Autolus Therapeutics Reports Second Quarter 2020 Financial Results and Operational Progress

August 6, 2020

- Conference call to be held on August 6, 2020 at 8:30 am EDT/1:30 pm BST -

LONDON, Aug. 06, 2020 (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, 2020.

"We have had a busy second quarter with data updates across our portfolio at key medical and scientific conferences," said Dr Christian Itin, chairman and chief executive officer of Autolus. "Both our later stage programs, AUTO1 and AUTO3, continue to show encouraging clinical activity with tolerable safety in adult patients with ALL and DLBCL, respectively, and we are excited by the potential for these product candidates to have differentiated profiles addressing indications with high unmet needs. We look forward to providing further updates in H2 2020, starting with AUTO3 ALEXANDER data at a mini oral session at ESMO in September."

"At AACR we presented data across a number of next generation programs," said Dr Martin Pule, chief scientific officer of Autolus. "These data demonstrate the strength of our binder discovery capabilities with highly selective targeting in AUTO5 for T Cell lymphoma, as well as the ability of our cell programming modules to address the hostile solid tumor microenvironment as shown for AUTO6NG and AUTO7 for small cell lung cancer and prostate cancer, respectively. We are excited to be progressing these next generation programs into Phase 1 in 2021."

Pipeline Updates:

- *AUTO1 in acute lymphocytic leukemia (ALL).* Positive data were presented at the European Hematology Association (EHA) meeting in June 2020. These data showed an encouraging durability of response without subsequent stem cell transplant and confirmed the safety profile. Autolus has now started enrolment of adult patients with relapsed / refractory ALL in its pivotal Phase 1b/2 AUTO1 program and is targeting to have full data by the end of 2021.

- *AUTO3 in diffuse large B-cell lymphoma (DLBCL).* Positive data were presented at the American Society of Clinical Oncology (ASCO) meeting in June 2020. These data showed a high level of complete remissions and a safety profile supportive of evaluation of outpatient use. Based on these data, Autolus selected its recommended Phase 2 dose range of 150 - 450 x 10^6 cells, with a single dose of pembrolizumab during preconditioning. In addition, the company has also commenced an outpatient cohort as an extension to its ongoing Phase 1/2 ALEXANDER study, with results expected in the second half of 2020. The data from this outpatient cohort will provide important insights that will be used to refine the design of the potential pivotal Phase 2 part of the ALEXANDER study. Autolus expects to present next updated data from the study at ESMO in September 2020.

- *AUTO5 in T cell lymphoma*. Positive preclinical data were presented at the American Association for Cancer Research II (AACR) Meeting in June 2020. The data highlight the specificity and selectivity of the company's T-cell lymphoma product candidate, AUTO5.

- *AUTO6NG in small cell lung cancer (SCLC).* Positive preclinical data were presented at the AACR Meeting in June 2020. Autolus has designed enhancing modules to specifically overcome tumor microenvironment (TME) defenses in solid tumor settings. The new data suggest that AUTO6NG can overcome the immune suppressive mechanisms in the TME.

- *AUTO7 in prostate cancer*. Positive preclinical data were presented at an oral presentation at the AACR Meeting in June 2020. The program builds on a novel and optimized CAR to PSMA designed to be highly active, even in an acidic environment, and combines modules introduced in AUTO6NG with a novel low level secretion of IL-12 to change the prostate tumor from an immunologically cold to an immunologically supportive environment.

Operational Highlights:

- Appointment of Dr Jay T Backstrom to Autolus' Board of Directors, effective August 1, 2020. Dr Backstrom currently serves as EVP, Head of Research & Development at Acceleron Pharma Inc. and prior to that served as CMO and Head of Regulatory Affairs at Celgene Corporation.

- Dr Nushmia Khokhar promoted to Senior Vice President, Clinical Development. Dr Khokhar will take over the clinical leadership role at Autolus. She is a board-certified oncologist with extensive early and late stage clinical development experience, having led several successful registration trials within the industry in both solid tumors and hematologic

malignancies, including the global daratumumab program at Janssen Oncology. Dr Vijay Peddareddigari, Senior Vice President, Chief Medical Officer will be leaving the Company to return to the United States.

- Expanded manufacturing capacity at the Cell and Gene Therapy Catapult to secure initial commercial launch capability.

Key Upcoming Clinical Milestones:

- Further update for AUTO3 at ESMO in Q3 2020.
- Further data updates for both AUTO1 and AUTO3 in Q4 2020.
- First data from outpatient cohort in the AUTO3 ALEXANDER study in H2 2020.
- Interim Phase 1 data for AUTO4 in T cell lymphoma in H1 2021.
- Initiation of Phase 1 study for AUTO1NG in pediatric ALL in H2 2020.
- Initiation of Phase 1 study for AUTO8 in multiple myeloma in H2 2020.
- Progression of additional next generation programs from preclinical stages to Phase 1 throughout 2021.
- Expansion of the company's suite of cell programming technologies to include additional modules designed for allogeneic applications, with the first novel allogeneic program expected to enter the clinic in Q4 2020.

Financial Results for the Quarter Ended June 30, 2020

Cash and equivalents at June 30, 2020 totaled $212.0 million, compared with $243.3 million at March 31, 2020.

Net total operating expenses for the three months ended June 30, 2020 were $39.5 million, net of grant income of $0.3 million, as compared to net operating expenses of $37.2 million, net of grant income of $0.3 million, for the same period in 2019.

