Equillium Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate & Clinical Development Updates

3/23/2022

Announced positive topline data from EQUATE study of itolizumab in first-line aGVHD

Initiated EQUATOR Phase 3 study of itolizumab in first-line aGVHD

Presented interim safety data and reduction in proteinuria from the EQUALISE study of itolizumab in lupus patients

Acquired Bioniz Therapeutics, adding two first-in-class clinical-stage assets to pipeline and proprietary product discovery platform

LA JOLLA, Calif.--(BUSINESS WIRE)-- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company focused on developing novel therapeutics to treat severe autoimmune and inflammatory disorders with high unmet medical need, today announced financial results for the fourth quarter and full year 2021 and provided corporate and clinical development updates.

“I’m proud of our team and the progress we have made since the beginning of last year,” said Bruce Steel, chief executive officer at Equillium. “In that short time, we have announced data from multiple clinical studies, strengthened our balance sheet with a direct investment from Decheng Capital, added two experienced members to our board of directors, and most recently completed the acquisition of Bioniz Therapeutics. Perhaps most exciting is what is still to come, as this acquisition expands our pipeline of first-in-class therapeutic candidates that have the potential to improve patient care and adds significantly to our future operational milestones and pending data catalysts.”

“Our clinical advancements were fueled initially by itolizumab, our novel monoclonal antibody that selectively targets the CD6-ALCAM pathway,” said Steve Connelly, chief scientific officer at Equillium. “Data from the EQUATE study in first-line acute graft-versus-host disease demonstrated continued positive and durable clinical responses in a severely ill patient population, leading us to our Phase 3 study initiated earlier this month. The versatility and potential therapeutic utility of itolizumab was also demonstrated in interim data from the Type A portion of the Phase 1b EQUALISE study in patients with systemic lupus

erythematosus showing a decline in proteinuria in a subset of patients with elevated urinary protein. The addition of two first-in-class clinical-stage assets and a proprietary product discovery platform from Bioniz transforms Equillium into a multi-asset company as we look to initiate studies in alopecia areata and celiac disease in the second half of the year."

2021 and 2022 Year-to-Date Clinical Highlights:

- Initiated Phase 3 EQUATOR study of itolizumab in first-line acute graft-versus-host disease (aGVHD), a randomized, double-blind global pivotal study assessing the efficacy and safety of itolizumab versus placebo as a first-line therapy for aGVHD in combination with corticosteroids that will enroll up to 200 patients. The primary endpoint assessment is complete response rate at Day 29, with key secondary endpoints of overall response rate at Day 29 and durability of complete response rate from Day 29 through Day 99.
- Publication of data in the Journal of Clinical Investigation confirming the role of T cells activated by the CD6-ALCAM pathway in the development of lupus nephritis.
- Presented positive data from the EQUATE study in first-line aGVHD.
    - American Society of Hematology Annual Meeting
    - European Hematology Association Virtual Congress
    - Transplantation and Cellular Therapy Meetings
    - Annual meeting of the European Society of Blood and Marrow Transplantation
- Announced favorable data from the Type A portion of the EQUALISE study in patients with systemic lupus erythematosus (SLE).
    - American Society of Nephrology Annual Meeting
    - American College of Rheumatology Annual Meeting
- Announced data from the Type A portion of the EQUALISE study in patients with SLE, without lupus nephritis, that had elevated baseline urine protein/creatinine and albumin/creatinine ratios demonstrating a mean decrease of 42% and 53%, respectively, by Day 57 following two doses of itolizumab.

2021 and 2022 Year-to-Date Corporate Highlights:

- Acquired Bioniz Therapeutics, a privately held clinical-stage biotechnology company, significantly expanding the company's pipeline of novel immunomodulatory drug candidates, including two first-in-class clinical-stage assets (EQ101 & EQ102) and a proprietary product discovery platform. Lead assets are multi-specific inhibitors of key disease-driving, clinically validated cytokine targets aimed at addressing unmet needs across a range of immuno-inflammatory indications.
- Completed a registered direct offering with Decheng Capital in February 2021, which strengthened Equillium's balance sheet raising $29.9 million in net proceeds.
- Strengthened leadership and positioned Equillium for scalable growth, including the following additions to Equillium's Board of Directors:

- Y. Katherine Xu, Ph.D., partner at Decheng Capital
- Barbara Troupin, M.D., formerly of Myokardia, ERX Pharmaceuticals, Aquinox and Apricus Biosciences

Anticipated Upcoming Milestones & Catalysts:

- Itolizumab - EQUALISE Phase 1b study: interim data from Type B patients (lupus nephritis) expected mid-2022
- EQ101 - Initiate Phase 2 study in alopecia areata expected 2H 2022
- EQ102 - Initiate Phase 1 study in celiac disease expected 2H 2022

Fourth Quarter and Full Year 2021 Financial Results

Research and development (R&D) expenses for the fourth quarter of 2021 were $7.5 million, compared with $6.6 million for the same period in 2020. The increase in the fourth quarter of 2021 compared to the same period in 2020 was driven by greater headcount and clinical development expenses primarily related to start-up costs for the Phase 3 EQUATOR study. For the full year of 2021, R&D expenses were $26.4 million, compared with $19.4 million for the full year of 2020. The year-over-year increase in R&D expenses was driven by greater headcount and clinical development expenses primarily related to start-up costs for the Phase 3 EQUATOR study, a lower R&D Tax Incentive benefit from the Australian Taxation Office, and higher costs associated with our EQUATE, EQUIP and EQUALISE clinical studies.

