Autolus Therapeutics Reports Second Quarter 2024 Financial Results and Business Updates

August 8, 2024 at 7:00 AM EDT

- *On track for potential US commercial launch of obe-cel; PDUFA date November 16, 2024*
- *Longer follow up and subset analyses from pivotal FELIX Phase 2 data presented at ASCO and EHA; majority of responders showed durable responses; 40% of patients in ongoing remission without subsequent stem cell transplant (SCT) or other intervention*
- *A Market Authorization Application (MAA) for obe-cel in relapsed/refractory r/r adult B-cell Acute Lymphoblastic Leukemia (B-ALL) was submitted to the Medicine and Healthcare products Regulatory Authority (MHRA) in the UK at the end of July 2024. The MAA review process continues with the European Medicines Agency (EMA)*
- *Conference call to be held today at 08:30 am EDT/13:30 pm BST: conference call participants should pre-register using the link at the bottom of this press release*

LONDON, Aug. 08, 2024 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces its financial results for the second quarter ended June 30, 2024, and provides additional operation and clinical updates.

"We are focused on driving commercial readiness activities across Autolus to bring our lead product obecabtagene autoleucel (obe-cel) to adult B-ALL patients. Applications for marketing authorizations are under review by regulatory agencies in the US, Europe and UK, and we are working towards a US Food and Drug Administration (FDA) PDUFA target date of November 16, 2024," **said Dr. Christian Itin, Chief Executive Officer of Autolus.** "Data from the FELIX Phase 1b/2 study with a median follow up of 21 months presented at ASCO and EHA indicate a long-term plateau forming in event-free and overall survival rates. Stem cell transplant post obe-cel did not appear to improve patient outcomes, and patients with long-term persisting obe-cel appear to have improved event free survival. The data support the potential for obe-cel as a stand-alone therapy in a portion of r/r adult ALL patients."

Key obe-cel updates and anticipated milestones:

- *Obe-cel in r/r adult B-ALL – The FELIX Study*
  - In the UK, an MAA was submitted to the MHRA at the end of July 2024. The Biologics License Application (BLA) is on track with the FDA, working towards a Prescription Drug User Fee Act (PDUFA) target action date of November 16, 2024. An MAA submitted to EMA was accepted in April 2024.
  - Pooled analysis of the FELIX Phase 1b/2 study were presented at the American Society of Oncology (ASCO) and European Hematology Association (EHA) annual meetings in June 2024, with a median follow-up of 21 months. Data showed stabilization of event-free survival and overall survival following treatment with obe-cel, with 40% of patients in ongoing remission. Of the 99 responders following treatment with obe-cel, 18 received a subsequent stem cell transplant (SCT) while in minimal residual disease (MRD)-negative response but did not show improved survival compared to patients who did not have a subsequent SCT. Patients with prolonged obe-cel persistence experienced improved event-free survival and data indicate that bridging of high tumor burden patients with inotuzumab could be effective at reducing tumor burden, cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) without increasing liver toxicity.
- *Obe-cel in B-cell mediated autoimmune diseases*
  - The Phase 1 dose confirmation study (CARLYSLE) in refractory systemic lupus erythematosus (SLE) patients is ongoing. Autolus continues to expect initial clinical data in late 2024.
- *Pipeline programs in collaboration with University College London*
  - Clinical programs AUTO8, AUTO6NG and AUTO1/22 are progressing well and we are planning data updates for all programs in 2025.

Operational Updates:

- During the quarter, Autolus promoted the following individuals to Senior Vice President: Andrea Braun, Regulatory Affairs; Markus Gruell, Corporate Quality; Claudia Mercedes Mayer, Manufacturing Strategy and Technology; Chris Gray, Technical Operations and Facilities and Dilip Patel, Market Access and Pricing Strategy. These individuals bring significant leadership experience and continue to drive Autolus' regulatory activities and preparation for the potential commercialization and launch of obe-cel.
- In April 2024, Autolus announced that the EMA had accepted its MAA for obe-cel for patients with r/r adult B-ALL.

- In April 2024, Autolus entered into a distribution services agreement with a subsidiary of Cardinal Health to support the ordering and distribution of obe-cel in the United States, if it receives regulatory approval.
- In April 2024, Autolus announced the appointment of Mike Bonney as Chairman of the Board, and Ravi Rao M.D. as Non-Executive Director. John H. Johnson stepped down from his roles as Chairman of the Board and Non-Executive Director, effective April 1, 2024.

2024 Expected News Flow:

Obe-cel U.S. FDA PDUFA target action date	November 16, 2024
Obe-cel FELIX data at American Society of Hematology (ASH) meeting	December 2024
Obe-cel in autoimmune disease – initial data from SLE Phase 1 study	Late 2024

Financial Results (Unaudited) for the Quarter Ended June 30, 2024

Cash and cash equivalents at June 30, 2024 totaled $705.9 million, as compared to $239.6 million at December 31, 2023.

Total operating expenses, net for the three months ended June 30, 2024 were $58.9 million, as compared to $44.4 million for the same period in 2023.

Research and development expenses increased from $33.2 million to $36.6 million for the three months ended June 30, 2024, compared to the same period in 2023. This change was primarily due to increases in operating costs related to our new manufacturing facility, employee salaries and related costs, and clinical trial and manufacturing costs related to obe-cel, partially offset by an increase in our U.K. reimbursable R&D tax credits that reduce R&D expense.

General and administrative expenses increased from $11.1 million to $21.9 million for the three months ended June 30, 2024, compared to the same period in 2023. This increase was primarily due to salaries and other employment-related costs driven by increased headcount supporting pre-commercialization activities.

