

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 14, 2024

Autolus Therapeutics plc
(Exact name of registrant as specified in its Charter)

England and Wales (State or other jurisdiction of incorporation or organization)	001-38547 (Commission File Number)	Not applicable (I.R.S. Employer Identification No.)
The Mediaworks 191 Wood Lane London W12 7FP United Kingdom (Address of principal executive offices)(Zip Code)		
(44) 20 3829 6230 (Registrant's telephone number, including area code)		
Not Applicable (Former name or former address, if changed since last report)		

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing one ordinary share, nominal value \$0.000042 per share	AUTL	The Nasdaq Global Select Market
Ordinary shares, nominal value \$0.000042 per share*	*	The Nasdaq Stock Market LLC*

* Not for trading, but only in connection with the listing of the American Depositary Shares on The Nasdaq Stock Market LLC.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Conditions.

On March 14, 2024, Autolus Therapeutics plc (the “*Company*”) issued a press release announcing its recent business highlights and financial results for year ended December 31, 2023. The press release also includes information regarding the Company’s previously announced conference call and webcast to be held at 8:30 am EDT/12:30 pm GMT on March 14, 2024 to discuss the results. A copy of the press release is furnished hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), or otherwise subject to the liabilities of that section. The information contained herein and in the accompanying exhibit is not incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended (the “*Securities Act*”), or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure.

In connection with its conference call on March 14, 2024 to discuss its results for the year ended December 31, 2023, the Company will utilize an updated corporate presentation, a copy of which is furnished as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.2 attached hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section. The information contained herein and in the accompanying exhibit is not incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On March 14, 2024, the Company also announced that Dr. Edgar Braendle, the Company’s Chief Development Officer, has tendered his resignation. Dr. Braendle will serve in a consulting capacity to ensure a smooth transition.

Item 9.01 Financial Statements and Exhibits

d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Press release dated March 14, 2024
99.2	Corporate Presentation dated March 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: March 14, 2024

AUTOLUS THERAPEUTICS PLC

By:

/s/Christian Itin, Ph.D.

Name: Christian Itin, Ph.D.

Title: Chief Executive Officer



Autolus Therapeutics Reports Full Year 2023 Financial Results and Business Updates

March 14, 2024 at 7:00 AM EDT

- Announced strategic collaboration and equity investment from BioNTech for aggregate proceeds of \$250 million upfront, plus underwritten offering of ADSs for \$350 million, for gross proceeds of \$600 million received in February 2024
- Submitted a Biologics License Application (BLA) for obecabtagene autoleucel (obe-cel), a potentially transformational treatment for relapsed/refractory (r/r) adult B-cell Acute Lymphoblastic Leukemia (ALL), to the US Food & Drug Administration (FDA); Prescription Drug User Fee Act (PDUFA) target action date November 16, 2024
- Successfully completed first facility inspection and obtained a Manufacturer's Importation Authorization (MIA) from the Medicines and Healthcare products Regulatory Agency (MHRA), enabling the commercial product supply for obe-cel at The Nucleus manufacturing facility
- Submitted a Market Authorization Application (MAA) for obe-cel in r/r adult ALL with the European Medicines Agency (EMA)
- Conference call to be held today at 08:30 am EDT/12:30 pm GMT: Conference call participants should pre-register using the link at the bottom of this press release

LONDON, March 14, 2024 (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, 2023.

"We're delighted to be starting 2024 in such a strong financial position; our recently announced strategic alliance with BioNTech, coupled with two equity financing transactions, raised gross proceeds of \$600 million. Combined with our 2023 ending cash of \$240 million, this enables us to drive the full launch and commercialization of obe-cel in r/r adult ALL and establish Autolus as a potential leader in the delivery of CAR T therapy to patients with autoimmune diseases," said Dr. Christian Itin, Chief Executive Officer of Autolus.

"2023 was a transformational year for the Company. Our lead program, obe-cel, demonstrated strong data in B-ALL in the pivotal FELIX study, we fully validated our commercial manufacturing facility, The Nucleus, to support our regulatory submissions and we submitted our first BLA for obe-cel to the United States Food and Drug Administration (FDA) in November, with a PDUFA target action date of November 16, 2024. We also just submitted an MAA to the European Medicines Agency (EMA).

"Beyond B-ALL, we see a significant opportunity for obe-cel in autoimmune disease. Our Phase 1 dose confirmation trial in refractory SLE is now open for enrollment. We believe obe-cel's clinical profile, together with our commercial product delivery base and infrastructure, will help to drive an accelerated and differentiated expansion in autoimmune diseases and we look forward to sharing initial data from the study in late 2024.

"For now, we remain fully focused on preparing for a potential obe-cel launch and successfully transitioning Autolus to a commercial stage company. Pre-commercial and product delivery activities are well underway, and we are on track to make obe-cel available to B-ALL patients as soon as possible, following a potential approval."

Key obecabtagene autoleucel (obe-cel) updates and anticipated milestones:

- Obe-cel in relapsed / refractory (r/r) adult ALL – The FELIX Study
 - Obe-cel BLA for r/r B-ALL submitted to the FDA in November 2023; PDUFA target action date of November 16, 2024. A marketing authorization application (MAA) to the European Medicines Agency (EMA) was just submitted and an MAA submission to the MHRA in the UK is planned for the second half of 2024.
 - Pooled analysis of the FELIX Phase 1b/2 study presented at ASH in December 2023 demonstrated prolonged event free survival and low overall immunotoxicity across all cohorts in r/r B-ALL, and particularly in patients with low leukemic burden at lymphodepletion. Additionally, data from a pooled analysis from the ALLCAR19 study and FELIX Phase 1b in r/r B-ALL showed durable remissions with obe-cel as a stand-alone therapy in a subset of patients after a median follow up of >3 years. Further long-term data from the FELIX study is anticipated at medical conferences in 2024.
- Obe-cel in B-cell mediated autoimmune diseases
 - The Phase 1 dose confirmation study in refractory systemic lupus erythematosus (SLE) patients has the first site open for enrollment; initial clinical data expected in late 2024.

