Autolus Therapeutics Reports Full Year 2022 Financial Results and Operational Progress

March 7, 2023 at 7:01 AM EST

- *Obe-cel, a potentially transformational treatment for relapsed/refractory (r/r) B-cell Acute Lymphoblastic Leukemia (ALL) met the primary endpoint in the pivotal Phase 2 FELIX study and is on track for next data update at a medical conference in mid-2023 with a Biologics License Application (BLA) submission to the US FDA planned by end of the year*
- *Obe-cel data presented at ASH demonstrated 35% of relapsed/refractory adult ALL patients in the ALLCAR19 study remain in complete remission at a median follow up of 36 months without the need for additional anti-leukemia therapy*
- *Potentially best-in-class profile of obe-cel supported by data observed in non-Hodgkin lymphoma (NHL) patients in the ALLCAR19 study, with continued high levels of clinical activity and an encouraging tolerability profile across DLBCL, MCL, FL and CLL*
- *Funds secured to drive obe-cel through the BLA submission process and preparing initial launch, with cash of $382.8m, underpinned by a successful fundraise adding total gross proceeds of approx. $163.9m, and $70m in non-dilutive funds from Blackstone Life Sciences*
- *Conference call to be held on March 7, 2023 at 8:30 am ET/1:30 pm GMT*
- *Autolus will host a Virtual Capital Markets Day on Thursday April 27, 2023, where members of the Executive Management Team and Key Opinion Leaders will present on the obe-cel opportunity. Further details of the event will be provided in due course*

LONDON, March 07, 2023 (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, 2022.

“Autolus had an exciting fourth quarter of 2022 with obe-cel reaching the primary endpoint of the pivotal FELIX study in an interim analysis and confirming its attractive safety profile in r/r adult ALL patients,” **said Dr. Christian Itin, Chief Executive Officer of Autolus**. “Progress with obe-cel triggered two milestones from Blackstone totaling $70m and with the successful fundraise in December 2022, raising gross proceeds of $163.9m, we are well positioned to bring this innovative and potentially transformative treatment to an underserved ALL patient population. In 2023 we will be fully focused on submitting a BLA application at the end of the year and working towards commercial launch in 2024. We look forward to presenting data from all patients treated in the FELIX study at a medical conference in mid-2023.”

Key obe-cel Updates During 2022:

- *Obecabtagene autoleucel (obe-cel) in relapsed / refractory (r/r) adult ALL – The FELIX Study*
  - The Company announced in December 2022 that the pivotal FELIX Phase 2 clinical trial met its primary endpoint, based on a pre-planned interim analysis of 50 patients with morphological disease, as verified by an independent data monitoring committee (IDMC). Next data is expected to be presented at a medical conference in mid-2023. The Company expects data from the FELIX study to form the basis of a BLA submission for obe-cel to the FDA at the end of 2023. The Company expects to present longer term follow up data at the American Society of Hematology (ASH) meeting in late 2023 as well as at medical conferences in H1 2024.
  - The Company is evaluating patients across the entire range of disease burden, including patients with minimal residual disease (MRD). Between the main study population and patients enrolled in the MRD cohort the Company believes it has sufficient data to support the utility of obe-cel across the full range of disease burden.

Obe-cel trials in collaboration with University College London

- *Obe-cel in r/r adult B-ALL patients – Phase 1 ALLCAR19 Study*
  - Long term follow-up data were presented at the 2022 ASH meeting. The data demonstrated that 35% of adult B-ALL patients remained in complete remission at a median follow up of 36 months without the need for additional anti-leukemia therapy. The Company expects to announce additional data from the ALLCAR19 study during 2023.

- *Obe-cel in r/r B-NHL and CLL patients – Phase 1 ALLCAR19 Extension Study*
    - Data presented at the 2022 ASH meeting in December demonstrated the potentially best-in-class profile of obe-cel supported by the data observed in B-cell non-Hodgkin lymphoma (NHL), with continued high levels of clinical activity paired with an encouraging tolerability profile across diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma (MCL), follicular lymphoma (FL) and chronic lymphocytic leukemia (CLL). Patients continue to be enrolled into the study and the Company expects to announce additional data during 2023.

