



Autolus Therapeutics Reports Third Quarter 2019 Financial Results and Operational Progress

November 7, 2019 at 7:06 AM EST

Conference call to be held on November 7, 2019 at 8:30 am EST/1:30 pm GMT

LONDON, Nov. 07, 2019 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announced its operational and financial results for the third quarter ended September 30, 2019.

"We are excited about the opportunity to share data updates at ASH on AUTO1 in ALL in three oral presentations, as well as an oral presentation on AUTO3 in DLBCL. We are also looking forward to presenting data on our other hematological clinical programs at ASH, and non-clinical data on our lead solid tumor program AUTO6NG at SITC," stated Dr. Christian Itin, chairman and chief executive officer of Autolus. "This quarter we have made significant operational progress, delivering cell products from our new manufacturing operations at the Cell and Gene Therapy Catapult and further strengthening our management team. Supported by a strong balance sheet, our key focus is on moving AUTO1 into our first pivotal clinical program in adult patients with ALL."

Pipeline Updates:

- On November 5, the United States Food and Drug Administration granted orphan drug designation for AUTO1 for the treatment of acute lymphoblastic leukemia (ALL).

- SITC Meeting Presentation

Solid tumors (AUTO6NG) - AUTO6NG: Next generation GD2-targeting CAR T-cell therapy with improved persistence and insensitivity to TGF β and checkpoint inhibition for relapsed/refractory neuroblastoma (Saturday November 9, poster presentation)

- ASH Meeting Presentations

Adult ALL (AUTO1) - AUTO1, a novel fast off CD19 CAR delivers durable remissions and prolonged CAR T cell persistence with low CRS or neurotoxicity in adult ALL (Saturday December 7, oral presentation)

Pediatric ALL (AUTO1) - Therapy of pediatric B-ALL with a lower affinity CD19 CAR leads to enhanced expansion and prolonged CAR T cell persistence in patients with low bone marrow tumor burden, and is associated with a favorable toxicity profile (Saturday December 7, oral presentation)

Integration Site Analysis (AUTO1) - Clonal dynamics of early responder and long-term persisting CAR-T cells in humans (Saturday December 7, oral presentation)

DLBCL (AUTO3) - Phase 1/2 study of AUTO3 the first bicistronic chimeric antigen receptor (CAR) targeting CD19 and CD22 followed by an anti-PD1 in patients with relapsed/refractory (r/r) Diffuse Large B Cell Lymphoma (DLBCL): Results of Cohort 1 and 2 of the ALEXANDER study (Saturday December 7, oral presentation)

Multiple Myeloma (AUTO2) - Phase 1 First-in-Human study of AUTO2, the first chimeric antigen receptor (CAR) T cell targeting APRIL for patients with relapsed/refractory Multiple Myeloma (RRMM) (Sunday December 8, poster presentation)

Pediatric ALL (AUTO3) - Phase 1 Study of AUTO3, a Bicistronic Chimeric Antigen Receptor (CAR) T-cell Therapy Targeting of CD19 and CD22, in Pediatric Patients with Relapsed/Refractory B-cell Acute Lymphoblastic Leukemia (r/r B-ALL): AMELIA Study (Sunday December 8, poster presentation)

Operational and Corporate Highlights:

- Manufacturing update

The Cell and Gene Therapy Catapult site is fully operational and is delivering clinical products for patients in both Europe and the US

- Significant change in shareholder base

In September, PPF Group announced that they had acquired, mainly from Woodford Investment Management, an approximate 19% holding of Autolus. Control of all the remaining shares of Autolus held by Woodford Investment Management are in the process of being transferred to Schroder UK Public Private Trust plc.

- Nature Medicine publication of AUTO1 CARPALL study in pediatric ALL

In September, Autolus announced that the journal *Nature Medicine* has published both pre-clinical results and clinical data from the ongoing Phase 1 CARPALL trial of AUTO1, demonstrating the potential of the company's novel CAR T therapy targeting CD19 in development for the treatment of pediatric acute lymphoblastic leukemia (ALL).

- Executive Leadership Team Changes

David Brochu has been named Senior Vice President, Head of Product Delivery to lead the transition of the company's manufacturing organization to deliver products for late-stage clinical studies and commercial sale. In addition, Vishal Mehta has been named Vice President, Head of Clinical Operations.

Key Upcoming Clinical Milestones:

- Initiation of the pivotal program of AUTO1 in adult ALL on track – dosing of first patients in the first half of 2020
- Go/no go decision on Phase 2 initiation of AUTO3 in DLBCL expected in mid-2020
- Interim Phase 1 data in T cell lymphoma with AUTO4 in the second half of 2020

Financial results for third quarter 2019

Cash and equivalents at September 30, 2019 totaled \$229.4 million, compared with \$247.1 million at September 30, 2018.

