
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the Month of May 2023

Commission File Number: 001-38547

Autolus Therapeutics plc
(Translation of registrant's name into English)

**The MediaWorks
191 Wood Lane
London W12 7FP
United Kingdom**
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:
x Form 20-F ☐ Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

INCORPORATION BY REFERENCE

The Company's Unaudited Condensed Consolidated Interim Financial Statements for the Three Months Ended March 31, 2023, included as Exhibit 99.1 of this Report on Form 6-K (the "Report") and the Management's Discussion and Analysis of Financial Condition and Results of Operations for the Three Months Ended March 31, 2023, included as Exhibit 99.2 of this Report, shall be deemed to be incorporated by reference into the registration statements on Form S-8 (File No. 333-226457), Form F-3 (File No. 333-258556), Form F-3 (File No. 333-264304), and Form F-3 (File No. 333-264650) of Autolus Therapeutics plc (the "Company") and any related prospectuses, as such registration statements and prospectuses may be amended from time to time, and to be a part thereof from the date on which this Report is filed, to the extent not superseded by documents or reports subsequently furnished.

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on the Company's expectations and assumptions as of the date of this Report. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from those expressed or implied by these forward-looking statements. For a discussion of risk factors that may cause the Company's actual results to differ from those expressed or implied in the forward-looking statements in this Report, you should refer to the Company's filings with the U.S. Securities and Exchange Commission (the "SEC"), including the "Risk Factors" sections contained therein. Except as required by law, the Company undertakes no obligation to publicly update any forward-looking statements, 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 Report.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Unaudited Condensed Consolidated Interim Financial Statements for the Three Months Ended March 31, 2023
99.2	Management's Discussion and Analysis of Financial Condition and Results of Operations for the Three Months Ended March 31, 2023
99.3	Press release as of May 04, 2023
101	The following materials from this Report on Form 6-K are formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three Months ended March 31, 2023 and 2022 (Unaudited), (ii) Condensed Consolidated Balance Sheets as at March 31, 2023 (Unaudited) and December 31, 2022, (iii) Condensed Consolidated Statements of Changes in Shareholders' Equity for the Three Months ended March 31, 2023 and 2022 (Unaudited), (iv) Condensed Consolidated Statements of Cash Flows for the Three Months ended March 31, 2023 and 2022 (Unaudited), and (v) Notes to Condensed Consolidated Financial Statements (Unaudited).

SIGNATURES

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

Autolus Therapeutics plc

Date: May 4, 2023

By: /s/ Christian Itin
Name Christian Itin, Ph.D.
Title: Chief Executive Officer

INDEX TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Condensed Consolidated Balance Sheets as of March 31, 2023 (Unaudited) and December 31, 2022	2
Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three Months Ended March 31, 2023 and 2022 (Unaudited)	3
Condensed Consolidated Statements of Shareholders' Equity for the Three Months Ended March 31, 2023 and 2022 (Unaudited)	4
Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2023 and 2022 (Unaudited)	5
Notes to Condensed Consolidated Financial Statements (Unaudited)	6

Condensed Consolidated Balance Sheets (Unaudited)
(In thousands, except share and per share amounts)

	Note	March 31, 2023	December 31, 2022
Assets			
Current assets:			
Cash and cash equivalents		\$ 343,027	\$ 382,436
Restricted cash		328	325
Prepaid expenses and other current assets	4	50,530	43,010
Total current assets		393,885	425,771
Non-current assets:			
Property and equipment, net	5	34,667	35,209
Prepaid expenses and other non-current assets		465	2,176
Operating lease right-of-use assets, net		26,861	23,210
Long-term deposits		1,821	1,832
Deferred tax asset		2,272	2,076
Total assets		\$ 459,971	\$ 490,274
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		353	531
Accrued expenses and other liabilities	6	34,463	40,797
Operating lease liabilities, current		4,821	5,038
Total current liabilities		39,637	46,366
Non-current liabilities:			
Operating lease liabilities, non-current		22,495	19,218
Liability related to future royalties and sales milestones, net	10	130,805	125,900
Other long-term payables		114	116
Total liabilities		193,051	191,600
Commitments and contingencies	12		
Shareholders' equity:			
Ordinary shares, \$0.000042 par value; 290,909,783 shares authorized as of March 31, 2023 and December 31, 2022; 173,074,510 shares issued and outstanding at March 31, 2023 and December 31, 2022		8	8
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at March 31, 2023 and December 31, 2022		—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at March 31, 2023 and December 31, 2022		118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at March 31, 2023 and December 31, 2022		—	—
Additional paid-in capital		1,010,041	1,007,625
Accumulated other comprehensive loss		(33,257)	(38,898)
Accumulated deficit		(709,990)	(670,179)
Total shareholders' equity		266,920	298,674
Total liabilities and shareholders' equity		\$ 459,971	\$ 490,274

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(In thousands, except share and per share amounts)

		Three Months Ended March 31,	
	Note	2023	2022
Grant income		\$ —	\$ 166
License revenue	3	1,292	—
Operating expenses:			
Research and development		(31,344)	(33,963)
General and administrative		(9,284)	(7,987)
Loss on disposal of property and equipment		(3,768)	—
Total operating expenses, net		(43,104)	(41,784)
Other income, net		782	860
Interest income		3,446	28
Interest expense		(4,905)	(1,790)
Total other expense, net		(677)	(902)
Net loss before income tax		(43,781)	(42,686)
Income tax benefit		3,970	5,624
Net loss attributable to ordinary shareholders		(39,811)	(37,062)
Other comprehensive income (loss):			
Foreign currency exchange translation adjustment		5,641	(7,455)
Total comprehensive loss		\$ (34,170)	\$ (44,517)
Basic and diluted net loss per ordinary share	9	\$ (0.23)	\$ (0.41)
Weighted-average basic and diluted ordinary shares	9	173,825,825	90,914,175

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Condensed Consolidated Statements of Shareholders' Equity (Unaudited)

(In thousands, except share amounts)

	Ordinary Shares		Deferred Shares		Deferred B Shares		Deferred C Shares		Additional Paid in Capital	Accumulated other comprehensive loss	Accumulated deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	173,074,510	\$ 8	34,425	\$ —	88,893,548	\$ 118	1	\$ —	\$ 1,007,625	\$ (38,898)	\$ (670,179)	\$ 298,674
Share-based compensation expense	—	—	—	—	—	—	—	—	2,416	—	—	2,416
Unrealized gain on foreign currency translation	—	—	—	—	—	—	—	—	—	5,641	—	5,641
Net loss	—	—	—	—	—	—	—	—	—	—	(39,811)	(39,811)
Balance at March 31, 2023	173,074,510	\$ 8	34,425	\$ —	88,893,548	\$ 118	1	\$ —	\$ 1,010,041	\$ (33,257)	\$ (709,990)	\$ 266,920

	Ordinary Shares		Deferred Shares		Deferred B Shares		Deferred C Shares		Additional Paid in Capital	Accumulated other comprehensive loss	Accumulated deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	90,907,830	\$ 4	34,425	\$ —	88,893,548	\$ 118	1	\$ —	\$ 843,108	\$ (8,570)	\$ (521,340)	\$ 313,320
Share-based compensation expense	—	—	—	—	—	—	—	—	2,340	—	—	2,340
Exercise of share options	111	—	—	—	—	—	—	—	—	—	—	—
Unrealized loss on foreign currency translation	—	—	—	—	—	—	—	—	—	(7,455)	—	(7,455)
Net loss	—	—	—	—	—	—	—	—	—	—	(37,062)	(37,062)
Balance at March 31, 2022	90,907,941	\$ 4	34,425	\$ —	88,893,548	\$ 118	1	\$ —	\$ 845,448	\$ (16,025)	\$ (558,402)	\$ 271,143

