Equillium Reports First Quarter 2021 Financial Results and Provides Clinical Development Update

May 13, 2021

Announced favorable data from Phase 1b EQUALISE study in patients with systemic lupus erythematosus

Cash runway into the second half of 2023

Multiple data and regulatory catalysts through the remainder of 2021

LA JOLLA, Calif., May 13, 2021 (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 first quarter 2021, and provided an update on its clinical development programs.

"During the quarter, we announced the first of multiple data catalysts across three indications expected in 2021 for itolizumab, highlighting its potential broad therapeutic utility," said Bruce Steel, chief executive officer at Equillium. "Data from the Type A group of patients in the Phase 1b EQUALISE study, our first from subcutaneous delivery, showed favorable safety and tolerability results in systemic lupus erythematosus patients. It also demonstrated a dose-dependent reduction in the pharmacodynamic marker of CD6 expression on effector T cells, and that these results were consistent with the promising data generated from intravenous dosing of itolizumab in the EQUATE study in acute graft-versus-host disease (aGVHD). We now look ahead to the EQUATE study where we expect to announce topline data before the end of this quarter, followed by regulatory feedback on our proposed pivotal study in first-line treatment of aGVHD in mid-2021. In the second half of the year we expect to announce data from the Type B group of patients with lupus nephritis in the EQUALISE study along with data from the EQUIP study in uncontrolled asthma."

2021 Year-to-Date Corporate & Clinical Highlights:

- Announced favorable data from the Type A group of patients with systemic lupus erythematosus in the EQUALISE study, where itolizumab:
  - Was found to be safe and well tolerated
  - Demonstrated a dose-dependent reduction of cell surface CD6 expression on effector T cells, a leading indicator of drug activity, consistent with its mechanism of action
  - Demonstrated changes in pharmacodynamic markers observed with subcutaneous dosing were consistent with intravenous dosing of itolizumab
- Presented positive interim data from the EQUATE study in patients with acute graft-versus-host disease at the following conferences:
  - 2021 Transplantation and Cellular Therapy Meetings Digital Experience
  - European Society for Blood and Marrow Transplantation
- Completed a registered direct offering with Decheng Capital on February 5, 2021, which raised $29.9 million in net proceeds, strengthening Equillium's balance sheet and extending its expected cash runway into the second half of 2023
- Strengthened the company's leadership, including the following additions since the beginning of this year:
  - Dolca Thomas, M.D., appointed as executive vice president of research and development and chief medical officer
  - Y. Katherine Xu, Ph.D., partner at Decheng Capital, appointed to Equillium's board of directors

Upcoming Catalysts:

- EQUATE Phase 1b study: topline data in first-line aGVHD, 1H 2021
- Regulatory feedback on proposed pivotal study in first-line aGVHD, mid-2021
- Initiate pivotal study in first-line aGVHD, 2H 2021*
- EQUALISE Phase 1b study: interim data from Type B patients (lupus nephritis), 2H 2021
- EQUIP Phase 1b study: topline data in uncontrolled asthma, 2H 2021

**Proposed protocol & timeline for site initiation contingent on regulatory review*

First Quarter 2021 Financial Results

Research and development (R&D) expenses for the first quarter of 2021 were $5.9 million, compared with $4.7 million for the same period in 2020. The increase in the first quarter of 2021 compared to the same period in 2020 was driven by an increase in clinical development expenses, primarily related to the EQUATE and EQUALISE studies as well as purchases of drug product from Equillium's collaboration partner, Biocon, for Equillium's ongoing clinical trials, greater headcount expenses, and greater research and translational science expenses. Those increases were partially offset by a reduction in overhead costs, primarily travel, and lower consulting expenses.

General and administrative (G&A) expenses for the first quarter of 2021 were $2.8 million, compared with $2.7 million for the same period in 2020.

The increase in the first quarter of 2021 compared to the same period in 2020 was driven by greater headcount expenses, partially offset by lower consulting expenses, legal fees, and travel expenses.

Net loss for the first quarter of 2021 was $9.0 million, or $(0.33) per basic and diluted share, compared with a net loss of $7.8 million, or $(0.45) per basic and diluted share for the same period in 2020. The increase in net loss was largely attributable to increased research and development expenses.

Cash used in operations for the first quarter of 2021 was $7.9 million compared to $8.3 million in the fourth quarter of 2020.

Cash, cash equivalents and short-term investments totaled $104.1 million as of March 31, 2021, compared to $82.2 million as of December 31, 2020. The increase was due to the registered direct offering with Decheng Capital in February 2021, which raised $29.9 million in net proceeds. Equillium believes that its cash and investments will be sufficient to fund its currently planned operations into the second half of 2023.

About Itolizumab
Itolizumab is a clinical-stage, first-in-class anti-CD6 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. Equillium acquired rights to itolizumab through an exclusive partnership with Biocon Limited.

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 is developing itolizumab for multiple severe immuno-inflammatory diseases, including acute graft-versus-host-disease (aGVHD), lupus/lupus nephritis and uncontrolled asthma.

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 potential benefit of treating patients with aGVHD, uncontrolled asthma, or lupus/lupus nephritis with itolizumab, Equillium's plans and expected timing for developing itolizumab including the expected timing of initiating, completing and announcing further results from the EQUATE, EQUIP, and EQUALISE studies, the potential for any of Equillium's ongoing or planned clinical studies to show safety or efficacy, statements regarding the impact of new leadership team members, Equillium's anticipated timing of regulatory review and feedback, Equillium's cash runway, and Equillium's plans and expected timing for developing itolizumab and potential benefits of itolizumab. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties related to the abilities of new leadership team members to integrate and perform as expected; Equillium's ability to execute its plans and strategies; risks related to performing clinical studies; the risk that interim results of a clinical study do not necessarily predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; potential delays in the commencement, enrollment and completion of clinical studies and the reporting of data therefrom; the risk that studies will not be completed as planned; Equillium's plans and product development, including the initiation and completion of clinical studies and the reporting of data therefrom; whether the results from clinical studies will validate and support the safety and efficacy of itolizumab; changes in the competitive landscape; uncertainties related to Equillium's capital requirements; and 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 SEC. 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)
(unaudited)

	March 31, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	$ 104,079	$ 82,163
Prepaid expenses and other assets	2,759	3,265
Total assets	$ 106,838	$ 85,428
Current liabilities	7,417	7,245
Long-term notes payable	7,506	8,275

Other non-current liabilities	35	54
Total stockholders' equity	91,880	69,854
Total liabilities and stockholders' equity	$ 106,838	$ 85,428

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

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 5,880	$ 4,706
General and administrative	2,815	2,746
Total operating expenses	8,695	7,452
Loss from operations	(8,695)	(7,452)
Other expense, net	(296)	(385)
Net loss	$ (8,991)	$ (7,837)
Net loss per common share, basic and diluted	$ (0.33)	$ (0.45)
Weighted-average number of common shares outstanding, basic and diluted	27,325,372	17,562,551