



Equillium Reports Third Quarter 2021 Financial Results and Provides Clinical Development Updates

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

Reported decrease in proteinuria observed in subgroup of patients with lupus following two doses of itolizumab

Reported interim safety data from first cohort of asthma patients in Phase 1b EQUIP study

Company reaffirms guidance for EQUIP Phase 1b topline data in Q4 2021, and updates guidance to commence acute GVHD pivotal study in early 2022 and for interim data from EQUALISE Phase 1b Type B lupus nephritis patients to mid-2022

LA JOLLA, Calif.--(BUSINESS WIRE)-- 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 third quarter 2021, and provided an update on its clinical programs.

"Following positive topline data from the EQUATE study, we started the third quarter by announcing our plans to advance itolizumab into a pivotal clinical study in first-line acute graft-versus-host disease, which we anticipate commencing early in the new year," said Bruce Steel, chief executive officer at Equillium. "Recent strategic activity in the GVHD therapeutic segment demonstrates industry's recognition of the high unmet medical need for effective treatments for patients suffering from this deadly disease, and we believe our pivotal study could position itolizumab to become the first approved therapy to treat patients with acute GVHD in the first-line setting. We are also encouraged by the reductions in proteinuria observed in the subgroup data from the Type A portion of the EQUALISE study in patients with systemic lupus erythematosus, without lupus nephritis, that had elevated baseline urine protein/creatinine and albumin/creatinine ratios. Based on the Type A data we amended the protocol in the Type B portion to include newly diagnosed patients in addition to refractory patients and selected the 1.6 mg/kg dose. As a result of these protocol enhancements and due to challenges in patient recruitment amid the ongoing global pandemic, we now expect to announce interim data from the Type B portion of the study in patients with lupus nephritis mid-year 2022. We look forward to initiating our pivotal study in first-line acute GVHD early in the new year and presenting topline data from our EQUIP study in moderate to severe asthma before the end of this year."

Corporate & Clinical Highlights Since Beginning of Q3 2021:

- Announced plans to initiate a pivotal study in first-line acute graft-versus-host disease (aGVHD) following positive topline results from the EQUATE study and an End-of-Phase 1 meeting with the FDA
- Reported additional data from the EQUALISE study's Type A systemic lupus erythematosus (SLE) patients, without lupus nephritis, that had elevated baseline urine protein/creatinine and albumin/creatinine ratios, demonstrating a mean decrease of 42% and 54%, respectively, at Day 57 following two doses of itolizumab
- Presented multiple posters at the American College of Rheumatology (ACR), the American Society of Nephrology (ASN) and the American College of Allergy, Asthma and Immunology (ACAAI)

ASN & ACR

- Sustained decrease in proteinuria observed in subgroup of SLE patients, without lupus nephritis, following two doses of itolizumab
- Itolizumab was safe and well tolerated at doses ranging from 0.4 to 2.4 mg/kg
- Dose dependent decreases in inflammatory marker CD6 following itolizumab administration

ACAAI

- Itolizumab was well tolerated in patients with moderate to severe uncontrolled asthma

Upcoming Catalysts:

- EQUIP Phase 1b study: topline data in uncontrolled asthma expected Q4 2021
- Initiate pivotal study in first-line aGVHD expected early 2022
- EQUALISE Phase 1b study: interim data from Type B lupus nephritis patients expected mid-2022

Third Quarter 2021 Financial Results

Research and development (R&D) expenses for the third quarter of 2021 were \$7.0 million, compared with \$4.2 million for the same period in 2020. The increase was driven by greater clinical development expenses related to EQUIP primarily resulting from a lower R&D Tax Incentive benefit from the Australian Taxation Office and by start-up expenses related to our planned pivotal study in aGVHD, partially offset by lower costs related to a Phase 3 COVID-19 clinical trial that we decided not to commence. Greater employee compensation and benefit expenses driven by increased headcount and greater overhead expenses and costs related to our non-clinical research activities also contributed to the increase in R&D expense.

General and administrative (G&A) expenses for the third quarter of 2021 were \$2.9 million, compared with \$2.3 million for the same period in 2020. The increase was driven by greater employee compensation and benefit expenses primarily related to increased headcount and by greater overhead expenses, partially offset by a decrease in consulting expenses.

Net loss for the third quarter of 2021 was \$10.3 million, or \$(0.35) per basic and diluted share, compared with a net loss of

\$6.6 million, or \$(0.31) 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 third quarter of 2021 was \$7.0 million compared to \$7.0 million in the second quarter of 2021.

Cash, cash equivalents and short-term investments totaled \$90.7 million as of September 30, 2021, compared to \$97.6 million as of June 30, 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 signaling pathway to selectively downregulate pathogenic T effector cells while preserving T regulatory cells critical for maintaining a balanced immune response. 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, many of which are outside of the Company's control, 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 the leadership team to 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; 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. Investors should take such risks into account and should not rely on forward-looking statements when making investment decisions. 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)

	September 30, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	\$ 90,694	\$ 82,163
Prepaid expenses and other assets	1,776	3,265
Total assets	<u>\$ 92,470</u>	<u>\$ 85,428</u>
Current liabilities	7,778	7,245
Long-term notes payable	8,873	8,275
Other non-current liabilities	17	54
Total stockholders' equity	75,802	69,854
Total liabilities and stockholders' equity	<u>\$ 92,470</u>	<u>\$ 85,428</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 6,965	\$ 4,218	\$ 18,830	\$ 12,817
General and administrative	2,896	2,298	8,569	7,761
Total operating expenses	<u>9,861</u>	<u>6,516</u>	<u>27,399</u>	<u>20,578</u>
Loss from operations	(9,861)	(6,516)	(27,399)	(20,578)
Other expense, net	(421)	(81)	(1,032)	(317)

Net loss	\$ (10,282)	\$ (6,597)	\$ (28,431)	\$ (20,895)
Net loss per common share, basic and diluted	\$ (0.35)	\$ (0.31)	\$ (0.99)	\$ (1.11)
Weighted-average number of common shares outstanding, basic and diluted	29,382,806	21,374,240	28,602,450	18,885,623

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