Autolus Therapeutics Reports Second Quarter 2022 Financial Results and Operational Progress

August 4, 2022 at 7:01 AM EDT

- Conference call to be held on August 4, 2022 at 8:30 am ET/1:30 pm BST -

LONDON, Aug. 04, 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 second quarter ended June 30, 2022.

“Autolus has had a successful second quarter, with progress made across all fronts. We were awarded Regenerative Medicine Advanced Therapy (RMAT) Designation for obecabtagene autoleucel (obe-cel) for the treatment of adult acute lymphoblastic leukemia (ALL) by the US Food and Drug Administration (FDA) in April 2022, showcased cell programming technology at the American Society of Gene and Cell Therapy (ASGCT) meeting in May 2022, and announced first clinical data from four pipeline programs at the European Hematology Association (EHA) congress in June 2022. During this time, we also continued to progress the pivotal Phase 2 FELIX clinical trial of obe-cel in r/r ALL, and the build of our commercial manufacturing site is progressing on schedule,” **said Dr. Christian Itin, CEO of Autolus.** “Obe-cel continues to show very encouraging activity with a high level of sustained complete remissions in B-NHL patients, without inducing severe CRS or neurotoxicity, and AUTO1/22 reached clinical proof of concept with a high level of activity observed in children with ALL who are not eligible for commercial CAR T therapy. We are particularly excited about AUTO4 reaching clinical proof of concept in patients with T cell lymphoma. We are looking forward to releasing initial results for the FELIX trial in Q4 2022 and are planning updates on our other clinical studies at the end of the year.”

Key Pipeline Updates:

- *Obecabtagene autoleucel (obe-cel) in relapsed / refractory (r/r) adult ALL*
  - The FELIX Phase 2 trial continues to progress well, and Autolus is on track to report initial results from the trial in Q4 2022. The Company continues to expect to report full data in H1 2023, with plans to present this data at a medical conference in mid-2023.
  - Following the RMAT designation granted to obe-cel in April 2022 by FDA, Autolus met with the FDA to review the regulatory pathway for obe-cel in r/r ALL. Consistent with prior guidance, and assuming a positive outcome from the FELIX trial in H1 2023, the Company expects the data to form the basis of a planned Biologics License Application (BLA) submission to FDA.
  - As previously announced, Autolus initiated a separate cohort of up to 50 additional patients with Minimal Residual Disease (MRD), with the intention of establishing the profile of obe-cel in patients across all levels of disease burden in adult ALL.

Pipeline updates at the European Hematology Congress (EHA), June 2022:

- *Obe-cel shows high level of sustained clinical activity in r/r B-NHL patients – ALLCAR19 Extension Trial*
  - Patients 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 EHA in June 2022. In this patient population, obe-cel continues to display a favorable safety profile with no neurotoxicity/immune effector cell-associated neurotoxicity (ICANS) or Grade ≥ 3 Cytokine Release Syndrome (CRS). Long term persistence of obe-cel in the peripheral blood was demonstrated by qPCR. Of the 20 patients evaluable for efficacy, the overall response rate was 18/20 (90%). In the B-NHL cohorts the CRR was 16/17 (94%) (FL: 7/7, MCL: 3/3, DBCL: 6/7). In the CLL cohort 2/3 patients achieved a PR, notably both achieved MRD-negativity in their marrow and both remain in PR at 10 and 6 months respectively. Of the responding MCL, DLBCL, FL and CLL patients, 17/18 (94%) are without disease progression at last follow-up. One MCL patient relapsed six months following treatment and 1 FL patient died in CR from COVID-19. Longer follow-up and enrolment of additional MCL, FL, DLBCL and CLL patients is ongoing.