- *Obe-cel in Primary CNS Lymphoma patients – Phase 1 CAROUSEL Study*
    - Data presented at the European Hematology Association (EHA) meeting in June 2022 demonstrated first activity in primary CNS lymphoma. Patients continue to be enrolled and the Company expects to announce additional data during 2023.

- *AUTO1/22 in pediatric B-ALL patients – Phase 1 CARPALL Study*
    - Data presented at the 2022 ASH meeting in December by the Company's UCL collaborators, showed encouraging response rates in patients ineligible for commercial CAR T therapy, with 83% of patients achieving minimal residual disease (MRD) negative complete responses (CRs). Importantly, there were no observed antigen negative relapses observed as of the data cut-off date. The Company expects to announce additional data during 2023.

Early-stage pipeline – leveraging academic collaborations to generate opportunity for non-dilutive funding opportunities

- *AUTO4 in T Cell Lymphoma patients – Phase 1/2 LibrA T1 Study*
    - Autolus has optimized the manufacturing process for AUTO4 and is enrolling additional patients into the trial to test this manufacturing change. Data presented at the 2022 ASH meeting in December demonstrated that some patients have experienced durable metabolic CRs, including one patient up to the one-year mark post treatment. The Company expects to announce additional data during 2023.

- *AUTO8 in Multiple Myeloma – Phase 1 MCARTY Study*
    - AUTO8 is a next-generation product candidate for multiple myeloma, which comprises two independent CARs for the multiple myeloma targets, BCMA and CD19. In collaboration with UCL, the Company initiated a study in Q1 2022, patients continue to be enrolled and initial data is expected in 2023.

- *AUTO6NG in Neuroblastoma*
    - AUTO6NG contains a CAR that targets GD2 alongside additional programming modules to enhance the activity and persistence. In collaboration with UCL, the Company is planning on initiating a clinical trial of AUTO6NG in 2023.

Key Operational Updates during 2022

- Company believes is has the financial strength to deliver on obe-cel launch with cash and cash equivalents (including restricted cash) of $382.8m at 31 December 2022, underpinned by a successful fundraise in December 2022 adding total gross proceeds of $163.9m, including the partial exercise of the greenshoe by the underwriters, with an additional $70m in non-dilutive funds from the Blackstone collaboration as a result of a development milestone of $35m achieved earlier than anticipated as a result of the positive interim analysis of Autolus' pivotal FELIX Phase 2 trial and a manufacturing milestone of $35m achieved as a result of completion of planned activities supporting the performance and qualification of the obe-cel manufacturing process.

- The build phase of the Company's new 70,000 square foot commercial manufacturing facility in Stevenage, UK has continued to progress on track with Phase 1 of the buildout complete in Q4 2022. This first phase includes the first of three cell product commercial manufacturing clean rooms in Stevenage. Final equipment installations and qualification by Autolus are on track for the commencement of Good Manufacturing Practice (GMP) operations in H2 2023. This facility has been designed for a capacity of 2,000 batches per year with the option to expand capacity as needed.

- Autolus is on schedule to complete the development work and report generation for the Chemistry Manufacturing and Controls (CMC) package planned to be submitted to the FDA. All work including process qualification activities in the new Stevenage facility are on track for submission of a BLA by the end of 2023.

- Autolus announced three collaborations, two during 2022 and one post period end, leveraging the Company's modular programming technology to generate safer and more effective therapies with the potential for value creation through near term option exercise fees, milestone payments and royalties from net sales:

    - Moderna Tx - Access to propriety binders for the development of mRNA-based therapeutics for the treatment of cancer;
    - Bristol Myers Squibb - Access to the RQR8 safety switch for selected cell therapy programs for the treatment of

cancer; and
- Cabaletta Bio – post period end - Access to the RQR8 safety switch for selected cell therapy programs for the treatment of autoimmune diseases.