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Condensed Consolidated Statements of Cash Flows (Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (39,811)	\$ (37,062)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,899	2,067
Non-cash share-based compensation	2,408	2,340
Non-cash interest expense	4,905	1,790
Foreign exchange differences	(2,985)	—
Loss on termination of operating lease	95	—
Loss on disposal of property and equipment	3,789	—
Deferred income tax	(195)	(174)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,889)	(5,429)
Prepaid expenses and other non-current assets	1,797	180
Long-term deposits	51	—
Accounts payable	(227)	(272)
Accrued expenses and other liabilities	(7,056)	1,890
Current and non-current operating lease liabilities, net of operating lease right of use assets	(1,200)	(360)
Net cash used in operating activities	(42,419)	(35,030)
Cash flows from investing activities:		
Purchases of property and equipment	(3,622)	(771)
Net cash used in investing activities	(3,622)	(771)
Cash flows from financing activities:		
Payments of equity issuance costs	(691)	(1)
Net cash used in financing activities	(691)	(1)
Effect of exchange rate changes on cash and restricted cash	7,326	(5,982)
Net decrease in cash, cash equivalents and restricted cash	(39,406)	(41,784)
Cash, cash equivalents and restricted cash, beginning of period	382,761	310,676
Cash, cash equivalents and restricted cash, end of period	\$ 343,355	\$ 268,892
Supplemental non-cash flow information		
Property and equipment purchases included in accounts payable and accrued expenses	\$ 3,692	\$ 593
Right of use assets obtained in exchange for operating lease liabilities	\$ 5,173	\$ —
Right of use assets terminated and obtained in exchange for operating lease liabilities, net	\$ (1,110)	\$ —
Capitalized implementation costs included in accrued expenses	\$ 270	\$ —
Issuance costs included in accounts payable and accrued expenses	\$ 272	\$ 16
Capitalized share-based compensation	\$ 8	\$ —
Reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets:		
Cash and cash equivalents	\$ 343,027	\$ 268,558
Restricted cash	328	334
Total cash and restricted cash	\$ 343,355	\$ 268,892

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Note 1. Nature of the Business

Autolus Therapeutics plc (the “Company”) is a biopharmaceutical company developing next-generation programmed T cell therapies for the treatment of cancer. Using its 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 attack and kill these cells. The Company believes its programmed T cell therapies have the potential to be best-in-class and to offer cancer patients substantial benefits over the existing standard of care, including the potential for cure in some patients.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from its product sales.

The Company has funded its operations primarily with proceeds from the sale of equity securities through public offerings and sales pursuant to the Company’s at-the-market facility, government grants, U.K. research and development tax credits and receipts from the U.K. RDEC Scheme, “RDEC”, out-licensing arrangements and strategic collaboration and financing agreements. The Company has incurred recurring losses since its inception, including net losses of \$39.8 million and \$37.1 million for the three months ended March 31, 2023 and 2022, respectively. The Company had an accumulated deficit of \$710.0 million and \$670.2 million as of March 31, 2023 and December 31, 2022, respectively. The Company expects to continue to generate operating losses in the foreseeable future. The Company’s inability to raise additional capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all. As of the date these unaudited condensed consolidated financial statements are issued, the Company expects that its forecast cash will be sufficient to fund the Company’s operations for at least twelve months from the issuance date of these unaudited condensed consolidated financial statements and accordingly have been prepared on the going concern basis.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include those of the Company and its wholly owned subsidiaries, Autolus Holdings (UK) Limited, Autolus Limited, Autolus Inc., and Autolus GmbH, and have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”). All intercompany accounts and transactions have been eliminated upon consolidation. The significant accounting policies used in preparation of these unaudited condensed consolidated financial statements are consistent with those discussed in Note 2, “Summary of Significant Accounting Policies” in the Company’s Annual Report on Form 20-F for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on March 7, 2023 (the “Annual Report”).

In the opinion of management, all adjustments considered necessary to present fairly the results of the interim periods have been included and consist only of normal and recurring adjustments. Certain information and footnote disclosures have been condensed or omitted as permitted under U.S. GAAP. The results for the three months ended March 31, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period. As such, the information included in these unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto as of and for the year ended December 31, 2022, included in the Annual Report.

Foreign Currency Translation

The reporting currency of the Company is the U.S. dollar. The Company has determined the functional currency of the ultimate parent company, Autolus Therapeutics plc, is pound sterling. The functional currency of subsidiary operations is the applicable local currency. Monetary assets and liabilities denominated in currencies other than the functional currency are translated into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates prevailing at the date of the transaction.

Exchange gains or losses arising from foreign currency transactions are included in the determination of net income (loss) for the respective periods. The Company recorded a foreign exchange gain of \$0.8 million for the three months ended March 31, 2023 and 2022, respectively, which are included in other income, net in the unaudited condensed consolidated statements of operations and comprehensive loss.

Recent Accounting Pronouncements Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). ASU 2016-13 requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. ASU 2016-13 requires enhanced qualitative and quantitative disclosures to help investors and other financial statement users better understand significant estimates and judgments used in estimating credit losses, as well as the credit quality and underwriting standards of an organization's portfolio. ASU 2016-13 is effective for fiscal years beginning after December 15, 2022, and interim periods within those fiscal years. The Company has evaluated that the adoption of this ASU does not have a material impact on the Company's financial statements and disclosures.

Note 3. License Revenue

Revenue comprised of license revenue for the three ended March 31, 2023, and 2022 and is represented in the table below by geographical location (in thousands):

	Three Months Ended March 31,	
	2023	2022
License revenue		
United States	1,292	\$ —
Total license revenue	\$ 1,292	\$ —

Research, Option and License Agreement with Cabaletta:

On January 9, 2023, the Company entered into an Option and License Agreement (the "Cabaletta Agreement") with Cabaletta Bio Inc. ("Cabaletta"), pursuant to which the Company granted to Cabaletta a non-exclusive license to research, develop, manufacture, have manufactured, use, and commercialize products incorporating the Company's safety switch technology, "RQR8 technology". Upon the execution of the Cabaletta Agreement, the Company made available the RQR8 licensed know-how to Cabaletta for a non-refundable license fee of \$1.2 million. The Company has no further material performance obligations related to the Cabaletta Agreement.

The Company further granted to Cabaletta the option to expand the rights and licenses granted hereunder to include the research, development, manufacture, use, or commercialization of licensed products up to a predetermined number of target options upon payment of an option exercise fee.

The Company identified the following material promises relating to the granting of a non-exclusive license for research, development, manufacturing and commercialization activities as well as the initial transfer of know-how and information to Cabaletta. The Company determined the option exercise fee is not offered at a significant and incremental discount. Accordingly, the option granted to Cabaletta does not represent a material right and, therefore, is not a performance obligation at the outset of the arrangement. The Company determined that the granting of the research license and the initial transfer of know-how were not distinct from one another and must be combined as a performance obligation, as Cabaletta requires the know-how to derive benefit from the license. Based on these determinations, the Company identified one distinct performance obligation at the inception of the contract.

