UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 27, 2023

Autolus Therapeutics plc
(Exact name of registrant as specified in its Charter)

England and Wales	**001-38547**	**Not applicable**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

The Mediaworks
191 Wood Lane
London W12 7FP
United Kingdom
(Address of principal executive offices)(Zip Code)

(44) 20 3829 6230
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing one ordinary share, par value $0.000042 per share	AUTL	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure

On November 27, 2023, Autolus Therapeutics plc issued a press release announcing it has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for obecabtagene autoleucel (obe-cel). The press release is furnished as Exhibit 99.1 and is incorporated by reference herein.

The information contained in the presentation furnished as Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is not incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits

d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Press release dated November 27, 2023

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AUTOLUS THERAPEUTICS PLC

Dated: November 27, 2023

By: /s/Christian Itin

Name: Christian Itin

Title: Chief Executive Officer

Autolus Therapeutics Submits Biologics License Application to U.S. Food and Drug Administration for obecabtagene autoleucel (obe-cel) for Patients with Relapsed/refractory (r/r) Adult B-Cell Acute Lymphoblastic Leukemia (ALL)

- *BLA submission includes results from pivotal Phase 2 FELIX study evaluating obe-cel in relapsed/refractory (r/r) adult B-cell Acute Lymphoblastic Leukemia (ALL)*
- *Company on track to submit a marketing authorization application to the European Medicines Agency (EMA) in the first half of 2024*

LONDON, November 27, 2023 – Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announces that it has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for obecabtagene autoleucel (obe-cel). Obe-cel is Autolus' lead investigational chimeric antigen receptor (CAR) T cell therapy, for the treatment of patients with relapsed/refractory (r/r) adult B-cell Acute Lymphoblastic Leukemia (ALL).

The BLA submission is based on data from the Pivotal Phase 2 FELIX study of obe-cel in adult r/r B-ALL. The data which were presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting in June 2023 and will be updated at the upcoming Annual Meeting of the American Society for Hematology Meeting in December in San Diego.

"We are looking forward to continuing working with the FDA through the regulatory approval process, **commented Dr. Christian Itin, Chief Executive Officer of Autolus**. "I would like to thank the treating physicians, patients, caregivers, and the dedicated team at Autolus for their support, trust and commitment for the program to reach this important milestone."

Autolus plans to submit a Marketing Authorization Application for obe-cel in relapsed/refractory ALL to the European Medicines Agency (EMA) in the first half of 2024.

Obe-cel has been granted Orphan Drug Designation by the FDA, Orphan Medical Product Designation by the EMA, Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA and PRIority MEdicines (PRIME) designation by the EMA for adult r/r B-ALL.

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, the Company 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. Clinical trials of obe-cel have demonstrated that this "fast off-rate" profile reduces 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, are being prepared for regulatory submissions with the FDA and EMA. 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 Ib/II clinical trial of obe-cel enrolled adult patients with relapsed / refractory B-precursor ALL. The trial had a Phase Ib component prior to proceeding to the single arm, Phase II 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 enrolled over 100 patients across 30 of the leading academic and non-academic centers in the United States, United Kingdom and Europe. [NCT04404660]

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 candidates, the status of clinical trials (including, without limitation, expectations regarding the data that is being presented, the expected timing of data releases and development, as well as completion of clinical trials) and development timelines for the Company's product candidates. 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 on March 7, 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.

Contact:

Julia Wilson
+44 (0) 7818 430877
j.wilson@autolus.com

Susan A. Noonan
S.A. Noonan Communications
+1-917-513-5303
susan@sanoonan.com

Lauren Williams
Investase
+44 23 9438 7760
lauren@investase.com