Post Period End:

- In January 2023 Autolus announced two changes to the Board of Directors:
  - The Company's non-executive Chairman, John H Johnson, who has held the role since September 2021, will not stand for re-election at Autolus' upcoming annual shareholder meeting. During his tenure as Chairman of Autolus he was appointed as Chief Executive Officer (CEO) of Reaction Biology and, therefore, he plans to focus his time on his operational role following his resignation from the board.
  - Dr. Jay T Backstrom, who has served on Autolus' Board of Directors since August 2020, stepped down from Autolus' Board of Directors at the end of February 2023.

Virtual Capital Markets Day

Autolus will be hosting a Virtual Capital Markets Day on Thursday April 27, 2023, where members of the Executive Management Team and Key Opinion Leaders will present on the obe-cel opportunity. Further details of the event will be provided in due course.

Financial Results for the Year Ended December 31, 2022

Cash and cash equivalents and restricted cash at December 31, 2022, totaled $382.8 million, as compared to $310.7 million at December 31, 2021. Net total operating expenses for the twelve months ended December 31, 2022 were $168.0 million, net of grant income and license revenue of $6.4 million, as compared to net operating expenses of $165.0 million, net of grant income and license revenue of $2.3 million, for the same period in 2021.

Research and development expenses increased by $7.2 million to $142.0 million for the year ended December 31, 2022 from $134.8 million for the year ended December 31, 2021 primarily due to (i) an increase of $11.6 million in clinical costs and manufacturing costs primarily relating to our obe-cel clinical product candidate, (ii) an increase of $0.4 million in legal fees and professional consulting fees in relation to our research and development activities, (iii) an increase of $0.2 million related to information technology infrastructure and support for information systems related to the conduct of clinical trials and manufacturing operations, (iv) an increase of $0.2 million in cell logistics costs, (v) a decrease of $3.7 million in facilities costs related to the termination and closure of our US manufacturing facility in 2021 and a shift in our overall manufacturing strategy, (vi) a decrease of $0.9 million in depreciation and amortization related to property and equipment and intangible assets, and (vii) a decrease of $0.6 million in salaries and other employment costs including share-based compensation expenses, which is mainly due to lower exchange rates used upon consolidation for the year ended December 31, 2022 compared to the year ended December 31, 2021, offset by an increase in employees engaged in research and development activities.

General and administrative expenses remained consistent at $31.9 million for the year ended December 31, 2022 and 2021, respectively primarily due to (i) an increase of $1.4 million, in salaries and other employment costs including share-based compensation expenses, is mainly driven by an increase in the average number of employees engaged in general and administrative activities, (ii) an increase of $0.3 million primarily related to information technology costs, (iii) a net increase of $0.1 million in legal fees and professional consulting fees in relation to our general and administrative activities, which is offset against lower director and officer insurance premium, (iv) a decrease of $1.0 million of commercial preparation costs due to the timing of related activities, (v) a decrease of $0.4 million in facilities costs related to the termination of certain lease agreements in the prior year, and (vi) a decrease of $0.4 million in depreciation and amortization related to property and equipment and intangible assets.

Interest income increased to $1.7 million for the year ended December 31, 2022 compared to $0.3 million for the year ended December 31, 2021. The increase in interest income of $1.4 million primarily relates to the increase in interest rates on the Company's interest-bearing bank accounts and short-term investments during the year ended December 31, 2022 compared to 2021.

Interest expense increased to $8.9 million for the year ended December 31, 2022 as compared to $1.1 million for the year ended December 31, 2021. Interest expense is primarily related to the liability for future royalties and sales milestones, which arose upon the execution of the Company's strategic collaboration and financing agreement with Blackstone in November 2021. The increase in interest expense for the year ended December 31, 2022 is primarily driven by the full year expense accrual of the liability related to the Blackstone collaboration in 2022 compared to a partial year liability accrued in 2021.

Other income (expense), net, increased to an income of $2.0 million for the year ended December 31, 2022 from an expense of $0.1 million for the year ended December 31, 2021. During the year ended December 31, 2022, the Company recognized a foreign exchange gain of $1.7 million, sublease income of $0.2 million and other income of $0.1 million. This compares to an expense of $0.1 million for the year ended December 31, 2021 which included a foreign exchange loss of $2.2 million offset by a gain on lease terminations of $2.0 million and other income of $0.1 million.

