Autolus Therapeutics Reports Second Quarter 2019 Financial Results and Operational Progress

August 8, 2019 at 7:49 AM EDT

Conference call to be held on August 8, 2019 at 8:30 am EDT/1:30 pm BST

LONDON, Aug. 08, 2019 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announced its financial and operational results for the second quarter ended June 30, 2019.

Operational Highlights:

- In April, Autolus announced the presentation of initial data from the ongoing Phase 1/2 ALLCAR19 clinical trial of AUTO1 in adult ALL at the American Association for Cancer Research (AACR) Annual Meeting 2019 in Atlanta, Georgia. As of the data cutoff date of May 18, 2019, 13 patients were leukapheresed, and products for 12 patients were manufactured, including 7 with Autolus' semi-automated, fully enclosed manufacturing process. Using the Lee criteria, there were no patients with severe cytokine release syndrome (CRS) (≥ Grade 3), and only 2 of 10 patients (20%) with Grade 2 CRS. Tocilizumab was used in 2 of 10 patients (20%). None of the patients were admitted to intensive care due to CRS. One patient developed delayed Grade 3 neurotoxicity following high levels of CAR T expansion, which resolved promptly following administration of steroids. Four patients died while enrolled in the trial, 2 due to progression of the disease and 2 due to sepsis, a common complication in patients with advanced ALL. Nine patients were evaluable for response at 1 month with 8 (88%) achieving a molecular complete response. One patient died of sepsis before the one-month evaluation point. At a median follow-up of 5 months (range 0.62-10.6 months), 6 of 10 patients were alive and continue to be in molecular remission with continued evidence of ongoing B cell aplasia and CAR T persistence.

- In April, Autolus completed an underwritten public offering of 4,830,000 American Depositary Shares ("ADSs") representing 4,830,000 ordinary shares, at a public offering price of $24.00 per ADS, which includes an additional 630,000 ADSs issued upon the exercise in full of the underwriters' option to purchase additional ADSs. Aggregate net proceeds to Autolus, after underwriting discounts but before estimated offering expenses, were $108.8 million.

Pipeline Updates and Anticipated Milestones:

- Initiation of a Phase 2 registration trial of AUTO1 in adult ALL in the fourth quarter of 2019 (pending regulatory feedback). Updated Phase 1 data from the ALLCAR19 clinical trial is expected at ASH 2019.

- Decision on Phase 2 initiation for the Alexander study of AUTO3 in DLBCL is expected for mid-2020. Interim Phase 1 data is expected at ASH 2019.

- Development of AUTO1 in pediatric ALL as part of a pediatric investigational program (PIP). Next data update from CARPALL clinical trial is expected at ASH 2019. Development program includes a next generation version of AUTO1 (AUTO1NG), which incorporates the CD19 CAR of AUTO1 and a novel CD22 CAR. First preclinical data on CD22 CAR expected to be presented at ASH 2019.

- Additional presentations targeted for ASH 2019 are: data from AMELIA clinical trial of AUTO3 in pediatric ALL and data from clinical trial of AUTO2 in multiple myeloma.

- Next generation (NG) programs for AUTO1, AUTO2, AUTO3 and AUTO6 are expected to enter the clinic in 2020.

"This quarter we have focused on expanding operations at our clinical manufacturing site at the Catapult Cell and Gene facility in Stevenage, UK, enabling us to meet our expected clinical trial demand, including a registration trial with AUTO1. In April, we presented encouraging data on our ALLCAR19 clinical trial of AUTO1 in adult ALL. These data show that AUTO1 is well differentiated from the standard of care in ALL and other CAR T products in development, reaching a high level of clinical activity without inducing severe cytokine release syndrome," stated Dr. Christian Itin, chairman and chief executive officer of Autolus. "For the remainder of 2019, our efforts are focused on moving AUTO1 into a Phase 2 registration trial in adult ALL and advancing AUTO3 in DLBCL toward a Phase 2 decision point in Q2 2020."

Financial results for second quarter 2019:

- Cash and equivalents at June 30, 2019 totaled $266.2 million, compared with $217.5 million at December 31, 2018.

- Net total operating expenses for the three months ended June 30, 2019 were $37.2 million, net of grant income of $0.3

million, as compared to net operating expenses of $16.5 million, net of grant income of $0.4 million, for the same period in 2018. The increase was due, in general, to the increase in development activity; increased headcount primarily in our development and manufacturing functions; and the cost of being a public company.

- Research and development expenses increased to $26.2 million for the three months ended June 30, 2019 from $8.9 million for the three months ended June 30, 2018. Cash costs, which exclude depreciation as well as share-based compensation, increased to $20.2 million from $7.1 million. The increase in research and development cash costs of $13.1 million consisted primarily of an increase of compensation-related costs of $5.6 million primarily due to an increase in headcount to support the advancement of our product candidates in clinical development, an increase of $2.3 million in facilities costs supporting the expansion of our research and translational science capability and investment in manufacturing facilities and equipment, an increase of $3.3 million in research and development program expenses related to the activities necessary to prepare, activate, and monitor clinical trial programs, an increase of $0.8 million in professional fees, an increase of $0.5 million in telecom and software costs, and other additional costs in the amount of $0.4 million.

