Autolus Therapeutics Reports Full Year 2023 Financial Results and Business Updates

March 14, 2024 at 7:00 AM EDT

- *Announced strategic collaboration and equity investment from BioNTech for aggregate proceeds of $250 million upfront, plus underwritten offering of ADSs for $350 million, for gross proceeds of $600 million received in February 2024*
- *Submitted a Biologics License Application (BLA) for obecabtagene autoleucel (obe-cel), a potentially transformational treatment for relapsed/refractory (r/r) adult B-cell Acute Lymphoblastic Leukemia (ALL), to the US Food & Drug Administration (FDA); Prescription Drug User Fee Act (PDUFA) target action date November 16, 2024*
- *Successfully completed first facility inspection and obtained a Manufacturer's Importation Authorization (MIA) from the Medicines and Healthcare products Regulatory Agency (MHRA), enabling the commercial product supply for obe-cel at The Nucleus manufacturing facility*
- *Submitted a Market Authorization Application (MAA) for obe-cel in r/r adult ALL with the European Medicines Agency (EMA)*
- *Conference call to be held today at 08:30 am EDT/12:30 pm GMT: Conference call participants should pre-register using the link at the bottom of this press release*

LONDON, March 14, 2024 (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 full year ended December 31, 2023.

"We're delighted to be starting 2024 in such a strong financial position; our recently announced strategic alliance with BioNTech, coupled with two equity financing transactions, raised gross proceeds of $600 million. Combined with our 2023 ending cash of $240 million, this enables us to drive the full launch and commercialization of obe-cel in r/r adult ALL and establish Autolus as a potential leader in the delivery of CAR T therapy to patients with autoimmune diseases," **said Dr. Christian Itin, Chief Executive Officer of Autolus.**

"2023 was a transformational year for the Company. Our lead program, obe-cel, demonstrated strong data in B-ALL in the pivotal FELIX study, we fully validated our commercial manufacturing facility, The Nucleus, to support our regulatory submissions and we submitted our first BLA for obe-cel to the United States Food and Drug Administration (FDA) in November, with a PDUFA target action date of November 16, 2024. We also just submitted an MAA to the European Medicines Agency (EMA).

"Beyond B-ALL, we see a significant opportunity for obe-cel in autoimmune disease. Our Phase 1 dose confirmation trial in refractory SLE is now open for enrollment. We believe obe-cel's clinical profile, together with our commercial product delivery base and infrastructure, will help to drive an accelerated and differentiated expansion in autoimmune diseases and we look forward to sharing initial data from the study in late 2024.

"For now, we remain fully focused on preparing for a potential obe-cel launch and successfully transitioning Autolus to a commercial stage company. Pre-commercial and product delivery activities are well underway, and we are on track to make obe-cel available to B-ALL patients as soon as possible, following a potential approval."

Key obecabtagene autoleucel (obe-cel) updates and anticipated milestones:

- *Obe-cel in relapsed / refractory (r/r) adult ALL – The FELIX Study*
  - Obe-cel BLA for r/r B-ALL submitted to the FDA in November 2023; PDUFA target action date of November 16, 2024. A marketing authorization application (MAA) to the European Medicines Agency (EMA) was just submitted and an MAA submission to the MHRA in the UK is planned for the second half of 2024.
  - Pooled analysis of the FELIX Phase 1b/2 study presented at ASH in December 2023 demonstrated prolonged event free survival and low overall immunotoxicity across all cohorts in r/r B-ALL, and particularly in patients with low leukemic burden at lymphodepletion. Additionally, data from a pooled analysis from the ALLCAR19 study and FELIX Phase 1b in r/r B-ALL showed durable remissions with obe-cel as a stand-alone therapy in a subset of patients after a median follow up of >3 years. Further long-term data from the FELIX study is anticipated at medical conferences in 2024.
- *Obe-cel in B-cell mediated autoimmune diseases*
  - The Phase 1 dose confirmation study in refractory systemic lupus erythematosus (SLE) patients has the first site open for enrollment; initial clinical data expected in late 2024.

Pipeline clinical trials, in collaboration with University College London (UCL), updates and anticipated milestones:

- *AUTO8 in Multiple Myeloma – Phase 1 MCARTY Study*
  - AUTO8 is a next-generation product candidate for multiple myeloma, which includes two CARs for the multiple myeloma targets, BCMA and CD19. Initial data from the MCARTY Phase 1 study in multiple myeloma presented at ASH in December 2023 showed AUTO8 was well tolerated, with responses observed in all patients. Further updates from the MCARTY study are anticipated during 2024.

