
**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 11, 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))

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 Condition.

On November 12, 2019, Equillum, Inc. (“Equillum” or the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 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 the Company whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 11, 2019, the Board of Directors of the Company (the “Board”) (i) approved the transition of Daniel M. Bradbury from the Company’s Chief Executive Officer to the Company’s Executive Chairman, (ii) appointed Bruce D. Steel, the Company’s current President and Chief Business Officer, as the Company’s President and Chief Executive Officer and (iii) appointed Christine Zedelmayer, the Company’s current Vice President Operations, as the Company’s Senior Vice President and Chief Operating Officer, each effective as of January 1, 2020.

Mr. Steel, age 53, has served as the Company’s President and Chief Business Officer since June 2018 and as a member of the Board since March 2017. Mr. Steel is a co-founder of Equillum. Mr. Steel is the founder and has served as the Managing Director of BioMed Ventures, an investment firm owned by BioMed Realty, LP, since 2010. From 2008 to 2010, Mr. Steel served as the Chief Business Officer at Anaphore, Inc., a privately-held pharmaceutical company. Prior to that, Mr. Steel was co-founder and Chief Executive Officer of Rincon Pharmaceuticals, Inc., a genetic engineering biotechnology company, from 2005 until its acquisition in 2008. Mr. Steel also previously served as the Head of Corporate Development at Ambit Biosciences Corporation from 2002 to 2005. Mr. Steel previously served on the board of directors of Zosano Pharma Corporation, a publicly-held biopharmaceutical company, from 2012 to 2017. Mr. Steel currently serves as a board member or observer for a number of other privately-held biotechnology companies. Mr. Steel received his B.A. degree from Dartmouth College and M.B.A. degree from the Marshall School of Business at the University of Southern California, and he holds the designation of Chartered Financial Analyst.

In June 2018, the Company entered into an offer letter with Mr. Steel (the “Steel Offer Letter”), which governs the terms of his employment with the Company. Under the terms of the Steel Offer Letter, Mr. Steel is entitled to an annual base salary of \$375,000 (which was increased by the Compensation Committee of the Board to \$400,000, effective March 1, 2019) and is eligible for an annual performance-based bonus opportunity at a target amount of 35% of his base salary (which was increased by the Compensation Committee of the Board to 40%), based on the attainment of individual and corporate objectives to be determined and approved by the Company. The payment and amount of the annual bonus will be in the Company’s sole discretion.

Pursuant to the Steel Offer Letter, if the Company terminates Mr. Steel’s employment without cause, Mr. Steel is entitled to receive (i) continuation of his then-current base salary for six months and (ii) payment of the premiums for group health insurance COBRA continuance coverage for six months or, if earlier, until the date on which Mr. Steel becomes eligible to receive comparable benefits from another employer. Additionally, if the Company terminates Mr. Steel’s employment without cause within one month prior to, or 12 months following, certain change of control and asset sale transactions, Mr. Steel is entitled to receive (i) continuation of his then-current base salary for 12 months, (ii) an amount equal to his target annual bonus and (iii) payment of the premiums for group health insurance COBRA continuance coverage for 12 months or, if earlier, until the date on which Mr. Steel becomes eligible to receive comparable benefits from another employer. In each case, the severance benefits are conditioned upon the execution and non-revocation of a general release of claims by Mr. Steel in a form provided by the Company. In addition, Mr. Steel is eligible to participate in the employee benefit plans generally available to the Company’s employees, and is subject to customary confidentiality covenants.

Mr. Steel has no family relationships with any of the Company’s directors or executive officers. Mr. Steel does have a direct or indirect material interest in certain transactions required to be disclosed pursuant to Item 404(a) of Regulation S-K, each as set forth in the Company’s definitive proxy statement on Schedule 14A, which was filed with the Securities and Exchange Commission on April 25, 2019.

