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): August 10, 2020

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 August 10, 2020, Equillium, Inc. (the "Company") issued a press release regarding positive initial data from the Company's ongoing Phase 1b/2 EQUATE study of itolizumab in acute graft-versus-host disease. A copy of the press release discussing these matters is filed as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

aGVHD

On August 10, 2020, the Company announced positive initial data from its ongoing Phase 1b/2 EQUATE study of itolizumab in acute graft-versus-host disease, whereby five of seven patients in the first two dose cohorts achieved a complete response at the day 29 endpoint. Additionally, the Company announced that it has submitted a request to the U.S. Food and Drug Administration for a pre-investigational new drug meeting to review its proposal to initiate a global randomized controlled clinical trial to study itolizumab in hospitalized patients with COVID-19.

The EQUATE study is evaluating itolizumab in severe aGVHD patients – Grades III and IV – as a first-line treatment concomitant with standard of care, which is typically comprised of high dose corticosteroids, as no other therapeutics are currently approved for this indication. Across the first two dose cohorts of the Phase 1b open-label portion of the study 71% of patients achieved a CR by Day 29. In the first cohort at the 0.4 mg/kg dose, two of four patients achieved a CR, resulting in a CR and overall response (OR) rate of 50%. In the second cohort at the 0.8 mg/kg dose, all three patients achieved a CR, resulting in a CR and OR rate of 100%. Additionally, these CRs occurred early during itolizumab treatment course, with all patients achieving a CR within the first 15 days of treatment.

Itolizumab has been well tolerated to date and adverse events have been consistent with those expected in this severely ill aGVHD patient population. Based on a thorough review of the available safety data across both cohorts, the independent data safety monitoring committee has recommended to proceed with dose escalation in the third cohort (1.6mg/kg) of the EQUATE study as planned.

The initial data from the first two dose cohorts of the EQUATE study are summarized in the table below.

Itolizumab aGHVD (Grades III & IV) Study: Complete and Overall Response Rate at Day 29

Cohort	Itolizumab Dose (mg)	Number of Patients	Number w/ Complete Response	Complete Response Rate % All / Evaluable	Number w/ Overall Response	Overall Response Rate % All / Evaluable
1	0.4 mg/kg	4*	2	50% / 66%	2	50% / 66%
2	0.8 mg/kg	3	3	100% / 100%	3	100% / 100%
1 & 2	see above	7	5	71% / 83%	5	71% / 83%

* *Per the EQUATE protocol, patients must receive two doses to be considered evaluable for dose limiting toxicities at Day 29. One patient in cohort 1 experienced aGVHD progression after the first dose of itolizumab, received rescue therapy at Day 7, and consequently was discontinued and replaced in the EQUATE study; the patient further progressed after receiving rescue therapy and died on Day 137.*

One patient in cohort 1 experienced mild/moderate infusion reaction associated with itolizumab treatment.

COVID-19

In July 2020, the Company announced that its partner, Biocon Limited (Biocon), reported a randomized, controlled, open label clinical trial conducted in India demonstrated that itolizumab (ALZUMAb) significantly reduced mortality over one month as compared to placebo in patients hospitalized with COVID-19, and that the Drugs Controller General of India granted emergency use of ALZUMAb for the treatment of cytokine release syndrome (CRS) in COVID-19 patients with moderate to severe acute respiratory distress syndrome (ARDS) in India.

Based on the encouraging results reported by Biocon in its COVID-19 study, the novel and differentiated T cell modulating mechanism of action of itolizumab, and the fact that no targeted immuno-modulating therapies are currently approved to treat COVID-19 patients, the Company continues to advance its plan to develop itolizumab to treat hospitalized patients with COVID-19. In accordance with the FDA's industry guidance for COVID-19 biological products, the Company has submitted a Pre-IND meeting request and supporting briefing package to FDA to review its proposal to conduct a global randomized placebo-controlled clinical trial in hospitalized COVID-19 patients. The Company and Biocon intend to work closely together in the further development of itolizumab in COVID-19 patients and, importantly, planning scale-up of manufacturing to support access to treatment for the greatest possible number of patients worldwide. A summary of Biocon's completed study results has been submitted to the ClinicalTrials.gov database and is available on Biocon's website.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit Number	Description.
99.1	Press release, dated August 10, 2020, issued by Equillium, Inc.