- *Obe-cel shows first activity in Primary CNS Lymphoma – CAROUSEL Trial*
  - Patients continue to be enrolled into the Phase 1 CAROUSEL trial. Data from the trial were presented at EHA in June 2022, where excellent expansion was observed in the peripheral blood by qPCR, with persistence in all treated patients at last follow-up. No Grade 3 or higher CRS was observed using IV or I-VEN AUTO1 administration. Two cases of Grade 3 ICANS were reported following IV infusion. In the first case the patient had several neurological deficits that evolved despite ICANS treatment and were compatible with progressive PCNSL, as confirmed with the month 1 MRI scan. The second case was a patient whose neurological deficits improved with steroids/anakinra. Encouraging response rates were observed: of 6 patients evaluable for efficacy following IV AUTO1, the ORR was 4/6 (67%), with 2 CRs and 2 PRs. These four responding patients are without disease

progression at last follow up. Two patients died from progressive PCNSL on study.

- *AUTO1/22 in pediatric ALL demonstrates encouraging and durable responses in children ineligible for commercial CAR T product – CARPALL Trial*
  - Autolus, in collaboration with UCL, continues to enroll patients into the AUTO1/22 Phase 1 CARPALL trial. The results from 11 treated patients, who were ineligible for receiving commercial CAR T therapy, were presented in an oral presentation at EHA in June 2022. AUTO1/22 has demonstrated a favorable safety profile with no incidences of severe CRS, and one Grade 4 ICANS which was indistinguishable from chemotherapy-related leukoencephalopathy. We have seen excellent CAR T expansion, with only 4 patients losing CAR T persistence at the last follow up. Overall, 9 out of 11 patients achieved a molecular complete response, with 2 non-responders. Notably, 2 out of 3 patients with CD19-negative disease achieved molecular complete response demonstrating the efficacy of the CD22 CAR. Two patients relapsed with CD19+CD22+ disease. No antigen negative relapses were seen in responding patients. At a median follow up of 8.7 months, 6 of 9 responding patients were in MRD-negative complete remission (1-12 months) and the median duration of B-cell aplasia has not been reached.

- *AUTO4 shows high level of clinical activity with a novel targeting approach for patients with T Cell Lymphoma – LibrA T1 Trial*
  - Autolus continues to enroll patients into the AUTO4 Phase 1 clinical trial. Interim Phase 1 data were presented as an oral presentation at EHA in June 2022 from 10 patients with TRBC1-positive r/r T-cell lymphoma (Peripheral T-cell lymphoma Not Otherwise Specified (PTCL-NOS), Angioimmunoblastic T-cell lymphoma (AITL), Anaplastic Large cell lymphoma (ALCL)) in a Phase 1 dose escalation trial. The median prior lines of treatment was 3 (1-5) and three patients had prior stem cell transplantation. After lymphodepletion with Flu/Cy, patients received either 25, 75, 225 or 450 x 10^6 CAR T cells. AUTO4 demonstrated a tolerable safety profile, with no patient experiencing any dose limiting toxicities, and no ICANS and no Grade 3 or higher infections. CRS was only seen at the highest dose level of 450 x 10^6 CAR T cells (Grade 3 in 1 patient; Grade 1-2 in 3 patients). As of April 26, 2022, 9 patients were evaluable for efficacy. At the highest dose level 3 of the 3 patients dosed achieved a complete metabolic remission (CMR) at 1 month. 2 of these patients remain in ongoing CMR by PET-CT at Month 3 and 6 respectively, whilst the 3rd relapsed at 3 months.

Other pipeline updates:

- *AUTO8 in Multiple Myeloma – MCARTY Trial*
  - Autolus, in collaboration with UCL, initiated a Phase 1 clinical trial of AUTO8, the Company's next-generation product candidate for multiple myeloma, in Q1 2022, with the first patient dosed during the quarter. AUTO8 comprises two independent CARs targeting BCMA and CD19 designed to induce deep and durable responses and extend the durability of effect.

