# 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): October 29, 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 8.01 Other Events.**

On October 29, 2020, Equillium, Inc. (the "**Company**") announced that it had received a Study May Proceed letter from the U.S. Food and Drug Administration (the "**FDA**") related to its recently filed investigational new drug application to evaluate itolizumab in hospitalized COVID-19 patients suffering from acute respiratory distress syndrome. The Company announced that it plans to start enrolling patients in its global, Phase 3 clinical trial, named EQUINOX, in the fourth quarter of 2020, and it expects initial clinical data mid-year 2021. The FDA has indicated that the trial, if it meets its primary and key secondary endpoints, may be sufficient to support regulatory filing of a Biologic License Application. A copy of the press release discussing these matters is filed as Exhibit 99.1, and incorporated by reference in, this report.

**Item 9.01 Financial Statements and Exhibits.**

(d)

| Exhibit Number | Description. |
|---|---|
| 99.1 | Press release, dated October 29, 2020, 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: October 29, 2020

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

**Equillium Receives FDA Clearance of COVID-19 IND for Phase 3 Trial**

***Equillium plans to initiate global Phase 3 COVID-19 trial – EQUINOX – during Q4 2020***

***FDA indicates study could support BLA filing***

**LA JOLLA, Calif., Oct. 29, 2020 –** Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced that it has received a Study May Proceed letter from the U.S. Food and Drug Administration (FDA) to begin a Phase 3 clinical trial, named EQUINOX, evaluating itolizumab in hospitalized COVID-19 patients suffering from acute respiratory distress syndrome (ARDS). Equillium plans to start enrolling patients during the fourth quarter of 2020, and initial clinical data is expected mid-year 2021. The FDA has indicated that the trial, if it meets its primary and key secondary endpoints, may be sufficient to support regulatory filing of a Biologic License Application (BLA).

“Itolizumab’s novel immune-modulating mechanism has the potential to regulate the cytokine cascade that is at the root of multiple complications seen in hospitalized COVID-19 patients, including blood clots, tissue damage and organ failure, as well as ARDS,” said Ivor S. Douglas, M.D., FRCP (UK) Professor of Medicine, Chief of Pulmonary and Critical Care and Medical Director, Medical Intensive Care Denver Health Medical Center and principal investigator for the EQUINOX trial. “As we are confronting surging rates of COVID-19 infections globally, I anticipate a sharp rise in patients with severe disease requiring oxygen support or other life-saving critical care measures. As the principal investigator in the EQUINOX trial, it is my hope that this study will help propel a highly effective new treatment option closer to availability for these vulnerable and high-risk patients.”

The Phase 3 EQUINOX trial will enroll a total of 800 patients at sites in the United States and abroad and include interim assessments at 20% and 50% of enrollment. Patients enrolled in the trial will be randomized 1:1 to receive either itolizumab or placebo in addition to best supportive care for the treatment of COVID-19. Patients will receive up to two doses of study drug (itolizumab or placebo) at Day 1 and Day 8 (if needed) and will be monitored through Day 28 while hospitalized or through post-discharge follow-up. The primary endpoint of the trial is to evaluate the benefit of itolizumab on recovery in patients hospitalized with COVID-19; key secondary endpoints include mortality benefit and other measures of clinical improvement. The trial will also evaluate the safety, tolerability and pharmacokinetics (PK) of itolizumab.

More details about the EQUINOX trial will be provided at an upcoming Analyst Day that Equillium will be hosting on December 4, 2020.

“While we feel a tremendous sense of urgency in the face of the COVID-19 pandemic, we remain committed to conducting studies with scientific rigor, which is why we are undertaking a robust, double-blind, placebo-controlled study, the gold standard for measuring a drug’s efficacy,” said Bruce Steel, chief executive officer of Equillium. “The initiation of the EQUINOX Phase 3 trial represents an important milestone for Equillium and for COVID-19 patients worldwide. We look forward to partnering with Dr. Douglas and our global sites to further evaluate itolizumab as a promising treatment for hospitalized COVID-19 patients.”

In July 2020, Equillium announced that its partner, Biocon Limited (Biocon), reported a Phase 2 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. 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 ARDS in India. In October 2020, Biocon initiated a 300-patient Phase 4 trial with ALZUMAb to treat COVID-19 patients in India to generate a larger body of scientific evidence to support the safety, efficacy and usefulness of itolizumab to treat COVID-19 patients.

Equillium and Biocon are working closely together on 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.

**About Itolizumab**

Itolizumab 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 is currently being evaluated in multiple clinical trials in patients with severe diseases, including acute graft-versus-host disease (aGVHD), lupus nephritis and uncontrolled asthma. Equillium acquired rights to itolizumab through an exclusive partnership with Biocon. Itolizumab is marketed in India under the trade name "ALZUMAb" for the treatment of chronic plaque psoriasis and has received emergency use approval in India to treat CRS in COVID-19 patients with moderate to severe ARDS.

**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 COVID-19, aGVHD, 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, the potential benefit of treating COVID-19 patients with itolizumab, Equillium's business strategy, Equillium's plans and expected timing for developing itolizumab, including the expected timing of initiating the EQUINOX clinical trial in patients with COVID-19 and receipt of initial clinical data, the potential for interim data results to be consistent with final results, once available, the potential benefits of itolizumab, whether the EQUINOX trial will meet its primary and key secondary endpoints or be sufficient to support a BLA application, the potential for any of Equillium's ongoing or planned clinical trials to show safety or efficacy, Equillium's plan to scale-up manufacturing of itolizumab and the impact of the COVID-19 pandemic. 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; the risk that studies will not be completed as planned; uncertainties related to Equillium's capital requirements; Equillium's plans and product development, including the initiation, restarting and completion of clinical trials, including the EQUINOX 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 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 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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