Autolus Therapeutics Reports Third Quarter 2022 Financial Results and Operational Progress

November 3, 2022 at 7:00 AM EDT

- *Pivotal FELIX Phase 2 clinical trial of obe-cel in relapsed/refractory (r/r) Acute Lymphoblastic Leukemia (ALL) on track for Q4 2022 update*
- *Commercial manufacturing site build on schedule for handover of first clean rooms to Autolus in Q4 2022*
- *Post-period end announcements: Bristol Myers Squibb licensed Autolus' proprietary safety switch and Moderna exercised its option for Autolus' proprietary binders*
- *Pipeline updates expected at American Society of Hematology (ASH) Annual Meeting in December 2022 – abstracts online November 3, 2022 at 09:00 am ET/1:00 pm GMT*
- *Conference call to be held on November 3, 2022 at 8:30 am ET/12:30 pm GMT*

LONDON, Nov. 03, 2022 (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, 2022.

"Autolus has continued to deliver further strategic and operational progress during the third quarter of 2022, with our pivotal FELIX trial on track for a Q4 2022 update, the commercial manufacturing facility build on schedule for the handover of the first clean rooms to Autolus, and the announcement post-period end of an agreement for our proprietary technology with Bristol Myers Squibb and an option exercise by Moderna," **said Dr. Christian Itin, CEO of Autolus** "Alongside this, we have continued progressing our pipeline candidates through Phase 1 clinical trials through our long-standing collaboration with UCL, laying the foundations for our clinical pipeline beyond obe-cel. We are looking forward to updating the market with our progress over the coming months as we remain fully focused on bringing obe-cel to market."

Key Pipeline Programs:

- *Obecabtagene autoleucel (obe-cel) in relapsed / refractory (r/r) adult ALL – The FELIX Trial*
  - The pivotal FELIX Phase 2 clinical trial is on track to report initial results in Q4 2022. Autolus plans to present FELIX Phase 2 data at a medical conference in mid-2023. Assuming a positive outcome from the FELIX trial, the Company expects the data to form the basis of a Biologics License Application (BLA) submission for obe-cel to the FDA at the end of 2023.

- *Obe-cel in r/r adult ALL patients – ALLCAR19 Trial*
  - In collaboration with University College London (UCL), Autolus expects to present long term follow-up data from the Phase 1 ALLCAR19 trial in Q4 2022 at the 2022 ASH meeting, to be held December 10-13, 2022. Abstracts will be online November 3, 2022 at 09:00 am ET/1:00 pm GMT.

- *Obe-cel in r/r B-NHL patients – ALLCAR19 Extension Trial*
  - In collaboration with UCL, patients continue to be enrolled into the Phase 1 ALLCAR19 extension trial. Data were presented at the European Hematology Congress (EHA) in June 2022, and longer-term follow up will be presented at the 2022 ASH meeting in December. Abstracts will be online November 3, 2022 at 09:00 am ET/1:00 pm GMT.

- *Obe-cel in Primary CNS Lymphoma patients – CAROUSEL Trial*
  - In collaboration with UCL, patients continue to be enrolled into the Phase 1 CAROUSEL trial. Data were presented at EHA in June 2022 - and longer-term follow up data is planned in 2023.

- *AUTO1/22 in pediatric ALL patients – CARPALL Trial*
  - In collaboration with UCL, patients continue to be enrolled into the AUTO1/22 Phase 1 CARPALL trial. Data were presented at EHA in June 2022, and longer-term follow up data will be presented at the 2022 ASH Meeting in December. Abstracts will be online November 3, 2022 at 09:00 am ET/1:00 pm GMT.

- *AUTO4 in T Cell Lymphoma patients – LibrA T1 Trial*
  - Autolus has optimized the manufacturing process for AUTO4, and is currently enrolling additional patients into the trial to test this manufacturing change. Data were presented at EHA in June 2022, and longer-term follow up data will be presented at the 2022 ASH Meeting in December. Abstracts will be online November 3, 2022 at 09:00 am ET/1:00 pm GMT.

- *AUTO8 in Multiple Myeloma – MCARTY Trial*
  - In collaboration with UCL, patients continue to be enrolled into the AUTO8 Phase 1 clinical trial, with first data

expected in H2 2023.

