



Autolus Therapeutics Reports First Quarter 2020 Financial Results and Operational Progress

May 7, 2020

- Conference Call to be held on May 7, 2020 at 8:30 am EDT/1:30 pm BST-

LONDON, May 07, 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 first quarter ended March 31, 2020.

"We've had a productive first quarter and remain on track with our clinical programs, despite the challenges of COVID-19," said Dr. Christian Itin, chairman and chief executive officer of Autolus. "The start of AUTO1-AL1, our first pivotal study, is progressing, with MHRA CTA approval and IND activated. Our first UK site opened in March and we expect to open the first US sites this quarter. Emerging data for AUTO3 suggest a differentiated profile on efficacy and safety, supporting the exploration of true out-patient use in DLBCL. We look forward to updating the market on clinical data for AUTO3 and AUTO1 at ASCO and EHA in the coming weeks."

Pipeline Updates:

- *AUTO1 in adult lymphocytic leukemia (ALL)*. After positive data were presented at the American Society of Hematology (ASH) in December 2019 demonstrating that AUTO1, a novel fast off CD19 CAR, was well-tolerated with a high level of clinical activity, the company has now progressed the program to a pivotal study, AUTO1-AL1. This follows FDA acceptance of the Initial New Drug (IND) application in April 2020 and approval of the Clinical Trial Application (CTA) by the Medicines and Healthcare products Regulatory Agency (MHRA) in January 2020, with the first site opening in the UK in March of this year. The company is on track to dose the first patient in this study in the second quarter of 2020 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 ASH in December 2019, with an update provided in a keynote lecture at EHA-EBMT 2nd European CAR T Cell Meeting in February 2020. These data demonstrated early encouraging signs of sustained complete response rates with low toxicity and minimal patient management, which is supportive of a profile suitable for all settings of care, significantly broadening the commercial opportunity for this program. This is an opportunity which we believe is not available to other earlier generation CD19 CAR T therapies. As such, the company plans to add a 20-patient cohort to its ongoing Ph1/2 ALEXANDER study in H2 2020, with treatment in an outpatient setting, to confirm feasibility of design for a potential pivotal study.

Operational and Corporate Highlights:

- Whilst the COVID-19 crisis has had varying degrees of impact across the industry and on the ability of clinical sites to operate normally, current expectations remain that the impact on the company will be minimal. With regards to the newly initiated pivotal AUTO1-AL1 study, the protocol calls for a run-in phase with a small number of patients scheduled to be enrolled in Q2 2020, therefore limiting the impact from the COVID-19 situation at this stage. More broadly, the company has continued to manufacture, without interruption, from its operations at the Cell and Gene Therapy Catapult located in Stevenage, UK, including supply of clinical product for the treatment of US DLBCL patients in its AUTO3 ALEXANDER study.
- Company signed a collaboration agreement with MolMed for the development and supply of viral vectors for future commercial supply.

Key Upcoming Clinical Milestones:

- Dosing of first patient in the pivotal program, AUTO1-AL1 in adult ALL in Q2 2020.
- Additional clinical data at upcoming conferences:
 - Annual Meeting of the American Society of Clinical Oncology (ASCO): Update on the AUTO3 ALEXANDER study in DLBCL patients
 - Annual Meeting of the European Hematology Association (EHA): Update on AUTO1 ALLCAR19 study in adult ALL patients

- Additional preclinical data at the American Association for Cancer Research II (AACR II) meeting across multiple programs; AUTO5 in T-cell lymphomas, AUTO6NG and AUTO7 in solid tumors.
- Ph2 decision for AUTO3 in DLBCL mid-2020.
- Initiation of an outpatient cohort in the AUTO3 ALEXANDER study in H2 2020.
- Further updates for both AUTO1 and AUTO3 in Q4 2020.
- Interim Ph1 data for AUTO4 in T cell lymphoma in Q4 2020.
- Progression of additional next generation programs from preclinical stages to Ph1 through H2 2020 into H1 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 March 31, 2020

