Equillium Reports Fourth Quarter and Full-Year 2019 Financial Results and Provides Business Update

March 26, 2020

EQUIP and EQUALISE Studies to be Paused in Response to the COVID-19 Pandemic

Company Reaffirms Guidance to Report Initial Data from the EQUATE Trial in Acute GVHD in 2H 2020

LA JOLLA, Calif., March 26, 2020 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company leveraging deep understanding of immunobiology to develop products to treat severe autoimmune and inflammatory disorders, today announced financial results for the fourth quarter and full-year ended December 31, 2019 and provided an update on its clinical development programs.

"COVID-19 and the global response to combat this pandemic may have unprecedented consequences to the healthcare system, including the ability to conduct clinical studies," said Bruce Steel, chief executive officer of Equillium. "In an abundance of caution to protect patients, caregivers, clinical site staff, company employees and contractors at this critical juncture, we have paused enrollment in the EQUIP trial for uncontrolled asthma and the EQUALISE trial for lupus nephritis. Our decision was not based on any safety events related to itolizumab and is in alignment with the FDA's guidance on the conduct of clinical trials during the COVID-19 pandemic issued March 20, 2020. The demands on medical institutions and the ability of clinicians to execute clinical studies during this global crisis were also considerations in our decision. As a result, we are suspending guidance on when we anticipate reporting initial data from these studies. We will continue to monitor the situation and are working closely with our partners and focusing on being operationally prepared to restart these trials when appropriate."

"We are continuing to enroll patients in the EQUATE study for patients with acute graft-versus-host disease (aGVHD) given the acute life-threatening severity of the disease. We are maintaining guidance that we anticipate reporting initial data from the EQUATE study during the second half of 2020. We also reiterate guidance that our cash on hand is sufficient to fund operations into the second half of 2021; this runway may be extended depending on the timing of restarting enrollment of the EQUIP and EQUALISE trials."

"We have made significant advances over the last year in the development of itolizumab in multiple indications. We eagerly await initial results from our aGVHD study where we believe itolizumab represents a potentially life-saving treatment for these severely ill patients. Additionally, depending on the course of COVID-19, we look forward to recommencing our studies in lupus nephritis and uncontrolled asthma to elucidate the potential of itolizumab as a novel therapeutic option for patients across a range of severe immuno-inflammatory diseases."

2019 Business Highlights:

- Initiated three Phase 1b proof-of-concept clinical trials of itolizumab:
  - EQUATE trial in aGVHD
  - EQUIP trial in uncontrolled asthma
  - EQUALISE trial in lupus nephritis
- Received fast track designation from the Food and Drug Administration (FDA) for the treatment with itolizumab in patients with aGVHD and lupus nephritis
- Received orphan drug designations from the FDA for both the prevention and treatment of aGVHD
- Expanded exclusive license agreement with Biocon Limited for itolizumab to include the territories of Australia and New Zealand, and obtained exclusive representation rights to third-party licensing rights to develop and commercialize itolizumab in select major markets outside of North America
- Secured a term debt facility for up to $20 million with Silicon Valley Bank and Oxford Finance LLC

Upcoming Catalysts:

- Initial data from the Phase 1b part of the EQUATE trial in aGVHD expected in 2H 2020

Fourth Quarter 2019 Financial Results

Research and development (R&D) expenses. Total R&D expenses for the three months ended December 31, 2019 were $5.4 million, compared with $2.5 million for the same period in 2018. The increase in R&D expenses was primarily driven by the ramp-up of clinical development activities associated with the EQUIP, EQUATE and EQUALISE clinical trials, increased headcount expenses, and preclinical research and translational science activities to support Equillium's clinical development programs.

General and administrative (G&A) expenses. Total G&A expenses for the three months ended December 31, 2019 were $2.2 million, compared with $1.7 million for the same period in 2018. The increase in G&A expenses was primarily driven by additional costs related to increased headcount expenses, costs related to being a public company, offset by lower legal fees.

Net loss. Net loss for the three months ended December 31, 2019 was $7.6 million, or $(0.44) per basic and diluted share, compared with a net loss of

$5.0 million, or $(0.31) per basic and diluted share for the same period in 2018.