Net total operating expenses for the three months ended September 30, 2019 were \$35.6 million, net of grant income of \$0.3 million, as compared to net operating expenses of \$17.1 million, net of grant income of \$0.3 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 \$27.3 million for the three months ended September 30, 2019 from \$10.1 million for the three months ended September 30, 2018. Cash costs, which exclude depreciation as well as share-based compensation, increased to \$21.6 million from \$9.0 million. The increase in research and development cash costs of \$12.6 million consisted primarily of an increase of compensation-related costs of \$5.2 million primarily due to an increase in employee headcount to support the advancement of our product candidates in clinical development, an increase of \$3.6 million in research and development program expenses related to the activities necessary to prepare, activate, and monitor clinical trial programs, including the manufacturing technical transfer activities required for AUTO1 to enable the commencement at the end of 2019 of a registration study in Adult Acute Lymphoblastic Leukemia, an increase of \$2.6 million in facilities costs supporting the expansion of our research and translational science capability and investment in manufacturing facilities and equipment, an increase of \$0.7 million in telecom and software costs, and an increase of \$0.5 million in other costs.

General and administrative expenses increased to \$8.6 million for the three months ended September 30, 2019 from \$7.3 million for the three months ended September 30, 2018. Cash costs, which exclude depreciation expense as well as share-based expense compensation decreased to \$5.6 million from \$5.7 million. Compensation related expenses decreased by \$0.6 million and IT, telecommunication, and general office expense costs decreased by \$0.7 million which were offset by an increase in legal and professional fees of \$0.9 million and an increase of \$0.3 million in commercial costs.

Net loss attributable to ordinary shareholders was \$27.2 million for the three months ended September 30, 2019, compared to \$12.9 million for the same period in 2018.

The basic and diluted net loss per ordinary share for the three months ended September 30, 2019 totaled \$(0.61) compared to a basic and diluted net loss per ordinary share of \$(0.33) for the three months ended September 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, November 7, at 8:30 a.m. EST/ 1:30pm GMT, 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 5075598. 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 5075598.

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 Statements

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.

Investor and media contact:

Silvia Taylor
Vice President, Corporate Affairs and Communications
Autolus
+1-240-801-3850
s.taylor@autolus.com

UK:

Julia Wilson
+44 (0) 7818 430877
j.wilson@autolus.com

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Grant income	\$ 297	\$ 307	\$ 2,599	\$ 1,176
Operating expenses:				
Research and development	(27,310)	(10,096)	(76,050)	(30,586)
General and administrative	(8,605)	(7,273)	(29,531)	(19,706)
Total operating expenses, net	(35,618)	(17,062)	(102,982)	(49,116)
Other income (expense):				
Interest income	509	796	2,124	1,351
Other income	3,263	1,206	6,659	4,655
Total other income, net	3,772	2,002	8,783	6,006
Net loss before income tax	(31,846)	(15,060)	(94,199)	(43,110)
Income tax benefit	4,598	2,200	11,294	5,883
Net loss attributable to ordinary shareholders	(27,248)	(12,860)	(82,905)	(37,227)
Other comprehensive loss:				
Foreign currency exchange translation adjustment	(9,044)	(973)	(12,865)	(7,215)
Total comprehensive loss	\$ (36,292)	\$ (13,833)	\$ (95,770)	\$ (44,442)
Basic and diluted net loss per ordinary share	\$ (0.61)	\$ (0.33)	\$ (1.95)	\$ (1.14)
Weighted-average basic and diluted ordinary shares	44,505,383	39,214,334	42,547,755	32,516,001

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

September 30,
2019

December 31,
2018

Assets**Current assets:**

Cash	\$ 229,366	\$ 217,450
Restricted cash	681	105
Prepaid expenses and other current assets	30,136	15,411
Total current assets	260,183	232,966

Non-current assets:

Property and equipment, net	28,413	19,968
Right of use asset, net	24,133	—
Long-term deposits	1,912	1,276
Total assets	\$ 314,641	\$ 254,210

Liabilities and shareholders' equity**Current liabilities:**

Accounts payable	2,733	2,022
Accrued expenses and other liabilities	15,548	19,054
Lease liability	2,282	—
Total current liabilities	20,563	21,076

Non-current liabilities:

Lease liability	24,407	—
Long-term lease incentive obligation	—	207
Other long-term payables	30	285
Total liabilities	45,000	21,568

Shareholders' equity:

Ordinary shares, \$0.000042 par value; 200,000,000 shares authorized as of September 30, 2019 and December 31, 2018; 44,982,378 and 40,145,617, shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	2	2	
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at September 30, 2019 and December 31, 2018	—	—	
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at September 30, 2019 and December 31, 2018	118	118	
Deferred C shares, £0.000001 par value; 1 share authorized, issued and outstanding at September 30, 2019 and December 31, 2018	—	—	
Additional paid-in capital	494,080	361,311	
Accumulated other comprehensive loss	(28,353) (15,488)
Accumulated deficit	(196,206) (113,301)
Total shareholders' equity	269,641	232,642	
Total liabilities and shareholders' equity	\$ 314,641	\$ 254,210	

Source: Autolus Therapeutics plc