- General and administrative expenses increased to $11.4 million for the three months ended June 30, 2019 from $8.1 million for the three months ended June 30, 2018. Cash costs, which exclude depreciation as well as share-based compensation, increased to $7.3 million from $6.9 million. The increase of $0.4 million consisted primarily of an increase in commercial costs of $1.2 million, compensation-related expense of $0.5 million due to an overall increase in headcount, offset by a decrease in legal and professional fees of $1.3 million related to certain corporate reorganization costs that were incurred in the three months ended June 30, 2018.

- Net loss attributable to ordinary shareholders was $28.5 million for the three months ended June 30, 2019, compared to $7.7 million for the same period in 2018.

- The basic and diluted net loss per ordinary share for the three months ended June 30, 2019 totaled $(0.65) compared to a basic and diluted net loss per ordinary share of $(0.26) for the three months ended June 30, 2018.

- Autolus anticipates that cash on hand provides a runway into the second half of 2021.

Conference Call and Presentation Information

Autolus management will host a conference call today, August 8, at 8:30 a.m. EDT/ 1:30pm BST, to discuss the company's financial results and operational update.

To listen to the webcast and view the accompanying slide presentation, please go to: https://www.autolus.com/investor-relations/news-events/events.

The call may also be accessed by dialing (866) 679-5407 for U.S. and Canada callers or (409) 217-8320 for international callers. Please reference conference ID 2763978. After the conference call, a replay will be available for one week. To access the replay, please dial (855) 859-2056 for U.S. and Canada callers or (404) 537-3406 for international callers. Please reference conference ID 2763978.

About Autolus Therapeutics plc

Autolus is a clinical-stage biopharmaceutical company developing next-generation, programmed T cell therapies for the treatment of cancer. Using a broad suite of proprietary and modular T cell programming technologies, the company is engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognize cancer cells, break down their defense mechanisms and eliminate these cells. Autolus has a pipeline of product candidates in development for the treatment of hematological malignancies and solid tumors. For more information please visit www.autolus.com.

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding Autolus' financial condition and results of operations, as well as statements regarding the anticipated development of Autolus' product candidates, including its intentions regarding the timing for providing further updates on the development of its product candidates, and the sufficiency of its cash resources. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in Autolus' Annual Report on Form 20-F filed on November 23, 2018 as well as discussions of potential risks, uncertainties, and other important factors in Autolus' future filings with the Securities and Exchange Commission from time to time. All information in this press release is as of the date of the release, and the company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Autolus Therapeutics PLC
Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)
(In thousands, except share and per share amounts)

	Three months ended	Six Months Ended

	June 30, 2019	2018	June 30, 2019	2018
Grant income	$ 338	$ 443	$ 2,302	$ 869
Operating expenses:				
Research and development	(26,173)	(8,863)	(48,738)	(20,490)
General and administrative	(11,370)	(8,103)	(20,926)	(12,433)
Total operating expenses, net	(37,205)	(16,523)	(67,362)	(32,054)
Other income (expense):				
Interest income	1,074	266	1,615	555
Other income	4,380	6,390	3,396	3,449
Total other income, net	5,454	6,656	5,011	4,004
Net loss before income tax	(31,751)	(9,867)	(62,351)	(28,050)
Income tax benefit	3,274	2,217	6,696	3,683
Net loss attributable to ordinary shareholders	(28,477)	(7,650)	(55,655)	(24,367)
Other comprehensive income:				
Foreign currency exchange translation adjustment	(8,872)	(11,206)	(3,821)	(6,242)
Total comprehensive loss	$ (37,349)	$ (18,856)	$ (59,476)	$ (30,609)
Basic and diluted net loss per ordinary share	$ (0.65)	$ (0.26)	$ (1.34)	$ (0.84)
Weighted-average basic and diluted ordinary shares	43,611,531	29,386,128	41,552,718	29,111,323

Autolus Therapeutics PLC
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash	$ 266,194	$ 217,450
Restricted cash	683	105
Prepaid expenses and other current assets	25,831	15,411
Total current assets	292,708	232,966
Non-current assets:		
Property and equipment, net	25,967	19,968
Right of use asset, net	25,505	—
Long-term deposits	1,965	1,276
Total assets	$ 346,145	$ 254,210
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	3,143	2,022
Accrued expenses and other liabilities	17,237	19,054
Lease liability	1,925	—
Total current liabilities	22,305	21,076
Non-current liabilities:		
Lease liability	25,497	—
Long-term lease incentive obligation	—	207
Other long-term payables	121	285
Total liabilities	47,923	21,568
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 200,000,000 shares authorized as of June 30, 2019 and December 31, 2018; 44,981,860 and 40,145,617, shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	2	2
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at June 30, 2019 and December 31, 2018	118	118
Deferred C shares, £0.000001 par value; 1 share authorized, issued and outstanding at June 30, 2019 and December 31, 2018	—	—

Additional paid-in capital	486,369	361,311
Accumulated other comprehensive loss	(19,309)	(15,488)
Accumulated deficit	(168,958)	(113,301)
Total shareholders' equity	298,222	232,642
Total liabilities and shareholders' equity	$ 346,145	$ 254,210

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Source: Autolus Therapeutics plc