The Company further determined that the license fee payable constituted the entirety of the consideration included in the transaction price at contract inception, which was allocated to one performance obligation. The amount of the transaction price allocated to the performance obligation is recognized as or when the Company satisfies the performance obligation. The Company determined that the performance obligation was recognized at a point-in-time, upon the delivery of the transfer of know-how and research license to Cabaletta. The Company recognized total license revenue of \$1.2 million, related to the Cabaletta Agreement, for the three months ended March 31, 2023.

Upon execution of the Cabaletta Agreement, the transaction price included only the \$1.2 million non-refundable license fee payable to the Company. The Company may receive further payments upon the exercise of the options for licensed targets, the achievement of certain development and sales milestones, as well as royalty payments based on net sales of each product covered by the licensed intellectual property.

AUTOLUS THERAPEUTICS PLC
Notes to Condensed Consolidated Financial Statements (Unaudited) - Continued

The future milestones, which represent variable consideration, will be evaluated under the most likely amount method, and were not included in the transaction price, as these amounts were fully constrained as of March 31, 2023.

Note 4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Research and development claims receivable	\$ 29,280	\$ 24,685
Accounts receivable	121	121
Prepayments	13,696	12,337
VAT receivable	2,787	2,701
Other assets	—	203
Other receivable	2,649	1,469
Deferred cost	1,997	1,494
Total prepaid expenses and other current assets	\$ 50,530	\$ 43,010

Note 5. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Lab equipment	\$ 26,712	\$ 31,188
Office equipment	3,822	3,573
Furniture and fixtures	1,248	1,221
Leasehold improvements	12,301	13,583
Assets under construction	17,406	13,186
Less: accumulated depreciation	(26,822)	(27,542)
Total property and equipment, net	\$ 34,667	\$ 35,209

Depreciation expense for the three months ended March 31, 2023 and 2022 was \$1.9 million and \$2.0 million, respectively.

Note 6. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Research and development costs	22,208	26,478
Compensation and benefits	\$ 7,817	\$ 10,181
Professional fees	4,111	3,745
Other liabilities	327	393
Total accrued expenses and other liabilities	\$ 34,463	\$ 40,797

Note 7. Shareholders' Equity

Ordinary Shares

Each holder of ordinary shares is entitled to one vote per ordinary share and to receive dividends when and if such dividends are recommended by the Company's board of directors and declared by the shareholders. As of March 31, 2023, the Company has not declared any dividends.

December 2022 public offering

In December 2022, the Company completed an underwritten public offering of 81,927,012 ADSs representing 81,927,012 ordinary shares, which includes the partial exercise by the underwriters to purchase an additional 6,927,012 ADSs, at a public offering price of \$2.00 per ADS. Aggregate net proceeds to the Company, after underwriting discounts and offering expenses, were \$152.4 million.

At March 31, 2023, 766,784 ordinary shares underlying restricted stock unit awards have vested, however, these restricted stock unit awards have not been issued and, as such are not included in the calculation of the Company's outstanding shares at March 31, 2023. Subsequent to March 31, 2023, 551,421 ordinary shares underlying restricted stock unit awards have been issued.

Note 8. Share-based Compensation Expense

Share-based compensation expense recorded as research and development expenses and general and administrative expenses is as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Research and development	\$ 1,681	\$ 1,384
General and administrative	727	956
Capitalized	\$ 8	\$ —
Total share-based compensation	\$ 2,416	\$ 2,340

Note 9. Net loss per share

Basic and diluted net loss per share attributable to ordinary shareholders was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2023	2022
Numerator		
Net loss	\$ (39,811)	\$ (37,062)
Net loss attributable to ordinary shareholders - basic and diluted	\$ (39,811)	\$ (37,062)
Denominator		
Weighted-average number of ordinary shares used in net loss per share - basic and diluted	173,825,825	90,914,175
Net loss per share - basic and diluted	\$ (0.23)	\$ (0.41)

For all periods presented, outstanding but unvested restricted shares and share options have been excluded from the calculation, because their effects would be anti-dilutive. Therefore, the weighted average number of ordinary shares used to calculate both basic and diluted loss per share is the same for all periods presented.

The following potentially dilutive securities have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	Three Months Ended March 31,	
	2023	2022
Unvested restricted shares and units	382,375	1,023,810
Share options	13,083,768	8,407,272
Warrants	3,265,306	3,265,306
Total potentially dilutive securities	16,731,449	12,696,388

Note 10. Liability related to future royalties and sales milestones, net

On November 6, 2021, the Company concurrently entered into the following agreements with BXL V - Autobahn L.P. ("Blackstone"): (i) Strategic Collaboration Agreement (the "Blackstone Collaboration Agreement"), (ii) Securities Purchase Agreement (the "Blackstone Securities Purchase Agreement"), (iii) Warrant Agreement (the "Blackstone Warrant") and (iv) a Registration Rights Agreement (the "Blackstone Registration Rights Agreement"). The Blackstone Collaboration Agreement, the Blackstone Securities Purchase Agreement, the Blackstone Warrant and the Blackstone Registration Rights Agreement are collectively referred to as the "Blackstone Agreements". The Blackstone Agreements were entered into and in contemplation of one another and, accordingly, the Company assessed the accounting for the Blackstone Agreements in the aggregate. For further details on the terms and accounting treatment considerations for these contracts, please refer to following notes to the Company's consolidated financial statements contained in the Company's Annual Report:

- Note 8, "Liability related to future royalties and sales milestones, net"
- Note 9, "Warrants"
- Note 10, "Shareholders' equity"

In November 2021, the upfront payment of \$50 million was paid by Blackstone upon execution of the Blackstone Collaboration Agreement. In December 2022, two Blackstone Development Payments were paid by Blackstone of \$35 million each as a result of (i) the joint steering committee's review of Autolus' interim analysis of pivotal FELIX Phase 2 clinical trial of obe-cel in relapsed/refractory (r/r) adult Acute Lymphoblastic Leukemia (ALL) and (ii) achievement of a pre-agreed manufacturing milestone as a result of completion of planned activities demonstrating the performance and qualification of the Company's obe-cel's manufacturing process. The remaining \$30 million will be payable to the Company on the achievement on certain specified regulatory milestones. The Company considers the regulatory approval as probable when actually achieved.

The carrying amount of the Blackstone Collaboration Agreement liability is based on the Company's estimate of the future royalties and sales milestones to be paid to Blackstone and the Blackstone Development payment to be received over the life of the arrangement as discounted using an effective interest rate. The excess estimated present value of future royalties and sales milestone payments over the initial carrying amount and future Blackstone Development Payments received, is recognized as a cumulative catch-up method within interest expense using the initial effective interest rate. The imputed rate of interest on the unamortized portion of the Blackstone Collaboration Agreement liability was approximately 15.80% as of March 31, 2023 and December 31, 2022, respectively.

On a quarterly basis, the Company assesses the amount and timing of expected royalty and sales milestone payments using a combination of internal projections and forecasts from external sources. To the extent the present value of such payments are greater or less than its initial estimates or the timing of such payments is materially different than its original estimates, the Company will adjust the amortization of the Blackstone Collaboration Agreement liability using the catch-up method. During the three months ended March 31, 2023, there have been no changes to the estimates used in the determination of the carrying amount of the Blackstone Collaboration Agreement liability.

There are a number of factors that could materially affect the probability, amount and timing of royalty and sales milestone payments to be made by the Company and Blackstone Development payment to be received from Blackstone, respectively, most of which are not within the Company's control. The Blackstone Collaboration Agreement liability is recognized using significant unobservable inputs. These inputs are derived using internal management estimates developed based on third party data and reflect management's judgements, current market conditions surrounding competing products, and forecasts. The significant unobservable inputs include regulatory approvals, estimated patient populations, estimated selling price, estimated sales, estimated peak sales and sales ramp, timing of the expected launch and its impact on the royalties as well as the overall probability of a success.