Full-Year 2019 Financial Results

Research and development (R&D) expenses. Total R&D expenses for the year ended December 31, 2019 were $17.6 million, compared with $4.9 million for the year ended December 31, 2018. The increase in R&D expenses was primarily driven by the initiation and ramp-up of clinical development activities associated with the EQUIP, EQUATE and EQUALISE clinical trials, increased headcount expenses, and preclinical research and translational science activities to support Equillium's clinical development programs.

General and administrative (G&A) expenses. Total G&A expenses for the year ended December 31, 2019 were $9.1 million, compared with $3.7 million for the year ended December 31, 2018. The increase in G&A expenses was primarily driven by additional costs related to increased headcount expenses, costs related to being a public company, and legal and other professional fees.

Net loss. Net loss for the year ended December 31, 2019 was $25.6 million, or $(1.47) per basic and diluted share, compared with a net loss of $13.3 million, or $(1.09) per basic and diluted share for the year ended December 31, 2018.

Cash, cash equivalents and short-term investments. Equillium held cash, cash equivalents and short-term investments totaling approximately $53.1 million at December 31, 2019, compared to $65.9 million at December 31, 2018.

About Equillium

Equillium is a clinical-stage biotechnology company leveraging deep understanding of immunobiology to develop novel products to treat severe autoimmune and inflammatory disorders with high unmet medical need.

Equillium's initial product candidate, itolizumab (EQ001), is a clinical-stage, first-in-class monoclonal antibody that selectively targets the CD6-ALCAM pathway. This pathway plays a central role in modulating the activity and trafficking of T cells that drive a number of immuno-inflammatory diseases. Itolizumab is a clinically-validated therapeutic that has demonstrated a favorable safety and tolerability profile. Equillium acquired rights to itolizumab through an exclusive partnership with Biocon Limited. Equillium believes that itolizumab has the potential to be a best-in-class disease modifying therapeutic and is advancing the clinical development of itolizumab in the following severe immuno-inflammatory disorders: uncontrolled asthma, acute graft-versus-host disease, and lupus nephritis. For more information, visit www.equilliumbio.com.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding Equillium's business strategy, Equillium's plans and expected timing for developing itolizumab, including the expected timing of results from the EQUATE clinical trial, the potential benefits of itolizumab, Equillium's cash runway and the impact of the COVID-19 pandemic. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties related to Equillium's plans and product development, including the initiation, restarting and completion of clinical trials, uncertainties related to the actual impacts and length of such impacts caused by the COVID-19 pandemic, uncertainties caused by the pausing of the EQUIP and EQUALISE clinical trials, whether the results from clinical trials will validate and support the safety and efficacy of itolizumab, having to use cash in ways or on timing other than expected and the impact of market volatility on cash reserves. These and other risks and uncertainties are described more fully under the caption "Risk Factors" and elsewhere in Equillium's filings and reports with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Equillium undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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Equillium, Inc.
Condensed Consolidated Balance Sheets
(In thousands)

	December 31, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 53,143	$ 65,913
Prepaid expenses and other assets	2,396	1,250
Total assets	$ 55,539	$ 67,163
Current liabilities	3,883	2,028
Long-term notes payable	9,681	-
Other non-current liabilities	127	200
Total stockholders' equity	41,848	64,935
Total liabilities and stockholders' equity	$ 55,539	$ 67,163

Equillium, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
	(unaudited)			
Operating expenses:				
Research and development	$ 5,449	$ 2,518	$ 17,640	$ 4,943
General and administrative	2,167	1,710	9,087	3,672
Total operating expenses	7,616	4,228	26,727	8,615
Loss from operations	(7,616)	(4,228)	(26,727)	(8,615)
Other income (expense), net	49	(764)	1,127	(4,635)
Net loss	$ (7,567)	$ (4,992)	$ (25,600)	$ (13,250)
Net loss per common share, basic and diluted	$ (0.44)	$ (0.31)	$ (1.47)	$ (1.09)
Weighted-average number of common shares outstanding, basic and diluted	17,383,615	16,209,576	17,378,096	12,190,245