Autolus Therapeutics Reports First Quarter 2026 Financial Results and Business Updates

May 14, 2026 at 7:00 AM EDT

- *AUCATZYL® (obecabtagene autoleucel; obe-cel) net product revenue of $26.2 million for the first quarter of 2026, reflecting strong launches in the US and most recently the UK*
- *Company achieves positive gross margin for the acute lymphoblastic leukemia (ALL) business*
- *Cost reduction initiative to drive gross profit margin improvement and path to profitability for the ALL business underway*
- *Obe-cel clinical development programs on track with trial enrollment ongoing in lupus nephritis, pediatric ALL and progressive multiple sclerosis (MS)*
- *Conference call to be held today at 8:30am EDT/1:30pm BST: conference call participants should pre-register using the link at the bottom of this press release*

LONDON and GAITHERSBURG, Md., May 14, 2026 (GLOBE NEWSWIRE) -- Autolus Therapeutics plc (Nasdaq: AUTL), a commercial-stage biopharmaceutical company developing, manufacturing and delivering next-generation programmed T cell therapies and candidates, today announces its operational and financial results for the first quarter ended March 31, 2026.

"In the first quarter, Autolus continued to expand market share for AUCATZYL in the US based on strong physician experience in adult ALL, and supported by reliable, high-quality product delivery. Our UK launch, which began in January, is off to a strong start, and we are expanding our reach in this market as well. We are pleased to report a turn to positive gross margin in the first quarter, and we expect continued improvement as we grow sales and manage costs," said **Dr. Christian Itin, Chief Executive Officer of Autolus.**

Dr. Itin continued, "Beyond adult ALL, given obe-cel's established profile, we remain focused on broadening obe-cel's utility in additional indications. Our Phase 2 pivotal studies, CATULUS in pediatric relapsed or refractory B-cell precursor ALL and LUMINA in severe lupus nephritis patients, and our Phase 1 BOBCAT trial in progressive MS, are underway and progressing well."

Dr. Itin concluded, "With good momentum with AUCATZYL and our pipeline, we continue optimizing our operating model and driving cost efficiency. The recently announced initiative will further enhance our margins, support scalable growth and position Autolus for long-term value creation."

Product and Pipeline Updates:

- *AUCATZYL® Launch*
  - Autolus reported net product revenue of $26.2 million for the three months ended March 31, 2026, compared to $9.0 million for the same period the prior year.
  - AUCATZYL launched in the UK in January 2026 and is now available under routine commissioning.
  - Data from the ROCCA (Real-World Outcomes Collaborative for CAR T in Adult ALL) consortium covering commercial patients during the first year of launch of AUCATZYL in the US was presented at the TANDEM meeting in February 2026. This real-world data showed consistency in both safety and efficacy with the pivotal FELIX clinical trial that was the basis for regulatory approvals. The ROCCA consortium registry covered approximately 60% of US commercial patients at a data cutoff of January 2026.

- *Obe-cel in pediatric r/r B-ALL*
  - The Phase 2 portion of the ongoing CATULUS Phase 1 trial of obe-cel in pediatric relapsed or refractory (r/r) B-cell precursor ALL (B-ALL) patients is underway and Autolus expects to report data at the end of 2027. The US Food and Drug Administration (FDA) has granted regenerative medicine advanced therapy (RMAT) designation to obe-cel for the treatment of pediatric patients with r/r B-ALL.

- *Obe-cel in lupus nephritis*
  - Data from the Phase 1 CARLYSLE trial in patients with severe refractory systemic lupus erythematosus supported progression of obe-cel as a treatment for lupus nephritis (LN) and selection of the recommended Phase 2 dose of 50 million cells. Following alignment with the FDA on a potential registrational path to approval, the pivotal LUMINA Phase 2 trial is enrolling and the Company expects to report data in 2028.

- *Obe-cel in progressive MS*
  - Autolus has advanced obe-cel into initial clinical development to explore treatment in progressive MS. The Phase 1

trial, expected to include up to 18 adult patients, is enrolling and will determine the safety, tolerability, and preliminary efficacy of obe-cel in participants with refractory progressive forms of MS. The Company expects to report initial data from the trial at the end of 2026 and full data in 2027.

- *AUTO8 in Light-Chain Amyloidosis*
  - The Phase 1 ALARIC trial evaluating AUTO8 in light-chain amyloidosis is ongoing and initial data are expected to be reported at the end of 2026.

