# 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 27, 2019**

# 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**<br>**La Jolla, CA**<br>**(Address of principal executive offices)** | **92037**<br>**(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 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 27, 2019, Equillium, Inc. ("Equillium") issued a press release announcing its financial results for the fourth quarter and full-year ended December 31, 2018 (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 27, 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.

**Equillium, Inc.**

Date: March 27, 2019

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

**EXHIBIT 99.1**

**Equillium Reports Fourth Quarter and Full-Year 2018 Financial Results and Recent Highlights**

*Initiated the EQUATE Phase 1b/2 trial in acute graft-versus-host disease in March 2019*

LA JOLLA, Calif., Mar. 27, 2019 – Equillium, Inc. (Nasdaq: EQ), a 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 fourth quarter and full-year ended December 31, 2018, and recent business highlights.

**Business Highlights:**

- Completed a successful initial public offering in October 2018 resulting in gross proceeds of $71.6 million
- Received FDA Fast Track designation and Orphan Drug designations for EQ001 for both the prevention and treatment of acute graft-versus-host disease (aGVHD)
- Initiated the Phase 1b portion of the EQUATE trial for the frontline treatment of aGVHD
- Announced plans to develop EQ001 for the treatment of lupus nephritis with a Phase 1b proof-of-concept clinical trial expected to commence in the second half of 2019

“The progress that we made during 2018, highlighted by our successful initial public offering in October, sets the stage for continued advancement of our pipeline this year with three clinical trials of our lead therapeutic candidate, EQ001, beginning with our EQUATE trial in aGVHD that commenced earlier this month,” said Daniel Bradbury, chairman and chief executive officer of Equillium. “The recent announcement that we are exploring the clinical utility of EQ001 in lupus nephritis, in addition to aGVHD and uncontrolled moderate to severe asthma, leverages our research into the role of CD6-ALCAM pathway in immuno-inflammatory diseases, and represents a natural expansion of our pipeline targeting this potentially promising pathway. As we progress through 2019, we have line-of-sight to multiple potentially value-creating data catalysts beginning early next year, and believe we are well positioned to introduce a new class of therapeutic that can transform the lives of patients suffering from these serious and underserved medical conditions.”

**Upcoming Milestones:**

- Planned initiation of Phase 1b EQUIP proof-of-concept trial evaluating EQ001 for the treatment of uncontrolled moderate to severe asthma by the end of the second quarter of 2019
- Planned initiation of Phase 1b proof-of-concept trial evaluating EQ001 for the treatment of lupus nephritis during the second half of 2019
- Data from the Phase 1b portion of the EQUATE aGVHD trial expected during the first quarter of 2020, approximately 12 months following initiation

**Fourth Quarter 2018 Financial Results**

**Research and development (R&D) expenses.** Total R&D expenses for the three months ended December 31, 2018 were $2.5 million, compared with $0.5 million for the same period in 2017. The increase in R&D expenses was primarily driven by additional costs related to increased headcount, regulatory and clinical activity, 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 December 31, 2018 were $1.7 million, compared with $0.2 million for the same period in 2017. The increase in G&A expenses was primarily driven by increased headcount and other costs associated with supporting the increased level of clinical and corporate activities as Equillium transitioned to a public company.

**Net loss.** Total net loss for the three months ended December 31, 2018 was $5.0 million, compared with a net loss of $1.1 million for the same period in 2017.

**Full-Year 2018 Financial Results**

**Research and development (R&D) expenses.** Total R&D expenses for the year ended December 31, 2018 were $4.9 million, compared with approximately $1.3 million for the period March 16, 2017 (inception) through December 31, 2017. The increase in R&D expenses was primarily driven by additional costs related to increased headcount, regulatory and clinical activity, and preclinical research activities to support Equillium's clinical development program.

**General and administrative (G&A) expenses.** Total G&A expenses for the year ended December 31, 2018 were $3.7 million, compared with $0.4 million for the period March 16, 2017 (inception) through December 31, 2017. The increase in G&A expenses was primarily driven by increased headcount and other costs incurred during the fourth quarter of 2018 associated with supporting the increased level of clinical and corporate activities as Equillium transitioned to a public company.

**Net loss.** Total net loss for the year ended December 31, 2018 was $13.3 million, compared with a net loss of $2.3 million for the period March 16, 2017 (inception) through December 31, 2017.

**Cash, cash equivalents and short-term investments.** Equillium held cash, cash equivalents and short-term investments totaling approximately $65.9 million at December 31, 2018, compared to $7.1 million at December 31, 2017. The increase was due to Equillium's initial public offering in October 2018, partially offset by cash used in operations during 2018.

**About Equillium**

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

Equillium's initial product candidate, EQ001 (itolizumab), 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 EQ001 through an exclusive partnership with Biocon Limited. Equillium believes that EQ001 has the potential to be a best-in-class disease modifying therapeutic and is advancing EQ001 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 EQ001, including the expected timing of clinical trial initiation and timing of results, and the potential benefits of EQ001. 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 EQ001. 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 Balance Sheets**
**(in thousands)**

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 65,913 | $ 7,103 |
| Prepaid expenses and other assets | 1,250 | 48 |
| Total assets | $ 67,163 | $ 7,151 |
| Current liabilities | 2,028 | 569 |
| Notes payable and other long-term liabilities | 200 | 8,834 |
| Total stockholders' equity (deficit) | 64,935 | (2,252) |
| Total liabilities and stockholders' equity (deficit) | $ 67,163 | $ 7,151 |

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

| | Three Months Ended December 31, | | Year Ended December 31, | Period March 16, 2017 (Inception) Through December 31, |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| | (unaudited) | | | |
| Operating expenses: | | | | |
| Research and development | $ 2,518 | $ 483 | $ 4,943 | $ 1,334 |
| General and administrative | 1,710 | 157 | 3,672 | 378 |
| Total operating expenses | 4,228 | 640 | 8,615 | 1,712 |
| Loss from operations | (4,228) | (640) | (8,615) | (1,712) |
| Other expense, net | 764 | 466 | 4,635 | 550 |
| Net loss | $ (4,992) | $ (1,106) | $ (13,250) | $ (2,262) |
| Net loss per common share, basic and diluted | $ (0.31) | $ (0.10) | $ (1.09) | $ (0.22) |
| Weighted-average number of common shares outstanding, basic and diluted | 16,209,576 | 10,708,074 | 12,190,245 | 10,106,760 |

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