Pipeline clinical trials, in collaboration with University College London (UCL), updates and anticipated milestones:

- AUTO8 in Multiple Myeloma – Phase 1 MCARTY Study
 - AUTO8 is a next-generation product candidate for multiple myeloma, which includes two CARs for the multiple myeloma targets, BCMA and CD19. Initial data from the MCARTY Phase 1 study in multiple myeloma presented at ASH in December 2023 showed AUTO8 was well tolerated, with responses observed in all patients. Further updates from the MCARTY study are anticipated during 2024.
- AUTO6NG in Neuroblastoma – Phase 1 MAGNETO Study
 - AUTO6NG contains a CAR that targets GD2 alongside additional programming modules to enhance the activity and persistence. A Phase 1 clinical study in children with r/r neuroblastoma was opened for enrollment in the fourth quarter of 2023.

Post-period:

Strategic developments:

Strategic alliance with BioNTech SE

In February 2024, BioNTech and Autolus announced a strategic CAR T cell therapy collaboration to advance their pipelines and expand late-stage programs, for \$50 million cash upfront and up to \$582 million in potential option exercise and milestone payments. Additionally, Autolus sold \$200 million of ADSs to BioNTech in a concurrent private placement financing transaction.

Overview:

- BioNTech has right to utilize Autolus' manufacturing capacity, know-how and cost-efficiencies to accelerate the planned clinical development and commercialization of BNT211
- BioNTech to support launch and expansion of development program of Autolus' lead cell therapy candidate obe-cel and will receive a royalty on net sales
- BioNTech has co-commercialization options for Autolus' AUTO1/22 and AUTO6NG programs, and an option to access a suite of Autolus target binders and cell programming technologies

Underwritten offering

In February 2024, Autolus completed an underwritten registered direct offering in the United States at a price of \$6.00 per ADS, for total gross proceeds of \$350 million.

Recent Operational Updates:

- In March 2024, following the most recent GMP inspection by the MHRA in February 2024, The Nucleus manufacturing facility in Stevenage obtained a Manufacturer's Importation Authorization (MIA), together with the accompanying GMP certificate. This authorization enables Autolus to manufacture products for global commercial and clinical supply at The Nucleus, effective as of March 18, 2024.
- In February 2024, Autolus promoted Dr. Chris Williams to Chief Business Officer and Alex Driggs to Senior Vice President, Legal Affairs and General Counsel. Chris has been with the Company since its inception, having negotiated on behalf of UCL the spin off and formation of Autolus. Alex has been with Autolus since 2018 in the role of General Counsel.
- Dr. Edgar Braendle has notified the Company that he will step down as Chief Development Officer to pursue other opportunities. Edgar will continue to advise the company during the BLA and MAA review process. Miranda Neville, SVP and obe-cel Program Leader will run the Development team.
- Autolus announced the appointment of Elisabeth (Lis) Leiderman, M.D. and Robert W. Azelby to its Board of Directors. Dr. Leiderman brings extensive transactional and financial expertise, and Mr. Azelby brings more than 30 years of biopharmaceutical leadership and commercial experience to Autolus' Board.

Scientific Publications:

- In January 2024, Autolus announced the publication of a paper in ACS Chemical Biology entitled: 'Designer small molecule control system based on Minocycline induced disruption of protein-protein interaction' - Jha et al., ACS Chemical Biology (2024) doi:10.1021/acscchembio.3c00521; [\[Link\]](#)
 - In February 2024, Autolus announced the publication of a paper in Nature Communications entitled: 'Structure-Guided Engineering of Immunotherapies Targeting TRBC1 and TRBC2 in T Cell Malignancies' – Ferrari et al., Nat Commun 15, 1583 (2024) doi:10.1038/s41467-024-45854-3; [\[Link\]](#)
 - In March 2024, Autolus announced the publication of a paper in Blood Cancer Journal entitled: 'Dual T-cell constant β chain (TRBC)1 and TRBC2 staining for the identification of T-cell neoplasms by flow cytometry – Horna et al., Blood Cancer J. 14, 34 (2024) doi: 10.1038/s41408-024-01002-0; [\[Link\]](#)
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2024 Expected News Flow:

Obe-cel FELIX data update at ASCO, EHA & ASH
Obe-cel Marketing Authorization Application to MHRA
Obe-cel U.S. FDA PDUFA target action date
Obe-cel in autoimmune disease – initial data from SLE Phase 1 study

June & Dec 2024
Second half 2024
November 16, 2024
Late 2024

Financial Results (Unaudited) for the Full Year Ended December 31, 2023

Cash and cash equivalents at December 31, 2023 totaled \$239.6 million, as compared to \$382.4 million at December 31, 2022.

Total operating expenses, net for the year ended December 31, 2023, were \$179.7 million, as compared to \$143.4 million, for the year ended December 31, 2022.

Research and development expenses increased from \$117.4 million to \$130.5 million for the year ended December 31, 2023, compared to the same period in 2022. This change was primarily due to increases in operating costs related to the Company's new commercial manufacturing facility, contractual milestone payments and employee salaries and related costs, a decrease in our U.K. reimbursable R&D tax credits claimable through the U.K. small and medium-sized entity (SME) scheme and partially offset by decreases in clinical and manufacturing costs related to the Company's obe-cel clinical product candidate.

In prior years, Autolus reported the R&D tax credits as income tax benefit on its statements of operations. The Company has revised its financial presentation, including the prior years, and will now present such tax credits as a reduction in research and development expense. As a result, income tax benefit has reduced by \$19.5 million and \$24.6 million for the years ended December 31, 2023, and 2022, respectively, with corresponding reductions in research and development expenses and total operating expenses.

