# 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 13, 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 July 13, 2020, Equillium, Inc. (the "**Company**") announced that a clinical trial conducted by its partner, Biocon Limited, demonstrated that itolizumab significantly reduced mortality in patients hospitalized with COVID-19 in India and that the Drugs Controller General of India, the regulatory agency that oversees drug approvals in India, has granted restricted emergency use of itolizumab for the treatment of cytokine release syndrome in COVID-19 patients with moderate to severe acute respiratory distress syndrome in India. The Company, which has the right to develop and commercialize itolizumab in the U.S., Canada, Australia and New Zealand, is planning to conduct a global randomized, controlled clinical trial of itolizumab in COVID-19 patients for which it will file a U.S. investigational new drug application. A copy of the press release discussing these matters is filed as Exhibit 99.01, and incorporated by reference in, this report.

**Item 9.01 Financial Statements and Exhibits.**

(d)

| Exhibit Number | Description. |
|---|---|
| 99.01 | Press release, dated July 13, 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: July 13, 2020

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

**Exhibit 99.01**

**Clinical Trial Shows Itolizumab Reduces Mortality in Patients Hospitalized with COVID-19**

***Equillium shares topline results of patients treated with itolizumab in clinical trial conducted in India by partner Biocon***

***Biocon has received emergency use approval from Drugs Controller General of India for itolizumab in the treatment of CRS in COVID-19 patients with moderate to severe ARDS***

***Equillium planning global randomized controlled clinical trial of itolizumab in COVID-19 patients under a U.S. IND***

**LA JOLLA, Calif., July 13, 2020 –** Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced that as reported by its partner, Biocon Limited, a clinical trial conducted in India by Biocon demonstrated that itolizumab significantly reduced mortality in patients hospitalized with COVID-19. Biocon has announced that the Drugs Controller General of India (DCGI), the regulatory agency that oversees drug approvals, has granted restricted emergency use of itolizumab 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 topline results of the study reported by Biocon and subsequent DCGI approval to treat COVID-19 patients, Equillium is planning to conduct a global randomized controlled clinical trial of itolizumab in COVID-19 patients for which it will file a U.S. investigational new drug application (IND).

Biocon conducted a randomized, controlled, open-label study at four hospitals in India, enrolling a total of 30 hospitalized COVID-19 patients with moderate to severe ARDS. Twenty patients were randomized to receive itolizumab plus best supportive care, while 10 patients received best supportive care alone. The primary endpoint was mortality at one month. As reported by Biocon:

- In the itolizumab arm there were no deaths and all patients have recovered; in the control arm three patients died and the remainder have recovered
- The mortality benefit observed in the itolizumab arm was statistically significant
- Consistent with the observed clinical improvement, patients who received itolizumab also experienced significant reductions in inflammatory cytokines such as IL-6 and TNFα

“The results of this clinical trial reported by Biocon are encouraging and support the hypothesis that itolizumab’s novel immune-modulating mechanism may have promise in addressing the severe immuno-inflammatory complications experienced by COVID-19 patients,” said Bruce Steel, co-founder and CEO of Equillium. “We are working with Biocon to review its full dataset with the goal to move swiftly in determining appropriate next steps to accelerate further development of itolizumab to treat moderate to severely ill COVID-19 patients in the U.S. and abroad in the face of this global crisis.”

“As the entire world grapples with the ongoing COVID-19 pandemic it is critical to identify new treatments that improve outcomes for the sickest patients, and these reported early clinical data suggest that itolizumab holds promise,” said Siddhartha Mukherjee, M.D., Ph.D., a clinical advisor to Equillium and Biocon, Pulitzer Prize Award-winning author, and an Associate Professor of Medicine at Columbia University’s Herbert Irving Comprehensive Cancer Center.

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, added “Patients with COVID-19 experience acute respiratory failure caused by the immune system flooding the bloodstream with inflammatory proteins, which can kill tissue, damage organs and pathologically activate clotting cascades in the lungs, heart, and kidneys. The novel mechanism of itolizumab, which works by inhibiting CD6 to reduce the activation and trafficking of pathogenic T cells that release pro-inflammatory cytokines, may be well suited to address SARS-CoV-2 induced inflammation that drives respiratory failure in patients with COVID-19. The preliminary data as reported by Biocon is encouraging and highlights the urgent importance of further evaluating the potential therapeutic efficacy of itolizumab in treating patients diagnosed with COVID-19.”

Itolizumab is a first-in-class immune-modulating antibody therapeutic with a novel mechanism of action that inhibits the activity and trafficking of pathogenic T cells that release pro-inflammatory cytokines in a range of autoimmune and inflammatory diseases. Equillium acquired rights to develop and commercialize itolizumab in the U.S., Canada, Australia and New Zealand through an exclusive collaboration and license agreement with Biocon. Equillium is currently evaluating itolizumab under two open U.S. INDs for the treatment of acute graft-versus-host disease and lupus nephritis, as well as conducting a clinical study in uncontrolled asthma in Australia and New Zealand.

Biocon previously developed and received approval of Itolizumab for the treatment of plaque psoriasis in India, demonstrating the product was safe and well tolerated. Biocon manufactures itolizumab at commercial scale at its cGMP bio-manufacturing facility that is regulated by the U.S. Food & Drug Administration.

In March of this year, as a result of the emerging COVID-19 pandemic, Equillium announced that it was pausing enrollment in the EQUIP trial for uncontrolled asthma and the EQUALISE trial for lupus nephritis. Today Equillium announces that patient enrollment in both of these studies has resumed.

**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, 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 a clinically validated therapeutic that has demonstrated a favorable safety and tolerability profile. Equillium acquired rights to itolizumab through an exclusive partnership with Biocon Limited. Itolizumab is currently marketed in India under the trade name, “ALZUMab” for the treatment of chronic plaque psoriasis and in July 2020 received emergency use approval in India to treat CRS in COVID-19 patients with moderate to severe ARDS. Equillium believes that itolizumab has the potential to be a best-in-class disease modifying therapeutic and is advancing the clinical development of itolizumab in the following severe immuno-inflammatory disorders: uncontrolled asthma, acute graft-versus-host disease, and lupus nephritis. 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 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 initiating a clinical trial in patients with COVID-19, and the impact of the COVID-19 pandemic. Risks that contribute to the uncertain nature of the forward-looking statements include uncertainties pending full review by Equillium of the Biocon dataset 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 pausing of the EQUIP and EQUALISE clinical trials, whether the results from clinical trials will validate and support the safety and efficacy of itolizumab, 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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