Forward-Looking Statements

Statements contained in this Current Report on Form 8-K 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, the potential for interim data results to be consistent with final results, once available; the potential for any of our ongoing clinical trials to show safety or efficacy, statements regarding the potential benefits of itolizumab in severe aGVHD patients, statements regarding the potential benefit of treating COVID-19 patients with itolizumab, planned clinical studies as a result of data reported by Biocon, Equillium's business strategy, Equillium's plans and expected

timing for developing itolizumab, including the expected timing of further results from the EQUATE study and initiating a clinical trial in patients with COVID-19, potential benefits of itolizumab and Equillium's plan to scale-up manufacturing of itolizumab. Risks that contribute to the uncertain nature of the forward-looking statements include 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, uncertainties related to the completeness and accuracy of Biocon data and review by Equillium of Biocon data, and uncertainties related to Equillium's capital requirements, Equillium's plans and product development, including the initiation, restarting and completion of clinical trials, including a clinical trial of patients with COVID-19, uncertainties related to the actual impacts and length of such impacts caused by the COVID-19 pandemic, uncertainties caused by the recent restarting of the EQUIP and EQUALISE clinical trials after a pause, whether the results from clinical trials will validate and support the safety and efficacy of itolizumab, and uncertainties related to 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 with the United States Securities and Exchange Commission. All forward-looking statements contained in this Current Report on Form 8-K 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.

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: August 10, 2020

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

Equillium Announces Positive Interim Data with Itolizumab in Acute GVHD Study

Complete response observed in five of seven patients in first two dose cohorts

COVID-19 Pre-IND meeting request and briefing package submitted to the FDA

LA JOLLA, Calif., August 10, 2020 – Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced positive interim data from the first two cohorts of the Phase 1b open label, dose escalation portion of the EQUATE study of itolizumab in acute graft-versus-host disease (aGVHD). Across the first two dose cohorts itolizumab has been generally well tolerated to date, and five of seven patients achieved a complete response (CR) by Day 29. Additionally, Equillium has submitted a request to the U.S. Food and Drug Administration (FDA) for a Pre-Investigational New Drug (Pre-IND) meeting to review its proposal to initiate a global randomized controlled clinical trial to study itolizumab in hospitalized patients with COVID-19.

aGVHD

The EQUATE study is evaluating itolizumab in severe aGVHD patients – Grades III and IV – as a first-line treatment concomitant with standard of care, which is typically comprised of high dose corticosteroids, as no other therapeutics are currently approved for this indication. Across the first two dose cohorts of the Phase 1b open-label portion of the study 71% of patients achieved a CR by Day 29. In the first cohort at the 0.4 mg/kg dose, two of four patients achieved a CR, resulting in a CR and overall response (OR) rate of 50%. In the second cohort at the 0.8 mg/kg dose, all three patients achieved a CR, resulting in a CR and OR rate of 100%. Additionally, these CRs occurred early during itolizumab treatment course, with all patients achieving a CR within the first 15 days of treatment.

Itolizumab has been well tolerated to date and adverse events have been consistent with those expected in this severely ill aGVHD patient population. Based on a thorough review of the available safety data across both cohorts, the independent data safety monitoring committee has recommended to proceed with dose escalation in the third cohort (1.6mg/kg) of the EQUATE study as planned.

“We are very encouraged by the early response rates observed in the first two cohorts of aGVHD patients dosed with itolizumab, particularly since the individuals enrolled in the EQUATE study had Grade III or IV disease, representing the most gravely ill patients,” said Krishna Polu, M.D., chief medical officer of Equillium. “Achieving clinical activity in a majority of these initial patients treated with itolizumab, with a time to the initial response within 15 days, is promising given the rapid progression and high acuity of aGVHD, where the time to an effective response may be critical. We believe these data, along with the encouraging results reported by Biocon from its recent COVID-19 study, continue to support the hypothesis that itolizumab’s novel immune-modulating mechanism may have promise in addressing a range of severe immuno-inflammatory disorders. We look forward to continuing to advance our development programs as rapidly as possible.”

The initial data from the first two dose cohorts of the EQUATE study are summarized in the table below.

