells were shown to be evident throughout the tumor and were associated with twice the amount of tumor necrosis than observed in treatment with the immuno-oncology agent alone. Accordingly, we believe CA4P may result in more and/or better clinical responses in patients with certain advanced cancers, including in patients who either have not experienced a response to immuno-oncology therapy, or in patients who have initially responded but subsequently progressed after treatment.

The next step for establishing CA4P as a safe and effective immuno-oncology agent is to initiate a clinical trial in a setting where immuno-oncology agents are currently used as standard therapy but have historically been associated with a low overall durable response rate. Therefore, Mateon plans to initiate a clinical trial evaluating CA4P in combination with an approved immuno-oncology agent, Opdivo® (nivolumab, marketed by Bristol-Myers Squibb), in patients with advanced metastatic melanoma who have previously failed Opdivo and consequently have a poor prognosis. Our goal is to improve the clinical outcomes for these patients, and obtain initial data from the study before the end of the year.

"We are excited about testing the ability of CA4P to enhance the efficacy of Opdivo in advanced melanoma in a new clinical trial," said William D. Schwieterman, M.D., Chief Executive Officer of Mateon Therapeutics. "Because CA4P works rapidly, specifically and powerfully in many tumor types to induce tumor-specific ischemic necrosis, it could be an ideal agent for boosting tumor-specific immune responses and enhancing the efficacy of currently approved immuno-oncology agents."

Financial Results

For the year ended December 31, 2017, Mateon reported a net loss of $13.8 million, an increase of $0.1 million from the net loss of $13.7 million for the year ended December 31, 2016. R&D expenses increased to $10.5 million in 2017 compared to $8.8 million in 2016, while general and administrative expenses decreased to $3.4 million in 2017 compared to $5.0 million in 2016.

At December 31, 2017, Mateon had cash and cash equivalents of $1.1 million.

About Mateon

Mateon Therapeutics, Inc. is a biopharmaceutical company developing investigational drugs for the treatment of orphan oncology indications, with programs in acute myeloid leukemia and immuno-oncology. Mateon is committed to leveraging its product development expertise and intellectual property to bring improved and medically necessary new therapies to cancer patients worldwide.

Safe Harbor Statement

Certain statements in this news release, including, but not limited to, those concerning the use of OXi4503 as a treatment for acute myeloid leukemia, the use of CA4P as an immuno-oncology agent, the planned clinical trials for these applications, the potential significance of this data and its relation to other clinical and pre-clinical studies are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. They can be affected by inaccurate assumptions Mateon might make or by known or unknown risks and uncertainties, including, but not limited to: the sufficiency of the Company's cash resources to continue in business and to conduct and complete future clinical and pre-clinical trials; the uncertainties as to the future success of ongoing and planned clinical trials; and the unproven safety and efficacy of products under development or that may be developed in the future. Consequently, no forward-looking statement can be guaranteed, and actual results may vary materially. Additional information concerning factors that could cause actual results to materially differ from those in the forward-looking statements is contained in Mateon's reports to the Securities and Exchange Commission, including Mateon's reports on Forms 10-Q, 8-K and 10-K. However, Mateon undertakes no obligation to publicly update forward-looking statements, whether because of new information, future events or otherwise.

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FINANCIAL DATA TO FOLLOW

Balance Sheet Data

	December 31,	
	2017	**2016**
	(all amounts in thousands)	
Assets		
Cash and short-term investments	$ 1,115	$ 12,047
Prepaid expenses and other current assets	-	2,023

Other assets	57	44
Total assets	$ 1,172	$ 14,114
Liabilities and stockholders' equity		
Accounts payable and accrued liabilities	$ 1,649	$ 1,614
Total stockholders' (deficit)/equity	(477)	12,500
Total liabilities and stockholders' equity	$ 1,172	$ 14,114

Statement of Operations Data

	2017	2016
	(all amounts in thousands, except per share data)	
Operating Expenses:		
Research and development	$ 10,471	$ 8,764
General and administrative	3,371	4,995
Total operating expenses	13,842	13,759
Loss from Operations	(13,842)	(13,759)
Interest income	35	106
Other income (expense)	(5)	(1)
Net loss and comprehensive loss	$ (13,812)	$ (13,654)
Basic and diluted net loss per common share attributable to common stock	$ (0.52)	$ (0.51)
Weighted-average number of common shares outstanding	26,545	26,545

Primary Logo

Source: Mateon Therapeutics

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