- *AUTO6NG in Neuroblastoma – Phase 1 MAGNETO Study*
  - AUTO6NG contains a CAR that targets GD2 alongside additional programming modules to enhance the activity and persistence. A Phase 1 clinical study in children with r/r neuroblastoma was opened for enrollment in the fourth quarter of 2023.

Post-period:

Strategic developments:

Strategic alliance with BioNTech SE

In February 2024, BioNTech and Autolus announced a strategic CAR T cell therapy collaboration to advance their pipelines and expand late-stage programs, for $50 million cash upfront and up to $582 million in potential option exercise and milestone payments. Additionally, Autolus sold $200 million of ADSs to BioNTech in a concurrent private placement financing transaction.

Overview:

- BioNTech has right to utilize Autolus' manufacturing capacity, know-how and cost-efficiencies to accelerate the planned clinical development and commercialization of BNT211
- BioNTech to support launch and expansion of development program of Autolus' lead cell therapy candidate obe-cel and will receive a royalty on net sales
- BioNTech has co-commercialization options for Autolus' AUTO1/22 and AUTO6NG programs, and an option to access a suite of Autolus target binders and cell programming technologies

Underwritten offering

In February 2024, Autolus completed an underwritten registered direct offering in the United States at a price of $6.00 per ADS, for total gross proceeds of $350 million.

Recent Operational Updates:

- In March 2024, following the most recent GMP inspection by the MHRA in February 2024, The Nucleus manufacturing facility in Stevenage obtained a Manufacturer's Importation Authorization (MIA), together with the accompanying GMP certificate. This authorization enables Autolus to manufacture products for global commercial and clinical supply at The Nucleus, effective as of March 18, 2024.
- In February 2024, Autolus promoted Dr. Chris Williams to Chief Business Officer and Alex Driggs to Senior Vice President, Legal Affairs and General Counsel. Chris has been with the Company since its inception, having negotiated on behalf of UCL the spin off and formation of Autolus. Alex has been with Autolus since 2018 in the role of General Counsel.
- Dr. Edgar Braendle has notified the Company that he will step down as Chief Development Officer to pursue other opportunities. Edgar will continue to advise the company during the BLA and MAA review process. Miranda Neville, SVP and obe-cel Program Leader will run the Development team.
- Autolus announced the appointment of Elisabeth (Lis) Leiderman, M.D. and Robert W. Azelby to its Board of Directors. Dr. Leiderman brings extensive transactional and financial expertise, and Mr. Azelby brings more than 30 years of biopharmaceutical leadership and commercial experience to Autolus' Board.

Scientific Publications:

- In January 2024, Autolus announced the publication of a paper in ACS Chemical Biology entitled: '*Designer small molecule control system based on Minocycline induced disruption of protein-protein interaction*' - Jha et al., ACS Chemical Biology (2024) doi:10.1021/acschembio.3c00521; [Link]
- In February 2024, Autolus announced the publication of a paper in Nature Communications entitled: '*Structure-Guided Engineering of Immunotherapies Targeting TRBC1 and TRBC2 in T Cell Malignancies*' – Ferrari et al., Nat Commun 15, 1583 (2024) doi:10.1038/s41467-024-45854-3; [Link]
- In March 2024, Autolus announced the publication of a paper in Blood Cancer Journal entitled: '*Dual T-cell constant β chain (TRBC)1 and TRBC2 staining for the identification of T-cell neoplasms by flow cytometry* – Horna et al., Blood Cancer J. 14, 34 (2024) doi: 10.1038/s41408-024-01002-0; [Link]

2024 Expected News Flow:

Obe-cel FELIX data update at ASCO, EHA & ASH	June & Dec 2024
Obe-cel Marketing Authorization Application to MHRA	Second half 2024
Obe-cel U.S. FDA PDUFA target action date	November 16, 2024
Obe-cel in autoimmune disease – initial data from SLE Phase 1 study	Late 2024

Financial Results (Unaudited) for the Full Year Ended December 31, 2023

Cash and cash equivalents at December 31, 2023 totaled $239.6 million, as compared to $382.4 million at December 31, 2023.

