Autolus Therapeutics Reports First Quarter 2022 Financial Results and Operational Progress

May 5, 2022 at 7:01 AM EDT

- Conference call to be held on May 5, 2022 at 8:30 am ET/1:30 pm BST -

LONDON, May 05, 2022 (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 quarter ended March 31, 2022.

“The momentum at Autolus has continued during the first quarter. We are delighted to note that the FELIX clinical trial of obe-cel in patients with relapsed/refractory (r/r) adult B-cell Acute Lymphoblastic Leukemia (ALL) passed its futility analysis during the period and we continue to enroll patients as planned, with initial data expected in the second half of 2022, with the full data in the first half of 2023,” said Dr. Christian Itin, Chief Executive Officer of Autolus. “obe-cel recently received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA), supporting our drive to bring this innovative therapy to patients as quickly as possible.”

“We also have updates at the European Hematology Association (EHA) Congress in early June from four Phase 1 clinical trials. Two trials are evaluating obe-cel in B-Cell Non-Hodgkin's Lymphoma (B-NHL) and primary CNS lymphoma (PCNSL). In addition, two oral presentations will cover the first clinical data for AUTO4 in TRBC1+ Peripheral T cell lymphoma (PTCL) and data for the dual targeting AUTO1/22 in pediatric ALL patients.”

Key Pipeline Updates:

- *Obecabtagene autoleucel (obe-cel) in relapsed / refractory (r/r) adult ALL*
  - During the quarter, the FELIX study passed its pre-specified futility analysis based on the results assessed by an independent response review committee. As previously guided, the morphological cohort is expected to complete enrollment in 2022 with initial data from the FELIX study expected to be reported in H2 2022 and full data in H1 2023. Assuming a positive outcome from the FELIX study, this data is expected to form the basis of a planned Biologics License Application (BLA) submission by the Company.
  - Autolus plans to evaluate a separate cohort of up to 50 additional patients with Minimal Residual Disease (MRD). The additional data aims to establish the profile of obe-cel in patients across all levels of disease burden in adult ALL.
  - In March 2022 obe-cel was granted Orphan Medical Product Designation by the European Medicines Agency (EMA) for the treatment of ALL, having previously received Orphan Drug Designation by the U.S. Food & Drug Administration (FDA) for B-ALL.

- *Obe-cel in r/r B-NHL – ALLCAR19 Extension Trial*
  - Subjects continue to be enrolled into the Phase 1 ALLCAR19 extension trial. The latest data readout from this extension study of obe-cel in patients with r/r B-Cell Non-Hodgkin's Lymphoma (B-NHL) and Chronic Lymphocytic Leukemia (CLL) were presented at ASH in December 2021. Updated data from the trial will be presented as a poster at the EHA Congress in June.

- *Obe-cel in PCNSL – CAROUSEL* Trial
  - Subjects continue to be enrolled into the Phase 1 CAROUSEL trial. Data from the trial will be presented as a poster at the EHA Congress in June.

- *AUTO1/22 in pediatric ALL – CARPALL Trial*
  - Autolus continues to enroll patients into the AUTO1/22 Phase 1 CARPALL trial. Initial clinical data from the trial will be presented as an oral presentation at the EHA Congress in June.

- *AUTO4 in Peripheral T Cell Lymphoma – LibrA T1 Trial*
  - Autolus continues to enroll patients into the AUTO4 Phase 1 clinical trial, which is progressing through its dose escalation phase. Interim Phase 1 data will be presented as an oral presentation at the EHA Congress in June.

- *AUTO6NG in Neuroblastoma*
  - Autolus plans to initiate a Phase 1 clinical trial of AUTO6NG in patients with neuroblastoma in H2 2022.

- *AUTO8 in Multiple Myeloma – MCARTY Trial*
  - During the period, Autolus initiated a Phase 1 clinical trial of AUTO8, the Company’s next-generation product candidate for multiple myeloma. AUTO8 comprises two independent CARs targeting BCMA and CD19 designed to induce deep and durable responses and extend the durability of effect.

Key Operational Updates during Q1 2022

- Effective March 31, 2022, Dr. Lucinda Crabtree was appointed as Chief Financial Officer succeeding Andrew J. Oakley upon his retirement. Dr. Crabtree served as SVP Finance prior to her promotion.
- Good progress is being made in the build phase of the Company's new 70,000 square foot commercial manufacturing facility in Stevenage, UK. This facility is expected to be ready for GMP operations by H2 2023 and is designed for a capacity of 2,000 batches a year with the option to expand.