Research and development expenses increased to $31.3 million for the three months ended June 30, 2020 from $26.2 million for the three months ended June 30, 2019. Cash costs, which exclude depreciation and amortization as well as share-based compensation, increased to $26.5 million from $20.2 million. The increase in research and development cash costs of $6.3 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 $1.8 million due to an increase in employee headcount to support the advancement of our product candidates in clinical development, (ii) an increase of $3.0 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 $1.3 million in facilities costs related to the commencement of a lease for an additional manufacturing suite and the continued scaling of operations in the manufacturing facility, and (iv) an increase in IT and telecoms, general office expense, and professional fees of $0.6 million, which is offset by a decrease in materials purchases of $0.4 million.

Non-cash costs decreased to $4.8 million for the three months ended June 30, 2020 from $6.0 million for the three months ended June 30, 2019. The decrease is primarily related to share-based compensation expense included in research and development expenses, which decreased by $1.3 million as a result of a lower fair value of stock options recognized in the period, offset by a small increase in depreciation.

General and administrative expenses decreased to $8.5 million for the three months ended June 30, 2020 from $11.4 million for the three months ended June 30, 2019. Cash costs, which exclude depreciation expense as well as share-based expense compensation decreased to $6.7 million from $7.3 million. Compensation related expenses decreased by $0.1 million aided by lower travel costs as described above. Further there was a decrease of $0.7 million in commercial activities. These decreases were offset by an increase of $0.1 million in legal and professional fees.

Non-cash costs decreased to $1.8 million for the three months ended June 30, 2020 from $3.9 million for the three months ended June 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 $1.1 million for three months ended June 30, 2020 due to lower interest rates.

Other income decreased to $0.5 million for the three months ended June 30, 2020 from other income of $4.4 million for the three months ended June 30, 2019 primarily due to a decrease of the U.S. dollar exchange rate relative to the pound sterling during the three months ending June 30, 2020 as compared to the three months ended June 30, 2019.

Income tax benefit increased to $7.0 million for the three months ended June 30, 2020 from $3.3 million for the three months ended June 30, 2019 due to increased R&D expenses, which 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 $32.0 million for the three months ended June 30, 2020, compared to $28.5 million for the same period in 2019.

The basic and diluted net loss per ordinary share for the three months ended June 30, 2020 totaled $(0.62) compared to a basic and diluted net loss per ordinary share of $(0.65) for the three months ended June 30, 2019.

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

Conference Call and Presentation Information

Autolus management will host a conference call today, August 6, at 8:30 a.m. EDT/ 1:30pm BST, to discuss the company's financial results and operational update.

To access the live and subsequent replay, as well as dial in information of this webcast and view the accompanying slide presentation, please register here.

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, including its expected cash runway; the development of Autolus' product candidates, including statements regarding the timing of initiation, completion and the outcome of preclinical studies or clinical trials and related preparatory work, and the periods during which the results of the studies and trials will become available; Autolus' plans to research, develop, manufacture and commercialize its product candidates; the potential for Autolus' product candidates to be alternatives in the therapeutic areas investigated; and Autolus' manufacturing capabilities and strategy. 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 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' 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Grant income	$ 293	$ 338	$ 631	$ 2,302
Operating expenses:				
Research and development	(31,328)	(26,173)	(62,615)	(48,738)
General and administrative	(8,509)	(11,370)	(16,123)	(20,926)
Total operating expenses, net	(39,544)	(37,205)	(78,107)	(67,362)
Other income (expense):				
Interest (expense) income	(47)	1,073	463	1,615
Other income	525	4,380	5,009	3,396
Total other income, net	478	5,453	5,472	5,011
Net loss before income tax	(39,066)	(31,752)	(72,635)	(62,351)
Income tax benefit	7,021	3,274	10,717	6,696
Net loss attributable to ordinary shareholders	(32,045)	(28,478)	(61,918)	(55,655)
Other comprehensive (loss) income:				

Foreign currency exchange translation adjustment	(1,819)	(8,872)	(19,520)	(3,821)
Total comprehensive loss	(33,864)	(37,350)	(81,438)	(59,476)
Basic and diluted net loss per ordinary share	$ (0.62)	$ (0.65)	$ (1.22)	$ (1.34)
Weighted-average basic and diluted ordinary shares	52,041,340	43,611,531	50,956,566	41,552,718

Condensed Consolidated Balance Sheets (Unaudited)
(In thousands, except share and per share amounts)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash	$ 212,044	$ 210,643
Restricted cash	786	787
Prepaid expenses and other assets, current	35,901	37,826
Total current assets	248,731	249,256
Non-current assets:		
Property and equipment, net	30,954	28,164
Right of use assets, net	25,100	23,409
Long-term deposits	2,354	2,040
Prepaid expenses and other assets, non-current	2,813	—
Deferred tax asset	410	410
Intangible assets, net	186	254
Total assets	$ 310,548	$ 303,533
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	626	1,075
Accrued expenses and other liabilities	22,753	21,398
Lease liabilities	3,888	2,511
Total current liabilities	27,267	24,984
Non-current liabilities:		
Lease liabilities	24,329	23,710
Total liabilities	51,596	48,694
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 200,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 52,250,404 and 44,983,006, shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	3	2
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at June 30, 2020 and December 31, 2019	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Additional paid-in capital	586,110	500,560
Accumulated other comprehensive loss	(28,211)	(8,691)
Accumulated deficit	(299,068)	(237,150)
Total shareholders' equity	258,952	254,839
Total liabilities and shareholders' equity	$ 310,548	$ 303,533

Source: Autolus Therapeutics plc