General and administrative (G&A) expenses for the fourth quarter of 2021 were $2.8 million, compared with $2.4 million for the same period in 2020. The increase in the fourth quarter of 2021 compared to the same period in 2020 was primarily due to greater headcount expenses. For the full year of 2021, G&A expenses were $11.4 million, compared with $10.2 million for the full year of 2020. The year-over-year increase was primarily due to increased headcount expenses and general overhead, partially offset by lower consulting and legal expenses.

Net loss for the fourth quarter of 2021 was $10.6 million, or $(0.36) per basic and diluted share, compared with a net loss of $8.9 million, or $(0.36) per basic and diluted share for the same period in 2020. Net loss for the full year of 2021 was $39.1 million, or $(1.36) per basic and diluted share, compared with a net loss of $29.8 million, or $(1.46) per basic and diluted share for the full year of 2020. The increase in net loss for the full year of 2021 compared to the full year of 2020 was driven primarily by greater operating expenses and to a lesser extent by lower interest income.

Cash used in operations for the fourth quarter of 2021 was $10.2 million compared to $7.0 million in the third quarter of 2021. Key drivers of the quarter-over-quarter increase in cash used in operations include costs preparing to initiate the Phase 3 EQUATOR study and payment of our annual directors and officers insurance premiums in the fourth quarter of 2021.

Cash, cash equivalents and short-term investments totaled $80.7 million as of December 31, 2021, compared to $82.2 million as of December 31, 2020. An operating cash burn of $32.1 million in 2021 was offset by $29.9 million in net proceeds raised in a registered direct offering with Decheng Capital in February 2021. Equillium believes that its cash and investments will be sufficient to fund its currently planned operations for at least the next 12 months.

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 a deep understanding of immunobiology to develop novel therapeutics to treat severe autoimmune and inflammatory disorders with high unmet medical need. The company's pipeline consists of the following novel immunomodulatory assets targeting immuno-inflammatory pathways. Itolizumab, a first-in-class monoclonal antibody that targets the CD6-ALCAM signaling pathway which plays a central role in the modulation of effector T cells, is currently in a Phase 3 study for patients with acute graft-versus-host disease (aGVHD) and is in a Phase 1b study for patients with lupus/lupus nephritis. EQ101, a first-in-class tri-specific cytokine inhibitor that selectively targets IL-2, IL-9, and IL-15, is Phase 2 ready and expected to begin enrolling patients in an alopecia areata study in the second half of 2022. EQ102, a bi-specific cytokine inhibitor that selectively targets IL-15 and IL-21, is ready for clinical development and expected to begin enrolling patients in a Phase 1 study to include patients with celiac disease in the second half of 2022.

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. Forward-looking statements may be identified by the use of words such as "anticipate," "believe," "could," "continue," "expect," "estimate," "may," "plan," "outlook," "future" and "project" and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. 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 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, Equillium's plans and expected timing for developing EQ101 and EQ102 including the expected timing of initiating, completing and announcing further results from Phase 2 and Phase 1 studies, respectively, the potential benefits and impact of the Bioniz acquisition, the potential for any of Equillium's ongoing or planned clinical studies to show safety or efficacy, statements regarding the impact of new members of the board of directors, Equillium's anticipated timing of regulatory review and feedback, Equillium's cash runway, and Equillium's plans and expected timing for developing its product candidates and potential benefits of its product candidates. 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; 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 Equillium's product candidates; 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, which may be accessed for free by visiting EDGAR on the SEC web site at http://www.sec.gov and on the Company's website under the heading "Investors." 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. 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.

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

	December 31, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	$ 80,711	$ 82,163
Prepaid expenses and other assets	3,049	3,265
Operating lease right-of-use assets	1,645	-
Total assets	$ 85,405	$ 85,428
Current liabilities	8,915	7,245
Long-term notes payable	8,750	8,275
Long-term operating lease liabilities	1,235	-
Other non-current liabilities	-	54
Total stockholders' equity	66,505	69,854
Total liabilities and stockholders' equity	$ 85,405	$ 85,428

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 7,549	$ 6,567	$ 26,379	$ 19,384

General and administrative	2,838	2,403	11,407	10,164
Total operating expenses	10,387	8,970	37,786	29,548
Loss from operations	(10,387)	(8,970)	(37,786)	(29,548)
Other (expense) income, net	(234)	52	(1,266)	(265)
Net loss	$ (10,621)	$ (8,918)	$ (39,052)	$ (29,813)
Net loss per common share, basic and diluted	$ (0.36)	$ (0.36)	$ (1.36)	$ (1.46)
Weighted-average number of common shares outstanding, basic and diluted	29,411,242	24,733,313	28,806,310	20,355,534

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