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, 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 2.02 Results of Operations and Financial Conditions.

On August 10, 2021, Equillium, Inc. ("***Equillium***") issued a press release announcing its financial results for the second quarter ended June 30, 2021 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) Exhibits

Exhibit No.	Description
99.1	Press Release dated August 10, 2021
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 hereunto duly authorized.

Equillium, Inc.

Date: August 10, 2021

By: /s/ Bruce D. Steel

Bruce D. Steel

President and Chief Executive Officer

Equillium Reports Second Quarter 2021 Financial Results and Provides Clinical Development Update

Announced positive topline results from the EQUATE study of itolizumab in first-line treatment of acute graft-versus-host disease

Announced plans to initiate a Phase 3 pivotal study of itolizumab in first-line treatment of acute graft-versus-host disease

LA JOLLA, California, August 10, 2021 - Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders with high unmet medical need, today announced financial results for the second quarter 2021, and provided an update on its clinical programs.

"The second quarter of the year was highlighted by positive data from our Phase 1b EQUATE study in acute graft-versus-host disease," said Bruce Steel, chief executive officer at Equillium. "These data were critical for achieving a positive outcome from our End-of-Phase 1 meeting with the FDA and accelerating our plans to immediately advance to a single, pivotal Phase 3 clinical study. This strategy, if successful, may position itolizumab to become the first approved therapy to treat patients with acute graft-versus-host disease in the first-line setting."

Corporate & Clinical Highlights Since Beginning of Q2 2021:

- Announced positive topline results from the EQUATE study in first-line treatment of acute graft-versus-host disease presented at the 2021 Virtual Congress of the European Hematology Association, and plans to initiate a Phase 3 pivotal study following an End-of-Phase 1 meeting with the FDA
  - Itolizumab continues to demonstrate favorable safety and efficacy profile
  - Rapid and durable complete responses resulted in clinically meaningful reduction in corticosteroid use
  - Data support clinical advancement of itolizumab in first-line treatment of aGVHD
- Presented multiple posters at the 104th annual meeting of the American Association of Immunologists; research highlighted:
  - Itolizumab's novel mechanism of action and its effect on modulating T cell responses through inhibition of the CD6-ALCAM pathway
  - Development of a pharmacodynamic biomarker assay to monitor target engagement and fate of CD6 on T cells in patients treated with itolizumab

Upcoming Catalysts:

- EQUALISE Phase 1b study: interim data from Type B patients (lupus nephritis) expected 2H 2021
- EQUIP Phase 1b study: topline data in uncontrolled asthma expected 2H 2021
- Initiate pivotal study in first-line aGVHD expected Q4 2021

Second Quarter 2021 Financial Results

Research and development (R&D) expenses for the second quarter of 2021 were $6.0 million, compared with $3.9 million for the same period in 2020. The increase was driven by greater employee compensation and benefit expenses primarily related to increased headcount, an increase in clinical development expenses primarily related to the EQUATE and EQUALISE studies, as well as greater consulting, overhead, and non-clinical research expenses.

General and administrative (G&A) expenses for the second quarter of 2021 were $2.9 million, compared with $2.7 million for the same period in 2020. The increase was driven by greater employee compensation and benefits primarily related to increased headcount, partially offset by a decrease in non-cash stock-based compensation mainly due to retention option grants issued to certain officers and directors in the second quarter of 2020.

Net loss for the second quarter of 2021 was $9.2 million, or $(0.31) per basic and diluted share, compared with a net loss of $6.5 million, or $(0.37) per basic and diluted share for the same period in 2020. The increase in net loss was largely attributable to greater operating expenses.

Cash used in operations for the second quarter of 2021 was $7.0 million compared to $7.9 million in the first quarter of 2021.
Cash, cash equivalents and short-term investments totaled $97.6 million as of June 30, 2021, compared to $104.1 million as of March 31, 2021. Equillium believes that its cash and investments will be sufficient to fund its currently planned operations into 2023.

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 acute graft-versus-host-disease (aGVHD), lupus/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, or lupus/lupus nephritis with itolizumab, Equillium's plans and expected timing for developing itolizumab

including the expected timing of initiating, completing and announcing further results from the EQUATE, EQUIP, and EQUALISE studies, 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, Equillium's cash runway, 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 the leadership team to 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" 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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Equillium, Inc.
Condensed Consolidated Balance Sheets
(In thousands)
(unaudited)

	June 30, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	$ 97,643	$ 82,163
Prepaid expenses and other assets	2,194	3,265
Total assets	$ 99,837	$ 85,428
Current liabilities	4,980	7,245
Long-term notes payable	10,067	8,275
Other non-current liabilities	17	54
Total stockholders' equity	84,773	69,854
Total liabilities and stockholders' equity	$ 99,837	$ 85,428

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 5,985	$ 3,893	$ 11,865	$ 8,599
General and administrative	2,858	2,717	5,673	5,463
Total operating expenses	8,843	6,610	17,538	14,062
Loss from operations	(8,843)	(6,610)	(17,538)	(14,062)
Other (expense) income, net	(315)	149	(611)	(236)
Net loss	$ (9,158)	$ (6,461)	$ (18,149)	$ (14,298)
Net loss per common share, basic and diluted	$ (0.31)	$ (0.37)	$ (0.64)	$ (0.81)
Weighted-average number of common shares outstanding, basic and diluted	29,076,562	17,692,731	28,205,805	17,627,641