Autolus Therapeutics Reports Third Quarter 2021 Financial Results and Operational Progress

November 3, 2021 at 7:00 AM EDT

Conference call to be held on November 3, 2021, at 8:30 am ET/12:30 pm GMT

LONDON, Nov. 03, 2021 (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 third quarter ended September 30, 2021.

"We continue to make good progress on the clinical evaluation of obe-cel in the Phase 2 portion of the FELIX study and remain on track to deliver primary endpoint data in the middle of 2022. We are also pleased to update that the response rate and safety data from patients in the multi-center Phase 1b cohort are consistent with the data reported from the academic ALLCAR19 study of obe-cel in relapsed/refractory adult B-acute lymphoblastic leukemia (ALL)," said Dr. Christian Itin, chief executive officer of Autolus. "In addition, we expect a busy end of the year with clinical data at the upcoming 63rd Annual Meeting of the American Society of Hematology (ASH), including an oral presentation, where we will provide early clinical data from the Phase 1b trial, as well as a poster presentation covering clinical data from the ALLCAR19 extension trial and a poster with initial clinical data for AUTO1/22."

Key Pipeline Updates:

- *Obecabtagene autoleucel (obe-cel) in relapsed / refractory (r/r) adult ALL*.
  - *FELIX Study* – Autolus continues to enroll patients in the Phase 2 portion of the FELIX study. The multi-center study is progressing well, with consistent one-month complete response rate and safety data observed from the initial 16 patients in the Phase 1b cohort as compared to data reported from the academic ALLCAR19 study of obe-cel in r/r adult ALL. Autolus expects to present early clinical data from the Phase 1b portion of the FELIX trial at the 63rd ASH Meeting in December 2021. The Company reiterates its expectation of pivotal data in 2022.

  - *ALLCAR19 Study* - Data were published in the Journal of Clinical Oncology (JCO) in September 2021 from the ALLCAR19 trial in r/r adult ALL patients. Obe-cel demonstrated a manageable adverse events profile, with no patients experiencing high grade (≥ grade 3) cytokine release syndrome (CRS), despite the majority having a high disease burden prior to lymphodepletion[1]. CAR T cell concentration reached very high levels at peak (mean peak CAR T concentration (Cmax) by quantitative polymerase chain reaction (qPCR) was 127,152 copies/µg genomic DNA[1]) and persistence in peripheral blood was evident in 15/20 (75%) patients at a median of 166.5 days, with 4/20 (20%) patients having follow-up duration over 2 years, and 3/4 of these patients with ongoing CAR persistence at the data cut-off date of February 26, 2021[1]. B-cell aplasia was ongoing in 15/20 patients at the last observation date of February 26, 2021[1]. Of the 20 patients, 85% patients achieved minimal residual disease (MRD) negative complete response (CR) at month 1[1]. Duration of response remains highly encouraging. With a data cut-off date of May 17, 2021, and as presented at the European Hematology Association (EHA) Virtual Congress in June 2021, event free survival (EFS) at 12 months and 24 months was 50.2%, with median EFS not reached across all patients treated[2].

[1]Roddie et al. "Durable responses and low toxicity after fast off-rate CD19 CAR-T therapy in adults with relapsed/ refractory B-ALL." DOI: 10.1200/JCO.21.00917 Journal of Clinical Oncology - published online before print August 31, 2021

[2]Roddie et al. "Early Safety and Efficacy Findings of AUTO1 (CAT19), a Fast-Off Rate CD19 CAR, in Relapsed/Refractory Indolent B Cell Lymphomas." EHA annual meeting, June 11 2021, abstract EP788. EHA Investor slide presentation

- *Obe-cel in r/r B-NHL – ALLCAR19 extension*
  - The latest data of obe-cel were presented by Autolus at EHA in June 2021 in r/r B-NHL (Follicular Lymphoma and Mantle Cell Lymphoma) patients. The trial is progressing well and Autolus plans to present updated data from the ALLCAR extension trial at the ASH Meeting in December 2021.

- *AUTO4 in Peripheral T Cell Lymphoma*
  - The AUTO4 Phase 1 clinical trial is progressing through dose escalation and Autolus expects to provide its next data update from the trial in the first half of 2022.

- *AUTO8 in Multiple Myeloma*
  - The Company is on track to start a Phase 1 trial in the fourth quarter of 2021.