The following table shows the activity within the liability related to future royalties and sales milestones, net for the three months ended March 31, 2023 (in thousands):

	Liability related to future royalties and sales milestones, net
Balance at December 31, 2022	\$ 125,900
Non-cash interest expense on liability related to future royalties and sales milestones	4,905
Balance at March 31, 2023	\$ 130,805

The following table shows the activity within the liability related to future royalties and sales milestones, net for the three months ended March 31, 2022 (in thousands):

	Liability related to future royalties and sales milestones, net
Balance at December 31, 2021	\$ 47,016
Non-cash interest expense on liability related to future royalties and sales milestones	1,790
Balance at March 31, 2022	\$ 48,806

11. Leases

The Company leases certain office space, laboratory space, and equipment. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present.

Operating Leases

In September 2017, the Company executed an arrangement with Cell Therapy Catapult Limited to lease a manufacturing suite at the Cell and Gene Therapy Catapult manufacturing center in Stevenage, United Kingdom for a term through May 2021, at which time the Company had the option to renew or terminate the lease. The lease had a six-month rent-free period. In December 2018, the Company executed an additional lease arrangement for additional manufacturing space for a term through September 2023, at which time the Company has the option to renew or terminate the lease. In addition, in May 2020, the Company executed an arrangement with Cell Therapy Catapult Limited to lease a manufacturing suite at the Cell and Gene Therapy Catapult manufacturing center in Stevenage, United Kingdom for a term through April 2024. In July 2022, the Company and Cell Therapy Catapult Limited mutually agreed: (i) to extend the lease term of a manufacturing suite leased by the Company from April 2024 to February 2025, and (ii) to reduce the lease term of a different manufacturing suite leased by the Company from July 2024 to June 2023. In March 2023, the Company and Cell Therapy Catapult Limited mutually agreed: (i) to terminate the lease relating to the leased manufacturing suite which originally had a lease term until February 2025, (ii) to extend the lease term of one of the remaining manufacturing suites from June 2023 to August 2024, and (iii) to extend the lease term of a third manufacturing suite leased by the Company from September 2023 to August 2024. The Company recognized a lease termination loss of \$0.1 million for the three months ended March 31, 2023 related to the manufacturing suite terminated and exited on March 31, 2023. In addition, during the period ended March 31, 2023, the Company recognized a loss on disposal on leasehold improvements of \$3.8 million arising from the manufacturing suite terminated and exited on March 31, 2023.

In October 2018, the Company executed an agreement to sublease office space in Rockville, Maryland for a term through October 2021. The Company then terminated the sublease in February 2020 and immediately entered into a five-year lease for the same space with the landlord. The lease related to this facility is classified as an operating lease.

In January 2019, the Company executed a lease agreement with Whitewood Media Village GP Limited and Whitewood Media Village Nominee Limited to lease the fifth floor of MediaWorks including laboratory space. In August 2021, MediaWorks became the Company's main corporate headquarters. The lease term is nine years and eleven months with an eighteen-month rent free period at the beginning of the lease term. The Company has the option to terminate the lease in November 2026.

AUTOLUS THERAPEUTICS PLC
Notes to Condensed Consolidated Financial Statements (Unaudited) - Continued

In February 2019, the Company entered into a fifteen-year lease for three manufacturing units in Enfield, United Kingdom with option to terminate the lease in February 2029. In addition to base rent, the Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts. In March 2021, one of the units was split into two separate units and the Company surrendered one of the units. Upon the surrender, the Company recognized a \$0.1 million gain in other (expense) income after recognizing a termination fee of \$0.2 million. The Company has no further obligations for the surrendered unit and the right of use asset and lease liability which were recorded for this unit have been written off in the relevant period. The Company subleased two of the three units to third parties with lease terms ranging from October, 2021 to February 2029 and October 2026, respectively. The Company is actively seeking to sublease or assign the lease arrangements relating to the final unit. The Company completed an asset impairment analysis of the right-of-use lease concluding the undiscounted cash flows exceeded the carrying value as of March 31, 2023.

In September 2021, the Company entered into an arrangement for lease with Forge Life Sciences Nominee, an affiliate of the Reef Group, for the design, construction and lease of a new 70,000 square foot manufacturing facility in Stevenage, United Kingdom. Under this arrangement, the landlord will lease the facility to the Company on agreed terms, upon satisfaction of certain conditions and completion of construction. This facility will form the basis of the Company's new commercial manufacturing facility. In November 2022 and February 2023, the landlord handed over one of three clean rooms and additional portions of the building, respectively. As the landlord provided access to the aforementioned section of the facility, the definition of a lease in accordance with ASC 842, was met. The remaining portion of the facility will be handed over by the landlord upon satisfaction of certain conditions and completion of the remaining construction. A lease agreement will be executed upon satisfactory completion and handover of the full facility. The Company has started the fit-out of the first of three clean rooms and other portions of the building for which the Company is responsible. These fit out costs and subsequent fit out costs in other areas of the building will be required to be removed at the end of the lease term and will represent an Asset Retirement Obligation ('ARO'). At March 31, 2023, the fit out of the handed over portions of the facility was still in progress. Once the fit-out and full handover of facility has been completed, a full estimate of the associated ARO will be made. Given the ongoing work, it was not possible to estimate an ARO as at March 31, 2023. The Company has appropriately assessed the impact of the handover of the first clean room and other portions of the building on the lease term thereby resulting in the recognition of an operating lease right-of-use asset and lease liability as of December 31, 2022 and March 31, 2023, respectively. The Company is required to pay a pro-rated rent for each portion of the facility to which we have been granted access. The Company cumulatively contributed \$6.9 million as part as of landlord works and tenant contributions towards the lease as of March 31, 2023 resulting in these payments being taken into account in the determination of the right of use asset for this facility.

The following table contains a summary of the lease costs recognized under Accounting Standards Update, "ASU" 2016-02 and other information pertaining to the Company's operating leases for the three months ended March 31, 2023 and 2022 (in thousands):

Lease costs	Three Months Ended March 31,	
	2023	2022
Operating lease costs	\$ 1,367	\$ 1,259
Variable costs	(271)	134
Short term lease costs	25	37
Total lease costs	\$ 1,121	\$ 1,430

During the three months ended March 31, 2023, the Company revised its previously estimated variable costs arising from the Company's Enfield, London facility resulting in a reduction in variable costs amounting to \$0.5 million.

Other information	Three Months Ended March 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows from operating leases (in thousands)	\$ 1,296	\$ 1,619
Right-of-use assets obtained in exchange for new operating lease liabilities (in thousands)	\$ —	\$ —
Weighted-average remaining lease term - operating leases (in years)	11.9 years	5.5 years
Weighted-average discount rate - operating leases	6.87 %	7.15 %

AUTOLUS THERAPEUTICS PLC
Notes to Condensed Consolidated Financial Statements (Unaudited) - Continued

Future fixed payments for non-cancellable operating leases in effect as of March 31, 2023 are payable as follows (in thousands):

Remainder of 2023	\$	4,661
2024	\$	5,299
2025	\$	3,815
2026	\$	3,587
2027	\$	3,587
Thereafter	\$	18,464
Total lease payments	\$	39,413
Less: imputed interest	\$	(12,097)
Present value of lease liabilities	\$	27,316

Sublease Agreements

In October 2021, the Company entered into two separate sub-lease agreements with two third parties for two manufacturing spaces in Enfield which are currently leased by the Company. The annual lease payments to be received for each of the sub-leased units are £97,000 and £109,000, over lease terms from October 2021 to February 2029 and October 2021 to October 2026, respectively. In October 2021, the Company received \$127,000 in rental deposits, arising from the sub-lease agreements which have been classified as restricted cash as of March 31, 2023 and 2022, respectively. Both sub-leases have been classified as operating leases. The Company recognized the sub-lease payments on a straight-line basis from the commencement of the sub-lease agreements.

