Equillium Reports Second Quarter 2020 Financial Results and Recent Highlights

August 12, 2020

LA JOLLA, Calif., Aug. 12, 2020 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced financial results for the second quarter 2020.

“We have made significant progress across a number of fronts since our last update,” said Bruce Steel co-founder and chief executive officer of Equillium. “The positive interim data we recently reported from the Phase 1b portion of our EQUATE clinical trial of itolizumab in patients with acute graft-versus-host-disease (aGVHD), historically a particularly challenging and deadly indication, enhances our confidence in itolizumab as a potential life-saving treatment for these patients. Together with the encouraging data reported by our partner, Biocon Limited (Biocon), demonstrating itolizumab (ALZUMAb™) reduced mortality in patients hospitalized with COVID-19 in their Phase 2 trial conducted in India, we have gained additional and timely early evidence of drug activity across multiple autoimmune and inflammatory conditions, which supports our conviction that itolizumab’s novel immune-modulating mechanism may have promise in addressing a range of severe immuno-inflammatory disorders. We are now positioned for a number of upcoming catalysts, including proceeding with additional cohorts in our EQUATE trial, initiating a global randomized controlled clinical trial in hospitalized patients with COVID-19, and advancing our Phase 1b EQUIP and EQUALISE trials in uncontrolled asthma and lupus nephritis, respectively.”

Business Highlights:

- Reported positive interim data from EQUATE clinical trial of itolizumab as a first line therapy for patients with aGVHD – 71% of patients treated to date achieved a complete response at Day 29
- Shared encouraging topline results as reported by Biocon from their randomized, controlled open label clinical trial conducted in India showing itolizumab (ALZUMAb) reduced mortality over one month as compared to placebo in patients hospitalized with COVID-19. As a result of the study, Biocon received emergency use approval from the Drugs Controller General of India (DCGI) for itolizumab in the treatment of cytokine release syndrome (CRS) in COVID-19 patients with moderate to severe acute respiratory distress syndrome (ARDS)
- Submitted a pre-investigational new drug (pre-IND) meeting request and supporting briefing package to the U.S. Food and Drug Administration (FDA) to study itolizumab in hospitalized patients with COVID-19
- Engaged prominent advisors Siddhartha Mukherjee, M.D., Ph.D., Pulitzer Prize Award-winning author, and an associate professor of medicine at Columbia University’s Herbert Irving Comprehensive Cancer Center, Ivor S. Douglas, M.D., FRCP (UK) professor of medicine, chief of pulmonary and critical care and medical director, Medical Intensive Care Denver Health Medical Center, and Atul Malhotra, M.D., research chief of pulmonary and critical care medicine at the University of California San Diego School of Medicine to help guide Equillium’s COVID-19 program
- Strengthened the balance sheet by raising a total of approximately $17.9 million in gross proceeds subsequent to the end of the second quarter 2020

Upcoming Catalysts:

- Initiation of a global trial of itolizumab in hospitalized patients with COVID-19
- Advancing ongoing EQUATE, EQUIP and EQUALISE trials

Second Quarter 2020 Financial Results

Research and development (R&D) expenses. Total R&D expenses for the three months ended June 30, 2020 were $3.9 million, compared with $4.3 million for the same period in 2019. The decrease in R&D expenses was primarily the result of lower clinical development expense driven by the higher startup costs incurred for the EQUIP trial in the second quarter of 2019 as well as the pausing of that study during the second quarter of 2020 due to the COVID-19 pandemic. Other contributors to the decrease in R&D expenses included lower consulting and travel expenses, offset by an increase in employee compensation and benefits primarily related to increased headcount.

General and administrative (G&A) expenses. Total G&A expenses for the three months ended June 30, 2020 were $2.7 million, compared with $2.2 million for the same period in 2019. The increase in G&A expenses was primarily driven by greater non-cash stock-based compensation expense, offset by decreases in outside legal expenses, salaries, and travel.

Net loss. Net loss for the three months ended June 30, 2020 was $6.5 million, or $(0.37) per basic and diluted share, compared with a net loss of $6.1 million, or $(0.35) per basic and diluted share for the same period in 2019.

Cash, cash equivalents and short-term investments. Equillium held cash, cash equivalents and short-term investments totaling $42.6 million at June 30, 2020, compared to $53.1 million at December 31, 2019.

Cash used in operations. Equillium used approximately $5.1 million of cash in its operations during the three months ended June 30, 2020,

compared to $6.3M in the prior quarter ended March 31, 2020.

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 has been clinically validated with a favorable safety and tolerability profile based on its approved uses in India. Equillium acquired rights to itolizumab through an exclusive partnership with Biocon. Biocon manufactures EQ001 and ALZUMAb at an FDA-regulated commercial scale facility; both products share the same primary monoclonal antibody sequence, but are manufactured in different cell lines, and EQ001 is available in both intravenous and subcutaneous dosing whereas ALZUMAb is currently available in intravenous dosing only. Biocon has recently reported results from a study of ALZUMAb in COVID-19 patients in India, and has subsequently received emergency use authorization from the Drugs Controller General of India for ALZUMAb for the treatment of CRS in COVID-19 patients with moderate to severe ARDS in India.

Equillium believes that itolizumab has the potential to be a best-in-class disease modifying therapeutic in several indications and is developing itolizumab in multiple severe immuno-inflammatory disorders – acute graft-versus-host disease, uncontrolled asthma, and lupus nephritis – and is planning to submit an investigational new drug application for the treatment of COVID-19 patients. 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 the impact of new advisors to guide the COVID-19 program, the potential benefit of treating COVID-19 patients with itolizumab, planned clinical studies as a result of data reported by Biocon, Equillium's business strategy, Equillium's plans and expected timing for developing itolizumab, including the ability to enroll additional cohorts in, and continue to report favorable result from, our EQUATE clinical trial and initiating a clinical trial in patients with COVID-19, 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 pending full review by Equillium of the Biocon dataset and uncertainties related to Equillium's capital requirements, Equillium's plans and product development, including the initiation, restarting and completion of clinical trials, including a clinical trial of patients with COVID-19, uncertainties related to the actual impacts and length of such impacts caused by the COVID-19 pandemic, uncertainties caused by the recent restarting of the EQUIP and EQUALISE clinical trials after a pause, 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)

	June 30, 2020 (Unaudited)	December 31, 2019
Cash, cash equivalents and short-term investments	$ 42,606	$ 53,143
Prepaid expenses and other assets	1,653	2,396
Total assets	$ 44,259	$ 55,539
Current liabilities	3,387	3,883
Long-term notes payable	9,810	9,681
Other non-current liabilities	90	127
Total stockholders' equity	30,972	41,848
Total liabilities and stockholders' equity	$ 44,259	$ 55,539

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

	Three Months Ended June 30,	
	2020	**2019**
	(unaudited)	
Operating expenses:		
Research and development	$ 3,893	$ 4,250
General and administrative	2,717	2,189
Total operating expenses	6,610	6,439
Loss from operations	(6,610)	(6,439)
Other (expense) income, net	149	370
Net loss	$ (6,461)	$ (6,069)
Net loss per common share, basic and diluted	$ (0.37)	$ (0.35)
Weighted-average number of common shares outstanding, basic and diluted	17,692,731	17,376,236