Operational Highlights:

- Updates to Autolus' Executive team
    - In July 2021, Autolus announced the appointment of Edgar Braendle M.D., Ph.D., as Chief Development Officer. Dr Braendle is an experienced oncologist who joined Autolus from Sumitomo Dainippon Pharma Oncology, where he held the position of Chief Medical Officer and Global Head of Development and was responsible for leading the global oncology development programs of Sumitomo Dainippon. In addition, in June 2021, Wolfram Brugger M.D., Ph.D. joined Autolus as its Vice President, Head of Clinical Development. Dr. Brugger joined Autolus from MorphoSys, where he was Head of Global Clinical Programs and oversaw the development of Monjuvi (tafasitamab).

    - In October 2021, Alexander Swan was promoted to Senior Vice President, Human Resources. Mr. Swan joined Autolus prior to its Nasdaq listing in 2018 as Vice President, Human Resources. Prior to that, he was EMEA Head of Human Resources for Kite where he was responsible for all aspects of human resources.

    - Also in October 2021, Dr. Chris Williams was promoted to Senior Vice President, Corporate Development. Dr. Williams was part of the team that founded Autolus in 2014, and he initially served on the Company's board of directors as a Non-Executive Director from September 2014 to July 2016. In 2016, Dr. Williams transitioned into the Company to establish Autolus' business development function. Previously he worked at UCL Business, Orchard Therapeutics, Eli Lilly, and GSK.

    - Matthias Alder, Senior Vice President, Chief Business Officer and Company Secretary, left Autolus at the end of September 2021. The Company would like to thank Mr. Alder for his contributions and wishes him well in the future.

- In September 2021, Autolus announced the appointment of John H. Johnson as non-executive chairman of its Board of Directors. Mr. Johnson brings to Autolus more than 30 years of experience in the life science industry. He most recently was chief executive officer and a director of Strongbridge Biopharma plc, a Nasdaq-listed commercial stage biopharmaceutical company. He previously served as the executive chairman of Strongbridge Biopharma from November 2019 to July 2020, and as chairman from March 2015 to November 2019. He is a recognized leader in the biopharmaceutical industry and has held executive, operations and commercial leadership roles at Eli Lilly & Company, ImClone, Johnson & Johnson, and Pfizer. He also currently serves as a member of the Board of Directors of Xeris Biopharma Holdings, Inc., Verastem, Inc. and Axogen, Inc. Mr. Johnson previously served on the Board of Directors of the Pharmaceutical Research and Manufacturers of America and the Health Section Governing Board of the Biotechnology Industry Organization (now known as the Biotechnology Innovation Organization).

- In September 2021, Autolus gave an update on its manufacturing strategy, announcing that planning approval had been granted to build the Company's new manufacturing facility in Stevenage, UK. The 70,000 square foot facility is being built by Merit Holdings Limited as general contractor for the Reef Group, who will lease the facility to Autolus. Global commercial launch capacity for obe-cel will initially be provided by the existing clinical trial manufacturing facility at The Cell and Gene Therapy Catapult facility, and will then move to the new Autolus facility, which will allow for good manufacturing practice capacity for approximately 2,000 batches a year initially, with scope to expand.

- As previously announced, in July 2021, Autolus announced its entry into an agreement with Moderna, Inc., granting Moderna an exclusive license to develop and commercialize mRNA-based therapeutics incorporating Autolus' proprietary binders for up to four immuno-oncology targets.

Key Anticipated Clinical Milestones:

- Updates on the FELIX trial, where Autolus is evaluating obe-cel in r/r adult ALL patients. The trial is currently enrolling patients into the Phase 2 portion. Initial data on the Phase 1b portion of the trial planned to be presented at the ASH Meeting in December 2021. Autolus expects data from the Phase 2 trial to be available in 2022

- Updates from the ALLCAR19 extension trial in patients with r/r B-NHL and longer-term follow-up of the fully enrolled r/r adult ALL cohort expected at ASH Annual Meeting in December 2021

- Updates on the obe-cel Phase 1 trial, CAROUSEL, in Primary CNS Lymphoma in Q1 2022

- Non-clinical data and initial data from the AUTO1/22 CARPALL extension trial in pediatric ALL expected at ASH in December 2021

- Updates on the AUTO4 Phase 1 trial in TRBC1+ Peripheral TCL expected in H1 2022

- Phase 1 trials are expected to be initiated in Q4 2021 with AUTO8 in Multiple Myeloma
- Phase 1 trials are expected to be initiated in H1 2022 with AUTO6NG in solid tumors and AUTO5 in TRBC2+ Peripheral TCL

Financial Results for the Quarter Ended September 30, 2021

Cash at September 30, 2021, totaled $173.1 million, as compared to $216.4 million at June 30, 2021.

