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 11, 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, California**	**92037**
(Address of Principal Executive Offices)	**(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 11, 2021, Equillium, Inc. (the "Company") issued a press release announcing the Company's positive top-line results from the EQUATE study in first-line treatment of Acute Graft-Versus-Host Disease.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated June 11, 2021, issued by Equillium, 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 11, 2021

By: /s/ Bruce D. Steel

Bruce D. Steel
President and Chief Executive Officer

Exhibit 99.1

Equillium Announces Positive Topline Results from the EQUATE Study in First-line Treatment of Acute Graft-Versus-Host Disease

Itolizumab continues to demonstrate favorable safety and efficacy profile

Rapid and durable responses resulted in clinically meaningful reduction in corticosteroid use

Data support clinical advancement of itolizumab in first-line treatment of aGVHD

Conference call today at 8:00 am eastern time

LA JOLLA, California, June 11, 2021 - Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced positive topline data from the Phase 1b EQUATE study in first-line acute graft-versus-host-disease (aGVHD). The EQUATE trial is evaluating itolizumab in severe aGVHD patients concomitant with standard of care, which is typically comprised of high dose corticosteroids. There are no approved treatments for this severe, life threatening disease. The results were presented this morning in an oral presentation at the European Hematology Association 2021 Virtual Congress by John Koreth, M.D., associate professor of medicine, Dana Farber Cancer Institute, Harvard Medical School.

All patients in the study (N=20) were evaluated as high-risk (grades 3 and 4) aGVHD and achieved complete response (CR) and overall response rates (ORR) at Day 29 of 55% and 70% respectively. Responses observed were generally rapid – within 15 days – and durable through Day 29 and beyond. Six patients received therapy between four and nine days after steroid administration and were generally characterized as steroid refractory. Fourteen patients were characterized as treatment naïve – receiving itolizumab within three days of first steroid administration – and achieved CR and ORR of 64% and 71% respectively. Additionally, responding patients experienced clinically meaningful reductions in steroid administration. Across all dosing cohorts, 60% of patients (12/20) reported serious adverse events with only 10% (2/20) of these events reported as treatment related. There were 4 (20%) adverse events that led to death, and none were treatment related. Overall survival at month six across all dosing cohorts was 67%. Adverse events reported are consistent with a hospitalized, high-risk aGVHD patient population.

“Topline results from the EQUATE study highlight that itolizumab continues to demonstrate promising safety and efficacy data in first-line treatment of acute graft-versus-host disease,” said Dolca Thomas, executive vice president of research and development and chief medical officer of Equillium. “The clinical responses achieved were rapid and durable. The complete response rates are particularly compelling given all patients in the study presented with high-risk aGVHD. These data support clinical advancement into pivotal studies in this severely ill patient population where no drugs are approved, and standard of care remains high-dose corticosteroid treatment.”

“Itolizumab has demonstrated highly promising results in the large unmet medical need of first-line aGVHD, as evidenced by early clinical responses associated with a rapid reduction in systemic corticosteroid use,” said Dr. Koreth. “Complete response rates in this study are impressive, which are critical for longer-term durability and, ultimately, overall survival for these extremely sick, high-risk aGVHD patients. The 71 percent ORR and 64 percent CR at Day 29 endpoint, for patients that had

received less than 4 days of steroid treatment, compares very favorably to historical data and demonstrates the need for the advancement of this clinical program."

EQUATE Study Results: Itolizumab Response Rates in First-line aGVHD

	Early Response: Day 15		Response Endpoint: Day 29		Treatment Naïve Response: Day 29 *Treatment ≤3 days on steroids*		
	CR	**ORR**	**CR**	**ORR**	**N**	**CR**	**ORR**
All Subjects, n (%)							
0.4 mg/kg (N=4)	2 (50.0)	3 (75.0)	2 (50.0)	2 (50.0)	4	2 (50.0)	2 (50.0)
0.8 mg/kg (N=7)	5 (71.4)	5 (71.4)	5 (71.4)	5 (71.4)	5	4 (80.0)	4 (80.0)
1.6 mg/kg (N=9)	4 (44.4)	7 (77.8)	4 (44.4)	7 (77.8)	5	3 (60.0)	4 (80.0)
TOTAL (N=20)	**11 (55.0)**	**15 (75.0)**	**11 (55.0)**	**14 (70.0)**	**14**	**9 (64.3)**	**10 (71.4)**

Equillium has received fast track designation from the FDA for the treatment of itolizumab in patients with aGVHD and orphan drug designations from the FDA for both the prevention and treatment of aGVHD. Equillium expects to engage with regulatory agencies in mid-2021 to discuss the company's plans to proceed with a pivotal study in first-line aGVHD.

Key findings from EQUATE

- Responses were rapid, typically achieved within 15 days and maintained at Day 29 and beyond; across all patients 55% (11/20) achieved CR and 70% (14/20) achieved ORR at Day 29
- In treatment naïve patients 64% (9/14) achieved CR and 71% (10/14) achieved ORR at Day 29
- Responses were durable, with most patients maintaining response off-treatment through six months (Day 169 visit)
- Patients experienced rapid and robust steroid tapering; across all cohorts average steroid dose reduction was 67% at Day 29 and maintained through six months
- Overall survival across all treatment groups was 67% at six months
- Across all cohorts, 60% of patients (12/20) reported serious adverse events with only 10% (2/20) of these events reported as treatment related; there were 4 (20%) adverse events that led to death, and none were treatment related
- Itolizumab has been well tolerated and adverse events have been consistent with those common in high-risk aGVHD
- Optimal dose range observed 0.8 to 1.6 mg/kg; no further dose escalation is anticipated

Webcast and Conference Call

Management will host a conference call accompanied by a slide presentation to discuss the topline EQUATE data for analysts and institutional investors, at 8:00 am ET today, June 11, 2021. To access the call, please dial (866) 930-5156 (North America) or (409) 937-8975 (International) and, if needed, provide confirmation number 4794299. A live webcast of the call will also be available on the company's

Investor Relations page at https://ir.equilliumbio.com/events-and-presentations. The webcast will be archived for 90 days.

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 its risk limits the number and type of patients receiving HSCT. GVHD results in 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. There are no approved treatments for first-line aGVHD. Published literature (MacMillan et al., 2015) describes background response rates to high-dose steroid administration in severe high-risk patients as 43% overall response 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, Equillium's

plans and expected timing for developing itolizumab including the expected timing of initiating, completing and announcing further results from the EQUATE study, 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 new leadership team members to integrate and 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 itolizumab; 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" in Equillium's Annual Report on Form 10-K for the year ended December 31, 2020, 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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