General and administrative expenses increased from \$31.9 million to \$46.7 million for the year ended December 31, 2023, compared to the same period in 2022. This increase was primarily due to salaries and other employment-related costs driven by an increase in general and administrative headcount supporting the overall growth of the business, primarily relating to pre-commercialization activities.

Net loss attributable to ordinary shareholders was \$208.4 million for the year ended December 31, 2023, compared to \$148.8 million for the same period in 2022. The basic and diluted net loss per ordinary share for the year ended December 31, 2023, totaled \$(1.20), compared to a basic and diluted net loss per ordinary share of \$(1.57) for 2022.

Autolus estimates that, with its current cash and cash equivalents and proceeds received from the strategic alliance with BioNTech and the private placement and underwritten equity financing, it is well capitalized to drive the full launch and commercialization of obe-cel in r/r adult ALL as well as to advance its pipeline development plans, which includes providing runway to data in the first pivotal study of obe-cel in autoimmune disease.

Financial Results for the Year Ended December 31, 2023
Selected Unaudited Consolidated Balance Sheet Data
(In thousands)

	December 31,	
	2023	2022
Assets		
Cash and cash equivalents	\$ 239,566	\$ 382,436
Total current assets	\$ 275,302	\$ 425,771
Total assets	\$ 375,381	\$ 490,274
Liabilities and shareholders' equity		
Total current liabilities	\$ 44,737	\$ 46,366
Total liabilities	\$ 263,907	\$ 191,600
Total shareholders' equity	\$ 111,474	\$ 298,674

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

	Year Ended December 31,	
	2023	2022
Grant income	\$ —	\$ 166
License revenues	1,698	6,194
Operating expenses:		
Research and development ¹	(130,481)	(117,354)
General and administrative	(46,745)	(31,899)
Loss on disposal of property and equipment	(3,791)	(515)
Impairment of operating lease right-right-of-use and related property equipment	(382)	—
Total operating expenses, net	(179,701)	(143,408)

Total other expenses, net	(28,701)	(5,159)
Net loss before income tax	(208,402)	(148,567)
Income tax benefit (expense) ¹	19	(272)
Net loss attributable to ordinary shareholders	(208,383)	(148,839)
Other comprehensive income (loss):		
Foreign currency exchange translation adjustment	9,906	(30,328)
Total comprehensive loss	<u>\$ (198,477)</u>	<u>\$ (179,167)</u>
Basic and diluted net loss per ordinary share	<u>\$ (1.20)</u>	<u>\$ (1.57)</u>
Weighted-average basic and diluted ordinary shares	<u>173,941,926</u>	<u>94,993,400</u>

Conference Call

Management will host a conference call and webcast at 08:30 am EDT/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.

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 and autoimmune disease. Using a broad suite of proprietary and modular T cell programming technologies, Autolus is engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognize target 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, solid tumors and autoimmune diseases. 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. Obe-cel is designed with a fast target binding off-rate to minimize excessive activation of the programmed T cells. In clinical trials of obe-cel, this "fast off-rate" profile reduced toxicity and T cell exhaustion, resulting in improved persistence and leading to high levels of durable remissions in r/r Adult ALL patients. The results of the FELIX trial, a pivotal trial for adult ALL, have been submitted and accepted by the FDA with a PDUFA target action date of November 16, 2024. A regulatory submission to the EMA was made in the first half of 2024. In collaboration with Autolus' academic partner, UCL, obe-cel is currently being evaluated in a Phase 1 clinical trials for B-NHL.

About obe-cel FELIX clinical trial

Autolus' Phase 1b/2 clinical trial of obe-cel enrolled 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 was overall response rate, and the secondary endpoints included duration of response, MRD negative CR rate and safety. The trial enrolled over 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 I clinical trial for patients with r/r pediatric ALL. [NCT02443831]

About AUTO6NG

AUTO6NG is a next generation programmed T cell product candidate in development for the treatment of both neuroblastoma and other GD2-expressing solid tumors. 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. A Phase 1 clinical trial of AUTO6NG in children with relapsed/refractory neuroblastoma was opened for enrollment in the fourth quarter of 2023.

About AUTO8

AUTO8 is a 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 designed for improved killing of target cells that express BCMA at low levels. This has been combined with fast off rate CD19 CAR from obe-cel, with the aim of inducing deep and durable responses and extending the durability of effect over other BCMA CARs currently in development. This product candidate is currently in a Phase I clinical trial for patients with r/r multiple myeloma. [NCT04795882]

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' development and commercialization of its product candidates, timing of data announcements and regulatory submissions, its cash resources and the market opportunity for obe-cel. 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; and possible safety and efficacy concerns. 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, or the SEC, on March 7, 2023 and in Autolus' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2023, 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. 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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¹ Includes the presentation of our U.K. SME R&D Tax Credit with Income tax benefit as contra research and development expense in the amounts of \$19.5 million and \$24.6 million for the years ended December 31, 2023, and 2022, respectively.



Full Year 2023 Financial Results and Business Updates

March 14, 2024



EX-99.2

Disclaimer

These slides contain 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' development of its product candidates, including the obe-cel program; the profile and potential application of obe-cel in additional disease settings; the future clinical development, efficacy, safety and therapeutic potential of the Company's product candidates, including progress, expectations as to the reporting of data, conduct and timing and potential future clinical and preclinical activity and milestones; expectations regarding the initiation, design and reporting of data from clinical trials and preclinical studies; the extension of the pipeline beyond obe-cel; expectations regarding the regulatory approval process for any product candidates; the benefits of the collaboration between Autolus and BioNTech, including the potential and timing of milestone payments and royalties under the terms of the strategic collaboration; the Company's current and future manufacturing capabilities; 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; and possible safety and efficacy concerns. 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, or the SEC, on March 7, 2023 and in Autolus' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2023, 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 presentation is as of the date of the presentation, 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 the Company's views as of any date subsequent to the date of this presentation.

