

**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) May 13, 2019

Equillum, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38692
(Commission
File Number)

82-1554746
(IRS Employer
Identification No.)

2223 Avenida de la Playa, Suite 105
La Jolla, CA
(Address of principal executive offices)

92037
(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))

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.

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

Item 2.02 Results of Operations and Financial Conditions.

On May 13, 2019, Equillium, Inc. (“Equillium”) issued a press release announcing its financial results for the quarter ended March 31, 2019 (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 May 13, 2019

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.

Date: May 13, 2019

Equillum, Inc.

By: /s/ Daniel M. Bradbury
Daniel M. Bradbury
Chief Executive Officer



Equillium Reports First Quarter 2019 Financial Results and Recent Highlights

EQUATE Phase 1b/2 trial in acute graft-versus-host disease (aGVHD) ongoing with data expected in 1Q 2020

On track to initiate Phase 1b proof-of-concept trials of itolizumab (EQ001) in uncontrolled moderate to severe asthma and lupus nephritis this year

LA JOLLA, Calif., May 13, 2019 – Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company leveraging deep understanding of immunobiology to develop products to treat severe autoimmune and inflammatory disorders with high unmet medical need, today announced financial results for the first quarter 2019, and recent business highlights.

“We achieved a significant milestone during the first quarter of 2019 with the initiation of the open label Phase 1b portion of our EQUATE trial evaluating itolizumab in acute GVHD, our initial indication,” stated Daniel Bradbury, chairman and chief executive officer of Equillium. “In parallel, we continue to advance plans to initiate two additional trials this year – uncontrolled asthma and lupus nephritis – all of which we believe set the stage for multiple opportunities to demonstrate the value of itolizumab in treating severe immuno-inflammatory diseases. The body of evidence implicating the CD6-ALCAM pathway in immuno-inflammatory diseases continues to grow. Itolizumab’s unique mechanism of action, which selectively targets CD6 and downregulates cellular pathways that modulate both the activity and trafficking of effector T cells, represents an entirely new approach to treating these serious diseases. We look forward to data from these important proof-of-concept trials.”

Business Highlights:

- Initiated the open label Phase 1b portion of the EQUATE trial for the first-line treatment of aGVHD
- Received FDA Orphan Drug and Fast Track designations for itolizumab for both the prevention and treatment of aGVHD
- Announced plans to develop itolizumab for the treatment of lupus nephritis

Upcoming Milestones:

- Initiation of the Phase 1b EQUIP proof-of-concept trial evaluating itolizumab for the treatment of uncontrolled moderate to severe asthma expected during the second quarter of 2019
- Initiation of a Phase 1b proof-of-concept trial of itolizumab for the treatment of lupus nephritis expected during the second half of 2019
- Data from the EQUATE aGVHD trial expected during the first quarter of 2020, approximately 12 months following initiation

First Quarter 2019 Financial Results

Research and development (R&D) expenses. Total R&D expenses for the three months ended March 31, 2019 were \$3.8 million, compared with \$0.7 million for the same period in 2018. The increase in R&D expenses was primarily driven by additional costs related to increased headcount and the ramp up in regulatory and clinical activity including initiation of the Phase 1b portion of the clinical trial of itolizumab in aGVHD, and preclinical research activities to support Equillium's clinical development program.

General and administrative (G&A) expenses. Total G&A expenses for the three months ended March 31, 2019 were \$2.6 million, compared with \$0.4 million for the same period in 2018. The increase in G&A expenses was primarily driven by additional costs related to increased headcount, legal and other professional fees and costs associated with being a public company.

Net loss. Net loss for the three months ended March 31, 2019 was \$6.0 million, or \$(0.34) per basic and diluted share, compared with a net loss of approximately \$1.6 million, or \$(0.15) per basic and diluted share, for the same period in 2018.

Cash and cash equivalents. As of March 31, 2019, Equillium reported total cash, cash equivalents and short-term investments of \$61.6 million, compared to \$65.9 million as of December 31, 2018.

About Equillium

Equillium is a clinical-stage biotechnology company leveraging deep understanding of immunobiology to develop products to treat severe autoimmune and inflammatory, or immuno-inflammatory, disorders with high unmet medical need.

Equillium's initial product candidate, itolizumab (EQ001), is a clinical-stage, first-in-class monoclonal antibody that selectively targets the novel immune checkpoint receptor CD6. CD6 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. Equillium believes that itolizumab has the potential to be a best-in-class disease modifying therapeutic and is advancing itolizumab into clinical development in multiple immuno-inflammatory indications with high unmet medical need. 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 Company's business strategy, the Company's plans and expected timing for developing itolizumab, including the expected timing of clinical trial initiation and timing of results, and the potential benefits of itolizumab. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties related to the Company's plans and product development, including the initiation and completion of clinical trials and whether the results from clinical trials will validate and support the safety and efficacy of itolizumab. 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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Equillum, Inc.
Condensed Consolidated Balance Sheets
(In thousands)

	<u>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
	<u>(Unaudited)</u>	
Cash, cash equivalents and short-term investments	\$ 61,607	\$ 65,913
Prepaid expenses and other assets	1,120	1,250
Total assets	<u>\$ 62,727</u>	<u>\$ 67,163</u>
Current liabilities	3,052	2,028
Non-current liabilities	181	200
Total stockholders' equity	59,494	64,935
Total liabilities and stockholders' equity	<u>\$ 62,727</u>	<u>\$ 67,163</u>

Equillum, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2019	2018
	(Unaudited)	
Operating expenses:		
Research and development	\$ 3,759	\$ 663
General and administrative	2,589	374
Total operating expenses	6,348	1,037
Loss from operations	(6,348)	(1,037)
Other income (expense), net	398	(540)
Net loss	<u>\$ (5,950)</u>	<u>\$ (1,577)</u>
Unrealized gain on available-for-sale securities, net	44	-
Comprehensive loss	<u>\$ (5,906)</u>	<u>\$ (1,577)</u>
Net loss per common share, basic and diluted	<u>\$ (0.34)</u>	<u>\$ (0.15)</u>
Weighted-average common shares outstanding, basic and diluted	<u>17,376,236</u>	<u>10,708,074</u>

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