

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 10, 2021

Equillium, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38692
(Commission File Number)

82-1554746
(IRS Employer
Identification No.)

2223 Avenida de la Playa
Suite 105
La Jolla, California
(Address of Principal Executive Offices)

92037
(Zip Code)

Registrant's Telephone Number, Including Area Code: 858 412-5302

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	EQ	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On June 10, 2021, Equillum, Inc. (the "Company") issued a press release announcing the Company's presentation of data on target engagement and modulation of CD6 on T Cells with Itolizumab at the International Society for Advancement of Cytometry.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated June 10, 2021, issued by Equillum, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

EQUILLIUM, INC.

Date: June 10, 2021

By: /s/ Bruce D. Steel

Bruce D. Steel

President and Chief Executive Officer



Equillium Presents Data on Target Engagement and Modulation of CD6 on T Cells with Itolizumab at the International Society for Advancement of Cytometry

Whole blood and proteomic stabilized blood assay used to elicit clinical pharmacodynamic CD6 biomarker in autoimmune diseases

LA JOLLA, California, June 10, 2021 – Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced a poster presented yesterday at the CYTO Virtual Interactive Meeting, highlighting a novel assay to measure target engagement and modulation of CD6 as a pharmacodynamic marker for effect on T cells following treatment with itolizumab. This assay was designed and validated to be both sensitive and selective in the quantification of CD6 receptor engagement, occupancy and modulation to help determine an optimal therapeutic dose in autoimmune and inflammatory diseases.

“As we advance itolizumab in the clinic and further characterize its potency, having a validated, sensitive and selective assay to quantify the engagement, occupancy and modulation of CD6 helps to further optimize dosing for patients,” said Stephen Connelly, Ph.D., chief scientific officer of Equillium. “The data presented at CYTO showed that in whole blood samples of healthy volunteers treated in vitro with itolizumab, receptor occupancy in fresh whole blood as high as 96% on CD4 T cells was achieved, providing efficient CD6 coverage and inhibition, a key mechanism needed in autoimmune and inflammatory diseases where the immune system is overactive. We look forward to the additional data being generated for itolizumab in our ongoing clinical trials in patients with acute graft versus host disease (aGVHD), lupus and lupus nephritis and uncontrolled asthma.”

Angelina R. Bisconte, Senior Director of Translational Biology & Biomarker Development, Precision for Medicine, the global precision medicine clinical research services organization, added, “Measuring cell-based receptor engagement has been challenging for patients on immune-modulatory therapies. In collaboration with Equillium, we have designed and validated a proprietary assay to be both sensitive and selective in the quantification of CD6 receptor occupancy and modulation to facilitate the determination of an optimal therapeutic dose in autoimmune and inflammatory diseases.”

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, 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 systemic lupus erythematosus and lupus nephritis with itolizumab, the ability of subcutaneous administration of itolizumab to be used in patients that require long term outpatient therapy, expected timing of further results from the EQUALISE study, 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: Equillium's ability to execute its plans and strategies; risks related to performing clinical trials; the risk that interim results of a clinical trial 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 trials 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 trials and the reporting of data therefrom; whether the results from clinical trials will validate and support the safety and efficacy of itolizumab; and changes in the competitive landscape. These and other risks and uncertainties are described more fully under the caption "Risk Factors" and elsewhere in Equillium's most recent Annual Report on Form 10-K and its other 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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