Agenda

- Welcome and Introduction: Olivia Manser, Director, Investor Relations
 - Operational Highlights: Dr. Christian Itin, CEO
 - Financial Results: Rob Dolski, CFO
 - Upcoming Milestones and Conclusion: Dr. Christian Itin, CEO
 - Q&A: Dr. Christian Itin and Rob Dolski
-

Strategic updates

Strong cash position: Year-end 2023 cash of \$240M & gross proceeds of \$600M from activities in February 2024

Financing

- **In February 2024 completed an underwritten registered direct equity financing**
 - Gross proceeds of \$350M

BioNTech collaboration

- **In parallel established strategic collaboration with BioNTech aimed at advancing both companies' autologous CAR T programs**
 - \$200M equity, \$50M cash upfront
 - Up to \$582 million in further option exercise and milestones payments
 - BioNTech to support launch and expansion of obe-cel in adult ALL for royalty on net sales
 - BioNTech has option to use Autolus' manufacturing capacity for BNT211
 - BioNTech has co-commercialization options for Autolus' AUTO1/22 and AUTO6NG programs and option on Autolus target binders and cell programming technologies

Obe-cel highlights in r/r B-ALL

FELIX data, regulatory review and preparation for launch

Clinical	<ul style="list-style-type: none">• Obe-cel in relapsed / refractory (r/r) adult ALL - pooled analysis presented at ASH in December 2023<ul style="list-style-type: none">— FELIX Phase 1b/2 study - prolonged event free survival and low overall immunotoxicity across all cohorts particularly in patients with low leukemic burden at lymphodepletion— ALLCAR19 study and FELIX Phase 1b - durable remissions with obe-cel as a stand-alone therapy in a subset of patients after a median follow up of >3 years
Manufacturing	<ul style="list-style-type: none">• Robust manufacturing process and state of the art commercial manufacturing<ul style="list-style-type: none">— Completed first facility inspection in February 2024 – the Nucleus manufacturing facility in Stevenage has obtained a Manufacturer’s Importation Authorization (MIA) together with accompanying GMP certificate— Poster presentation at ASH on obe-cel manufacturing performance
Regulatory	<ul style="list-style-type: none">• Biologics License Application (BLA) accepted by US Food and Drug Administration (FDA)<ul style="list-style-type: none">— PDUFA target action date of November 16, 2024• Marketing Authorization Application (MAA) recently submitted to EMA
Commercial Readiness	<ul style="list-style-type: none">• Commercial capability and infrastructure preparation on track<ul style="list-style-type: none">— Commercial systems setup on track— Focus on clinical center onboarding and medical affairs

Other pipeline highlights

Expanding opportunity beyond ALL

Obe-cel in
Autoimmune
Diseases

- **Obe-cel in B-cell mediated autoimmune diseases – Phase 1 CARLYSLE Study**
 - Phase 1 dose confirmation study in refractory SLE patients – first trial site opened for enrollment in Q1 2024
 - Potential best-in-class risk/benefit profile, based on data from pivotal FELIX trial in adult ALL

AUTO8

- **AUTO8 in Multiple Myeloma – Phase 1 MCARTY Study**
 - Initial data in multiple myeloma presented at ASH in December 2023 demonstrated AUTO8 was well tolerated, with responses observed in all patients

AUTO6NG

- **AUTO6NG in Neuroblastoma – Phase 1 MAGNETO Study**
 - A Phase 1 clinical study in children with r/r neuroblastoma was opened for enrollment in Q4 2023

Organizational changes

- **Promotions of Dr Chris Williams to Chief Business Officer and Alex Driggs to Senior Vice President, Legal Affairs and General Counsel**
 - **Dr. Edgar Braendle to step down as Chief Development Officer to pursue other opportunities. Edgar will continue to advise the Company through the BLA and MAA review process**
 - **Miranda Neville, Senior Vice President and obe-cel Program Leader, to run Development team**
 - **Strengthening of the Board with the appointments of Dr. Elisabeth (Lis) Leiderman and Robert W. Azelby**
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LEAD CLINICAL PROGRAM

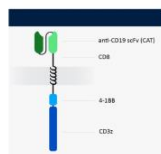
Obe-cel

A standalone, potentially best-in-class
CD19 CAR T cell therapy candidate

We believe obe-cel has a unique mechanism of action

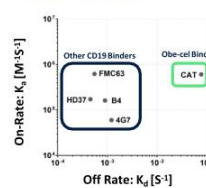
Designed for increased activity and reduced toxicity

Differentiated CD19 binder



CD19 binder with fast off-rate

Fast off-rate



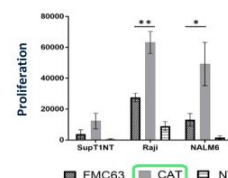
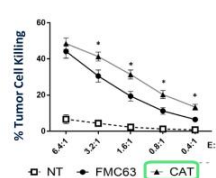
Shorter half-life of interaction compared to binders used in approved products

- obe-cel = 9.8 seconds
- Kymriah® = 21 minutes

Potential for improved potency, reduced toxicity

- Avoided over-activation of CAR T cells ➡ Reduced toxicities
- Increased CAR T peak expansion ➡ Improved persistence
- Avoided exhaustion of CAR T-cells ➡ Improved engraftment
Improved persistence