The following table shows the sublease rental income for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
Sublease rental income	2023	2022
Sublease rental income (included in other income, net)	\$ 59	\$ 65
Total sublease rental income	\$ 59	\$ 65

Future fixed receipts for non-cancellable operating subleases in effect as of March 31, 2023 are receivable as follows (in thousands):

Remainder of 2023	\$	180
2024		255
2025		255
2026		198
2027		120
Thereafter		103
Total lease payments receivable	\$	1,111

Note 12. Commitments and Contingencies

License Agreements

The Company has entered into an exclusive license agreement with UCL Business Ltd, ("UCLB") which has subsequently been amended and restated. In connection with the UCLB license agreement, the Company is required to make annual license payments and may be required to make payments to UCLB upon the achievement of specified milestones. During the three months ended March 31, 2023, less than \$0.1 million was payable to UCLB by the Company relating to the income allocable to the value of the sublicensed intellectual property rights.

In November 2019, the Company entered into an exclusive license agreement with Noile-Immune Biotech Inc. ("Noile") under which the Company will have the right to develop CAR T cell therapies incorporating Noile's PRIME (proliferation-inducing and migration-enhancing) technology. The Company may be obligated to make additional payments to Noile upon the achievement of development milestones and receipt of regulatory approvals product sale milestones, as well as royalty payments based on possible future sales resulting from the utilization of the licensed technology.

In July 2022, the Company renegotiated a master services agreement with Adaptive Biotechnologies Corporation ("Adaptive"), under which Adaptive's assay is used to analyze patient samples from relapsed/refractory B Cell Acute Lymphoblastic Leukemia (rB-ALL) patients. Under the agreement, the Company is obligated to make specified payments to Adaptive upon the achievement and receipt of certain regulatory approvals and achievement of commercial milestones in connection with the Company's use of the Adaptive assay.

The Company considers the regulatory approval and commercial milestones probable when actually achieved. The Company concluded that, as of March 31, 2023, there were no milestones for which the likelihood of achievement was currently probable relating to either of the UCLB, Noile- or Adaptive contracts.

Legal Proceedings

From time to time, the Company may be a party to litigation or subject to claims incident to the ordinary course of business. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors. The Company was not a party to any litigation and did not have contingency reserves established for any liabilities as of March 31, 2023 and December 31, 2022.

Blackstone Strategic Collaboration and Financing Agreement

Refer to Note 10, "Liability related to future royalties and sales milestone, net" for further details to the Blackstone Collaboration Agreement.

Leases

Lease payments under operating leases as of March 31, 2023 and information about the Company's lease arrangements are disclosed in Note 11, "Leases".

Note 13. Related parties

Blackstone Agreements

In November 2021, the Company concurrently entered into the Blackstone Agreements. Subsequent to the execution of the Blackstone Agreements, Blackstone became a related party of the Company. Blackstone owns more than 10% of the Company's outstanding voting securities and is therefore one of the principal owners of the Company. In addition, Blackstone received and exercised their right to nominate one director to the board of directors of the Company.

As of March 31, 2023, the carrying amount of the Blackstone Collaboration Agreement liability was \$130.8 million which included aggregated cumulative non-cash interest expense and cumulative catch-up adjustment of \$14.9 million. As of December 31, 2022, the carrying amount of the Blackstone Collaboration Agreement liability was \$125.9 million which included aggregated cumulative non-cash interest expense (including cumulative catch-up adjustments), of \$10.0 million. Refer to Note 10, "Liability related to sales of future royalties and sales milestone, net" for further details.

Syncona Portfolio Limited

Syncona Portfolio Limited is a related party of the Company as Syncona Portfolio Limited owns more than 10% of the Company's outstanding voting securities and is therefore one of the principal owners of the Company. In addition, the chair of the ultimate parent company of Syncona Portfolio Limited is also member of the board of directors of the Company.

AUTOLUS THERAPEUTICS PLC
Notes to Condensed Consolidated Financial Statements (Unaudited) - Continued

In connection with the Company's December 2022 public offering, certain of the Company's related parties purchased the Company's ADSs from the underwriters at the public offering price of \$2.00 per ADSs, and on the same terms as other investors in the Company's public offering. The following table summarizes purchases of ADS by the Company's related parties:

Related party	ADSs purchased	Total purchase price (in millions)
Syncona Portfolio Limited (1)	14,000,000	\$ 28.0
Deep Track Capital, LP (2)	15,000,000	30.0
Qatar Investment Authority (3)	15,000,000	30.0
Armistice Capital, LLC (4)	10,000,000	20.0
Entities affiliated with Blackstone (5)	2,500,000	5.0
	56,500,000	\$ 113.0

(1) Syncona Portfolio Limited is a holder of more than 5% of our capital stock.

(2) In connection with this transaction, Deep Track Capital, LP became a holder of more than 5% of our capital stock.

(3) In connection with this transaction, Qatar Investment Authority became a holder of more than 5% of our capital stock.

(4) In connection with this transaction, Armistice Capital, LLC became a holder of more than 5% of our capital stock.

(5) Entities affiliated with Blackstone collectively hold more than 5% of our capital stock.

Note 14. Subsequent Events

The Company evaluated subsequent events through May 4, 2023, the date on which these unaudited condensed consolidated financial statements were issued. The Company has concluded that no subsequent event has occurred that requires disclosure.

MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with the unaudited condensed consolidated financial statements and the related notes to those statements included as Exhibit 99.1 to this Report on Form 6-K submitted to the Securities and Exchange Commission, or the SEC, on May 4, 2023. We also recommend that you read our discussion and analysis of financial condition and results of operations together with our audited financial statements and the notes thereto, which appear in our Annual Report on Form 20-F for the year ended December 31, 2022 as filed with the Securities and Exchange Commission, or the SEC on March 7, 2023.

We maintain our books and records in pounds sterling, our results are subsequently converted to U.S. dollars, and we prepare our consolidated financial statements in accordance with generally accepted accounting principles in the United States, or U.S. GAAP, as issued by the Financial Accounting Standards Board, or FASB. All references in this Report on Form 6-K to “\$” are to U.S. dollars and all references to “£” are to pounds sterling. Our unaudited condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2023 and 2022 have been translated from pounds sterling into U.S. dollars at the rate of £1.00 to \$1.2145 and £1.00 to \$1.3417, respectively. Our unaudited condensed consolidated balance sheet as of March 31, 2023 and audited consolidated balance sheet December 31, 2022 have been translated from pounds sterling into U.S. dollars at the rate of £1.00 to \$1.2367 and £1.00 to \$1.2090, respectively. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as of that or any other date.

Unless otherwise indicated or the context otherwise requires, all references to “Autolus,” the “Company,” “we,” “our,” “us” or similar terms refer to Autolus Therapeutics plc and its consolidated subsidiaries.

