



Autolus Therapeutics Reports Financial and Operational Results for the Transition Period from October 1 to December 31, 2018

February 25, 2019 at 6:00 AM EST

- Conference Call to be held on February 25, 2019 at 8:00 am EST/1:00 pm GMT -

LONDON, Feb. 25, 2019 /PRNewswire/ -- Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies, today announced its financial and operational results for the transition period from October 1 to December 31, 2018. On December 19, 2018, the board of directors approved a change of fiscal year end from September 30 to December 31. The Company will also file a report on Form 20-F with the Securities and Exchange Commission for the transition period, after market close today.

Key recent 2019 events and 2018 highlights include:

Clinical

- In February 2019, Autolus announced updated data from the ongoing Phase 1 CARPALL trial of AUTO1 in pediatric patients with relapsed/refractory acute lymphoblastic leukemia (pALL) at the European Hematology Association 1st European CAR T Cell Meeting held in Paris, France. Consistent with the original presentation at the 59th American Society of Hematology (ASH) Annual Meeting in Atlanta, the emerging safety profile appears to be manageable and differentiated. Notably, none of the patients experienced severe cytokine release syndrome (CRS) (Grade 3-5) and none of the patients required treatment with tocilizumab or steroids. Thirteen patients experienced CRS at Grade 1 or 2. As previously reported, one patient experienced Grade 4 neurotoxicity; there were no other reports of severe neurotoxicity (Grade 3-5). Eleven patients experienced cytopenia that was not resolved by day 28 or recurring after day 28 (Grades 1-4). Two patients developed significant infections, and 1 patient died from sepsis while in molecular complete response (CR). In the trial, AUTO1 combined a high molecular complete response rate (86% after a single dose of AUTO1) with robust persistence at one year follow-up in pediatric acute B cell leukemia patients. The median duration of remission in responding patients was 7.3 months with a median follow-up of 14 months. Event-free survival was 46% with overall survival of 63% at 12 months.
- In December 2018, Autolus announced preliminary results from the ongoing Phase 1/2 AMELIA clinical trial of AUTO3 in patients with relapsed/refractory pediatric acute lymphoblastic leukemia (pALL) at the 60th ASH Annual Meeting in San Diego, California. Researchers reported on ten patients with relapsed or refractory pALL who received an AUTO3 infusion as a single dose or split dose dependent on their tumor burden. It was observed that AUTO3 was generally well-tolerated with no severe CRS and only one case of Grade 3 neurotoxicity observed, which was considered unlikely related to AUTO3 and primarily attributed to prior intrathecal chemotherapy. Eight out of ten patients achieved minimal residual disease-(MRD) negative CR and higher response rates were observed at doses $\geq 3 \times 10^6$ /kg dose levels with all patients achieving MRD-negative remission. In the higher dose group, four out of six patients had an ongoing molecular CR as of the cutoff date and, importantly, no loss of CD19 or CD22 was noted among the relapsed patients.
- At the 60th ASH Annual Meeting in December 2018, Autolus also announced preliminary results of the ongoing Phase 1/2 ALEXANDER clinical trial of AUTO3 in patients with relapsed/refractory diffuse large B cell lymphoma (DLBCL). The principal investigator reported that AUTO3 followed by consolidation with a limited duration of anti-PD1 therapy appeared to have a manageable safety profile at the doses evaluated. Out of the seven patients evaluable for safety, none developed CRS grade 3 or higher and one patient had Grade 3 neurotoxicity, considered possibly related to AUTO3. No dose limiting toxicities were observed and dose escalation continues. Six patients were evaluable for response; two patients achieved a CR (which was ongoing at six and three months post-treatment, respectively) and two patients had a partial response; two patients did not respond.
- In December 2018, Autolus announced an update on its novel CAR T cell program for peripheral T cell lymphoma. The first patient was dosed in the Phase 1/2 LibrA T1 clinical trial of AUTO4, a developmental therapy for the treatment of relapsed or refractory TRBC1-positive peripheral T cell lymphoma (PTCL). Also, the preclinical data from the sister program AUTO5, targeting TRBC2-positive lymphoma, were presented at the 60th ASH Annual Meeting.
- Autolus will host an R&D Day in New York City on March 26, 2019 for the investment community. This event will provide an update on Autolus' current clinical programs and highlight the company's next-generation programmed T cell products for

hematological and solid tumor indications.