Operational Updates:

- In April 2026, Autolus announced a strategic initiative and plan to improve operational efficiency and reduce operating expenses. As part of this initiative, Autolus is implementing a reduction in force affecting approximately 13% of its existing overall workforce, impacting all areas of the business. The actions are expected to reduce operating expenses by approximately $15 million on an annualized basis beginning in 2027. As a result of the reorganization, which includes employee-related actions taken beginning in the second half of 2025, the Company expects to incur total restructuring charges of approximately $8 million, consisting primarily of employee severance and related costs, the majority of which will be recognized in the first half of 2026. The implementation of the workforce reduction plan is expected to be substantially complete by the third quarter of 2026.

- In April 2026, the Company held a virtual investor event entitled: Spotlight on Acute Lymphoblastic Leukemia (ALL) Program. The event included key opinion leaders Dr. Jae Park from Memorial Sloan Kettering Cancer Center; Dr. Lori Muffly from Stanford School of Medicine; Dr. Elias Jabbour from MD Anderson Cancer Center and Dr. Michael Pulsipher from University of Utah Huntsman Cancer Institute. A recording of the event is available in the Investor Relations section of the Company's website, under " Events".

Outlook:

Autolus reiterates its full year 2026 outlook for AUCATZYL net product revenue of between $120 million to $135 million, up from $74 million in 2025, as well as continued positive gross margin in 2026.

Based on current operating plans, including anticipated AUCATZYL net revenues, Autolus expects that its current and projected cash, cash equivalents and marketable securities will be sufficient to fund the Company's operations into Q4 2027.

Summary of Anticipated News Flow:

Longer-term follow up data from CARLYSLE trial in patients with severe refractory systemic lupus erythematosus	By year-end 2026
Initial clinical data from BOBCAT Phase 1 trial in patients with progressive MS	By year-end 2026
Initial clinical data from ALARIC Phase 1 trial in patients with light-chain amyloidosis	By year-end 2026
Phase 1 full data from BOBCAT trial in patients with progressive MS	In 2027
Phase 2 data from CATULUS trial in patients with pediatric r/r B-ALL	By year-end 2027
Phase 2 data from LUMINA trial in patients with LN	In 2028

Financial Results for the Quarter Ended March 31, 2026

Product revenue, net increased to $26.2 million for the three months ended March 31, 2026, compared to $9.0 million the same period in 2025.

Cost of sales increased to $24.6 million for the three months ended March 31, 2026, compared to $18.0 million the same period in 2025. This increase was primarily due to costs related to increased product sales of AUCATZYL in the three months ended March 31, 2026 including inventory reserves and write offs compared to the same period in the prior year. Gross profit was $1.6 million in the first quarter of 2026, compared to a loss in all prior quarters.

Research and development expenses decreased to $21.2 million for the three months ended March 31, 2026, compared to $26.7 million in the same period in 2025. This change was primarily due to a decrease in research and development activities including clinical trial and clinical manufacturing supply costs.

Selling, general and administrative expenses increased to $39.9 million for the three months ended March 31, 2026, compared to $29.5 million in the same period in 2025. This increase was primarily due to salaries, other employment-related costs and professional fees supporting commercialization activities in the US and UK. In addition, this quarter also included one-time termination-related expenses, relating to the strategic operational efficiency and cost reduction initiative announced in April 2026.

Loss from operations for the three months ended March 31, 2026, was $59.5 million, as compared to $65.2 million for the same period in 2025.

Net loss was $71.6 million for the three months ended March 31, 2026, compared to $70.2 million for the same period in 2025. Basic and diluted net loss per ordinary share for the three months ended March 31, 2026, totaled $(0.27), compared to basic and diluted net loss per ordinary share of $(0.26) for the same period in 2025.

Cash, cash equivalents and marketable securities at March 31, 2026, totaled $229.4 million, as compared to $300.7 million at December 31, 2025.

The decrease was primarily driven by net cash used in operating activities.