The statements in this discussion regarding our expectations regarding our future performance, liquidity and capital resources and other non-historical statements are forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, the risks and uncertainties set forth in the “Risk Factors” section of our Annual Report and any subsequent reports that we file with the SEC.

Overview

We are a biopharmaceutical company developing next-generation programmed T cell therapies for the treatment of cancer. Using our broad suite of proprietary and modular T cell programming technologies, we are engineering precisely targeted, controlled and highly active T cell therapies that are designed to better recognize cancer cells, break down their defense mechanisms and attack and kill these cells. We believe our programmed T cell therapies have the potential to be best-in-class and to offer cancer patients substantial benefits over the existing standard of care, including the potential for cure in some patients.

Since our inception, we have incurred significant operating losses. For the three months ended March 31, 2023 and 2022, we incurred net losses of \$39.8 million and \$37.1 million, respectively, and had an accumulated deficit of \$710.0 million and \$670.2 million as of March 31, 2023 and December 31, 2022, respectively.

As of March 31, 2023, we had cash and cash equivalents of \$343.0 million. Based on our current clinical development plans, we believe our existing cash and cash equivalents will be sufficient to fund our current and planned operating expenses and capital expenditure requirements through at least the next twelve months from the date of issuance of our unaudited condensed consolidated financial statements.

Recent Developments

Key obe-cel Updates:

- *Obecabtagene autoleucel (obe-cel) in relapsed / refractory (r/r) adult ALL – The FELIX Study*
 - Oral presentations of FELIX pivotal study to be presented at ASCO and EHA. We expect data from the FELIX study to form the basis of a BLA submission for obe-cel to the FDA at the end of 2023 and plans to present longer term follow up data and subgroup analysis data at the American Society of Hematology (ASH) meeting in late 2023, as well as at medical conferences in H1 2024.

Obe-cel trials in collaboration with University College London

- *Obe-cel in r/r adult B-ALL patients – Phase 1 ALLCAR19 Study*
 - Long term follow-up data were presented at the Tandem Meetings: Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR). The data demonstrated that 35% of adult B-ALL patients remained in complete remission at a median follow up of 36 months without the need for additional anti-leukemia therapy.
- *Obe-cel in r/r B-NHL and CLL patients – Phase 1 ALLCAR19 Extension Study*
 - Data presented at the ASH meeting in December 2022 demonstrated the potentially best-in-class profile of obe-cel supported by the data observed in B-cell non-Hodgkin lymphoma (NHL), with continued high levels of clinical activity paired with an encouraging tolerability profile across diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma (MCL), follicular lymphoma (FL) and chronic lymphocytic leukemia (CLL). Patients continue to be enrolled into the study and we expect to publish the full results in a peer-reviewed journal.
- *Obe-cel in Primary CNS Lymphoma patients – Phase 1 CAROUSEL Study*
 - Data presented at the European Hematology Association (EHA) meeting in June 2022 demonstrated first activity in primary CNS lymphoma. Patients continue to be enrolled and we expect to publish the full results in a peer-reviewed journal.
- *AUTO1/22 in pediatric B-ALL patients – Phase 1 CARPALL Study*
 - Data presented at the European Society for Blood and Marrow Transplantation (EBMT) Annual Meeting in April 2023 by our UCL collaborators, showed favorable safety profile and good efficacy in a heavily pre-treated cohort of patients. Importantly, there were no observed antigen negative relapses observed as of the data cut-off date, indicating that the combining of our optimized CD22 CAR design with the CD19 CAR used in obe-cel may be effective in preventing antigen-loss driven relapse in pediatric B-ALL. The preclinical data supporting this program was published in Molecular Therapy in March 2023.

Early-stage pipeline – leveraging academic collaborations to generate opportunity for non-dilutive funding

- *AUTO4 in T Cell Lymphoma patients – Phase 1/2 LibrA T1 Study*
 - We have optimized the manufacturing process for AUTO4 and we are enrolling additional patients into the trial to evaluate this manufacturing change. The next update is planned as an oral presentation at the international conference on Malignant Lymphoma in June 2023.
- *AUTO8 in Multiple Myeloma – Phase 1 MCARTY Study*
 - AUTO8 is a next-generation product candidate for multiple myeloma, which comprises two independent CARs for the multiple myeloma targets, BCMA and CD19. In collaboration with UCL, we initiated a study in Q1 2022, patients continue to be enrolled and initial data is expected in 2023.

- *AUTO6NG in Neuroblastoma*
- AUTO6NG contains a CAR that targets GD2 alongside additional programming modules to enhance the activity and persistence. In collaboration with UCL, we are planning on initiating a clinical trial of AUTO6NG in 2023.

Key Operational Updates during Q1 2023

- The Company's new 70,000 square foot commercial manufacturing facility in Stevenage, UK has continued to progress on track. Key equipment installation and validation were completed by Autolus in Q1 2023 enabling operational qualifications commencing in Q2 2023. Activities are on track for the commencement of Good Manufacturing Practice (GMP) operations in H2 2023. The 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 is on track for submission of a BLA by the end of 2023.
- We announced a collaboration with Cabaletta Bio in January 2023. We received an upfront payment for non-exclusive access to the RQR8 safety switch for use in Cabaletta's CD19-CAR T cell therapy program for the treatment of autoimmune disease, with the potential for near term option exercise fees and development and regulatory milestone payments. In addition, we are entitled to receive royalties on net sales of all Cabaletta cell therapy products that incorporate the RQR8 safety switch.

Components of Our Results of Operations

Grant Income

Grant income consists of proceeds from government research grants used to perform specific research and development activities. We recognize grant income over the period in which we recognize the related costs covered under the terms and conditions of the grant. We have received grants from the U.K. government, which are repayable under certain circumstances, including breach or noncompliance with the terms of the grant. For grants with refund provisions, we review the grant to determine the likelihood of repayment. If the likelihood of repayment of the grant is determined to be remote, then the grant is recognized as grant income. We have concluded that the likelihood of any repayment events included in our current grants is remote.

License Revenue

We account for our revenue pursuant to the provisions of Accounting Standards Codification, or ASC Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606").

We have no products approved for commercial sale and have not generated any revenue from commercial product sales. The total revenue to date has been generated principally from license agreements. As of March 31, 2023, we have entered into various license agreements which included non-refundable upfront license fees, options for future commercial licenses, payments based upon achievement of clinical development and regulatory objectives, payments based upon achievement of certain levels of product sales, and royalties on product sales.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under our agreements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

License Fees and Multiple Element Arrangements

If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, upfront fees allocated to the license at such time as the license is transferred to the licensee and the licensee is able to use, and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligations to determine whether the combined performance obligations are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Appropriate methods of measuring progress include output methods and input methods. In determining the appropriate method for measuring progress, we consider the nature of the service that we promise to transfer to the customer. When we decide on a method of measurement, we will apply that single method of measuring progress for each performance obligation satisfied over time and will apply that method consistently to similar performance obligations and in similar circumstances.

Customer options

If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options that are not determined to be material rights are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. We evaluate the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. We allocate the transaction price to material rights based on the relative standalone selling price, which is determined based on any identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised.

Contingent Research Milestone Payments

ASC Topic 606 constrains the amount of variable consideration included in the transaction price in that either all, or a portion, of an amount of variable consideration should be included in the transaction price. The variable consideration amount should be included only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The assessment of whether variable consideration should be constrained is largely a qualitative one that has two elements: the likelihood of a change in estimate, and the magnitude thereof. Variable consideration is not constrained if the potential reversal of cumulative revenue recognized is not significant, for example.