- Autolus presented three abstracts at the American Society of Gene & Cell Therapy (ASGCT) meeting in May 2022. The three abstracts focused 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 covered: 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 Operational Updates during Q2 2022

- The build phase of the Company's new 70,000 square foot commercial manufacturing facility in Stevenage, UK continues to progress on track with the anticipated schedule. This facility is expected to be ready for Good Manufacturing Practice (GMP) operations by H2 2023 and is designed for a capacity of 2,000 batches per year with the option to expand capacity as needed.

Key Anticipated Clinical Milestones:

- Initial clinical results from the pivotal FELIX Phase 2 trial in Q4 2022 and Autolus plans to present full data at a medical meeting in H1 2023.

- Longer-term follow up data from Phase 1 ALLCAR19 extension trial of obe-cel in patients with r/r B-NHL and CLL planned in H2 2022.

- Longer-term follow up data from Phase 1 CAROUSEL trial of obe-cel in patients with Primary CNS Lymphoma planned in 2023.

- Longer-term follow up data from the Phase 1 CARPALL extension trial of AUTO1/22 in pediatric ALL patients planned in H2 2022.

- Longer-term follow up data from Phase 1 LibrA T1 trial of AUTO4 in patients with Peripheral T Cell Lymphoma planned in H2 2022.

- AUTO6NG Phase 1 clinical trial in patients with neuroblastoma expected to start H2 2022. First data is expected in H2 2023.

- AUTO8 Phase 1 MCARTY clinical trial in patients with multiple myeloma has started, with the first patient dosed. First data is expected in H2 2023.

Financial Results for the Quarter Ended June 30, 2022

Cash at June 30, 2022, totaled $216.4 million, as compared to cash of $310.3 million at December 31, 2021.

Total operating expenses for the three months ended June 30, 2022, were $46.5 million, as compared to total operating expenses, net of grant income and license revenue of $1.6 million, of $37.7 million for the same period in 2021.

Research and development expenses increased by $6.1 million to $38.2 million from $32.1 million for the three months ended June 30, 2022 as compared to the same period in 2021. The net increase in research and development expenses of $6.1 million was primarily due to:

- an increase of $3.5 million in clinical costs and manufacturing costs primarily relating to the obe-cel clinical product candidate,

- an increase of $1.4 million in salaries and other employment related costs including share-based compensation expense, which is mainly driven by an increase in the number of employees engaged in research and development activities,

- an increase of $1.4 million in legal fees and professional consulting fees in relation to the Company's research and development activities,

- an increase of $0.5 million related to information technology infrastructure and support for information systems related to the conduct of clinical trials and manufacturing operations,

- a decrease of $0.5 million in facilities costs related to the termination and closure of the Company's US manufacturing facility in 2021 and shift in its manufacturing strategy, and

- a decrease of $0.2 million in depreciation and amortization related to property, plant and equipment and intangible assets.

General and administrative expenses increased by $1.1 million to $8.3 million for the three months ended June 30, 2022 from $7.2 million for the three months ended June 30, 2021 primarily due to:

- an increase of $1.3 million in salaries and other employment related costs including share-based compensation expenses, which was mainly driven by an increase in the number of employees engaged in general and administrative activities,

- an increase of $0.1 million primarily related to higher directors' and officers' liability insurance premiums, professional fees and information technology costs,

- a decrease of $0.2 million in facilities costs related to the termination by the Company of certain lease agreements in the prior year, and

- a decrease of $0.1 million in depreciation and amortization related to property, plant and equipment and intangible assets.

Other expense, net decreased by $0.5 million to $1.3 million for the three months ended June 30, 2022 from $1.8 million for the three months ended June 30, 2021, relating primarily due to the strengthening of the U.S. dollar exchange rate relative to the pound sterling.

Interest expense increased to $1.8 million for the three months ended June 30, 2022 and relates to the liability related to sales of future royalties and sales milestones which arose upon the Company's entry into the strategic collaboration and financing agreement with Blackstone, in November 2021. There was no interest expense during the comparable period in 2021.