Total operating expenses, net for the year ended December 31, 2023, were $179.7 million, as compared to $143.4 million, for the year ended December 31, 2022.

Research and development expenses increased from $117.4 million to $130.5 million for the year ended December 31, 2023, compared to the same period in 2022. This change was primarily due to increases in operating costs related to the Company's new commercial manufacturing facility, contractual milestone payments and employee salaries and related costs, a decrease in our U.K. reimbursable R&D tax credits claimable through the U.K. small and medium-sized entity (SME) scheme and partially offset by decreases in clinical and manufacturing costs related to the Company's obe-cel clinical product candidate.

In prior years, Autolus reported the R&D tax credits as income tax benefit on its statements of operations. The Company has revised its financial presentation, including the prior years, and will now present such tax credits as a reduction in research and development expense. As a result, income tax benefit has reduced by $19.5 million and $24.6 million for the years ended December 31, 2023, and 2022, respectively, with corresponding reductions in research and development expenses and total operating expenses.

General and administrative expenses increased from $31.9 million to $46.7 million for the year ended December 31, 2023, compared to the same period in 2022. This increase was primarily due to salaries and other employment-related costs driven by an increase in general and administrative headcount supporting the overall growth of the business, primarily relating to pre-commercialization activities.

Net loss attributable to ordinary shareholders was $208.4 million for the year ended December 31, 2023, compared to $148.8 million for the same period in 2022. The basic and diluted net loss per ordinary share for the year ended December 31, 2023, totaled $(1.20), compared to a basic and diluted net loss per ordinary share of $(1.57) for 2022.

Autolus estimates that, with its current cash and cash equivalents and proceeds received from the strategic alliance with BioNTech and the private placement and underwritten equity financing, it is well capitalized to drive the full launch and commercialization of obe-cel in r/r adult 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 Year Ended December 31, 2023
Selected Unaudited Consolidated Balance Sheet Data
(In thousands)

	December 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 239,566	$ 382,436
Total current assets	**$ 275,302**	**$ 425,771**
Total assets	**$ 375,381**	**$ 490,274**
Liabilities and shareholders' equity		
Total current liabilities	**$ 44,737**	**$ 46,366**
Total liabilities	**$ 263,907**	**$ 191,600**
Total shareholders' equity	**$ 111,474**	**$ 298,674**

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

	Year Ended December 31, 2023	Year Ended December 31, 2022
Grant income	$ —	$ 166
License revenues	1,698	6,194
Operating expenses:		
Research and development[1]	(130,481)	(117,354)
General and administrative	(46,745)	(31,899)
Loss on disposal of property and equipment	(3,791)	(515)
Impairment of operating lease right-right-of-use and related property equipment	(382)	—
Total operating expenses, net	**(179,701)**	**(143,408)**

Total other expenses, net	(28,701)	(5,159)
Net loss before income tax	**(208,402)**	**(148,567)**
Income tax benefit (expense)[1]	19	(272)
Net loss attributable to ordinary shareholders	**(208,383)**	**(148,839)**
Other comprehensive income (loss):		
Foreign currency exchange translation adjustment	9,906	(30,328)
Total comprehensive loss	**$ (198,477)**	**$ (179,167)**
Basic and diluted net loss per ordinary share	$ (1.20)	$ (1.57)
Weighted-average basic and diluted ordinary shares	173,941,926	94,993,400

Conference Call

Management will host a conference call and webcast at 08:30 am EDT/12:30 pm GMT 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)
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. 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 r/r Adult ALL patients. The results of the FELIX trial, a pivotal trial for adult ALL, have been submitted and accepted by the FDA with a PDUFA target action date of November 16, 2024. A regulatory submission to the EMA was made in the first half of 2024. In collaboration with Autolus' academic partner, UCL, obe-cel is currently being evaluated in a Phase 1 clinical trials for B-NHL.

About obe-cel FELIX clinical trial
Autolus' Phase 1b/2 clinical trial of obe-cel enrolled 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 was overall response rate, and the secondary endpoints included duration of response, MRD negative CR 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 I 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, 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 20-F filed with the Securities and Exchange Commission, or the SEC, on March 7, 2023 and in Autolus' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2023, 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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[1] Includes the presentation of our U.K. SME R&D Tax Credit with Income tax benefit as contra research and development expense in the amounts of $19.5 million and $24.6 million for the years ended December 31, 2023, and 2022, respectively.