If the consideration in a contract includes a variable amount, we will estimate the amount of consideration in exchange for transfer of promised goods or services. The consideration also can vary if our entitlement to the consideration is contingent on the occurrence or non-occurrence of a future event. We consider contingent research milestone payments to fall under the scope of variable consideration, which should be estimated for revenue recognition purposes at the inception of the contract and reassessed ongoing at the end of each reporting period.

We assess whether contingent research milestones should be considered variable consideration that should be constrained and thus not part of the transaction price. This includes an assessment of the probability that all or some of the milestone revenue could be reversed when the uncertainty around whether or not the achievement of each milestone is resolved, and the amount of reversal could be significant.

U.S. GAAP provides factors to consider when assessing whether variable consideration should be constrained. All of the factors should be considered, and no factor is determinate. We consider all relevant factors.

Royalty Revenue

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Operating Expenses

Research and Development Expenses

Research and development expenses consist of costs incurred in connection with the research and development of our product candidates, which are partially offset by U.K. research and development expenditure tax credits provided by His Majesty's Revenue & Customs, or HMRC. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials;
- employee-related expenses, including salaries, related benefits, travel and share-based compensation expense for employees engaged in research and development functions;
- expenses incurred for outsourced professional scientific development services;
- costs for laboratory materials and supplies used to support our research activities;
- allocated facilities costs, depreciation and other expenses, which include rent and utilities; and
- upfront, milestone and management fees for maintaining licenses under our third-party licensing agreements.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers.

Our direct research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to outside consultants and CROs in connection with our preclinical development, manufacturing and clinical development activities. Our direct research and development expenses by program also include fees incurred under license agreements. We do not allocate employee costs or facility expenses, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to oversee research and development as well as for managing our preclinical development, process development, manufacturing and clinical development activities.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next few years as we increase personnel costs, initiate and conduct additional clinical trials and prepare regulatory filings related to our product candidates. We also expect to incur additional expenses related to milestone, royalty payments and maintenance fees payable to third parties with whom we have entered into license agreements to acquire the rights related to our product candidates.

The successful development and commercialization of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from sales of any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with development and commercialization activities, including the uncertainty of:

- the scope, progress, outcome and costs of our clinical trials and other research and development activities, including establishing an appropriate safety profile with IND-directed studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- development and timely delivery of commercial-grade drug formulations that can be used in our clinical trials and for commercial manufacturing;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- maintaining a continued acceptable safety profile of the product candidates following approval; and
- significant competition and rapidly changing technologies within the biopharmaceutical industry.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. Any changes in the outcome of any of these variables with respect to the development of our product candidates in clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the EMA, the FDA, or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate. Commercialization of our product candidates will take several years and millions of dollars in development costs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits, travel and share-based compensation expense for personnel in executive, finance, legal and other administrative functions. General and administrative expenses also include allocated facility-related costs, patent filing and prosecution costs and professional fees for marketing, insurance, legal, consulting, and accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the planned development of our product candidates. Additionally, if we believe a regulatory approval of one of our product candidates appears likely, we anticipate an increase in payroll and third-party expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidate.

We have experienced, and expect to continue to experience, increased expense with being a public company, including increased accounting, audit, legal, regulatory and compliance costs associated with maintaining compliance with Nasdaq listing rules and SEC requirements, director and officer insurance premiums, as well as higher investor and public relations costs.

Loss on disposal of property and equipment

Loss on disposal of property and equipment primarily consists of losses arising from the disposal of all categories of property and equipment.

Other income, net

Other income, net consists primarily of foreign currency transaction gains and losses, sublease income and gains or losses arising from the termination of leases. Other expense consists primarily of foreign currency transaction losses.

Interest Income

Interest income consists primarily of interest received from banks and money market funds on our cash and cash equivalents balances. We invest funds in a variety of short-term interest-bearing instruments.

Interest Expense

Interest expense consists primarily of non-cash interest expense arising from amortization of the liability related to future royalties and sales milestones, pursuant to our Collaboration Agreement with Blackstone, using the effective interest rate method. On a quarterly basis, we assess the expected present value of the future Blackstone Development payment which may be received by us and future royalties and sales milestone payments to Blackstone which may be paid by us. To the extent the amount or timing of such receipts or payments is materially different than our previous estimates we record a cumulative catch-up adjustment to the liability related to future royalties and sales milestones. The adjustment to the carrying amount is recognized as an adjustment to finance expense in the period in which the change in estimate occurred.

Income Tax Benefit

We are subject to corporate taxation in the United Kingdom, United States, Germany and Switzerland. Due to the nature of our business, we have generated losses since inception. Our income tax benefit recognized represents the sum of the research and development tax credits recoverable in the United Kingdom and income tax payable in the United States.

As a company that carries out extensive research and development activities, we benefit from the U.K. research and development tax credit regime under the scheme for small or medium-sized enterprises, or SMEs, and also claim a Research and Development Expenditure Credit, or RDEC, to the extent that our projects are grant funded. Under the SME regime, we are able to surrender some of our trading losses that arise from our qualifying research and development activities for a cash rebate of up to 33.35% of such qualifying research and development expenditure. The UK Government recently enacted changes which reduce the potential cash rebate under the SME regime to 18.6% for qualifying expenditure incurred on or after April 1, 2023. Additionally, the UK Government announced further changes including the introduction of a new rate for R&D intensive companies of 27% (which we currently expect to qualify for) and come into effect for expenditure incurred after April 1, 2023. We have not accounted for these latest changes in our financial statements as they have not yet been enacted.

The net tax benefit of the RDEC reflected in our unaudited condensed consolidated financial statements was 10.5% for each of the three months ended March 31, 2023 and 2022. Following recent proposed changes by the UK Government the net tax benefit of the RDEC for qualifying expenditure incurred on or after April 1, 2023 has been increased to 15%. We currently meet the conditions of the SME regime, but also can make claims under the RDEC regime to the extent that our projects are grant funded. We may not be able to continue in the future to qualify as a small or medium-sized enterprise under the SME Program, based on size criteria concerning employee headcount, turnover and gross assets. If we cease to qualify under the SME regime, we may make a claim under the RDEC regime. It should be noted, however, that the types of qualifying expenditure in respect of which we may make claims under the RDEC Program are more restricted than under the SME Program (for example, it may be the case that certain subcontracted costs in respect of which claims may be made under the SME Program do not qualify for relief under the RDEC Program).

Un-surrendered U.K. losses may be carried forward indefinitely to be offset against future taxable profits, subject to numerous utilization criteria and restrictions. The amount that can be offset each year is limited to £5.0 million plus an incremental 50% of United Kingdom taxable profits. After accounting for tax credits receivable, we had accumulated tax losses for carry forward in the U.K. of \$342.1 million as of March 31, 2023. No deferred tax assets are recognized on our U.K. losses and tax credit carryforwards because there is currently no indication that we will make sufficient taxable profits to utilize these tax losses and tax credit carryforwards. We carry a \$2.3 million deferred tax asset balance related to the U.S. entity. For the three months ended March 31, 2023, we have recorded a valuation allowance against the net deferred tax asset where the recoverability due to future taxable profits is unknown. On April 1, 2023 the main rate of the U.K. corporation tax was increased to 25% for companies with profits in excess of £250,000, or the small profits rate of 19% for companies with profits of £50,000 or less (with marginal relief from the main rate available to companies with profits between £50,000 and £250,000).

