



## Equillium Reports Second Quarter 2021 Financial Results and Provides Clinical Development Update

August 10, 2021

*Announced positive topline results from the EQUATE study of itolizumab in first-line treatment of acute graft-versus-host disease*

*Announced plans to initiate a Phase 3 pivotal study of itolizumab in first-line treatment of acute graft-versus-host disease*

LA JOLLA, Calif.--(BUSINESS WIRE)--Aug. 10, 2021-- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders with high unmet medical need, today announced financial results for the second quarter 2021, and provided an update on its clinical programs.

"The second quarter of the year was highlighted by positive data from our Phase 1b EQUATE study in acute graft-versus-host disease," said Bruce Steel, chief executive officer at Equillium. "These data were critical for achieving a positive outcome from our End-of-Phase 1 meeting with the FDA and accelerating our plans to immediately advance to a single, pivotal Phase 3 clinical study. This strategy, if successful, may position itolizumab to become the first approved therapy to treat patients with acute graft-versus-host disease in the first-line setting."

### Corporate & Clinical Highlights Since Beginning of Q2 2021:

- Announced positive topline results from the EQUATE study in first-line treatment of acute graft-versus-host disease presented at the 2021 Virtual Congress of the European Hematology Association, and plans to initiate a Phase 3 pivotal study following an End-of-Phase 1 meeting with the FDA
  - Itolizumab continues to demonstrate favorable safety and efficacy profile
  - Rapid and durable complete responses resulted in clinically meaningful reduction in corticosteroid use
  - Data support clinical advancement of itolizumab in first-line treatment of aGVHD
- Presented multiple posters at the 104th annual meeting of the American Association of Immunologists; research highlighted:
  - Itolizumab's novel mechanism of action and its effect on modulating T cell responses through inhibition of the CD6-ALCAM pathway
  - Development of a pharmacodynamic biomarker assay to monitor target engagement and fate of CD6 on T cells in patients treated with itolizumab

### Upcoming Catalysts:

- EQUALISE Phase 1b study: interim data from Type B patients (lupus nephritis) expected 2H 2021
- EQUIP Phase 1b study: topline data in uncontrolled asthma expected 2H 2021
- Initiate pivotal study in first-line aGVHD expected Q4 2021

### Second Quarter 2021 Financial Results

**Research and development (R&D) expenses** for the second quarter of 2021 were \$6.0 million, compared with \$3.9 million for the same period in 2020. The increase was driven by greater employee compensation and benefit expenses primarily related to increased headcount, an increase in clinical development expenses primarily related to the EQUATE and EQUALISE studies, as well as greater consulting, overhead, and non-clinical research expenses.

**General and administrative (G&A) expenses** for the second quarter of 2021 were \$2.9 million, compared with \$2.7 million for the same period in 2020. The increase was driven by greater employee compensation and benefits primarily related to increased headcount, partially offset by a decrease in non-cash stock-based compensation mainly due to retention option grants issued to certain officers and directors in the second quarter of 2020.

**Net loss** for the second quarter of 2021 was \$9.2 million, or \$(0.31) per basic and diluted share, compared with a net loss of \$6.5 million, or \$(0.37) per basic and diluted share for the same period in 2020. The increase in net loss was largely attributable to greater operating expenses.

**Cash used in operations** for the second quarter of 2021 was \$7.0 million compared to \$7.9 million in the first quarter of 2021.

**Cash, cash equivalents and short-term investments** totaled \$97.6 million as of June 30, 2021, compared to \$104.1 million as of March 31, 2021. Equillium believes that its cash and investments will be sufficient to fund its currently planned operations into 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 Equillum

Equillum 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. Equillum 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](http://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, Equillum'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 Equillum's ongoing or planned clinical studies to show safety or efficacy, statements regarding the impact of new leadership team members, Equillum's anticipated timing of regulatory review and feedback, Equillum's cash runway, and Equillum'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 the leadership team to perform as expected; Equillum'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; Equillum'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 Equillum'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 Equillum'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. Equillum undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

**Equillum, Inc.**  
**Condensed Consolidated Balance Sheets**  
(In thousands)  
(unaudited)

	June 30, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	\$ 97,643	\$ 82,163
Prepaid expenses and other assets	2,194	3,265
Total assets	<u>\$ 99,837</u>	<u>\$ 85,428</u>
Current liabilities	4,980	7,245
Long-term notes payable	10,067	8,275
Other non-current liabilities	17	54
Total stockholders' equity	<u>84,773</u>	<u>69,854</u>
Total liabilities and stockholders' equity	<u>\$ 99,837</u>	<u>\$ 85,428</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 5,985	\$ 3,893	\$ 11,865	\$ 8,599
General and administrative	2,858	2,717	5,673	5,463
Total operating expenses	<u>8,843</u>	<u>6,610</u>	<u>17,538</u>	<u>14,062</u>
Loss from operations	(8,843)	(6,610)	(17,538)	(14,062)
Other (expense) income, net	(315)	149	(611)	(236)
Net loss	<u>\$ (9,158)</u>	<u>\$ (6,461)</u>	<u>\$ (18,149)</u>	<u>\$ (14,298)</u>
Net loss per common share, basic and diluted	<u>\$ (0.31)</u>	<u>\$ (0.37)</u>	<u>\$ (0.64)</u>	<u>\$ (0.81)</u>

Weighted-average number of common  
shares outstanding, basic and diluted 29,076,562 17,692,731 28,205,805 17,627,641

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