The foregoing description of the Steel Offer Letter is only a summary and is qualified in its entirety by reference to the Steel Offer Letter, a copy of which is filed as an exhibit to the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Ms. Zedelmayer, age 50, has served as the Company’s Vice President Operations since February 2018 and served as a consultant from August 2017 until January 2018. Prior to Equillum, Ms. Zedelmayer was owner and principal consultant at Centerra Consulting, LLC, a project management and investor relations consulting firm focused on life sciences, from 2012 to February 2018, where she led strategic business development projects for clients and served as head of investor relations for a variety of medical device companies. Prior to Centerra, from 2003 to 2012, Ms. Zedelmayer held a variety of roles at Amylin Pharmaceuticals, Inc., a publicly-held biopharmaceutical company, including Senior Director of Alliance Management, where she led the global collaboration with Eli Lilly and as Executive Director of Investor Relations. Before joining Amylin, Ms. Zedelmayer held various leadership positions within project management at Amgen Inc., a publicly-held biotechnology company, Ligand Pharmaceuticals, Inc., a publicly-held

biopharmaceutical company, and Hybritech, Inc., a privately-held medical diagnostics company. Ms. Zedelmayer received her B.S. in Electrical Engineering at San Diego State University and a M.B.A. with Finance emphasis at California Lutheran University.

In January 2018, the Company entered into an offer letter with Ms. Zedelmayer (the “Zedelmayer Offer Letter”), which governs the terms of her employment with the Company. Under the terms of the offer letter, Ms. Zedelmayer is entitled to an annual base salary of \$230,000 (which was increased by the Compensation Committee of the Board to \$300,000, effective March 1, 2019) and is eligible for an annual performance-based bonus opportunity at a target amount of 30% of her base salary, based on the attainment of individual and corporate objectives to be determined and approved by the Company. The payment and amount of the annual bonus will be in the Company’s sole discretion. In addition, Ms. Zedelmayer is eligible to participate in the employee benefit plans generally available to the Company’s employees, and is subject to customary confidentiality covenants.

Ms. Zedelmayer has no family relationships with any of the Company’s directors or executive officers, and she has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

The foregoing description of the Zedelmayer Offer Letter is only a summary and is qualified in its entirety by reference to the Zedelmayer Offer Letter, a copy of which will be filed as an exhibit to the Company’s Annual Report on Form 10-K for the fiscal year ending December 31, 2019.

Item 8.01 Other Events.

On November 12, 2019, the Company issued a press release announcing the Company management updates referenced in Item 5.02 of this Current Report on Form 8-K. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 12, 2019
99.2	Press Release dated November 12, 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: November 12, 2019

Equillium, Inc.

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



Equillium Reports Third Quarter 2019 Financial Results and Recent Highlights

LA JOLLA, November 12, 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 third quarter 2019 and recent business highlights.

“With the recent initiation of the EQUALISE trial in lupus nephritis and ongoing studies in uncontrolled asthma and aGVHD, we are concurrently running clinical studies of itolizumab in three indications where effective treatments are lacking for patients,” said Dan Bradbury, chairman and chief executive officer of Equillium. “As we continue to efficiently execute our clinical programs, we anticipate important data readouts next year that may establish the foundation for broadly developing itolizumab in severe autoimmune and inflammatory disorders for patients in urgent need of novel treatments.”

Business Highlights:

- Secured a term loan for up to \$20 million that, together with cash on-hand, is expected to provide sufficient resources to fund currently planned development programs into the second half of 2021 and through anticipated initial data readouts
- Obtained exclusive rights to negotiate third-party licensing rights to develop and commercialize itolizumab in select major markets outside of North America
- Initiated Phase 1b EQUALISE proof-of-concept trial evaluating itolizumab for the treatment of lupus nephritis
- Continued to advance itolizumab in Phase 1b development for both the treatment of uncontrolled asthma and the frontline treatment of aGVHD

Upcoming Milestones

Itolizumab initial data from the Phase 1b:

- EQUIP trial in uncontrolled asthma expected in 2H 2020
 - EQUATE trial in aGVHD expected in 2H 2020
 - EQUALISE trial in lupus nephritis – systemic lupus erythematosus (SLE) cohort expected in 2H 2020, lupus nephritis cohort expected in 1H 2021
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Third Quarter 2019 Financial Results

Research and development (R&D) expenses. Total R&D expenses for the three months ended September 30, 2019 were \$4.2 million, compared with \$1.2 million for the same period in 2018. The increase in R&D expenses was primarily driven by additional costs related to regulatory and clinical development activities associated with the EQUIP, EQUATE and EQUALISE clinical trials, increased headcount expenses, 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 September 30, 2019 were \$2.1 million, compared with \$1.0 million for the same period in 2018.

