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): July 12, 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 July 12, 2021, Equillium, Inc. (the "Company") issued a press release announcing the Company's plans to initiate a single phase 3 pivotal study of itolizumab in first-line treatment of acute graft-versus-host disease following an end-of-phase 1 meeting with the FDA.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release, dated July 12, 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: July 12, 2021

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

Equillium Announces Plans to Initiate Phase 3 Pivotal Study of Itolizumab in First-line Treatment of Acute Graft-Versus-Host Disease Following End-of-Phase 1 Meeting with the FDA

Single pivotal Phase 3 study in acute graft-versus-host disease to support filing of biologics license application

On track to initiate study in Q4 2021

LA JOLLA, California, July 12, 2021 - Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced the completion of an End-of-Phase 1 meeting with the U.S. Food and Drug Administration (FDA) for itolizumab in first-line treatment of patients with acute graft-versus-host disease (aGVHD). The meeting confirmed a path to advance itolizumab into a single Phase 3 pivotal study to support the Biologics License Application (BLA) filing for itolizumab in first-line treatment of aGVHD patients. The company plans to initiate the Phase 3 study in Q4 2021.

“Following the positive outcome of our meeting with the FDA, we will immediately advance to a pivotal clinical study, moving one step closer to developing the first approved therapy to treat aGVHD patients in the first-line setting,” said Dolca Thomas, executive vice president of research and development and chief medical officer of Equillium. “This extremely ill patient population is significantly underserved by today’s standard of care – high-dose corticosteroids. Our EQUATE Phase 1b study demonstrated rapid and durable complete clinical responses and a swift reduction in systemic corticosteroid use that are critical for positive longer-term patient outcomes. Itolizumab has received FDA fast track and orphan drug designations for the treatment of aGVHD, and with this feedback from the FDA we are immediately transitioning to late-stage development and look forward to collecting the data needed to support a BLA filing.”

The meeting provided guidance from the FDA on the pivotal study design, as well as advice on chemistry, manufacturing and controls (CMC), nonclinical and regulatory-related topics to support Equillium’s proposed single pivotal clinical study and BLA submission of itolizumab for the first-line treatment of aGVHD in combination with corticosteroids. The randomized double-blinded pivotal study will evaluate one dosing regimen of itolizumab versus standard of care (high-dose corticosteroids) and will include complete response at Day 29 as the primary endpoint, with an interim evaluation for futility and efficacy at 50% patient enrollment. Equillium is finalizing details of the Phase 3 protocol based on feedback and guidance from the FDA.

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 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 a planned pivotal study in acute graft-versus-host-disease (aGVHD), a Phase 1b study in lupus/lupus nephritis and a Phase 1b study in 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. Words such as “expect,” “estimate,” “project,” “budget,” “forecast,” “anticipate,” “intend,” “plan,” “may,” “will,” “could,” “should,” “believes,” “predicts,” “potential,” “continue” and similar expressions are intended to identify such forward-looking statements. 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 capitalization, resources and funding of Equillium, 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 acute graft-versus-host disease program, 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, 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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