Autolus Therapeutics Reports Third Quarter 2024 Financial Results and Business Updates

November 12, 2024 at 7:00 AM EST

- *AUCATZYL® (obecabtagene autoleucel) approved by US FDA on November 8, ahead of target PDUFA date of November 16; US commercial launch initiated*
- *BLA approval triggers $30m milestone payment to Autolus from Blackstone*
- *Marketing authorizations for obe-cel under review with both the MHRA EMA*
- *Matthias Will M.D. appointed as Chief Development Officer, effective September 30, 2024*
- *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, Nov. 12, 2024 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), an early commercial-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces its financial results for the third quarter ended September 30, 2024, and provides additional operational and clinical updates.

"With the U.S. Food and Drug Administration (FDA) having approved AUCATZYL® (obe-cel) for the treatment of adult B-cell Acute Lymphoblastic Leukemia (B-ALL) patients, we are all systems go with our commercial efforts in the US across the Company," **said Dr. Christian Itin, Chief Executive Officer of Autolus.** "This first FDA approval is just the beginning for Autolus; we have great belief in our pipeline and our manufacturing capabilities and are excited for the future."

Key updates and anticipated milestones:

- AUCATZYL® was approved by the FDA for the treatment of adult patients with relapsed and refractory B-cell acute lymphoblastic leukemia on November 8, 2024.
- *Obe-cel in r/r adult B-ALL – The FELIX Study and regulatory updates*
  - Obe-cel is under regulatory review in both the EU and the UK, with marketing authorization submissions accepted by the European Medicines Agency in April 2024, and the UK Medicines and Healthcare products Regulatory Agency in August 2024.
  - Post period, Autolus submitted obe-cel for appraisal by the U.K. National Institute for Health and Care Excellence (NICE) and Autolus looks forward to working with NICE and NHS England to make obe-cel available to patients in England and Wales, if approved.
  - Autolus presented updated data from the pivotal Phase 1b/2 FELIX study at the Society of Hematologic Oncology (SOHO) meeting in August 2024 which demonstrated the rationale for tumor burden (TB)-guided dosing by analyzing the impact of bone marrow (BM) blast percentage in patients treated with obe-cel. The data demonstrated the importance of administering a split dose and highlighted the differentiation of obe-cel based on its unique biding properties and tumor burden-guided approach.
  - Post period, Autolus presented data at the 2024 Lymphoma, Leukemia & Myeloma Congress on October 16-19. The poster presentation suggested that adult patients with r/r B-ALL achieve comparable outcomes irrespective of the timing of stem cell transplant (SCT) pre or post obe-cel, suggesting no further benefit of consolidative transplant based on this post-hoc analysis. Additionally, obe-cel given as a sole treatment to patients with lower Tumor Burden (TB) at Lymphodepletion (LD) was associated with better outcomes.
- *Obe-cel in B-cell mediated autoimmune diseases*
  - The Phase 1 dose confirmation study (CARLYSLE) in refractory systemic lupus erythematosus (SLE) patients is ongoing and Autolus expects to complete enrolment and patient dosing, as well as present initial data in Q1 2025. The Company anticipates that full data with adequate follow-up will be targeted for 2H 2025 at a medical conference.
- *Pipeline programs in collaboration with University College London*
  - Clinical programs AUTO8, AUTO6NG and AUTO1/22 are progressing and the Company is planning data updates for all programs in 2025.

Operational Updates:

- The FDA approval for AUCATZYL triggers a $30 million milestone payment to Autolus from Blackstone in accordance with the terms of the collaboration agreement between the parties. In addition, Autolus will make a £10 million regulatory

milestone payment to UCL Business Ltd. in accordance with the license agreement between the parties.

- In September 2024, Autolus announced the appointment of Matthias Will M.D. as Chief Development Officer, effective September 30, 2024. Dr. Will joins Autolus from Dren Bio, Inc., a privately held biotech company, where he served as Chief Medical Officer. During his tenure, Matthias led the expansion of the clinical team and oversaw the submission of two INDs for candidates to potentially treat hematologic cancers. Prior to that he served as Vice President of Clinical Development for CRISPR Therapeutics where he led the development of the company's allogeneic CAR T programs targeting CD70 in T-cell lymphomas and renal cell carcinoma and the early stage CD70-NK cell program in collaboration with NKarta Inc.