Manufacturing and Product Delivery

- In February 2019, the Medicines and Healthcare Products Regulatory Agency approved an extension to the GMP license of the Cell and Gene Therapy Catapult Manufacturing Centre in Stevenage, which, with its innovative operational and licensing model, enables Autolus to manufacture clinical trial supply from this facility.
- In January 2019, Autolus announced it has signed a long-term, full-building lease with Alexandria Real Estate Equities, Inc. for the construction and development of an 85,000 square foot build-to-suit facility to be located in the Shady Grove Life Sciences Center in Rockville, Maryland. The new facility will house offices for Autolus' U.S.-based research and development, commercial and corporate functions and serve as its first full commercial-scale manufacturing center, with a planned capacity of producing 5,000 T cell therapies annually.
- Also in January, Autolus initiated the build-out of a manufacturing facility in Enfield, U.K. The facility is planned to open in 2020 and will provide global supply of viral vector as well as a planned capacity of 1,000 T cell therapies annually.
- Autolus is establishing a series of intelligent systems to efficiently manage all aspects of manufacture and certification of supply. Costs will be partly covered through a grant from Innovate UK. To date, Autolus has been awarded Innovate UK grants totaling £6.7 million (approximately \$8.6 million).

Corporate Highlights

- In December 2018, Autolus announced that it had been selected for addition to the NASDAQ Biotechnology Index (Nasdaq: NBI) as part of the annual re-ranking.
- Autolus strengthened its management and board during 2018. Key company management appointments included Andrew J. Oakley as senior vice president and chief financial officer and Adam Hacker, PhD as senior vice president for regulatory affairs and quality. Key board of directors appointments included Linda Bain, current chief financial officer of Codiak BioSciences, Inc., and Cynthia M. Butitta, former chief operating officer of Kite Pharma.
- In June 2018, Autolus completed a U.S. initial public offering of American Depositary Shares, representing a total of 10,147,059 ordinary shares, including full exercise of the underwriters' over-allotment, for net proceeds, after deducting underwriting discounts and commissions and offering expenses, of \$156.5 million.

"In 2019, we expect significant progress that will build on the momentum of last year," stated Dr. Christian Itin, chairman and chief executive officer of Autolus. "Our robust pipeline of clinical and pre-clinical programs is progressing well, and we expect to move two programs into registrational trials and provide updates on all of our active programs at conferences during the course of this year. The next scheduled data presentation will be for AUTO1 in adult acute lymphoblastic leukemia at the American Association for Cancer Research's Annual Meeting in April."

Financial results for the period from October 1 through December 31, 2018:

- As stated above, we are transitioning to reporting our results on a calendar year basis. As such we are presenting audited results for the three-month period from October 1, 2018 to December 31, 2018, and the comparative period for 2017, which is unaudited.
- Cash and equivalents at December 31, 2018 totaled \$217.5 million, compared with \$129.0 million at December 31, 2017, due primarily to the \$156.5 million in net proceeds resulting from Autolus' U.S. initial public offering, which closed in June 2018.
- Net total operating expenses for the three months ended December 31, 2018 were \$25.0 million, net of grant income of \$0.3 million, as compared to net operating expenses of \$8.4 million, net of grant income of \$0.2 million, for the same period in 2017. The increase was due, in general, to the increase in clinical trial activity, which is expected to deliver on key milestones in 2019; increased headcount; and the cost of being a public company.
- Research and development expenses increased to \$17.7 million for the three months ended December 31, 2018 from \$5.6 million for the three months ended December 31, 2017. Cash costs, which exclude depreciation as well as share-based compensation, increased to \$15.2 million from \$5.1 million. The increase in research and development cash costs of \$10.1 million consisted primarily of an increase of \$4.3 million in project expenses related to the activities necessary to prepare, activate, and monitor clinical trial programs, an increase in compensation-related costs of \$3.8 million primarily due to an increase in headcount to support the advancement of our product candidates in clinical development, and an increase of \$2.0 million in facilities costs and consumables supporting the expansion of our research and translational science capability and investment in manufacturing facilities and equipment.
- General and administrative expenses increased to \$7.6 million for the three months ended December 31, 2018 from \$3.1

million for the three months ended December 31, 2017. Cash costs, which exclude depreciation as well as share-based compensation, increased to \$5.7 million from \$2.5 million. The increase of \$3.2 million consisted primarily of an increase of \$2.3 million in insurance, patent costs, commercial costs, investor relations and communication costs and additional facility costs, as well as an increase in compensation-related expense of \$0.9 million.

- Net loss attributable to ordinary shareholders was \$20.6 million for the three months ended December 31, 2018, compared to \$7.5 million for the same period in 2017.
- The basic and diluted net loss per ordinary share for the three months ended December 31, 2018 totaled \$(0.52) compared to a basic and diluted net loss per ordinary share of \$(0.26) for the three months ended December 31, 2017.
- Autolus anticipates that cash on hand provides a runway into calendar year 2021.

Conference Call and Presentation Information

Autolus management will host a conference call today, February 25, at 8:00 a.m. EST/ 1:00pm GMT to discuss the company's financial results and operational update.

To listen to the webcast and view the accompanying slide presentation, please go to: <https://www.autolus.com/investor-relations/news-events/events>.