Itolizumab aGHVD (Grades III & IV) Study: Complete and Overall Response Rate at Day 29

Cohort	Itolizumab Dose (mg/kg)	Number of Patients	Number with Complete Response	Complete Response Rate % All / Evaluable	Number with Overall Response	Overall Response Rate % All / Evaluable
1	0.4	4*	2	50% / 66%	2	50% / 66%
2	0.8	3	3	100% / 100%	3	100% / 100%
1 & 2	see above	7	5	71% / 83%	5	71% / 83%

* *Per the EQUATE protocol, patients must receive two doses to be considered evaluable for dose limiting toxicities at Day 29. One patient in cohort 1 experienced aGVHD progression after the first dose of itolizumab, received rescue therapy at Day 7, and consequently was discontinued and replaced in the EQUATE study; the patient further progressed after receiving rescue therapy and died on Day 137.*

One patient in cohort 1 experienced mild/moderate infusion reaction associated with itolizumab treatment.

“These early response data are very promising as patients with severe aGVHD typically have a lower response to steroids,” said principal investigator of the EQUATE study, John Koreth, MBBS DPhil., director of translational research, stem cell transplantation, Dana-Farber Cancer Institute. “I am optimistic about the future of itolizumab as a potential treatment for aGVHD patients in need of effective and well-tolerated therapies. With the increase in the number of stem cell transplants to address aggressive/advanced hematologic malignancies, there continues to be significant need for new treatment options for GVHD, particularly for the patients at highest risk of mortality.”

COVID-19

In July 2020, Equillium announced that its partner, Biocon Limited (Biocon), reported a randomized, controlled, open label clinical trial conducted in India demonstrated that itolizumab (ALZUMAb™) significantly reduced mortality over one month as compared to placebo in patients hospitalized with COVID-19, and that the Drugs Controller General of India granted emergency use of ALZUMAb for the treatment of cytokine release syndrome (CRS) in COVID-19 patients with moderate to severe acute respiratory distress syndrome (ARDS) in India.

Based on the encouraging results reported by Biocon in its COVID-19 study, the novel and differentiated T cell modulating mechanism of action of itolizumab, and the fact that no targeted immuno-modulating therapies are currently approved to treat COVID-19 patients, Equillium continues to advance its plan to develop itolizumab to treat hospitalized patients with COVID-19. In accordance with the FDA’s industry guidance for COVID-19 biological products, Equillium has submitted a Pre-IND meeting request and supporting briefing package to FDA to review its proposal to conduct a global randomized placebo-controlled clinical trial in hospitalized COVID-19 patients. Equillium and Biocon intend to work closely together in the further development of itolizumab in COVID-19 patients and, importantly, planning scale-up of manufacturing to support access to treatment for the greatest possible number of patients worldwide. A summary of Biocon’s completed study results has been submitted to the ClinicalTrials.gov database and is available on Biocon’s website.

About Graft-Versus-Host Disease

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 standard risk patients, e.g. Grades II thru IV, of 69% OR and 48% CR, whereas in high-risk patients, e.g. Grades III thru IV, response rates observed were 43% OR and 27% CR.

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 study is an open-label dose escalation study in adult patients who present with high-risk aGVHD (Grades III and IV) 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 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's initial product candidate, itolizumab (EQ001), is a clinical-stage, first-in-class 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. Itolizumab has been clinically validated with a favorable safety and tolerability profile based on its approved uses in India. Equillium acquired rights to itolizumab through an exclusive partnership with Biocon. Biocon manufactures EQ001 and ALZUMAb at an FDA-regulated commercial scale facility; both products share the same primary monoclonal antibody sequence, but are manufactured in different cell lines, and EQ001 is available in both intravenous and subcutaneous dosing whereas ALZUMAb is currently available in intravenous dosing only.

Biocon has recently reported results from a study of ALZUMAb in COVID-19 patients in India, and has subsequently received emergency use authorization from the Drugs Controller General of India for ALZUMAb for the treatment of CRS in COVID-19 patients with moderate to severe ARDS in India.

Equillium believes that itolizumab has the potential to be a best-in-class disease modifying therapeutic in several indications and is developing itolizumab in multiple severe immuno-inflammatory disorders – acute graft-versus-host disease, uncontrolled asthma, and lupus nephritis – and is planning to submit an investigational new drug application for the treatment of COVID-19 patients. For more information, visit www.equilliumbio.com.

Forward Looking Statements

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