Post Period Updates:

- On 25 April, the FDA granted Regenerative Medicine Advanced Therapy (RMAT) designation to obe-cel, in recognition of the therapy's potential to address significant unmet medical needs in patients with serious or life-threatening conditions. RMAT designation provides important benefits in the drug development process, designed to facilitate and expedite development and regulatory review. Obe-cel also received PRIME designation from EMA and ILAP from MHRA.

- On 2 May, Autolus announced the online publication of three abstracts submitted to the American Society of Gene & Cell Therapy (ASGCT) to be held May 16-19, 2022. The three abstracts focus on Autolus' modular approach to CAR T product development, using innovative technology to improve our pipeline of precise, controlled and highly active products. The three abstracts cover: 1) enhancing CAR T therapy using constitutively active cytokine receptors, 2) engineering CAR T cells to express a Fas-CD40 to increase its persistence and tumor cytotoxicity and 3) developing a minocycline mediated protein-protein displacement platform to make cell therapies tunable, dose dependent and reversible.

Key Anticipated Clinical Milestones:

- Initial clinical data from the FELIX Phase 2 trial in H2 2022 and full data in H1 2023.

- Updated Phase 1 data from the ALLCAR19 extension trial in patients with r/r B-NHL and CLL presented as a poster at the EHA Congress in June 2022.

- Updates on the obe-cel Phase 1 CAROUSEL trial in Primary CNS Lymphoma presented as a poster at the EHA Congress in June 2022.

- Initial clinical data from the AUTO1/22 CARPALL extension trial in pediatric ALL presented as an oral presentation at the EHA Congress in June 2022, with longer follow up in H2 2022.

- Initial clinical data from AUTO4 LibraT1 Phase 1 trial in TRBC1+ Peripheral TCL presented as an oral presentation at the EHA Congress in June 2022.

- AUTO6NG Phase 1 clinical trial in neuroblastoma expected to start in H2 2022. Expect first data in H2 2023.

- AUTO8 Phase 1 clinical trial in patients with multiple myeloma has started, expect first data in H2 2023.

Financial Results for the Quarter Ended March 31, 2022

Cash at March 31, 2022, totaled $268.6 million, as compared to $310.3 million at December 31, 2021.

Total operating expenses, net of grant income of $0.2 million, for the three months ended March 31, 2022, were $41.8 million, as compared to total operating expenses, net of grant income of $0.3 million, of $39.9 million for the same period in 2021.

Grant income decreased by $0.1 million to $0.2 million for the three months ended March 31, 2022, as compared to $0.3 million for the same period in the prior year. The decrease is due to a corresponding decrease in reimbursable expenditures.

Research and development expenses increased to $34.0 million for the three months ended March 31, 2022, as compared to $30.7 million for the three months ended March 31, 2021. Cash costs decreased to $30.6 million from $30.7 million. The decrease in research and development cash costs of $0.1 million consisted primarily of (i) $2.8 million decrease in compensation and employment related costs which was due to a combination of lower retention, severance payments and timing and salary mix of new employee hires, (ii) $0.9 million decrease in facilities costs related to the termination and exit of the Company's US manufacturing facility in 2021 and shift in its manufacturing strategy, and (iii) $0.2 million in research and development costs related to cell logistics.

This was offset by an increase of (i) $2.9 million in clinical costs and manufacturing costs primarily relating to the Company's obe-cel clinical product candidate, (ii) $0.8 million increase in legal fees and professional consulting fees in relation to our research and development activities, and (iii) $0.1 million increase related to information technology infrastructure and support for information systems related to the conduct of clinical trials and manufacturing operations.

Non-cash costs increased to $3.4 million for the three months ended March 31, 2022 from $36,000 for the three months ended March 31, 2021. The increase is primarily attributable to an increase of $3.1 million in share-based compensation expense included in research and development expenses as a result of retention of employees post the reduction of workforce that was implemented during the three months ended March 31, 2021. In addition,

depreciation and amortization expense increased by $0.3 million.