The increase in G&A expenses was primarily driven by additional costs related to increased headcount expenses, costs related to being a public company and legal and professional fees.

Net loss. Net loss for the three months ended September 30, 2019 was \$6.0 million, or \$(0.35) per basic and diluted share, compared with a net loss of approximately \$4.9 million, or \$(0.44) per basic and diluted share, for the same period in 2018.

Cash and cash equivalents. As of September 30, 2019, Equillium reported total cash, cash equivalents and short-term investments of \$62.2 million, compared to \$65.9 million as of December 31, 2018. The amount of cash and investments at September 30, 2019 included approximately \$9.9 million of net proceeds from the initial advancement from the term loan.

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, 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 the following severe immuno-inflammatory disorders: uncontrolled asthma, acute graft-versus-host disease, and lupus nephritis. 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 Equillium's business strategy, Equillium's plans and expected timing for developing itolizumab, including the expected timing of clinical trial initiation and timing of results, the potential benefits of itolizumab, and cash runway. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties related to Equillium's plans and product development, including the initiation and completion of clinical trials, whether the results from clinical trials will validate and support the safety and efficacy of itolizumab, and having to use cash in ways or on timing other than expected. 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)

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
	<u>(Unaudited)</u>	
Cash, cash equivalents and short-term investments	\$ 62,238	\$ 65,913
Prepaid expenses and other assets	757	1,250
Total assets	<u>\$ 62,995</u>	<u>\$ 67,163</u>
Current liabilities	4,274	2,028
Long-term notes payable	9,616	-
Other non-current liabilities	146	200
Total stockholders' equity	<u>48,959</u>	<u>64,935</u>
Total liabilities and stockholders' equity	<u>\$ 62,995</u>	<u>\$ 67,163</u>



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

	Three Months Ended		Nine Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
Operating expenses:				
Research and development	\$ 4,182	\$ 1,222	\$ 12,191	\$ 2,425
General and administrative	2,142	1,004	6,920	1,963
Total operating expenses	6,324	2,226	19,111	4,388
Loss from operations	(6,324)	(2,226)	(19,111)	(4,388)
Other income (expense), net	310	(2,691)	1,078	(3,871)
Net loss	\$ (6,014)	\$ (4,917)	\$ (18,033)	\$ (8,259)
Net loss per common share, basic and diluted	\$ (0.35)	\$ (0.44)	\$ (1.04)	\$ (0.76)
Weighted-average common shares outstanding, basic and diluted	17,376,236	11,078,840	17,376,236	10,835,483

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Equillium Announces Leadership Updates

Effective January 1, 2020 Bruce Steel will assume role of Chief Executive Officer, and Dan Bradbury will remain on the Board of Directors as Executive Chairman.

Krishna Polu, M.D., and Christine Zedelmayer will be promoted to Executive Vice President Research & Development and Chief Operating Officer, respectively.

LA JOLLA, Calif., November 12, 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, today announced the appointment of Bruce Steel, the company's current president and chief business officer, as president and chief executive officer effective January 1, 2020. Dan Bradbury, the company's current chief executive officer, will transition to the role of executive chairman of the company's Board of Directors. Additionally, Krishna Polu, M.D., the company's chief medical officer will be promoted to executive vice president research & development, and Christine Zedelmayer will assume the role of senior vice president and chief operating officer, each effective January 1, 2020.

"As one of Equillium's co-founders, Bruce has made significant contributions toward Equillium's growth and successful development program implementation since the company's inception," said Dan Bradbury. "He has a deep understanding of our business and strategy and has demonstrated a proven commitment to our employees, patients and stockholders. His extensive background in strategic biotechnology investments, experience on various biotechnology leadership teams, as well as his contributions as part of Equillium's executive team will enable him to successfully lead the company."

