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): **March 15, 2021**

EQUILLIUM, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38692**	**82-1554746**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2223 Avenida de la Playa, Suite 105, La Jolla, CA	**92037**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(858) 412-5302**

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 (see General Instruction A.2. below):

☐ 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	The Nasdaq Global 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 March 15, 2021, Equillium, Inc. issued a press release announcing positive data for itolizumab in acute graft-versus-host disease in two presentations at the 47th annual meeting of the European Society for Blood and Marrow Transplantation (the "Press Release"). A copy of the Press Release is furnished hereto as Exhibit 99.1 and is incorporated by reference herein.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit Number	Description.
99.1	Press release, dated March 15, 2021, issued by Equillium, Inc.

SIGNATURE

Pursuant to the requirement 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: March 15, 2021

By: */s/ Bruce D. Steel*
Bruce D. Steel
President and Chief Executive Officer

Exhibit 99.1

Equillium Announces Positive Data for Itolizumab in Acute Graft-Versus-Host Disease in Two Presentations at the 47th Annual Meeting of the European Society for Blood and Marrow Transplantation

EQUATE acute graft-versus host disease (aGVHD) study observed rapid response and durability through day 85

EQUATE aGVHD study reported a clinically meaningful reduction in corticosteroid use

Translational data demonstrates itolizumab's impact on T cell effector function in aGVHD

LA JOLLA, California, March 15, 2021 - Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced positive data supporting the role of itolizumab as a potential treatment for acute graft-versus-host disease (aGVHD). The data, presented on-demand at the virtual 47th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT), confirms that a majority of patients in the EQUATE study achieved a complete response (CR) within 15 days, which was maintained through day 85. Importantly, there was a clinically meaningful reduction in corticosteroid use in these patients. Data was also presented showing that itolizumab inhibited pathogenic T cell proliferation.

"The high rate of complete responses coupled with adverse events consistent with those observed in high-risk acute GVHD, suggests itolizumab may be a very promising treatment for these patients," said Dr. John Koreth, Associate Professor of Medicine, Harvard Medical School. "It's important that we consider how sick these patients are when they present with acute GVHD, and the very limited treatment options that are available. The rapidity of efficacy onset, durability of response and concomitant steroid reduction supports itolizumab's potential as a first-line treatment and is very meaningful to physicians looking for treatment options, and patients suffering from this life-threatening condition."

"The translational work presented in this oral presentation characterizes CD6 expression levels and demonstrates the suppressive effect of itolizumab on the activity of CD4 and CD8 T cells from transplant patients with acute GVHD," said Jerome Ritz, M.D., executive director of the Connell and O'Reilly Families Cell Manipulation Core Facility at Dana-Farber Cancer Institute and professor of medicine at Harvard Medical School. "The growing critical mass of data underscores the important role of the CD6-ALCAM pathway in modulating effector T cell function and provides further validation for the use of itolizumab and the targeting of CD6 in aGVHD."

Itolizumab is a first-in-class anti-CD6 monoclonal antibody that selectively targets the CD6-ALCAM pathway, which plays a central role in modulating the activity and trafficking of the pathogenic T cells driving a number of immuno-inflammatory diseases.

Title:	Preliminary Safety and Efficacy of Itolizumab, A Novel Targeted Anti-CD6 Therapy, in Newly Diagnosed Severe Acute Graft-Versus-Host Disease: Interim Results from Equate Study
First Author:	Dr. John Koreth, MBBS, DPhil, Associate Professor of Medicine, Harvard Medical School, Director of Translational Research – Stem Cell Transplantation, Dana-Farber Cancer Institute

Presentation: ePoster presentation
Program Code: P195

Key Highlights, Summary and Conclusions from ePoster Presentation:

- Responses have been rapid and durable, with a majority of patients achieving a CR within the first 15 days and maintaining responses through Day 85
- Median steroid dose reduction at Day 85 was 93%, 87%, and 91% for Cohorts 1, 2, and 3, respectively
- Pharmacodynamic (PD) data from the first three cohorts suggests an optimal dose range of 0.8 to 1.6 mg/kg
- Itolizumab was generally well tolerated across all doses in high-risk aGVHD patients
- Key findings for itolizumab
    - Dose-dependent reduction of CD6 expression on CD4+ and CD8+ T-cells is consistent with proposed mechanism of action
    - Strong response for higher dose level cohorts (0.8 and 1.6 mg/kg) with overall response rate (ORR) of 100% (N=6) at Day 29, most have been complete responses (one very good partial response, or VGPR)

Title: Early Reconstitution of CD6+ T cells After Hematopoietic Cell Transplantation Identifies a Suitable Target for Acute Graft-Versus-Host Disease Treatment Using anti-CD6 Monoclonal Antibody Itolizumab
First Author: Benedetta Rambaldi, M.D., Research Fellow in Medicine, Dana-Farber Cancer Institute, Department of Hematologic Malignancies and Harvard Medical School
Presentation: Oral presentation
Program Code: OS9-6

Key Highlights, Summary and Conclusions from Oral Presentation:

- CD6+ T cells reconstituted early after transplant
- Itolizumab inhibits T cell proliferation and activation in patients with aGVHD
- Itolizumab demonstrates pathway specificity by inhibiting T cell proliferation in the presence of ALCAM-Fc and antiCD3 antibody, with no effect in the presence of antiCD3 antibody alone
- Functional inhibition of the CD6-ALCAM pathway may be a novel therapeutic strategy for treating aGVHD and translational data supports the ongoing EQUATE Phase 1b study of itolizumab in this setting

Both presentations are available on the Publications & Presentations page on Equillium's website.

About Graft-Versus-Host Disease (GVHD)
GVHD is a multisystem disorder that is a common complication of allogeneic hematopoietic stem cell transplants (allo-HSCT) caused by the transplanted immune system recognizing and attacking the recipient's body. Symptoms of GVHD include rash, itching, skin discoloration, nausea, vomiting, diarrhea, and jaundice, as well as eye dryness and irritation.

GVHD is the leading cause of non-relapse mortality in cancer patients receiving allo-HSCT, and the risk of GVHD limits the number and type of patients receiving HSCT. GVHD results in very high morbidity and mortality, with five-year survival of approximately 53% in patients who respond to steroid treatment and mortality as high as 95% in patients who do not respond to steroids. In the first-line aGVHD setting, published literature (MacMillan et al., 2015) describes background response rates to high-dose steroid administration in severe high-risk patients as 43% overall response rate and 27% complete response.

About the EQUATE Study
The EQUATE study is a Phase 1b/2 trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and clinical activity of itolizumab for first-line treatment in patients who present with aGVHD (NCT 03763318). The Phase 1b part of the trial is an open-label dose escalation study in adult patients who present with high-risk aGVHD and typically respond poorly to steroids. The Phase 1b data will inform selection of the dose to be used in the next phase of development for the program.

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 with itolizumab, the ability of Equillium to transition to later-stage development, the expected optimal dose range of itolizumab, 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 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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