Income tax benefit increased to $24.4 million for the year ended December 31, 2022 from $23.9 million for the year ended December 31, 2021 due to an increase in qualifying research and development expenditures for the period.

Net loss attributable to ordinary shareholders was $148.8 million for the twelve months ended December 31, 2022, compared to $142.1 million for the same period in 2021. The basic and diluted net loss per ordinary share for the twelve months ended December 31, 2022, totaled $(1.57) compared to a basic and diluted net loss per ordinary share of $(1.97) for the twelve months ended December 31, 2021.

Autolus estimates that its current cash and cash equivalents on hand and anticipated future milestone payments from Blackstone will extend the Company's runway into 2025.

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 382,436	$ 310,338
Restricted cash	325	338
Prepaid expenses and other current assets	43,010	36,276
Total current assets	**425,771**	**346,952**
Non-current assets:		
Property and equipment, net	35,209	33,541
Prepaid expenses and other non-current assets	2,176	2,362
Operating lease right-of-use assets, net	23,210	18,775
Long-term deposits	1,832	2,039
Deferred tax asset	2,076	1,826
Intangible assets, net	—	65
Total assets	**490,274**	**405,560**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	531	431
Accrued expenses and other liabilities	40,797	23,667
Operating lease liabilities, current	5,038	4,453
Total current liabilities	**46,366**	**28,551**
Non-current liabilities:		
Operating lease liabilities, non-current	19,218	16,545
Liability related to future royalties and sales milestones, net	125,900	47,016
Other long term payables	116	128
Total liabilities	**191,600**	**92,240**
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 290,909,783 and 200,000,000 shares authorized at December 31, 2022 and 2021, 173,074,510 and 90,907,830 shares issued and outstanding at December 31, 2022 and 2021	8	4
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at December 31, 2022 and 2021	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at December 31, 2022 and 2021	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at December 31, 2022 and 2021	—	—
Additional paid-in capital	1,007,625	843,108
Accumulated other comprehensive loss	(38,898)	(8,570)
Accumulated deficit	(670,179)	(521,340)
Total shareholders' equity	**298,674**	**313,320**
Total liabilities and shareholders' equity	**$ 490,274**	**$ 405,560**

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021	December 31, 2020
Grant income	$ 166	$ 823	$ 1,473
License revenue	6,194	1,507	242
Operating expenses:			
Research and development	(141,992)	(134,789)	(134,888)
General and administrative	(31,899)	(31,865)	(34,972)
Loss on disposal of leasehold improvements	(515)	(676)	—

Total operating expenses, net	**(168,046)**	**(165,000)**	**(168,145)**
Other income (expense):			
Interest income	1,708	262	536
Interest expense	(8,905)	(1,105)	—
Other income (expense)	2,038	(145)	1,352
Total other (expense) income, net	(5,159)	(988)	1,888
Net loss before income tax	**(173,205)**	**(165,988)**	**(166,257)**
Income tax benefit	24,366	23,892	24,163
Net loss attributable to ordinary shareholders	**(148,839)**	**(142,096)**	**(142,094)**
Other comprehensive (loss) income:			
Foreign currency exchange translation adjustment	(30,328)	(2,709)	2,830
Total comprehensive loss	**$ (179,167)**	**$ (144,805)**	**$ (139,264)**
Basic and diluted net loss per ordinary share	$(1.57)	$(1.97)	$(2.76)
Weighted-average basic and diluted ordinary shares	94,993,400	72,084,078	51,558,075

Conference Call

Management will host a conference call and webcast at 8:30 am ET/1:30 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. 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 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 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 continued development of Autolus' obe-cel program including timing of and expectations regarding planned readouts as well as expectations that the final data set will be confirmatory of the data from the interim analysis; expectations the trial will result in sufficient data to support the utility of obe-cel across the full range of disease burden; 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; the planned submission of a Biologics License Application for obe-cel by the end of 2023; the expected benefits of the Company's collaborations and partnerships as well as the anticipated receipt of milestone payments; and the sufficiency of the Company's cash resources and its anticipated cash runway into 2025. 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.

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