Net loss was $58.3 million for the three months June 30, 2024, compared to $45.6 million for the same period in 2023. Basic and diluted net loss per ordinary share for the three months ended June 30, 2024, totaled $(0.22), compared to basic and diluted net loss per ordinary share of $(0.26) for the same period in 2023.

Autolus estimates that, with its current cash and cash equivalents, it is well capitalized to drive the full launch and commercialization of obe-cel in r/r adult B-ALL as well as to advance its pipeline development plans, which includes providing runway to data in the first pivotal study of obe-cel in autoimmune disease.

Financial Results for the Quarter Ended June 30, 2024
Selected Unaudited Condensed Consolidated Balance Sheet Data
(In thousands)

	June 30 2024	December 31 2023
Assets		
Cash and cash equivalents	$ 705,939	$ 239,566
Total current assets	$ 758,600	$ 275,302
Total assets	$ 853,620	$ 375,381
Liabilities and shareholders' equity		
Total current liabilities	$ 40,904	$ 44,737
Total liabilities	$ 325,776	$ 263,907
Total shareholders' equity	$ 527,844	$ 111,474

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
License revenue	$ —	$ —	$ 10,091	$ 1,292
Operating expenses:				
Research and development	(36,612)	(33,232)	(67,283)	(60,620)
General and administrative	(21,903)	(11,122)	(40,080)	(20,406)
Loss on disposal of property and equipment	—	(23)	—	(3,791)
Impairment of operating lease right-of-use assets and related property and equipment	(414)	—	(414)	—
Total operating expenses, net	**(58,929)**	**(44,377)**	**(97,686)**	**(83,525)**

Total other income (expense), net	**708**	**(1,135)**	**(13,233)**	**(1,812)**
Net loss before income tax	**(58,221)**	**(45,512)**	**(110,919)**	**(85,337)**
Income tax expense	(51)	(40)	(43)	(26)
Net loss	**(58,272)**	**(45,552)**	**(110,962)**	**(85,363)**
Other comprehensive income (loss):				
Foreign currency exchange translation adjustment	1,026	5,300	1,084	10,941
Total comprehensive loss	**$ (57,246)**	**$ (40,252)**	**$ (109,878)**	**$ (74,422)**
Basic and diluted net loss per ordinary share	$ (0.22)	$ (0.26)	$ (0.43)	$ (0.49)
Weighted-average basic and diluted ordinary shares	266,025,783	173,860,491	255,131,873	173,843,249

Conference Call
Management will host a conference call and webcast at 08:30 am EDT/13:30 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.

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 and autoimmune disease. Using a broad suite of proprietary and modular T cell programming technologies, Autolus is engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognize target 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, solid tumors and autoimmune diseases. For more information, please visit www.autolus.com

About obe-cel (AUTO1)
Obecabatagene autoleucel (obe-cel) is a B-lymphocyte antigen CD19 (CD19) chimeric antigen receptor (CAR) T cell investigational therapy designed to overcome the limitations in clinical activity and safety compared to current CD19 CAR T cell therapies. Obe-cel is designed with a fast target binding off-rate to minimize excessive activation of the programmed T cells. In clinical trials of obe-cel, this "fast off-rate" profile reduced toxicity and T cell exhaustion, resulting in improved persistence and leading to high levels of durable remissions in relapsed/refractory (r/r) Adult B-cell Acute Lymphoblastic Leukemia (B-ALL) patients. The results of the FELIX trial, a pivotal trial for adult B-ALL, have been submitted and accepted by the FDA with a PDUFA target action date of November 16, 2024. In the EU a regulatory submission to the EMA was accepted in April 2024, while in the UK, an MAA was submitted to MHRA in July 2024. In collaboration with Autolus' academic partner, University College London, obe-cel is currently being evaluated in a Phase 1 clinical trial for B-cell non-Hodgkin lymphoma (B-NHL).

About obe-cel FELIX clinical trial
Autolus' Phase 1b/2 clinical trial of obe-cel enrolled adult patients with r/r B-precursor ALL. The trial had a Phase 1b component prior to proceeding to the single arm, Phase 2 clinical trial. The primary endpoint was overall response rate, and the secondary endpoints included duration of response, MRD negative complete remission rate and safety. The trial enrolled over 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 and 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 AUTO6NG
AUTO6NG is a next generation programmed T cell product candidate in development for the treatment of both neuroblastoma and other GD2-expressing solid tumors. 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. A Phase 1 clinical trial of AUTO6NG in children with relapsed/refractory neuroblastoma was opened for enrollment in the fourth quarter of 2023.

About AUTO8
AUTO8 is a next-generation product candidate for multiple myeloma which comprises two independent CARs for the multiple myeloma targets, B-cell maturation antigen (BCMA) and CD19. We have developed an optimized BCMA CAR designed for improved killing of target cells that express BCMA at low levels. This has been combined with fast off rate CD19 CAR from obe-cel, with the aim of inducing deep and durable responses and extending the durability of effect over other BCMA CARs currently in development. This product candidate is currently in a Phase I clinical trial for patients with r/r multiple myeloma. [NCT04795882]

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' development and commercialization of its product candidates, timing of data announcements and regulatory submissions, its cash resources and the market opportunity for obe-cel. 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; and possible safety and efficacy concerns. 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 10-K filed with the Securities and Exchange Commission, or the SEC, on March 21, 2024 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. You should, therefore, not rely on these forward-looking statements as representing Autolus' views as of any date subsequent to the date of this press release.

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