Selected Consolidated Statements of Operations and Comprehensive Loss Data

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2026	**2025**
Revenue:		
Product revenue, net	$ 26,218	$ 8,982
Total revenue, net	**26,218**	**8,982**
Cost and operating expenses:		
Cost of sales	(24,568)	(17,951)
Research and development expenses, net	(21,210)	(26,734)
Selling, general and administrative expenses	(39,953)	(29,537)
Loss from operations	**(59,513)**	**(65,240)**
Total other (expenses) income, net	**(11,222)**	**(2,696)**
Net loss before income tax	**(70,735)**	**(67,936)**
Income tax expense	(863)	(2,225)
Net loss	**(71,598)**	**(70,161)**
Other comprehensive (loss) income:		
Total other comprehensive (loss) income, net of tax	**(1,271)**	**11,068**
Total comprehensive loss	**$ (72,869)**	**$ (59,093)**
Basic and diluted net loss per ordinary share	$ (0.27)	$ (0.26)
Weighted-average basic and diluted ordinary shares	266,143,425	266,126,548

Financial Results for the Three Months Ended March 31, 2026

Selected Consolidated Balance Sheet Data

(In thousands)

	March 31, 2026	**December 31, 2025**
Assets		
Cash and cash equivalents	$ 130,925	$ 104,132
Marketable securities - Available-for-sale debt securities	$ 98,509	$ 196,578
Total current assets	$ 368,835	$ 435,915
Total assets	$ 527,065	$ 589,068
Liabilities and shareholders' equity		
Total current liabilities	$ 63,599	$ 73,440
Total liabilities	$ 418,239	$ 410,939
Total shareholders' equity	$ 108,826	$ 178,129

Conference Call

Management will host a conference call and webcast today at 8:30am EDT/1:30pm BST to discuss the company's financial results. 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 at https://www.autolus.com/investor-relations-media/events/.

About Autolus Therapeutics plc

Autolus Therapeutics plc (Nasdaq: AUTL) is a commercial-stage biopharmaceutical company developing, manufacturing and delivering next-generation T cell therapies and candidates for the treatment of cancer and autoimmune disease. Using a broad suite of proprietary and modular T cell programming technologies, Autolus is engineering precisely targeted and controlled T cell therapies that are designed to better recognize target cells, break down their defense mechanisms and eliminate these cells. Autolus has a marketed therapy, AUCATZYL®, and 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 AUCATZYL® (obecabtagene autoleucel; obe-cel)

AUCATZYL is a B-lymphocyte antigen CD19 (CD19) chimeric antigen receptor (CAR) T cell therapy designed to overcome the limitations in clinical activity and safety compared to current CD19 CAR T cell therapies. AUCATZYL is designed with a fast target binding off-rate to minimize excessive activation of the programmed T cells. AUCATZYL was approved by the FDA for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia on November 8, 2024, and was granted conditional marketing authorization by MHRA in the UK and EMA in the EU in 2025.

INDICATION
AUCATZYL® is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, and SECONDARY HEMATOLOGICAL MALIGNANCIES

- **Cytokine Release Syndrome (CRS) occurred in patients receiving AUCATZYL. Do not administer AUCATZYL to patients with active infection or inflammatory disorders. Prior to administering AUCATZYL, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage CRS *[see Dosage and Administration (2.2, 2.3), Warnings and Precautions (5.1)].***
- **Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), including fatal or life-threatening reactions, occurred in patients receiving AUCATZYL, including concurrently with CRS or after CRS resolution. Monitor for neurologic signs and symptoms after treatment with AUCATZYL. Prior to administering AUCATZYL, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage neurologic toxicities. Provide supportive care and/or corticosteroids, as needed *[see Dosage and Administration (2.2, 2.3), Warnings and Precautions (5.2)].***
- **T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies *[see Warnings and Precautions (5.8)].***

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome (CRS)
Cytokine Release Syndrome (CRS) occurred following treatment with AUCATZYL. CRS was reported in 75% (75/100) of patients including Grade 3 CRS in 3% of patients. The median time to onset of CRS was 8 days following the first infusion (range: 1 to 23 days) with a median duration of 5 days (range: 1 to 21 days). The most common manifestations of CRS included fever (100%), hypotension (35%), and hypoxia (19%).

Cytokine Release Syndrome (CRS) occurred following treatment with AUCATZYL. CRS was reported in 75% (75/100) of patients including Grade 3 CRS in 3% of patients. The median time to onset of CRS was 8 days (range: 1 to 23 days) with a median duration of 5 days (range: 1 to 21 days). Sixty-eight percent of patients (51/75) experienced CRS after the first infusion, but prior to the second infusion of AUCATZYL with a median time to onset of 6 days (range: 1 to 10 days). Among patients with CRS, the most common manifestations of CRS included fever (100%), hypotension (35%) and hypoxia (19%). The primary treatment for CRS was tocilizumab (73%; 55/75), with patients also receiving corticosteroids (21%; 16/75).