- Cash and equivalents at March 31, 2020 totaled \$243.3 million, compared with \$210.6 million at December 31, 2019.
- Net total operating expenses for the three months ended March 31, 2020 were \$38.6 million, net of grant income of \$0.3 million, as compared to net operating expenses of \$30.2 million, net of grant income of \$2.0 million, for the same period in 2019. The increase was due, in general, to the continued increase in clinical trial activity and project expenses, which is expected to deliver on key milestones throughout the rest of 2020; increased headcount; and an increase in public company costs.
- Research and development expenses increased to \$31.3 million for the three months ended March 31, 2020 from \$22.6 million for the three months ended March 31, 2019. Cash costs, which exclude depreciation and amortization as well as share-based compensation, increased to \$25.6 million from \$17.5 million. The increase in research and development cash costs of \$8.1 million consisted primarily of an increase of compensation-related costs of \$2.2 million due to an increase in employee headcount to support the advancement of our product candidates in clinical development, an increase of \$3.7 million in project expenses due to the advancement our clinical portfolio which includes research and process development and manufacturing activities necessary to prepare, activate, and monitor clinical trial programs, an increase of \$1.8 million in licenses, legal fees and consulting services related to an option to negotiate a future license as well as IT infrastructure and support, and other additional costs in the amount of \$0.4 million.
- General and administrative expenses decreased to \$7.6 million for the three months ended March 31, 2020 from \$9.6 million for the three months ended March 31, 2019. Cash costs, which exclude depreciation expense as well as share-based expense compensation decreased to \$5.9 million from \$6.3 million. Compensation related expenses decreased by \$0.3 million and IT, telecommunication, facility and general office expense costs decreased by \$0.3 million, and a decrease of \$0.3 million in commercial costs which were offset by an increase in public company costs of \$0.5 million primarily related to insurance premiums. Non-cash costs decreased to \$1.7 million for the three months ended March 31, 2020 from \$3.3 million for the three months ended March 31, 2019. The decrease is attributed to share-based compensation expense included in general and administrative expenses, which decreased by \$1.6 million as a result of the lower fair value of stock options recognized during the period.
- Net loss attributable to ordinary shareholders was \$29.9 million for the three months ended March 31, 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 March 31, 2020 totaled \$(0.60) compared to a basic and diluted net loss per ordinary share of \$(0.69) for the three months ended March 31, 2019.
- Company anticipates that cash on hand provides a runway into 2022.

Conference Call and Presentation Information

Autolus management will host a conference call today, May 7, 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-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 3395995. 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 3395995.

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 pre-clinical 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 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.

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

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(In thousands, except share and per share amounts)

| | Three Months Ended | |
|---|---------------------------|---------------------|
| | March 31, | |
| | 2020 | 2019 |
| Grant income | \$ 338 | \$ 1,964 |
| Operating expenses: | | |
| Research and development | (31,287 |) (22,565 |
| General and administrative | (7,614 |) (9,556 |
| Total operating expenses, net | (38,563 |) (30,157 |
| Other income (expense): | | |
| Interest income | 510 | 541 |
| Other income (expense) | 4,484 | (984 |
| Total other income, net | 4,994 | (443 |
| Net loss before income tax | (33,569 |) (30,600 |
| Income tax benefit | 3,696 | 3,421 |
| Net loss attributable to ordinary shareholders | (29,873 |) (27,179 |
| Other comprehensive loss: | | |
| Foreign currency exchange translation adjustment | (17,701 |) 5,051 |
| Total comprehensive loss | \$ (47,574 |) \$ (22,128 |
| Basic and diluted net loss per ordinary share | \$ (0.60 |) \$ (0.69 |

Weighted-average basic and diluted ordinary shares

49,859,739

39,471,029

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

| | March 31, 2020 | December 31, 2019 |
|---|---------------------------|------------------------------|
| Assets | | |
| Current assets: | | |
| Cash | \$ 243,312 | \$ 210,643 |
| Restricted cash | 786 | 787 |
| Prepaid expenses and other assets, current | 36,844 | 37,826 |
| Total current assets | 280,942 | 249,256 |
| Non-current assets: | | |
| Property and equipment, net | 29,800 | 28,164 |
| Right of use assets, net | 23,713 | 23,409 |
| Long-term deposits | 1,933 | 2,040 |
| Prepaid expenses and other assets, non-current | 652 | — |
| Deferred tax asset | 410 | 410 |
| Intangible assets, net | 214 | 254 |
| Total assets | \$ 337,664 | \$ 303,533 |
| Liabilities and shareholders' equity | | |
| Current liabilities: | | |
| Accounts payable | 1,057 | 1,075 |
| Accrued expenses and other liabilities | 22,471 | 21,398 |
| Lease liabilities | 2,523 | 2,511 |
| Total current liabilities | 26,051 | 24,984 |
| Non-current liabilities: | | |
| Lease liabilities | 24,135 | 23,710 |
| Total liabilities | 50,186 | 48,694 |
| Shareholders' equity: | | |
| Ordinary shares, \$0.000042 par value; 200,000,000 shares authorized as of March 31, 2020 and December 31, 2019; 52,247,932 and 44,983,006, shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively | 3 | 2 |
| Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at March 31, 2020 and December 31, 2019 | — | — |
| Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at March 31, 2020 and December 31, 2019 | 118 | 118 |
| Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at March 31, 2020 and December 31, 2019 | — | — |
| Additional paid-in capital | 580,772 | 500,560 |
| Accumulated other comprehensive loss | (26,392) | (8,691) |
| Accumulated deficit | (267,023) | (237,150) |
| Total shareholders' equity | 287,478 | 254,839 |
| Total liabilities and shareholders' equity | \$ 337,664 | \$ 303,533 |



Source: Autolus Therapeutics plc