Net total operating expenses for the three months ended September 30, 2021, were $40.4 million, net of grant income of $0.2 million, as compared to net operating expenses of $42.7 million, net of grant income of $0.4 million and license revenue of $0.2 million, for the same period in 2020.

Research and development expenses decreased to $32.3 million for the three months ended September 30, 2021 from $33.5 million for the three months ended September 30, 2020. Cash costs, which exclude depreciation and amortization as well as share-based compensation, decreased to $29.4 million from $30.0 million. The decrease in research and development cash costs of $0.6 million consisted primarily of (i) $1.4 million decrease in clinical costs and manufacturing costs (ii) $0.2 million decrease of consultancy fees related to our clinical pipeline, (iii) $0.3 million decrease in facilities costs related to the termination of our US manufacturing facility and shift in manufacturing strategy, (iv) $0.4 million in research and development costs related to cell logistics and (v) $0.1 million decrease related to information technology infrastructure and support for information systems related to the conduct of clinical trials and manufacturing operations . This was offset by (i) an increase of $1.0 million related to purchased consumables for the manufacture of obe-cel in our Phase 2 FELIX clinical trial and (ii) an increase in compensation and employment related costs of $0.8 million net, due to a combination of severance payments which are offset by a reduction in employment costs for a decrease in headcount.

Non-cash costs decreased to $2.9 million for the three months ended September 30, 2021 from $3.5 million for the three months ended September 30, 2020. The decrease is primarily related to share-based compensation expense included in research and development expenses, which decreased by $1.6 million as a result of the lower fair value of stock options granted during the period, combined with forfeitures of incentive share options and unvested RSU awards. This was offset by an increase in depreciation expense of $1.0 million.

General and administrative expenses decreased to $8.3 million for the three months ended September 30, 2021 from $9.8 million for the three months ended September 30, 2020. Cash costs, which exclude depreciation expense as well as share-based expense compensation decreased to $7.2 million from $7.7 million. The decrease in general and administrative cash costs of $0.5 million related to decreases of (i) $0.2 million associated with compensation expense due to a reduction in headcount, (ii) $0.8 million of expenses related to preparations for becoming a commercial stage company, and (iii) $0.4 million in facilities costs related to the termination lease and exit of our lease agreements. These decreases were offset by an increase of $0.8 million which was primarily related to professional services fees and directors and officers liability insurance premiums and $0.1 million in costs related to IT infrastructure and support for information systems.

Non-cash costs decreased to $1.1 million for the three months ended September 30, 2021 from $2.1 million for the three months ended September 30, 2020. The decrease is mainly attributed to share-based compensation expense as a result of the lower fair value of stock options recognized during the period, combined with forfeitures of incentive share options and unvested RSU awards related to employees affected by our reduction in workforce.

Other income / (expense) increased by $3.5 million for the three months ended September 30, 2021, from other expense of $2.5 million for the three months ended September 30, 2020 to other income of $1.0 million. The increase was primarily due to the strengthening of the U.S. dollar exchange rate relative to the pound sterling during the three months ended September 30, 2021 as compared to the three months ended September 30, 2020.

Income tax benefit decreased to $5.4 million for the three months ended September 30, 2021 from $7.9 million for the three months ended September 30, 2020 due to a decrease in the research and development expenditures which were qualifying for the quarter. As research and development credits fell at a faster rate than our net loss before income tax, this led to a lower effective tax rate. Research and development credits are obtained at a maximum rate of 33.35% of our qualifying research and development expenses, and the decrease in the net credit was primarily attributable to a decrease in our eligible research and development expenses.

