Autolus Therapeutics Reports Third Quarter 2020 Financial Results and Operational Progress

November 5, 2020

- Conference call to be held on November 5, 2020 at 8:30 am EDT/1:30 pm GMT -

LONDON, Nov. 05, 2020 (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, 2020.

"We have made steady progress in the third quarter and continued to enroll in our AUTO3 ALEXANDER outpatient cohort, as well as our AUTO1 program as planned. For the fourth quarter and into the winter months we will continue to monitor the COVID-19 situation and adjust our trial conduct accordingly," said Dr. Christian Itin, chairman and chief executive officer of Autolus. "At ESMO we presented data from our recommended Phase 2 dose cohort from the ALEXANDER trial of AUTO3, showing a high level of complete remissions and a well tolerated safety profile. We look forward to presenting an update from the study at the ASH meeting in December, along with data from our AUTO1 ALLCAR study in adult ALL."

Pipeline Updates:

- Data presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020 from our recommended Phase 2 dose cohort from the ALEXANDER trial of AUTO3, a CD19 and CD22 dual targeting CAR T product candidate in relapsed/refractory diffuse large B cell lymphoma (DLBCL).
- Data on both AUTO1 and AUTO3 will be presented in oral presentations at the American Society of Hematology (ASH) in December 2020
  - AUTO1 in adult Acute Lymphoblastic Leukemia (ALL) - longer term follow up
  - AUTO3 in DLBCL - updated data and longer term follow up from ALEXANDER study.
- Plans to progress the solid tumor programs, AUTO6NG in GD2 positive tumors and AUTO7 in prostate cancer, into the clinic in 2021.

Key Upcoming Clinical Milestones:

- Clinical updates for AUTO1 in adult ALL (ALLCAR study) at ASH in December 2020.
- Clinical update for AUTO3 in DLBCL (ALEXANDER study) at ASH.
- Initiation of Phase 1 study for AUTO1/22 in pediatric ALL in Q4 2020.
- Phase 1 interim data for AUTO4 in T cell lymphoma in 2021.
- Initiation of Phase 1 studies for AUTO6NG and AUTO7 in solid tumors in 2021.
- First exploratory allogeneic program expected to enter the clinic in Q1 2021.

Financial results for third quarter 2020

Cash and equivalents at September 30, 2020 totaled $177.7 million, compared with $212.0 million at June 30, 2020.

Net total operating expenses for the three months ended September 30, 2020 were $42.7 million, net of grant income of $0.4 million and license revenue of $0.2 million, as compared to net operating expenses of $35.6 million, net of grant income of $0.3 million, for the same period in 2019.

Research and development expenses increased to $33.5 million for the three months ended September 30, 2020 from $27.3 million for the three months ended September 30, 2019. Cash costs, which exclude depreciation and amortization as well as share-based compensation, increased to $30.0 million from $21.6 million. The increase in research and development cash costs of $8.4 million consisted primarily of (i) an increase in compensation and employment related costs, net of lower travel costs as a result of the ongoing pandemic, of $1.5 million due to an increase in employee headcount to support the advancement of our product candidates in clinical development, (ii) an increase of $3.6 million in project expenses as a consequence of the advancement of our clinical portfolio which includes research and process development and manufacturing activities necessary to prepare, activate, and monitor clinical trial programs, (iii) an increase of $2.1 million in facilities costs related to the commencement of a lease for a manufacturing facility and the continued scaling of manufacturing operations, (iv) an increase of $1.4 million in IT infrastructure and support for information systems related to the conduct of clinical trials, (v) an increase of $0.8 million related to cell logistics and (vi) an increase of $0.4 million in legal and professional fees, which is offset by decreases in materials purchases of $1.3 million.

Non-cash costs decreased to $3.5 million for the three months ended September 30, 2020 from $5.7 million for the three months ended September 30, 2019. The decrease is primarily related to share-based compensation expense included in research and development expenses, which decreased by $2.5 million as a result of a lower fair value of stock options recognized in the period, offset by a $0.3 million increase in depreciation.

General and administrative expenses increased to $9.8 million for the three months ended September 30, 2020 from $8.6 million for the three months ended September 30, 2019. Cash costs, which exclude depreciation expense as well as share-based expense compensation, increased to $7.7 million from $5.6 million. There was an increase of (i) $1.0 million in commercial activities, (ii) an increase of $0.7 million in patent legal fees, audit fees, and costs incurred as a result of being a public company, and (iii) an increase of $0.3 million in compensation and employment related costs due to an increase in headcount, net of lower travel costs.

Non-cash costs decreased to $2.1 million for the three months ended September 30, 2020 from $3.0 million for the three months ended September 30, 2019. The decrease is attributed to share-based compensation expense as a result of the lower fair value of stock options recognized during the period.

Interest income decreased by $0.5 million for three months ended September 30, 2020 due to lower interest rates for cash held on deposit.

Other (expense)/ income decreased by $5.8 million for the three months ended September 30, 2020 from other income of $3.3 million for the three months ended September 30, 2019 to other expense of $2.5 million primarily due to a decrease of $7.1 million with regard to weakening of the U.S. dollar exchange rate relative to the pound sterling during the three months ended September 30, 2020, as compared to the three months ended September 30, 2019, offset by lease termination gains of $1.3 million.