Income tax benefit increased by $1.1 million to $7.5 million for the three months ended June 30, 2022 from $6.4 million for the three months ended June 30, 2021 due to an increase in qualifying research and development expenditures for the quarter.

Net loss attributable to ordinary shareholders was $42.1 million for the three months ended June 30, 2022, as compared to $33.2 million for the same period in 2021. The basic and diluted net loss per ordinary share for the three months ended June 30, 2022, totaled $(0.46) compared to a basic and diluted net loss per ordinary share of $(0.47) for the three months ended June 30, 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 June 30, 2022

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash	$ 216,437	$ 310,338
Restricted cash	325	338
Prepaid expenses and other assets, current	42,198	36,276
Total current assets	**258,960**	**346,952**
Property and equipment, net	33,794	33,541
Prepaid expenses and other non-current assets	1,888	2,362
Operating lease right-of-use assets	15,230	18,775
Long-term deposits	1,835	2,039
Deferred tax asset	2,244	1,826
Intangible assets, net	25	65
Total assets	**$ 313,976**	**$ 405,560**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 162	$ 431
Accrued expenses and other liabilities	31,360	23,667
Operating lease liabilities	3,995	4,453
Total current liabilities	**35,517**	**28,551**
Operating lease liabilities, net of current portion	13,208	16,545
Liability related to sale of future royalties and sales milestones, net	50,615	47,016
Other long-term payables	115	128
Total liabilities	**99,455**	**92,240**
Commitments and contingencies (Note 12)		
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 290,909,783 and 200,000,000 shares authorized as of June 30, 2022 and December 31, 2021, respectively; 90,909,783 and 90,907,830, shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	4	4
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at June 30, 2022 and December 31, 2021	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	848,370	843,108
Accumulated other comprehensive loss	(33,510)	(8,570)
Accumulated deficit	(600,461)	(521,340)
Total shareholders' equity	**214,521**	**313,320**
Total liabilities and shareholders' equity	**$ 313,976**	**$ 405,560**

Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Grant income	$ —	$ 138	$ 166	$ 407
License revenue	—	1,507	—	1,507
Operating expenses:				
Research and development	(38,212)	(32,131)	(72,175)	(62,862)
General and administrative	(8,269)	(7,237)	(16,256)	(15,975)
Loss on disposal of leasehold improvements	—	—	—	(672)
Total operating expenses, net	**(46,481)**	**(37,723)**	**(88,265)**	**(77,595)**
Other (expense) income:				

Other expense, net	(1,331)	(1,849)	(471)	(1,011)
Interest income	89	42	117	85
Interest expense	(1,810)	—	(3,599)	—
Total other (expense) income, net	**(3,052)**	**(1,807)**	**(3,953)**	**(926)**
Net loss before income tax	**(49,533)**	**(39,530)**	**(92,218)**	**(78,521)**
Income tax benefit	7,474	6,357	13,098	12,081
Net loss attributable to ordinary shareholders	**(42,059)**	**(33,173)**	**(79,120)**	**(66,440)**
Other comprehensive (loss) income:				
Foreign currency exchange translation adjustment	(17,485)	1,542	(24,941)	2,815
Total comprehensive loss	**$ (59,544)**	**$ (31,631)**	**$ (104,061)**	**$ (63,625)**
Basic and diluted net loss per ordinary share	$ (0.46)	$ (0.47)	$ (0.87)	$ (1.00)
Weighted-average basic and diluted ordinary shares	90,931,964	70,832,077	90,923,119	66,663,003

Conference Call
Management will host a conference call and webcast at 8:30 am ET/1:30 pm BST to discuss the Company's financial results and provide a general business update. Conference call participants should pre-register using this link to receive the dial-in numbers and a personal PIN, which are required to access the conference call. The conference call system has changed, so please make sure you dial in 15 minutes before to ensure timely access to the call.

A simultaneous audio webcast and replay will be accessible on the events section of Autolus' website.

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 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 express 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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