"Under Dan's leadership the company has made substantial progress in advancing itolizumab as a promising novel treatment for patients with severe immuno-inflammatory conditions," said Bruce Steel. "Stepping into the role as CEO, I'm eager to guide the company toward fully realizing itolizumab's potential, and I look forward to further collaborating with Dan, our Board, and our management team as we continue building the company. As part of this transition we are also recognizing the leadership and operational contributions of both Krishna and Christine as critical members of our executive team and the importance of their roles going forward."

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, 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 the following severe immuno-inflammatory disorders: uncontrolled asthma, acute graft-versus-host disease, and lupus nephritis. For more information, visit www.equilliumbio.com.

Executive Biographies

Bruce Steel is a co-founder and director of Equillium, and has served as its president and chief business officer since June 2018 and a member of the Board since March 2017. Prior to Equillium Bruce was the founder and managing director of BioMed Ventures, the strategic investment arm of BioMed Realty, LP, in which he directed investments in over 30 biotechnology companies since 2010. Previously Bruce was co-founder and chief executive officer of Rincon Pharmaceuticals, a genetic engineering biotechnology company, until its acquisition in 2008, and he was chief business officer at Anaphore and head of corporate development at Ambit Biosciences. Bruce currently serves as a board member or observer for a number of other private biotechnology companies. Bruce holds a Master of Business Administration from the Marshall School of Business at the University of Southern California and received his Bachelor of Arts Degree from Dartmouth College, and he holds the designation of Chartered Financial Analyst.

Krishna Polu, M.D., has served as the chief medical officer at Equillium since August 2018. Prior to Equillium, he was an entrepreneur-in-residence at Frazier Healthcare. Previously Krishna was the chief medical officer at Raptor Pharmaceuticals until its acquisition by Horizon Pharmaceuticals in 2016 for \$800M. In that role, he oversaw clinical development, regulatory affairs, pharmacovigilance and medical affairs, and was responsible for securing additional drug approvals for Procysbi in nephropathic cystinosis and supporting product launches for Quinsair in Cystic Fibrosis. Prior to Raptor, Krishna served as chief medical officer at CytomX Therapeutics, and he led clinical development and pharmacovigilance activities at Affymax where he was instrumental in securing FDA approval of peginesatide for the treatment of anemia in patients on dialysis. Krishna also held senior level positions in clinical development at Amgen and was responsible for leading clinical development programs in heart failure, anemia of chronic kidney disease, and diabetes. Krishna received his Bachelor of Arts in Human Biology from Stanford University and an M.D. from the University of Texas Health Science Center, San Antonio. He completed his residency in internal medicine at the University of Colorado followed by a clinical and research fellowship in nephrology at Harvard Medical School at the Brigham and Women's Hospital and Massachusetts General Hospital. Krishna has co-authored several scientific and clinical publications in the areas of genetics and renal disease.

Christine Zedelmayer has served as vice president of operations at Equillium since February 2018. Prior to Equillium, she was owner and principal consultant at Centerra Consulting, a project management and investor relations consulting firm focused on life sciences where she led strategic business development projects for clients and served as head of investor relations for a variety of medical device companies. Prior to Centerra, Christine held a variety of roles during her tenure at Amylin Pharmaceuticals, including senior director of alliance management, where she led the global collaboration with Eli Lilly and as executive director of investor relations. Before joining Amylin, Christine also held various leadership positions within project management at Amgen, Ligand Pharmaceuticals and Hybritech. Christine



received her Bachelor of Science in Electrical Engineering at San Diego State University and a Master of Business Administration with Finance emphasis at California Lutheran University. She is also a certified Project Management Professional (PMI-PMP, license # 1602309).

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 Equillium's plans and expected timing for certain management changes, the impacts of such management changes and the potential benefits of itolizumab. Risks that contribute to the uncertain nature of the forward-looking statements include uncertainties related to whether the results of such management changes will be as expected and risks related to the clinical development 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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