General and administrative expenses decreased by $0.7 million to $8.0 million for the three months ended March 31, 2022, from $8.7 million for the three months ended March 31, 2021. Cash costs, which exclude depreciation and amortization as wells as share-based compensation decreased to $7.0 million from $7.6 million. The decrease in general and administrative cash costs of $0.6 million related to decreases of (i) $0.5 million in facilities costs related to the termination and exit of the Company's lease agreements in the prior year, (ii) $0.4 million of commercial preparation costs due to the timing of related activities and (iii) $0.3 million associated with compensation expense due to fewer contracted staff. These decreases were offset by increases of $0.5 million primarily related to higher directors' and officers' liability insurance premiums and professional fees in relation to business development opportunities and $0.1 million in costs related to information technology infrastructure and support for information systems.

Non-cash costs decreased by $0.1 million to $1.0 million for the three months ended March 31, 2022 from $1.1 million for the three months ended March 31, 2021. The decrease of $0.1 million primarily related to a decrease in depreciation and amortization expense.

There were no disposals of leasehold improvements for the three month period ended March 31, 2022. For the three months ended March 31, 2021, the Company incurred a loss on disposal of leasehold improvements of $0.7 million related to the leasehold improvements no longer being utilized in its facility in White City, London.

Other income, net for the three months ended March 31, 2022, was consistent with the three months ended March 31, 2021. During the three months ended March 31, 2022 there was a strengthening of the U.S. dollar exchange rate relative to the pound sterling resulting in a foreign exchange gain of $0.8 million. This compares to the three months ended March 31, 2021 where there was a gain on lease terminations of $2.0 million offset by other expenses of $1.2 million related to a foreign exchange loss.

Interest expense increased to $1.8 million for the three months ended March 31, 2022 and relates to the liability related to sales of future royalties and sales milestones which arose upon entering into the Blackstone Strategic Collaboration and Financing Agreement with BXLS V - Autobahn L.P., in November 2021. There was no interest expense during the comparable period in 2021.

Income tax benefit decreased by $0.1 million to $5.6 million for the three months ended March 31, 2022 from $5.7 million for the three months ended March 31, 2021 due to a decrease in the research and development expenditures which were qualifying for the quarter. As research and development credits fell at a faster rate than the Company's net loss before income tax, this led to a lower effective tax rate.

Net loss attributable to ordinary shareholders was $37.1 million for the three months ended March 31, 2022, compared to $33.3 million for the same period in 2021. The basic and diluted net loss per ordinary share for the three months ended March 31, 2022, totaled $(0.41) compared to a basic and diluted net loss per ordinary share of $(0.53) for the three months ended March 31, 2021.

Autolus estimates that its current cash on hand and anticipated milestone payments from Blackstone extends the Company's runway into 2024.

Unaudited Financial Results for the Quarter Ended March 31, 2022

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash	$ 268,558	$ 310,338
Restricted cash	334	338
Prepaid expenses and other assets, current	40,571	36,276
Total current assets	309,463	346,952
Property and equipment, net	31,017	33,541
Prepaid expenses and other non-current assets	2,119	2,362
Operating lease right-of-use assets	17,366	18,775
Long-term deposits	1,983	2,039
Deferred tax asset	2,000	1,826
Intangible assets, net	46	65
Total assets	$ 363,994	$ 405,560
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 153	$ 431
Accrued expenses and other liabilities	24,513	23,667
Operating lease liabilities	4,174	4,453
Total current liabilities	28,840	28,551
Operating lease liabilities, net of current portion	15,081	16,545
Liability related to sale of future royalty and sales milestones, net	48,806	47,016
Other long-term payables	124	128
Total liabilities	92,851	92,240
Commitments and contingencies (Note 11)		
Shareholders' equity:		

Ordinary shares, $0.000042 par value; 200,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 90,907,941 and 90,907,830, shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	4	4
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at March 31, 2022 and December 31, 2021	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Additional paid-in capital	845,448	843,108
Accumulated other comprehensive loss	(16,025)	(8,570)
Accumulated deficit	(558,402)	(521,340)
Total shareholders' equity	271,143	313,320
Total liabilities and shareholders' equity	$ 363,994	$ 405,560

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

	Three Months Ended March 31,	
	2022	**2021**
Grant income	$ 166	$ 269
Operating expenses:		
Research and development	(33,963)	(30,731)
General and administrative	(7,987)	(8,738)
Loss on disposal of leasehold improvements	—	(672)
Total operating expenses, net	(41,784)	(39,872)
Other income (expense):		
Interest income	28	44
Other income, net	860	838
Interest expense	(1,790)	—
Total other (expense) income, net	(902)	882
Net loss before income tax	(42,686)	(38,990)
Income tax benefit	5,624	5,724
Net loss attributable to ordinary shareholders	(37,062)	(33,266)
Other comprehensive (loss) income:		
Foreign currency exchange translation adjustment	(7,455)	1,273
Total comprehensive loss	$ (44,517)	$ (31,993)
Basic and diluted net loss per ordinary share	$ (0.41)	$ (0.53)
Weighted-average basic and diluted ordinary shares	90,914,175	62,447,606

Conference Call

Management will host a conference call and webcast today at 8:30 am ET/1:30 pm BST 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 the events section of Autolus' website.