Enhanced cytotoxicity and proliferation



Ghorashian et al. *Nature Medicine* 2019



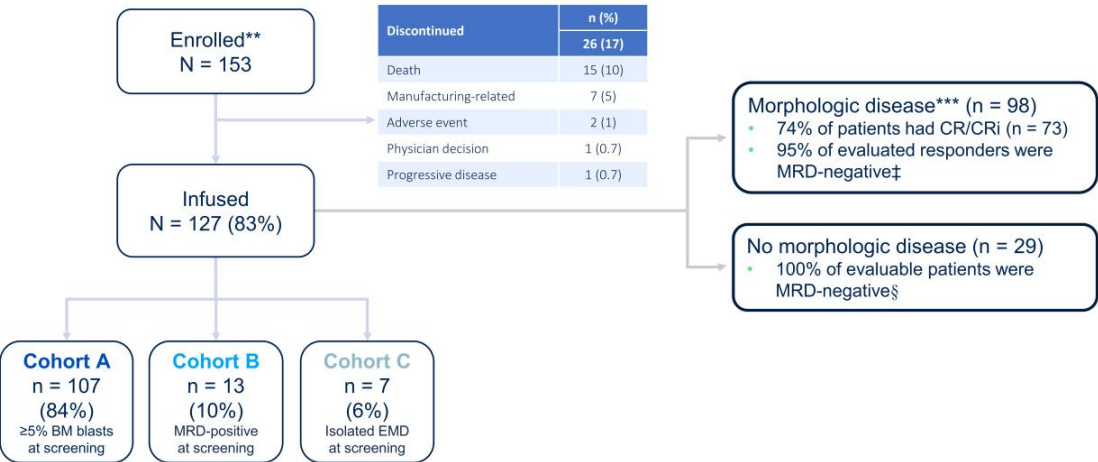
ASH 2023

Obe-cel pooled analysis

FELIX Phase 1b/2 trial

FELIX Phase 1b/2 pooled analysis: patient disposition

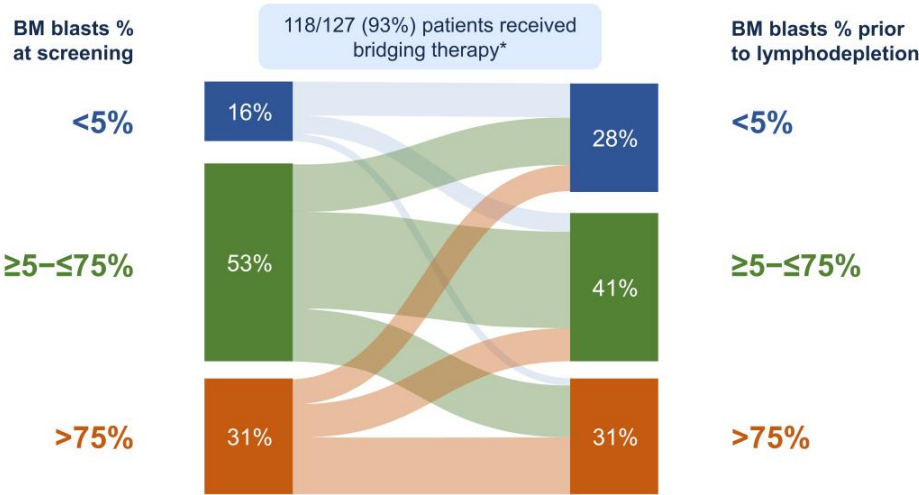
127/153 (83%) enrolled patients received obe-cel*



*Seven patients received Dose 1 only; **All eligibility criteria met and the leukapheresate accepted for manufacturing; obe-cel, obecabtagene autoleucel; Roddie et al., ASH 2023, Data cut-off date: September 13, 2023
***Morphologic disease defined as ≥5% BM blasts or presence of EMD regardless of BM blast status; †MRD status available for 64/73 patients, as assessed by NGS or flow cytometry; ‡MRD status available for 27/29 patients, as assessed by NGS or flow cytometry; §MRD status available for 27/29 patients, as assessed by NGS or flow cytometry; BM, bone marrow; CR, complete remission; CRi, CR with incomplete hematologic recovery; EMD, extramedullary disease; MRD, measurable residual disease; NGS, next-generation sequencing; obe-cel, obecabtagene autoleucel

FELIX Phase 1b/2 pooled analysis: leukemic burden in all treated patients

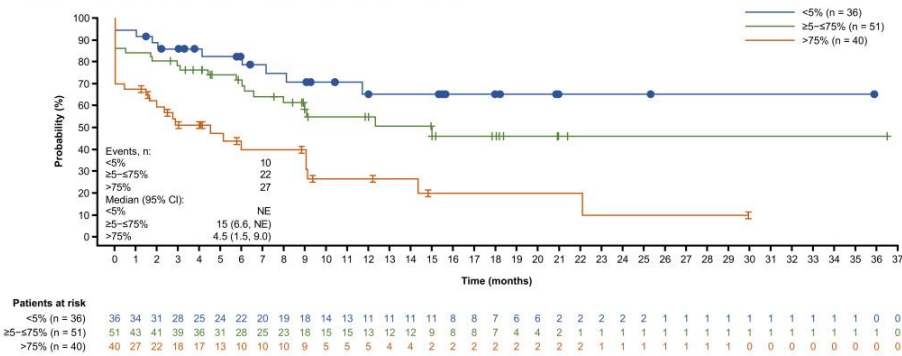
Leukemic burden at screening is not predictive of leukemic burden prior to lymphodepletion



*Bridging therapy per physician's choice, including inotuzumab ozogamicin; BM, bone marrow; Roddie et al., ASH 2023