The call may also be accessed by dialing 877-270-2148 (U.S.) and 412-902-6510 (international) and asking the operator to join the Autolus Therapeutics conference call. After the conference call, a replay will be available for one week. To access the replay, please dial 877-344-7529 (U.S.) or 412-317-0088 (international) and enter replay access code 10129000.

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.

Forward-Looking Statement

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' financial condition and results of operations, as well as statements regarding the anticipated development of Autolus' product candidates, including its intentions regarding the timing for providing further updates on the development of its product candidates, and the sufficiency of its cash resources. 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. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our 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 on November 23, 2018 as well as discussions of potential risks, uncertainties, and other important factors in Autolus' future filings with the Securities and Exchange Commission from time to time. All information in this press release is as of the date of the release, and the company 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.

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

	Three Months Ended December 31,	For the Year Ended September 30,		
	2018	2018	2017	2016
Grant income	\$ 296	\$ 1,407	\$ 1,693	\$ 1,212
Operating expenses:				
Research and development	(17,713)	(36,150)	(16,012)	(10,436)
General and administrative	(7,593)	(22,790)	(9,099)	(5,152)
Total operating expenses, net	<u>(25,010)</u>	<u>(57,533)</u>	<u>(23,418)</u>	<u>(14,376)</u>
Other income (expense):				
Interest income	660	1,532	84	75
Other income (expense)	1,097	3,970	(46)	(26)
Total other income, net	<u>1,757</u>	<u>5,502</u>	<u>38</u>	<u>49</u>
Net loss before income tax	<u>(23,253)</u>	<u>(52,031)</u>	<u>(23,380)</u>	<u>(14,327)</u>
Income tax benefit	2,605	7,280	3,653	1,777
Net loss attributable to ordinary shareholders	<u>(20,648)</u>	<u>(44,751)</u>	<u>(19,727)</u>	<u>(12,550)</u>
Other comprehensive (loss) income:				

Foreign currency exchange translation adjustment	(5,568)	(6,071)	802	(2,942)
Total comprehensive loss	<u>(26,216)</u>	<u>(50,822)</u>	<u>(18,925)</u>	<u>(15,492)</u>
Basic and diluted net loss per ordinary share	\$ (0.52)	\$ (1.42)	\$ (1.43)	\$ (1.26)
Weighted-average basic and diluted ordinary shares	39,366,634	31,557,034	13,783,222	9,933,399

Autolus Therapeutics PLC
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	<u>December 31,</u> <u>2018</u>	<u>September 30,</u> <u>2018</u>	<u>September 30,</u> <u>2017</u>
Assets			
Current assets:			
Cash	\$ 217,450	\$ 246,984	\$ 137,070
Restricted cash	105	105	—
Prepaid expenses and other current assets	15,411	12,189	5,412
Total current assets	<u>232,966</u>	<u>259,278</u>	<u>142,482</u>
Non-current assets:			
Property and equipment, net	19,968	13,528	6,180
Long-term deposits	1,276	—	—
Intangible assets, net	—	399	—
Total assets	<u>\$ 254,210</u>	<u>\$ 273,205</u>	<u>\$ 148,662</u>
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable	2,022	3,036	1,946
Accrued expenses and other liabilities	19,054	14,103	3,087
Total current liabilities	<u>21,076</u>	<u>17,139</u>	<u>5,033</u>
Non-current liabilities:			
Long-term lease incentive obligation	207	221	265
Other long-term payables	285	380	763
Total liabilities	<u>21,568</u>	<u>17,740</u>	<u>6,061</u>
Shareholders' equity:			
Ordinary shares, \$0.000042 par value; 200,000,000 shares authorized as of December 31, 2018 and September 30, 2018, 37,426,509 authorized as of September 30, 2017; 40,145,617, 40,146,182, and 29,962,741 shares issued and outstanding at December 31, 2018 and September 30, 2018 and 2017, respectively	2	2	1
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at December 31, 2018 and September 30, 2018, respectively; no shares authorized, issued or outstanding at September 30, 2017	—	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at December 31, 2018 and September 30, 2018; no shares authorized, issued or outstanding at September 30, 2017	118	118	—
Deferred C shares, £0.000001 par value; 1 share authorized, issued and outstanding at December 31, 2018 and September 30, 2018; no shares authorized, issued or outstanding at September 30, 2017	—	—	—
Additional paid-in capital	361,311	357,918	194,351
Accumulated other comprehensive loss	(15,488)	(9,920)	(3,849)
Accumulated deficit	(113,301)	(92,653)	(47,902)
Total shareholders' equity	<u>232,642</u>	<u>255,465</u>	<u>142,601</u>
Total liabilities and shareholders' equity	<u>\$ 254,210</u>	<u>\$ 273,205</u>	<u>\$ 148,662</u>


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