# 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): November 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 2.02 Results of Operations and Financial Conditions.**

On November 10, 2020, Equillium, Inc. ("***Equillium***") issued a press release announcing its financial results for the third quarter ended September 30, 2020 and providing a business update (the "***Press Release***"). A copy of the Press Release is furnished hereto as Exhibit 99.1 and is incorporated by reference herein.

The information contained in this Item 2.02 and in the Press Release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in the Press Release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by Equillium whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d)

| Exhibit Number | Description. |
|---|---|
| 99.1 | Press release, dated November 10, 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: November 10, 2020

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

**Exhibit 99.1**

**Equillium Reports Third Quarter 2020 Financial Results and Business Highlights**

LA JOLLA, Calif., Nov 10, 2020 — Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced financial results for the third quarter 2020.

“We continue to make significant progress towards our goal of bringing itolizumab to patients suffering from a range of severe immuno-inflammatory disorders,” said Bruce Steel, chief executive officer of Equillium. “We are well positioned to continue advancing our core trials including the Phase 1b EQUATE trial in acute graft-versus-host disease (aGVHD) where we recently reported positive response rates across the first three dose cohorts, as well as our Phase 1b EQUIP and EQUALISE trials in uncontrolled asthma and lupus nephritis, respectively. In parallel, we are poised to initiate the global Phase 3 EQUINOX trial of itolizumab in hospitalized COVID-19 patients during this quarter. We look forward to sharing additional updates at our upcoming Analyst Day in December.”

**Business Highlights:**

- Reported 100% overall response rate in cohort 3 and 80% overall response rate across all cohorts to date from the EQUATE Phase 1b study of itolizumab in the first-line treatment of severe aGVHD patients
- Received US Food and Drug Administration clearance to initiate global EQUINOX Phase 3 randomized, placebo-controlled trial of itolizumab in hospitalized COVID-19 patients
- Presented pre-clinical data demonstrating that modulation of the CD6-ALCAM pathway with itolizumab improves kidney and skin pathology in systemic lupus erythematosus (SLE) at the 2020 American College of Rheumatology (ACR) Virtual Convergence
- Presented new data and insights on the CD6-ALCAM pathway in uncontrolled asthma at the European Respiratory Society International Congress 2020
- Strengthened the balance sheet by raising a total of $53.0 million in net proceeds from financings in the third quarter 2020, resulting in $90.5 million in cash and investments at the end of the quarter

**Upcoming Catalysts:**

- Initiate EQUINOX Phase 3 trial in Q4 2020, initial data expected mid-year 2021
- Report topline data from the EQUATE Phase 1b open label dose escalation study in first-line treatment of patients with aGVHD in the first half of 2021
- Continue to advance the EQUALISE and EQUIP Phase 1b trials
- Host company-sponsored virtual Analyst Day on December 4, 2020

**Third Quarter 2020 Financial Results**

**Research and development (R&D) expenses.** Total R&D expenses for the three months ended September 30, 2020 were $4.2 million, compared with $4.2 million for the same period in 2019. Although total R&D expenses remained flat compared to the prior period, significant changes included a reduction of R&D expenses due to an R&D tax benefit realized by Equillium’s Australian subsidiary as well as lower travel expenses offset by an increase in employee compensation and benefits primarily related to increased headcount as well as an increase in clinical expense primarily related to startup costs associated with the EQUINOX COVID-19 Phase 3 trial.

**General and administrative (G&A) expenses.** Total G&A expenses for the three months ended September 30, 2020 were $2.3 million, compared with $2.1 million for the same period in 2019. The increase in G&A expenses was primarily due to a $0.2 million increase in corporate consulting expenses.

**Net loss.** Net loss for the three months ended September 30, 2020 was $6.6 million, or $(0.31) per basic and diluted share, compared with a net loss of $6.0 million, or $(0.35) per basic and diluted share for the same period in 2019.

**Cash, cash equivalents and short-term investments.** Equillium held cash, cash equivalents and short-term investments totaling $90.5 million at September 30, 2020, compared to $53.1 million at December 31, 2019. The increase in cash was driven by $53.8 million in total net proceeds raised from equity financings in 2020 through September 30.

**Cash used in operations.** Equillium used $4.9 million of cash in its operations during the three months ended September 30, 2020, compared to $5.1 million in the prior quarter ended June 30, 2020. Over the nine-month period ended September 30, 2020, Equillium has used approximately $16.4 million of cash in its operations.

**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 aGVHD, lupus nephritis, uncontrolled asthma, and will soon be evaluated in a clinical trial of patients with COVID-19. Equillium acquired rights to itolizumab through an exclusive partnership with Biocon Limited. Itolizumab is marketed in India under the trade name “ALZUMAb-L” for the treatment of chronic plaque psoriasis and has received emergency use approval in India to treat cytokine release syndrome in COVID-19 patients with moderate to severe acute respiratory distress syndrome.

**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, statements regarding the potential benefit of treating patients with aGVHD, uncontrolled asthma, lupus nephritis or COVID-19 with itolizumab, Equillium’s business strategy, Equillium’s plans and expected timing for developing itolizumab, including the expected timing of initiating, completing and announcing further results from the EQUATE, EQUIP, EQUALISE and EQUINOX studies, the potential benefits of itolizumab, the potential for the any of Equillium’s ongoing or planned clinical trials to show safety or efficacy, 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; 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; changes in the competitive landscape, and uncertainties 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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**Equillium, Inc.**
**Condensed Consolidated Balance Sheets**
**(In thousands)**

| | September 30, 2020 (Unaudited) | December 31, 2019 |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 90,537 | $ 53,143 |
| Prepaid expenses and other assets | 1,848 | 2,396 |
| Total assets | $ 92,385 | $ 55,539 |
| Current liabilities | 5,145 | 3,883 |
| Long-term notes payable | 9,043 | 9,681 |
| Other non-current liabilities | 71 | 127 |
| Total stockholders' equity | 78,126 | 41,848 |
| Total liabilities and stockholders' equity | $ 92,385 | $ 55,539 |

**Equillium, Inc.**
**Condensed Consolidated Statements of Operations**
**(In thousands, except share and per share data)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| | (Unaudited) | | (Unaudited) | |
| Operating expenses: | | | | |
| Research and development | $ 4,218 | $ 4,182 | $ 12,817 | $ 12,191 |
| General and administrative | 2,298 | 2,142 | 7,761 | 6,920 |
| Total operating expenses | 6,516 | 6,324 | 20,578 | 19,111 |
| Loss from operations | (6,516) | (6,324) | (20,578) | (19,111) |
| Other (expense) income, net | (81) | 310 | (317) | 1,078 |
| Net loss | $ (6,597) | $ (6,014) | $ (20,895) | $ (18,033) |
| Net loss per common share, basic and diluted | $ (0.31) | $ (0.35) | $ (1.11) | $ (1.04) |
| Weighted-average number of common shares outstanding, basic and diluted | 21,374,240 | 17,376,236 | 18,885,623 | 17,376,236 |