FELIX Ph1b/2 pooled: EFS by leukemic burden prior to lymphodepletion*

Lower leukemic burden is associated with better outcomes

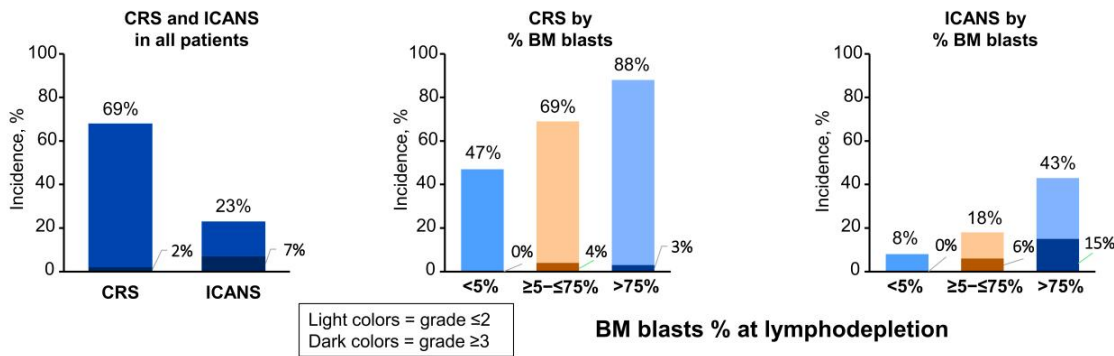


BM blasts % prior to lymphodepletion	<5% (n = 36)	≥5-≤75% (n = 51)	>75% (n = 40)
Median EFS (95% CI), months	NE	15.0 (6.6, NE)	4.5 (1.5, 9.0)
6-month EFS (95% CI), %	83 (65, 92)	72 (57, 82)	40 (23, 56)
12-month EFS (95% CI), %	65 (44, 80)	55 (38, 69)	27 (12, 44)

*Censoring new non-protocol anti-cancer therapies including SCT with disease assessment by IRRRC (data cut-off date: September 13, 2023); BM, bone marrow; CI, confidence interval; EFS, event-free survival; IRRRC, Independent Response Review Committee; NE, not evaluable; SCT, stem cell transplant; Roddie et al., ASH 2023

FELIX Phase 1b/2 pooled analysis: CRS and ICANS

Low rates of Grade ≥ 3 CRS and/or ICANS were observed



- No grade ≥ 3 CRS and/or ICANS were observed in patients with $<5\%$ BM blasts at lymphodepletion
- Vasopressors were used to treat CRS in 2.4% of patients
- The treatment was generally well tolerated
- Two deaths were considered treatment-related per investigator assessment: neutropenic sepsis ($n = 1$); acute respiratory distress syndrome and ICANS ($n = 1$)

BM, bone marrow; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; ICU, intensive care unit; Roddie et al., ASH 2023



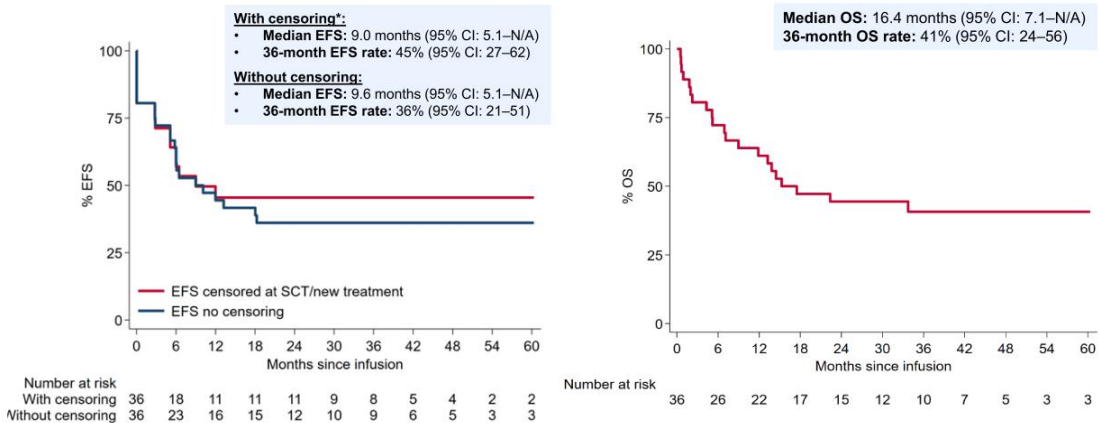
ASH 2023

Obe-cel pooled analysis

ALLCAR19 Phase 1b /FELIX Ph 1b

Long-term follow up in R/R B-ALL demonstrates favorable EFS and OS

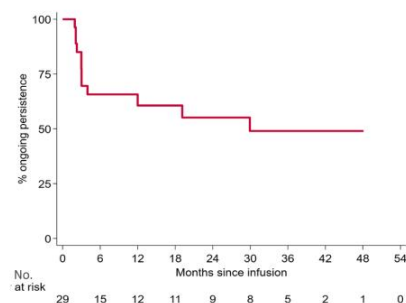
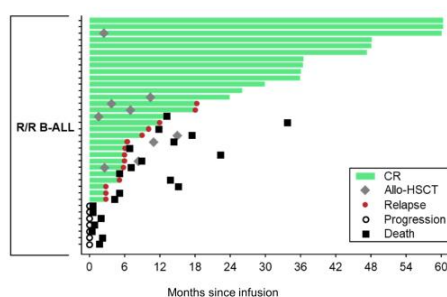
Median follow up 36.5 months; pooled analysis Phase 1b ALLCAR19/Phase 1b FELIX



*Censored for allo-HSCT and other anti-cancer treatment. Investigator-assessed disease evaluations were performed locally by CT and BM biopsy for B-ALL. Allo-HSCT, allogeneic hematopoietic stem cell transplant; B-ALL, B-cell acute lymphoblastic leukemia; BM, bone marrow; CI, confidence interval; CT, computed tomography; EFS, event-free survival; N/A, not available; obe-cel, obecabtagene autoleucel; OS, overall survival; R/R, relapsed/refractory. Roddie et al, ASH 2023, Poster 2114.