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: 3245616. 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: 3245616.

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.

About obe-cel (AUTO1)
Obe-cel is a CD19 CAR T cell investigational therapy designed to overcome the limitations in clinical activity and safety compared to current CD19 CAR T cell therapies. Designed to have a fast target binding off-rate to minimize excessive activation of the programmed T cells, obe-cel may reduce toxicity and be less prone to T cell exhaustion, which could enhance persistence and improve the ability of the programmed T cells to engage in serial killing of target cancer cells. In collaboration with Autolus' academic partner, UCL, obe-cel is currently being evaluated in a Phase 1 clinical trials for B-NHL. Autolus has progressed obe-cel to the FELIX trial, a potential pivotal trial for adult ALL.

About obe-cel FELIX clinical trial
Autolus' Phase 1b/2 clinical trial of obe-cel is enrolling adult patients with relapsed / refractory B-precursor ALL. The trial had a Phase 1b component prior to proceeding to the single arm, Phase 2 clinical trial. The primary endpoint is overall response rate, and the secondary endpoints include duration of response, MRD negative CR rate and safety. The trial is designed to enroll approximately 100 patients across 30 of the leading academic and non-academic centers in the United States, United Kingdom and Europe. [NCT04404660]

About AUTO1/22
AUTO1/22 is a novel dual targeting CAR T cell based therapy candidate based on obe-cel. It is designed to combine the enhanced safety, robust expansion & persistence seen with the fast off rate CD19 CAR from obe-cel with a high sensitivity CD22 CAR to reduce antigen negative relapses. This product candidate is currently in a Phase 1 clinical trial for patients with r/r pediatric ALL. [NCT02443831]

About AUTO4
AUTO4 is a programmed T cell product candidate in clinical development for T cell lymphoma, a setting where there are currently no approved programmed T cell therapies. AUTO4 is specifically designed to target TRBC1 derived cancers, which account for approximately 40% of T cell lymphomas, and is a complement to the AUTO5 T cell product candidate, which is in pre-clinical development.

About AUTO5
AUTO5 is a programmed T cell product candidate in pre-clinical development for T cell lymphoma, a setting where there are currently no approved programmed T cell therapies. AUTO5 is specifically designed to target TRBC2 derived cancers, which account for approximately 60% of T cell lymphomas, and is a complement to the AUTO4 T cell product candidate currently in clinical development.

About AUTO6NG
AUTO6NG is a next generation programmed T cell product candidate in pre-clinical development. AUTO6NG builds on preliminary proof of concept data from AUTO6, a CAR targeting GD2-expression cancer cell currently in clinical development for the treatment of neuroblastoma. AUTO6NG incorporates additional cell programming modules to overcome immune suppressive defense mechanisms in the tumor microenvironment, in addition to endowing the CAR T cells with extended persistence capacity. AUTO6NG is currently in pre-clinical development for the potential treatment of both neuroblastoma and other GD2-expressing solid tumors.

About AUTO8
AUTO8 is our next-generation product candidate for multiple myeloma which comprises two independent CARs for the multiple myeloma targets, BCMA and CD19. We have developed an optimized BCMA CAR which is designed for improved killing of target cell that expresses BCMA at low levels. This has been combined with fast off rate CD19 CAR from obe-cel. We believe that the design of AUTO8 has the potential to induce deep and durable responses and extend the durability of effect over other BCMA CARs currently in development.

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 development of Autolus' product candidate pipeline and achievement of expected near- and long-term milestones; the development of the obe-cel program including planned readouts after the completed futility analysis and completion of patient enrollment; the future clinical development, efficacy, safety and therapeutic potential of its other product candidates such as AUTO1/22, AUTO4. AUTO5, AUTO6NG, and AUTO8, including progress, expectations as to the reporting of data, conduct and timing and potential future clinical activity and milestones; expectations regarding regulatory approval process for any product candidates; Autolus' eligibility for potential milestone and royalty payments, and the Company's anticipated cash runway. 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 10, 2022, 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 Autolus 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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