Equillium Reports Third Quarter 2019 Financial Results and Recent Highlights

November 12, 2019

LA JOLLA, Calif., Nov. 12, 2019 (GLOBE NEWSWIRE) -- 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

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)

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

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

	Three Months Ended September 30,		Nine Months Ended September 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