Durable remissions and prolonged persistence in patients with R/R B-ALL

Pooled analysis Phase 1b ALLCAR19 / Phase 1b FELIX



- ORR: 80.6% (95% CI: 64.0–91.8)
- All patients in ongoing remission were MRD-negative at last assessment
- Median DOR: Not reached (95% CI: 5.1–N/A)
- Ongoing CAR T persistence
 - 12 months: 60.6% (95% CI: 38.9–76.8)
 - 24 months: 55.1% (95% CI: 33.1–72.6)

Safety: No \geq grade 3 CRS reported; 4/36 \geq grade 3 ICANS; No new safety signals or deaths related to obe-cel

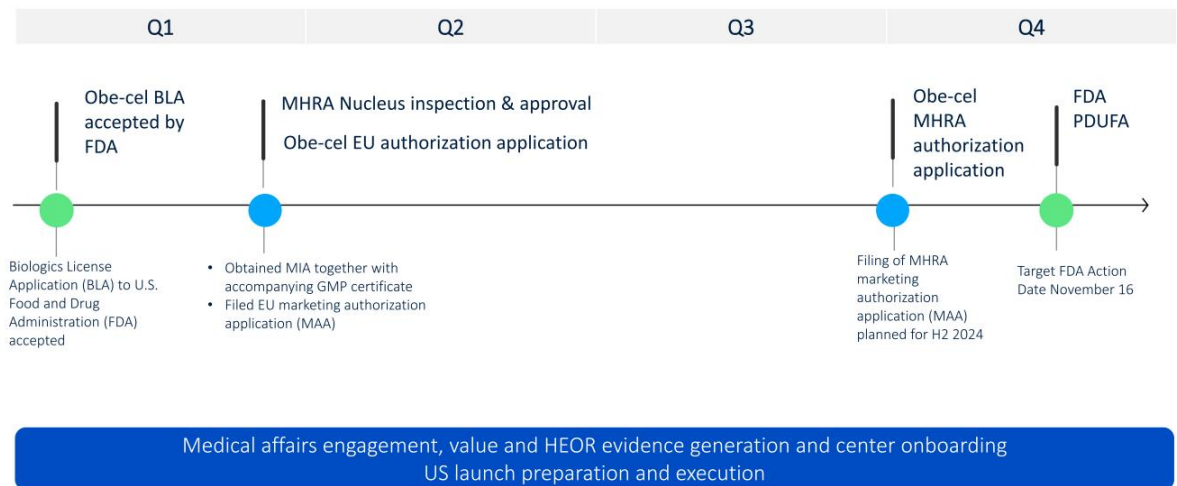
MRD status was determined using flow cytometry or IgH PCR/NGS (MRD-negative: $<10^{-4}$ [$<0.01\%$]). Loss of CAR T persistency was defined as the time from first obe-cel infusion to undetectable CAR T transgene (copies/ μ g DNA) in peripheral blood. Patients who proceeded to allo-HSCT with ongoing CAR T persistency were censored at the last result prior to receiving allo-HSCT. Allo-HSCT, allogeneic hematopoietic stem cell transplant; B-ALL, B-cell acute lymphoblastic leukemia; BM, bone marrow; CI, confidence interval; CR, complete remission; CT, computed tomography; DOR, duration of response; MRD, measurable residual disease; N/A, not available; NGS, next-generation sequencing; ORR, overall response rate; PCR, polymerase chain reaction; R/R, relapsed/refractory. Roddie et al, ASH 2023, Poster 2114.



Commercial Launch Readiness

Obe-cel steps to commercialization in r/r adult B-ALL

Roadmap to a 2024 commercial launch

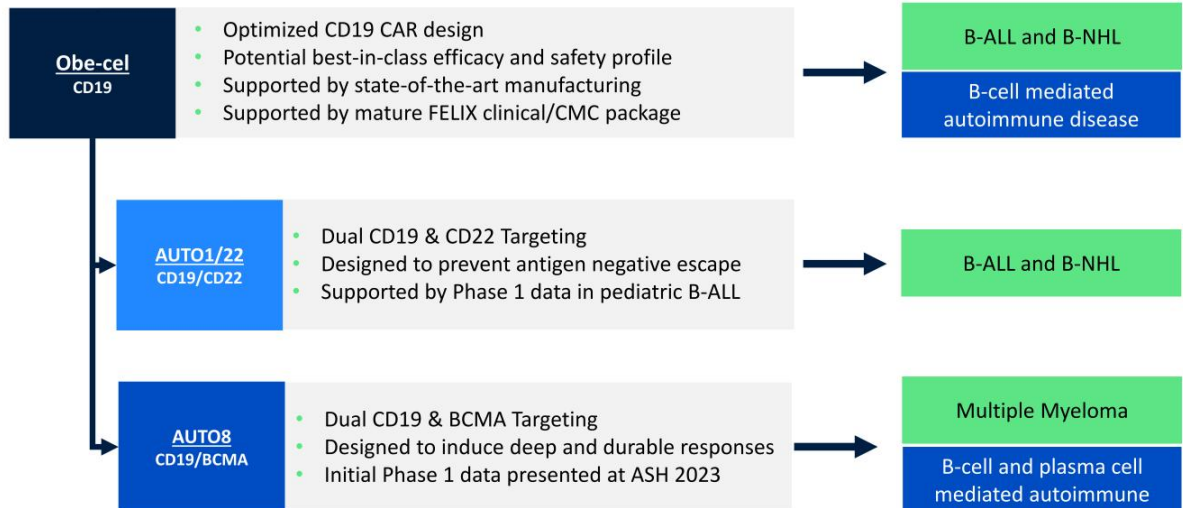




Expanding the obe-cel opportunity

Deep value program with potentially broad applicability

The obe-cel product family and franchise opportunity



Phase 1 SLE study – CARLYSLE trial

A Single-Arm, Open-Label, Phase I Study to Determine the Safety, Tolerability and Preliminary Efficacy of Obecabtagene Autoleucel in Patients with Severe, Refractory Systemic Lupus Erythematosus (SLE)