2024/2025 Expected News Flow:

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	Q1 2025
Initial data from PY01 trial of obe-cel in pediatric ALL	H2 2025
SLE Phase 1 trial presentation at medical conference	H2 2025

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

Cash and cash equivalents at September 30, 2024 totaled $657.1 million, as compared to $239.6 million at December 31, 2023.

Total operating expenses, net for the three months ended September 30, 2024 were $67.9 million, as compared to $42.9 million for the same period in 2023.

Research and development expenses increased from $32.3 million to $40.3 million for the three months ended September 30, 2024, compared to the same period in 2023. This change was primarily due to increases in employee salaries and related costs, and clinical trial and manufacturing costs related to obe-cel, partially offset by a decrease in professional fees and an increase in our U.K. R&D tax credits that reduce R&D expense.

General and administrative expenses increased from $10.6 million to $27.3 million for the three months ended September 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 $82.1 million for the three months ended September 30, 2024, compared to $45.8 million for the same period in 2023. Basic and diluted net loss per ordinary share for the three months ended September 30, 2024, totaled $(0.31), 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 September 30, 2024
Selected Unaudited Condensed Consolidated Balance Sheet Data
(In thousands)

	September 30, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 657,067	$ 239,566
Total current assets	$ 718,114	$ 275,302
Total assets	$ 827,490	$ 375,381
Liabilities and shareholders' equity		
Total current liabilities	$ 52,474	$ 44,737
Total liabilities	$ 350,525	$ 263,907
Total shareholders' equity	$ 476,965	$ 111,474

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
License revenue	$ —	$ 406	$ 10,091	$ 1,698
Operating expenses:				
Research and development	(40,323)	(32,318)	(107,606)	(92,938)
General and administrative	(27,330)	(10,611)	(67,410)	(31,017)
Loss on disposal of property and equipment	(223)	—	(223)	(3,791)

Impairment of operating lease right-of-use assets and related property and equipment	—	(382)	(414)	(382)
Total operating expenses, net	**(67,876)**	**(42,905)**	**(165,562)**	**(126,430)**
Total other expenses, net	**(14,196)**	**(2,965)**	**(27,428)**	**(4,777)**
Net loss before income tax	**(82,072)**	**(45,870)**	**(192,990)**	**(131,207)**
Income tax (expense) benefit	(22)	21	(66)	(5)
Net loss	**(82,094)**	**(45,849)**	**(193,056)**	**(131,212)**
Other comprehensive income (loss):				
Foreign currency exchange translation adjustment	27,010	(5,837)	28,094	5,104
Total comprehensive loss	**$ (55,084)**	**$ (51,686)**	**$ (164,962)**	**$ (126,108)**
Basic and diluted net loss per ordinary share	$ (0.31)	$ (0.26)	$ (0.77)	$ (0.75)
Weighted-average basic and diluted ordinary shares	266,084,589	173,984,101	251,480,521	173,890,666

Conference Call
Management will host a conference call and webcast at 8:30 am EDT/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.

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

About Autolus Therapeutics plc
Autolus is a 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 recognize target cells, break down their defense mechanisms and eliminate these cells. Autolus has an FDA approved product, AUCATZYL®, and 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 Aucatzyl® (obecabtagene autoleucel, AUTO1)
AUCATZYL® is a B-lymphocyte antigen CD19 (CD19) chimeric antigen receptor (CAR) T cell therapy approved by the FDA for the treatment of relapsed/refractory (r/r) Adult B-cell Acute Lymphoblastic Leukemia (B-ALL). Please see full **Prescribing Information,** including **BOXED WARNING** and Medication Guide. Obe-cel is designed with a fast target binding off-rate to minimize excessive activation of the programmed T cells. 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 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 the market opportunity for AUCATZYL®, Autolus' development and commercialization of its product candidates, and the timing of data announcements and regulatory submissions. 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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