- *AUTO6NG in Neuroblastoma – MCARGD2 Trial*
  - In collaboration with UCL, the first patient is expected to be dosed in the Phase 1 MCARGD2 clinical trial in H1 2023, with initial data expected towards the end of 2023.

Key Operational Updates during Q3 2022

- 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 the planned schedule during Q3 2022, with Phase 1 of the buildout scheduled to 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.

Post Period End:

- In October 2022, Autolus announced a new collaboration with Bristol Myers Squibb, and the exercise of an option by Moderna under an existing license and option agreement announced in August 2021. These two technology deals underscore the scientific capabilities and expertise at Autolus.

  - Bristol Myers Squibb entered into a licensing agreement with Autolus for access to the Company's proprietary RQR8 rituximab-induced safety switch for incorporation into a set of selected cell therapy programs, in return for an upfront payment, with potential for near term option exercise fees and development milestone payments plus royalties.

  - Moderna exercised an option on one of the proprietary binders being developed against an undisclosed immuno-oncology target for the delivery of pioneering messenger RNA (mRNA) therapeutics, in return for an upfront payment, development and commercial milestone payments for each product successfully commercialized, as well as royalties on net sales of all products commercialized under the agreement.

    This license option stems from a deal announced on August 2, 2021, granting Moderna an exclusive option to license Autolus' proprietary binders for incorporation in certain mRNA therapeutics.

Financial Results for the Quarter Ended September 30, 2022

Cash at September 30, 2022, totaled $163.1 million, as compared to cash of $310.3 million at December 31, 2021. Post period end the company received $19.1m in relation to its 2021 U.K research and development tax credit claim.

Net total operating expenses for the three months ended September 30, 2022, were $43.5 million, which included license revenue income of $2.4 million, as compared to net operating expenses of $40.4 million, which included grant income of $0.2 million, for the same period in 2021.

Research and development expenses increased by $5.3 million to $37.6 million for the three months ended September 30, 2022 from $32.3 million for the three months ended September 30, 2021 primarily due to:

- an increase of $3.6 million in clinical costs and manufacturing costs primarily relating to the Company's obe-cel clinical product candidate,
- an increase of $2.0 million in salaries and other employment related costs including share-based compensation expense, which was mainly driven by an increase in the number of employees engaged in research and development activities,
- an increase of $0.8 million in legal fees and professional consulting fees in relation to the Company's research and development activities,
- 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.
- a decrease of $0.7 million in facilities costs related to the termination and closure of the Company's US manufacturing facility in 2021 and a shift in the Company's overall manufacturing strategy, and
- a decrease of $0.6 million in depreciation and amortization related to property, plant and equipment and intangible assets.

General and administrative expenses decreased by $0.1 million to $8.2 million for the three months ended September 30, 2022 from $8.3 million for the three months ended September 30, 2021 primarily due to:

- an increase of $1.0 million in salaries and other employment related costs including share-based compensation expenses, which was mainly driven by an increase in the number of employees engaged in general and administrative activities,

- an increase of $0.1 million in facilities costs due to the increased space utilized for general and administrative activities,
- a decrease of $1.1 million primarily related to a reduction in directors' and officers' liability insurance premiums, as well as reduced professional fees and information technology costs, and
- a decrease of $0.1 million in depreciation and amortization related to property, plant and equipment and intangible assets.

Other (expense) / income net, decreased to an expense of $3.7 million from an income of $1.0 million for the three months ended September 30, 2022 and 2021, respectively. The decrease of $4.7 million is primarily due to the weakening of the pound sterling relative to the U.S. dollar exchange rate during the three month period.

Interest expense increased to $1.9 million for the three months ended September 30, 2022 and relates primarily to the liability related to sale of future royalties and sales milestones which arose upon the Company's entry into the strategic collaboration and financing agreement with Blackstone, in November 2021. There was no interest expense during the comparable period in 2021.

Income tax benefit increased by $0.8 million to $6.2 million for the three months ended September 30, 2022 from $5.4 million for the three months ended September 30, 2021 due to an increase in qualifying research and development expenditures for the quarter.