Net loss attributable to ordinary shareholders was $34.0 million for the three months ended September 30, 2021, compared to $37.3 million for the same period in 2020. The basic and diluted net loss per ordinary share for the three months ended September 30, 2021, totaled $(0.47) compared to a basic and diluted net loss per ordinary share of $(0.72) for the three months ended September 30, 2020.

Autolus estimates that its current cash on hand will provide the Company with a cash runway into H1 2023.

Financial Results for the Quarter Ended September 30, 2021

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Grant income	$ 236	$ 438	$ 643	$ 1,069
License revenue	—	242	1,507	242
Operating expenses:				
Research and development	(32,292)	(33,545)	(95,154)	(96,160)

General and administrative	(8,299)	(9,843)	(24,274)	(25,966)
Loss on disposal of leasehold improvements	—	—	(672)	—
Total operating expenses, net	(40,355)	(42,708)	(117,950)	(120,815)
Other income (expense):				
Interest income	28	37	113	500
Other income (expense)	951	(2,509)	(59)	2,500
Total other income (expense), net	979	(2,472)	54	3,000
Net loss before income tax	(39,376)	(45,180)	(117,896)	(117,815)
Income tax benefit	5,385	7,865	17,466	18,582
Net loss attributable to ordinary shareholders	(33,991)	(37,315)	(100,430)	(99,233)
Other comprehensive (loss) income:				
Foreign currency exchange translation adjustment	(6,463)	10,915	(3,648)	(8,605)
Total comprehensive loss	(40,454)	(26,400)	(104,078)	(107,838)
Basic and diluted net loss per ordinary share	$ (0.47)	$ (0.72)	$ (1.46)	$ (1.93)
Weighted-average basic and diluted ordinary shares	72,896,362	52,093,826	68,770,962	51,339,662

Condensed Consolidated Balance Sheets (Unaudited)

(In thousands, except share and per share amounts)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash	$ 173,060	$ 153,299
Restricted cash	210	786
Prepaid expenses and other assets, current	64,407	42,899
Total current assets	237,677	196,984
Non-current assets:		
Property and equipment, net	33,962	38,046
Right of use assets, net	19,196	51,637
Long-term deposits	1,796	2,625
Prepaid expenses and other assets, non-current	2,512	3,033
Deferred tax asset	1,406	1,754
Intangible assets, net	87	158
Total assets	$ 296,636	$ 294,237
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	1,462	2,263
Accrued expenses and other liabilities	28,634	27,781
Lease liabilities	4,467	3,590
Total current liabilities	34,563	33,634
Non-current liabilities:		
Lease liabilities	17,343	50,571
Total liabilities	51,906	84,205
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 200,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 72,918,994 and 52,346,231, shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	3	3
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at September 30, 2021 and December 31, 2020	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Additional paid-in capital	733,792	595,016
Accumulated other comprehensive loss	(9,509)	(5,861)

Accumulated deficit	(479,674)	(379,244)
Total shareholders' equity	244,730	210,032
Total liabilities and shareholders' equity	$ 296,636	$ 294,237

Conference Call

Management will host a conference call and webcast today at 8:30 am ET/12:30 pm GMT to discuss the Company's financial results and provide a general business update. To listen to the webcast and view the accompanying slide presentation, please go to the events section of Autolus' website.

The call may also be accessed by dialing (866) 679-5407 for U.S. and Canada callers or (409) 217-8320 for international callers. Please reference conference ID 6984737. After the conference call, a replay will be available for one week. To access the replay, please dial (855) 859-2056 for U.S. and Canada callers or (404) 537-3406 for international callers. Please reference conference ID 6984737.

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 its academic partner, UCL, obe-cel is currently being evaluated in a Phase 1 clinical trial in adult ALL and B-NHL. The Company has also progressed obe-cel to the FELIX trial, a potential pivotal trial.

About obe-cel FELIX trial
The FELIX clinical trial is enrolling adult patients with relapsed / refractory ALL. The trial has a short Phase 1b component prior to proceeding to a single arm Phase 2 clinical trial. The primary endpoint is overall response rate, and the key 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.

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.

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 future clinical development, efficacy, safety, and therapeutic potential of obe-cel, including progress, expectations as to the reporting of data, conduct and timing and potential future clinical activity and milestones; expectations regarding the initiation, design and reporting of data from clinical trials; [and Autolus' expected cash runway]. 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 4, 2021, 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.

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