- **Study details**
 - **Number of patients:** 6
 - (option to add further cohort of 6 patients)
 - **Primary endpoint:** to establish the tolerability and safety of obe-cel in patients with severe, refractory SLE
 - **Secondary endpoints:** to evaluate the preliminary efficacy of obe-cel using measures of SLE disease activity
 - **Dosing:** 50×10^6 ($\pm 20\%$) CD19 CAR-positive T cells
 - **Follow up:** up to 12 months
-



Other pipeline programs and technologies

A broad portfolio of potential next generation modular T cell therapies

Autolus pipeline

Obe-cel product family						
PRODUCT	INDICATION	TARGET	STUDY NAME	PARTNER	PHASE	STATUS/EXPECTED MILESTONES
Obe-cel	Adult B-ALL	CD19	FELIX		Pivotal	H1 2024: MAA Application to EMA November 16, 2024: PDUFA date
Obe-cel	Systemic Lupus Erythematosus	CD19	CARLYSLE		Phase 1	Study open for enrollment
Obe-cel	B-NHL and CLL	CD19	ALLCAR19		Phase 1	Data in peer reviewed journal
Obe-cel	PCNSL	CD19	CAROUSEL		Phase 1	Data in peer reviewed journal
AUTO1/22	Pediatric ALL	CD19 & CD22	CARPALL	  *	Phase 1	Data in BLOOD August 2023
AUTO8	Multiple Myeloma	CD19 & BCMA	MCARTY		Phase 1	Updated clinical data in 2024

Additional pipeline programs						
AUTO4	TRBC1+ Peripheral TCL	TRBC1	LibrA T1		Phase 1	Data in peer reviewed journal
AUTO5	TRBC2+ Peripheral TCL	TRBC2	-		Preclinical	Data in peer reviewed journal
AUTO6NG	Neuroblastoma	GD2	MAGNETO	  *	Phase 1	Study open for enrollment
AUTO9	Acute Myeloid Leukemia	CD33, CD123 & CLL1	TBD		Preclinical	Estimated Phase 1 start 2025

 Oncology

 Autoimmune

* BioNTECH holds an option to co-fund and co-commercialize



Financial Results

Financial summary (unaudited)

USD	Q4 2023 YTD (\$ '000)	Q4 2022 YTD (\$ '000)	Variance (\$ '000)
Grant Income	-	166	(166)
License revenues	1,698	6,194	(4,496)
R&D ¹	(130,481)	(117,354)	(13,127)
G&A	(46,745)	(31,899)	(14,846)
Loss on disposal of property and equipment	(3,791)	(515)	(3,276)
Impairment of right-of-use and related assets	(382)	-	(382)
Total operating expense, net	(179,701)	(143,408)	(36,293)
Other income (expense), net	2,861	2,038	823
Interest Income	13,505	1,708	11,797
Interest expense	(45,067)	(8,905)	(36,162)
Income tax benefit (expense) ¹	19	(272)	291
Net loss after tax	(208,383)	(148,839)	(59,544)
USD	Q4 2023 (\$ '000)	Q4 2022 (\$ '000)	Variance (\$ '000)
Cash and cash equivalents	239,566	382,436	(142,870)

¹Includes the presentation of our U.K. SME R&D Tax Credit with Income tax benefit as contra research and development expense in the amounts of \$19.5 million and \$24.6 million for the years ended December 31, 2023 and 2022, respectively.



Upcoming news flow

Autolus planned news flow

Anticipated Milestone or Data Catalysts	Anticipated Timing
Obe-cel FELIX data update at ASCO, EHA & ASH 2024	June & December 2024
Obe-cel Marketing Authorization Application to MHRA	Second half 2024
Obe-cel U.S. FDA PDUFA target action date	November 16, 2024
Obe-cel in autoimmune disease – initial data from SLE Phase 1 study	End 2024



Summary

Building a leading CAR T company developing therapies for cancer and autoimmune diseases

Scaling company toward commercialization



Obe-cel potentially best in class CAR T for r/r adult ALL

- FELIX pivotal trial showed high ORR, encouraging EFS and favorable tolerability with low levels of high-grade CRS and ICANS
- PDUFA date 16 Nov 2024
- EMA filing submitted



Pipeline expansion strategy

- Expand obe-cel opportunity in B cell malignancies, autoimmune diseases & life cycle strategy
 - SLE
 - B-NHL indications
 - Bi-specific therapies (CD19 /CD22; CD19/BCMA)
- Expand to additional indications with novel CAR T therapies, alone or with partners



Scalable manufacturing and in-house facility

- Demonstrated reliable clinical trial supply (96% target dose reached in FELIX pivotal study)
- New commercial cell manufacturing facility in qualification stage; planned annual capacity 2,000+ batches
- Expected vein-to-delivery time at launch of ~16 days



Strategic collaborations

- Strategic multi-platform R&D collaboration with BioNTech
- Established technology collaborations with Moderna, BMS and Cabaletta
- Long-standing academic collaboration with University College London



Strong cash position

- Cash \$240M (Q4 2023) and gross proceeds of \$600m from financing and BioNTech transaction
- Fully funds obe-cel launch and allows for autoimmune program acceleration

Abbreviations and notes: r/r ALL - relapsed/refractory acute lymphoblastic leukemia; B-NHL - B-cell non-Hodgkin's lymphoma; SLE - systemic lupus erythematosus.

Autolus

Thank you

autolus.com