Net loss attributable to ordinary shareholders was $42.8 million for the three months ended September 30, 2022, compared to $34.0 million for the same period in 2021. The basic and diluted net loss per ordinary share for the three months ended September 30, 2022, totaled $(0.47) compared to a basic and diluted net loss per ordinary share of $(0.47) for the three months ended September 30, 2021.

Autolus estimates that its current cash on hand and anticipated milestone payments in the relevant period from Blackstone extends the Company's runway into 2024.

Unaudited Financial Results for the Quarter Ended September 30, 2022

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash	$ 163,053	$ 310,338
Restricted cash	315	338
Prepaid expenses and other assets, current	48,943	36,276
Total current assets	**212,311**	**346,952**
Non-current assets:		
Property and equipment, net	32,474	33,541
Prepaid expenses and other non-current assets	1,718	2,362
Operating lease right-of-use assets	13,235	18,775
Long-term deposits	1,688	2,039
Deferred tax asset	2,396	1,826
Intangible assets, net	8	65
Total assets	**$ 263,830**	**$ 405,560**
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 334	$ 431
Accrued expenses and other liabilities	34,669	23,667
Operating lease liabilities	3,815	4,453
Total current liabilities	**38,818**	**28,551**
Non-current liabilities:		
Operating lease liabilities, net of current portion	11,310	16,545
Liability related to sale of future royalties and sales milestones, net	52,443	47,016
Other long-term payables	105	128
Total liabilities	**102,676**	**92,240**
Commitments and contingencies (Note 12)		
Shareholders' equity:		
Ordinary shares, $0.000042 par value; 290,909,783 and 200,000,000 shares authorized as of September 30, 2022 and December 31, 2021, respectively; 91,132,356 and 90,907,830, shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	4	4
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at September 30, 2022 and December 31, 2021	—	—

Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at September 30, 2022 and December 31, 2021	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	851,824	843,108
Accumulated other comprehensive loss	(47,564)	(8,570)
Accumulated deficit	(643,228)	(521,340)
Total shareholders' equity	**161,154**	**313,320**
Total liabilities and shareholders' equity	**$ 263,830**	**$ 405,560**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Grant income	$ —	$ 236	$ 166	$ 643
License revenue	2,369	—	2,369	1,507
Operating expenses:				
Research and development	(37,632)	(32,292)	(109,806)	(95,154)
General and administrative	(8,231)	(8,299)	(24,487)	(24,274)
Loss on disposal of leasehold improvements	—	—	—	(672)
Total operating expenses, net	**(43,494)**	**(40,355)**	**(131,758)**	**(117,950)**
Other (expense) income:				
Other (expense) income, net	(3,740)	951	(4,214)	(59)
Interest income	165	28	282	113
Interest expense	(1,850)	—	(5,448)	—
Total other (expense) income, net	**(5,425)**	**979**	**(9,380)**	**54**
Net loss before income tax	**(48,919)**	**(39,376)**	**(141,138)**	**(117,896)**
Income tax benefit	6,152	5,385	19,250	17,466
Net loss attributable to ordinary shareholders	**(42,767)**	**(33,991)**	**(121,888)**	**(100,430)**
Other comprehensive loss:				
Foreign currency exchange translation adjustment	(14,054)	(6,463)	(38,994)	(3,648)
Total comprehensive loss	**$ (56,821)**	**$ (40,454)**	**$ (160,882)**	**$ (104,078)**
Basic and diluted net loss per ordinary share	$ (0.47)	$ (0.47)	$ (1.34)	$ (1.46)
Weighted-average basic and diluted ordinary shares	91,240,801	72,896,362	91,028,562	68,770,962

Conference Call

Management will host a conference call and webcast at 8:30 am ET/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. The webcast can be accessed at this link.

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 & 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 development of Autolus' product candidate pipeline and achievement of expected near- and long-term milestones; the development of the obe-cel program including planned readouts after the completed futility analysis and completion of patient enrollment; the future clinical development, efficacy, safety and therapeutic potential of its other product candidates such as AUTO1/22, AUTO4. AUTO5, AUTO6NG, and AUTO8, including progress, expectations as to the reporting of data, conduct and timing and potential future clinical activity and milestones; expectations regarding regulatory approval process for any product candidates; Autolus' eligibility for potential milestone and royalty payments, and the Company's anticipated 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 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.

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