Income tax benefit increased to $7.9 million for the three months ended September 30, 2020 from $4.6 million for the three months ended September 30, 2019 due to increased research and development credits. As research and development credits grew at a faster rate than our net loss before income tax, this led to a higher effective tax rate. Research and development credits are obtained at a maximum rate of 33.35% of our qualifying research and development expenses, and the increase in the net credit was primarily attributable to an increase in our eligible research and development expenses.

Net loss attributable to ordinary shareholders was $37.3 million for the three months ended September 30, 2020, compared to $27.2 million for the same period in 2019.

The basic and diluted net loss per ordinary share for the three months ended September 30, 2020 totaled $(0.72), compared to a basic and diluted net loss per ordinary share of $(0.61) for the three months ended September 30, 2019.

The Company anticipates that cash on hand is sufficient to fund operations into 2022.

Conference Call and Presentation Information

Management will host a conference call and webcast at 8:30 am ET/1:30 pm GMT to discuss the company's financial results and provide a general business update. To listen to the webcast and view the accompanying slide presentation, please go to: https://www.autolus.com/investor-relations/news-and-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 5562455. 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 5562455.

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 the efficacy, safety and therapeutic potential of AUTO3 and the future clinical development of AUTO3 including progress, expectations as to the reporting of data, conduct and timing. 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. These risks and uncertainties include, but are not limited to, the risks that Autolus' preclinical or clinical programs do not advance or result in approved products on a timely or cost effective basis or at all; the results of early clinical trials are not always being predictive of future results; the cost, timing and results of clinical trials; that many product candidates do not become approved drugs on a timely or cost effective basis or at all; the ability to enroll patients in clinical trials; possible safety and efficacy concerns; and the impact of the ongoing COVID-19 pandemic on Autolus' business. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Autolus' 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 with the Securities and Exchange Commission on March 3, 2020, as amended, as well as discussions of potential risks, uncertainties, and other important factors in Autolus' subsequent filings with the Securities and Exchange Commission. 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.

Contact:
Lucinda Crabtree, PhD
Vice President, Investor Relations and Corporate Communications

+44 (0) 7587 372 619
l.crabtree@autolus.com

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

Susan A. Noonan
S.A. Noonan Communications
+1-212-966-3650
susan@sanoonan.com

Autolus Therapeutics PLC

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Grant income	$ 438	$ 297	$ 1,069	$ 2,599
License revenue	242	—	242	—
Operating expenses:				
Research and development	(33,545)	(27,310)	(96,160)	(76,050)
General and administrative	(9,843)	(8,605)	(25,966)	(29,531)
Total operating expenses, net	(42,708)	(35,618)	(120,815)	(102,982)
Other income (expense):				
Interest income	37	509	500	2,124
Other (expense) income	(2,509)	3,263	2,500	6,659
Total other (expense) income, net	(2,472)	3,772	3,000	8,783
Net loss before income tax	(45,180)	(31,846)	(117,815)	(94,199)
Income tax benefit	7,865	4,598	18,582	11,294
Net loss attributable to ordinary shareholders	(37,315)	(27,248)	(99,233)	(82,905)
Other comprehensive (loss) income:				
Foreign currency exchange translation adjustment	10,915	(9,044)	(8,605)	(12,865)
Total comprehensive loss	$ (26,400)	$ (36,292)	$ (107,838)	(95,770)
Basic and diluted net loss per ordinary share	$ (0.72)	$ (0.61)	$ (1.93)	$ (1.95)
Weighted-average basic and diluted ordinary shares	52,093,826	44,505,383	51,339,662	42,547,755

Condensed Consolidated Balance Sheets (Unaudited)

(In thousands, except share and per share amounts)

	September 30, 2020	**December 31, 2019**
Assets		
Current assets:		
Cash	$ 177,695	$ 210,643
Restricted cash	786	787
Prepaid expenses and other assets, current	50,388	37,826
Total current assets	228,869	249,256
Non-current assets:		
Property and equipment, net	32,755	28,164
Right of use assets, net	49,535	23,409
Long-term deposits	2,446	2,040
Prepaid expenses and other assets, non-current	2,890	—
Deferred tax asset	410	410
Intangible assets, net	172	254
Total assets	$ 317,077	$ 303,533
Liabilities and shareholders' equity		
Current liabilities:		

Accounts payable	1,997	1,075
Accrued expenses and other liabilities	25,400	21,398
Lease liabilities	3,413	2,511
Total current liabilities	30,810	24,984
Non-current liabilities:		
Lease liabilities	49,456	23,710
Total liabilities	80,266	48,694
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 200,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 52,298,876 and 44,983,006, shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	3	2
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at September 30, 2020 and December 31, 2019	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at September 30, 2020 and December 31, 2019	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at September 30, 2020 and December 31, 2019	—	—
Additional paid-in capital	590,369	500,560
Accumulated other comprehensive loss	(17,296)	(8,691)
Accumulated deficit	(336,383)	(237,150)
Total shareholders' equity	236,811	254,839
Total liabilities and shareholders' equity	$ 317,077	$ 303,533

Source: Autolus Therapeutics plc