Prior to administering AUCATZYL, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage CRS. During and following treatment with AUCATZYL, closely monitor patients for signs and symptoms of CRS daily for at least 7 days following each infusion. Continue to monitor patients for CRS for at least 2 weeks following each infusion with AUCATZYL. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, immediately evaluate the patient for hospitalization and institute treatment with supportive care based on severity and consider further management per current practice guidelines.

Neurologic Toxicities
Neurologic toxicities including Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS), which were fatal or life-threatening, occurred following treatment with AUCATZYL. Neurologic toxicities were reported in 64% (64/100) of patients, including Grade ≥ 3 in 12% of patients.

The median time to onset of neurologic toxicities was 10 days (range: 1 to 246 days) with a median duration of 13 days (range: 1 to 904 days). Fifty-five percent of patients (35/64) experienced neurologic toxicities after the first infusion but prior to the second infusion of AUCATZYL with a median time to onset of 6 days (range: 1 to 11 days). Among patients with neurologic toxicities, the most common symptoms (> 5%) included ICANS (38%), headache (34%), encephalopathy (33%), dizziness (22%), tremor (13%), anxiety (9%), insomnia (9%), and delirium (8%).

Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS)
ICANS events occurred in 24% (24/100) of patients, including Grade ≥ 3 in 7% (7/100) of patients. Of the 24 patients who experienced ICANS, 33% (8/24) experienced an onset after the first infusion, but prior to the second infusion of AUCATZYL. The median time to onset for ICANS events after the first infusion was 8 days (range: 1 to 10 days) and 6.5 days (range: 2 to 22 days) after the second infusion, with a median duration of 8.5 days (range: 1 to 53 days). Eighty-eight percent (21/24) of patients received treatment for ICANS. All treated patients received high-dose corticosteroids and 42% (10/24) of patients received anti-epileptics prophylactically. Prior to administering AUCATZYL, ensure that healthcare providers have immediate access to medications and resuscitative equipment to manage ICANS.

During and following AUCATZYL administration, closely monitor patients for signs and symptoms of Neurologic Toxicity/ICANS. Following treatment with AUCATZYL, monitor patients daily for at least 7 days. Continue to monitor patients for at least 2 weeks following treatment with AUCATZYL. Avoid driving for at least 2 weeks after each infusion. Counsel patients to seek medical attention should signs or symptoms of neurologic toxicity/ ICANS occur. At the first sign of Neurologic Toxicity/ICANS, immediately evaluate patients for hospitalization and institute treatment with supportive care based on severity and consider further management per current practice guidelines.

Prolonged Cytopenias
Patients may exhibit cytopenias including anemia, neutropenia, and thrombocytopenia for several weeks after treatment with lymphodepleting chemotherapy and AUCATZYL. In patients who were responders to AUCATZYL, Grade ≥ 3 cytopenias that persisted beyond Day 30 following AUCATZYL infusion were observed in 71% (29/41) of patients and included neutropenia (66%, 27/41) and thrombocytopenia (54%, 22/41). Grade 3 or higher cytopenias that persisted beyond Day 60 following AUCATZYL infusion was observed in 27% (11/41) of patients and included neutropenia (17%, 7/41) and thrombocytopenia (15%, 6/41). Monitor blood counts after AUCATZYL infusion.

Infections
Severe, including life-threatening and fatal infections occurred in patients after AUCATZYL infusion. Non-COVID-19 infections of all grades occurred in 67% (67/100) of patients. Grade 3 or higher non-COVID-19 infections occurred in 41% (41/100) of patients. AUCATZYL should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection before and after AUCATZYL infusion and treat appropriately. Administer prophylactic antimicrobials according to local guidelines.
Grade 3 or higher febrile neutropenia was observed in 26% (26/100) of patients after AUCATZYL infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care as medically indicated.
Viral reactivation, potentially severe or life-threatening, can occur in patients treated with drugs directed against B cells. There is no experience with manufacturing AUCATZYL for patients with a positive test for human immunodeficiency virus (HIV) or with active hepatitis B virus (HBV) or active hepatitis C virus (HCV). Perform screening for HBV, HCV and HIV in accordance with clinical guidelines before collection of cells for manufacturing.

