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) March 24, 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, 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 obligations 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	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 March 24, 2021, Equillium, Inc. ("***Equillium***") issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 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) Exhibits

Exhibit No.	Description
99.1	Press Release dated March 24, 2021

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: March 24, 2021

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

Exhibit 99.1

Equillium Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Clinical Development Update

Cash runway into the second half of 2023

Announced positive interim data from EQUATE study in aGVHD

Multiple data and regulatory catalysts in 2021

LA JOLLA, California, March 24, 2021 - Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced financial results for the fourth quarter and full year 2020, and provided an update on its clinical development programs.

"It was an exciting year of clinical advancement for Equillium and our lead asset, itolizumab, a first-in-class anti-CD6 monoclonal antibody that selectively targets the CD6-ALCAM pathway," said Bruce Steel, chief executive officer at Equillium. "As the pathway plays a central role in a number of immuno-inflammatory diseases, we think of itolizumab as a pipeline in a product and are currently evaluating the therapeutic in acute graft-versus-host disease, lupus and lupus nephritis, and uncontrolled asthma. While the pandemic caused delays in our clinical studies last year, we look forward to our forthcoming data from all three studies in 2021. We anticipate the data this year will be important for all stakeholders, but none more so than the patients with these severe and life-threatening diseases."

2020 and 2021 Year-to-Date Corporate Highlights:

- Raised a total of $83.7 million in financing net proceeds in 2020 and through the registered direct offering completed in February 2021, strengthening Equillium's balance sheet and extending its expected cash runway into the second half of 2023
- Announced positive interim data from EQUATE study in acute graft-versus-host disease (aGVHD)
- Presented translational data in aGVHD demonstrating the impact of itolizumab on effector T cell function at the:
    - Transplantation & Cellular Therapy Meetings of ASTCT & CIBMTR
    - Annual Meeting of the American Society of Hematology
    - 2021 Transplantation and Cellular Therapy Meetings Digital Experience
- Presented data at the 2020 American College of Rheumatology Meeting, demonstrating that CD6 modulation improves kidney and skin pathology in preclinical models of systemic lupus erythematosus (SLE)
- Presented data at the European Respiratory Society International Congress 2020 demonstrating that the CD6-ALCAM pathway may contribute in multiple ways to asthma pathology
- Strengthened leadership and positioned Equillium for organizational growth, including the following additions since the beginning of this year:
    - Dolca Thomas, M.D., appointed as executive vice president of research and development and chief medical officer

- Y. Katherine Xu, Ph.D., partner at Decheng Capital, appointed to Equillium's board of directors

Upcoming Catalysts:

- EQUALISE Phase 1b study: topline data from Type A patients (SLE), 1Q 2021
- EQUATE Phase 1b study: topline data in first-line aGVHD, 1H 2021
- Regulatory feedback on proposed pivotal study in first-line aGVHD, Mid-2021
- Initiate pivotal study in first-line aGVHD, 2H 2021*
- EQUALISE Phase 1b study: interim data from Type B patients (lupus nephritis), 2H 2021
- EQUIP Phase 1b study: topline data in uncontrolled asthma, 2H 2021

**Proposed protocol & timeline for site initiation contingent on regulatory review*

Fourth Quarter and Full Year 2020 Financial Results

Research and development (R&D) expenses for the fourth quarter of 2020 were $6.6 million, compared with $5.4 million for the same period in 2019. The increase in the fourth quarter of 2020 compared to the same period in 2019 was due to greater headcount expenses, greater research and translational science expenses, and an increase in clinical development expenses driven by approximately $0.9 million in expenses incurred in the fourth quarter of 2020 associated with preparing to launch a registrational study in COVID-19 patients, which was discontinued. Those increases were partially offset by a reduction in overhead costs, especially travel, and lower consulting expenses. For the full year of 2020, R&D expenses were $19.4 million, compared with $17.6 million for the same period in 2019. The year-over-year increase in R&D expenses was primarily driven by greater headcount expenses and research expenses, offset by lower overhead costs, especially related to travel and recruiting, and lower total clinical development expenses related to the EQUIP study and the Australian R&D tax incentive credit, partially offset by increases in expenses associated with the EQUALISE study and preparing to initiate a study in COVID-19 patients.

General and administrative (G&A) expenses for the fourth quarter of 2020 were $2.4 million, compared with $2.2 million for the same period in 2019. The increase in the fourth quarter of 2020 compared to the same period in 2019 was due to greater headcount expenses, driven by higher stock-based compensation, and greater consulting expenses, partially offset by a reduction in overhead expenses driven by lower insurance costs. For the full year of 2020, G&A expenses were $10.2 million, compared with $9.1 million for the same period in 2019. The year-over-year increase was primarily due to increased headcount expenses, driven by greater stock-based-compensation but partially offset by lower salary expense, and greater consulting expenses, offset by lower legal costs and overhead expenses, especially related to travel.

Net loss for the fourth quarter of 2020 was $8.9 million, or $(0.36) per basic and diluted share, compared with a net loss of $7.6 million, or $(0.44) per basic and diluted share for the same period in 2019. Net loss for the full year of 2020 was $29.8 million, or $(1.46) per basic and diluted share, compared with a net loss of $25.6 million, or $(1.47) per basic and diluted share for the same period in 2019. The increase in net loss for the full year of 2020 compared to the

same period in 2019 was driven primarily by greater operating expenses and to a lesser extent by lower interest income and higher interest expense.

Cash used in operations for the fourth quarter of 2020 was $8.3 million compared to $4.9 million in the third quarter of 2020. Key drivers of the quarter-over-quarter increase in cash used in operations include the resumption in enrollment in the EQUIP and EQUALISE studies following a pause earlier in the year due to COVID-19, payment of directors and officers annual insurance premiums in the fourth quarter, spending in the fourth quarter associated with preparing to launch a registrational study in COVID-19 patients that was discontinued, and a reimbursement from the Australian Taxation Office associated with our 2019 R&D tax incentive claim that was received in the third quarter.

Cash, cash equivalents and short-term investments totaled $82.2 million as of December 31, 2020, compared to $53.1 million as of December 31, 2019. Subsequent to 2020, Equillium further strengthened its balance sheet through the completion of a registered direct offering with Decheng Capital, which raised $29.9 million in net proceeds. Equillium believes that its cash and investments will be sufficient to fund its currently planned operations into the second half of 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 the 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 new leadership team members to integrate and 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)

	December 31, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 82,163	$ 53,143
Prepaid expenses and other assets	3,265	2,396
Total assets	$ 85,428	$ 55,539
Current liabilities	7,245	3,883
Long-term notes payable	8,275	9,681
Other non-current liabilities	54	127
Total stockholders' equity	69,854	41,848
Total liabilities and stockholders' equity	$ 85,428	$ 55,539

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 6,567	$ 5,449	$ 19,384	$ 17,640
General and administrative	2,403	2,167	10,164	9,087
Total operating expenses	8,970	7,616	29,548	26,727
Loss from operations	(8,970)	(7,616)	(29,548)	(26,727)
Other income (expense), net	52	49	(265)	1,127
Net loss	$ (8,918)	$ (7,567)	$ (29,813)	$ (25,600)
Net loss per common share, basic and diluted	$ (0.36)	$ (0.44)	$ (1.46)	$ (1.47)
Weighted-average number of common shares outstanding, basic and diluted	24,733,313	17,383,615	20,355,534	17,378,096