Hypogammaglobulinemia
Hypogammaglobulinemia and B-cell aplasia can occur in patients after AUCATZYL infusion. Hypogammaglobulinemia was reported in 10% (10/100) of patients treated with AUCATZYL including Grade 3 events in 2 patients (2%).
Immunoglobulin levels should be monitored after treatment with AUCATZYL and managed per institutional guidelines including infection precautions, antibiotic or antiviral prophylaxis, and immunoglobulin replacement.
The safety of immunization with live viral vaccines during or following treatment with AUCATZYL has not been studied. Vaccination with live viral vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy treatment, during AUCATZYL treatment, and until immune recovery following treatment with AUCATZYL.

Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS)
HLH/MAS including fatal and life-threatening reactions occurred after treatment with AUCATZYL. HLH/MAS was reported in 2% (2/100) of patients and included Grade 3 and Grade 4 events with a time of onset at Day 22 and Day 41, respectively. One patient experienced a concurrent ICANS events after AUCATZYL infusion and died due to sepsis with ongoing HLH/MAS that had not resolved. Administer treatment for HLH/MAS according to institutional standards.

Hypersensitivity Reactions
Serious hypersensitivity reactions, including anaphylaxis, may occur due to dimethyl sulfoxide (DMSO), an excipient used in AUCATZYL. Observe patients for hypersensitivity reactions during and after AUCATZYL infusion.

Secondary Malignancies
Patients treated with AUCATZYL may develop secondary malignancies. T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies. Mature T cell malignancies, including CAR-positive tumors, may present as soon as weeks following infusion, and may include fatal outcomes. Monitor lifelong for secondary malignancies. In the event that a secondary malignancy occurs, contact Autolus at 1-855-288-5227 for reporting and to obtain instructions on the collection of patient samples for testing.

Adverse Reactions
The safety of AUCATZYL was evaluated in the FELIX study in which 100 patients with relapsed or refractory B-cell acute lymphoblastic leukemia (B-ALL) received AUCATZYL at a median dose of 410 × 10^6 CD19 CAR-positive viable T cells (range: 10 to 480 × 10^6 CD19 CAR-positive viable T cells with 90% of patients receiving the recommended dose of 410 × 10^6 +/- 25%).

The most common serious adverse reactions of any Grade (incidence ≥ 2%) included infections-pathogen unspecified, febrile neutropenia, ICANS, CRS, fever, bacterial infectious disorders, encephalopathy, fungal infections, hemorrhage, respiratory failure, hypotension, ascites, HLH/MAS, thrombosis and hypoxia. Nine patients (9%) experienced fatal adverse reactions which included infections (sepsis, pneumonia, peritonitis), ascites, pulmonary embolism, acute respiratory distress syndrome, HLH/MAS and ICANS. Of the 9 patients, five patients who died from infections had pre-existing and ongoing neutropenia prior to receiving bridging therapy, lymphodepletion chemotherapy treatment and/or AUCATZYL.

Please see full **Prescribing Information,** including **BOXED WARNING** and Medication Guide.

Cautionary Note Regarding 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 Autolus' future expectations, plans and prospects, including guidance on 2026 AUCATZYL net product revenue and gross margin, and the impact of recently announced restructuring activities; Autolus' anticipated cash runway; the therapeutic potential and expected clinical benefits of AUCATZYL for adult patients with r/r B-ALL and obe-cel in additional indications including LN and progressive MS; Autolus' ability to generate revenues from AUCATZYL; Autolus' ability to obtain and maintain regulatory approval for obe-cel for adult r/r B-ALL in additional territories and the timing thereof; expectations regarding the commercialization, marketing and manufacturing of AUCATZYL for adult r/r B-ALL, including expanding into additional territories and the related timing of reaching patients in such territories; the development of obe-cel in autoimmune indications and of additional product candidates, including statements regarding the initiation, timing, progress and the results of clinical studies or trials and related preparatory work; the period during which the results of clinical studies or trials will become available; Autolus' plans to expand, develop and enhance its manufacturing activities; and Autolus' pursuit of expanded market access across Europe. 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 identified in the section titled "Risk Factors" in Autolus' Annual Report on Form 10-K filed with the Securities and Exchange Commission (the SEC), on March 27, 2026 and any of its subsequent Quarterly Reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in Autolus' subsequent filings with the SEC. 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. You should, therefore, not rely on these forward-looking statements as representing Autolus' views as of any date subsequent to the date of this press release.

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