In the event we generate revenues in the future, we may benefit from the United Kingdom “patent box” regime that allows profits attributable to revenues from patents or patented products to be taxed at an effective rate of 10%.

Value Added Tax, or VAT, is broadly charged on all taxable supplies of goods and services by VAT-registered businesses. Under current rates, an amount of 20% of the value, as determined for VAT purposes, of the goods or services supplied is added to all sales invoices and is payable to HMRC. Similarly, VAT paid on purchase invoices is generally reclaimable from HMRC.

Results of Operations

Comparison of Three Months Ended March 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023, and 2022 (in thousands):

	Three Months Ended March 31,		Change
	2023	2022	
Grant income	\$ —	\$ 166	\$ (166)
License revenue	1,292	—	1,292
Operating expenses:			
Research and development	(31,344)	(33,963)	2,619
General and administrative	(9,284)	(7,987)	(1,297)
Loss on disposal of property and equipment	(3,768)	—	(3,768)
Total operating expenses, net	(43,104)	(41,784)	(1,320)
Other income, net	782	860	(78)
Interest income	3,446	28	3,418
Interest expense	(4,905)	(1,790)	(3,115)
Total other expense, net	(677)	(902)	225
Net loss before income tax	(43,781)	(42,686)	(1,095)
Income tax benefit	3,970	5,624	(1,654)
Net loss attributable to ordinary shareholders	\$ (39,811)	\$ (37,062)	\$ (2,749)

Grant Income

There was no grant income recognized for the three months ended March 31, 2023 as compared to \$0.2 million in reimbursable expenditures for the same period in the prior year.

License Revenue

License revenue increased to \$1.3 million for the three months ended March 31, 2023, primarily due to the execution of the Cabaletta Bio Inc., ("Cabaletta") Option and License Agreement which included recognition of a non-refundable license fee payable to us. During the three months ended March 31, 2022, we did not recognize any license revenue.

Research and Development Expenses

The following tables provide additional detail on our research and development expenses (in thousands):

	Three Months Ended March 31,		Change
	2023	2022	
Direct research and development expenses			
B cell malignancies (Obe-cel, AUTO1/22 & AUTO3)	\$ 4,008	\$ 10,773	\$ (6,765)
Other projects (AUTO4, AUTO5, AUTO6, AUTO7 & AUTO8)	842	319	523
Total direct research and development expense	\$ 4,850	\$ 11,092	\$ (6,242)
Indirect research and development expense and unallocated costs:			
Personnel related (including share-based compensation)	14,222	12,831	1,391
Indirect research and development expense	12,272	10,040	2,232
Total research and development expenses	\$ 31,344	\$ 33,963	\$ (2,619)

Research and development expenses decreased by \$2.7 million to \$31.3 million for the three months ended March 31, 2023 from \$34.0 million for the three months ended March 31, 2022 primarily due to:

- a decrease of \$5.5 million in clinical trial and manufacturing costs which is offset by an increase of \$0.8 million in manufacturing material costs due to increased validation activities undertaken, primarily relating to our obe-cel clinical product candidate,
- a decrease of \$0.2 million in depreciation and amortization related to property, plant and equipment and intangible assets due to the reduction in our depreciable asset base,
- a decrease of \$0.1 million in legal fees and professional consulting fees in relation to our research and development activities,
- an increase of \$1.4 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 \$0.7 million related to information technology infrastructure and support for information systems related to the conduct of clinical trials and manufacturing operations, and
- an increase of \$0.2 million in facilities costs related to our new manufacturing facility, the "Nucleus", in Stevenage, United Kingdom as well as increases in costs related to maintaining our current leased properties.

General and Administrative Expenses

General and administrative expenses increased by \$1.3 million to \$9.3 million for the three months ended March 31, 2023 from \$8.0 million for the three months ended March 31, 2022 primarily due to:

- an increase of \$0.7 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 \$0.7 million in commercial readiness costs due to increased commercial readiness activities being undertaken,
- an increase of \$0.1 million in general office supplies and expenses facilities costs due to the increase in space utilized for general and administrative activities,
- a decrease of \$0.2 million primarily related to a reduction in directors' and officers' liability insurance premiums, legal and professional fees.

Loss on disposal of property and equipment

For the three months ended March 31, 2023, we recognized a loss on disposal of property and equipment of \$3.8 million related to fixed assets no longer being utilized in the manufacturing facility exited in Stevenage, United Kingdom. There were no such disposals for the three months ended March 31, 2022.

Other income, net

Other income, net decreased to \$0.8 million from \$0.9 million for the three months ended March 31, 2023 and 2022, respectively. The decrease of \$0.1 million is primarily due to the recognition of a lease termination loss arising from the termination and exit of one of our manufacturing suites in Stevenage, United Kingdom.

Interest Income

Interest income increased to \$3.4 million for the three months ended March 31, 2023, as compared to \$28,000 for the three months ended March 31, 2022. The increase in interest income of \$3.4 million primarily relates to the increase in interest rates on our interest-bearing bank accounts and short-term investments during the three months ended March 31, 2023 as compared to the three months ended March 31, 2022.

Interest expense

Interest expense increased to \$4.9 million for the three months ended March 31, 2023 as compared to \$1.8 million for the three months ended March 31, 2022. Interest expense is primarily related to the liability for future royalties and sales milestones, net associated with our strategic collaboration agreement with Blackstone.

Income Tax Benefit

Income tax benefit decreased by \$1.6 million to \$4.0 million for the three months ended March 31, 2023 from \$5.6 million for the three months ended March 31, 2022 due to a combination of a decrease in qualifying research and development expenditures for the quarter and the reduction in effective tax rate related to the U.K. research and development tax credit regime under the scheme for SMEs.

Liquidity and Capital Resources

Since our inception, we have not generated any commercial product revenue and have incurred operating losses and negative cash flows from our operations. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through preclinical and clinical development and seek regulatory approval and pursue commercialization of any approved product candidates. We expect that our research and development and general and administrative expenses may increase in connection with our planned research, clinical development and potential commercialization activities. As a result, we will need significant additional capital to fund our operations until such time as we can generate significant revenue from product sales.

We do not currently have any approved products and have never generated any commercial revenue from product sales. We have funded our operations to date primarily with proceeds from government grants, sales of our equity securities, through public offerings and sales pursuant to our at-the-market facility, reimbursable U.K. research and development tax credits and receipts from the U.K. RDEC Scheme, out-licensing arrangements and strategic collaboration agreements. From our inception in 2014 through March 31, 2023, we have raised \$1.1 billion from these capital sources.

As of March 31, 2023, we had cash and cash equivalents of \$343.0 million.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	\$ (42,419)	\$ (35,030)
Net cash used in investing activities	(3,622)	(771)
Net cash used in financing activities	(691)	(1)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	7,326	(5,982)
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (39,406)</u>	<u>\$ (41,784)</u>

Net Cash Used in Operating Activities

During the three months ended March 31, 2023, operating activities used \$42.4 million of cash, resulting from our net loss of \$39.8 million, and net cash used resulting from changes in our operating assets and liabilities of \$12.5 million, partially offset by non-cash charges of \$9.9 million. Net cash used in operating activities resulting from changes in our operating assets and liabilities for the three months ended March 31, 2023 consisted primarily of a net increase of \$4.1 million in prepaid expenses and other current and non-current assets, decreases in accrued expenses and other liabilities of \$7.1 million, accounts payable of \$0.2 million and a \$1.2 million decrease in right of use assets from amortization and operating lease liabilities, net.

During the three months ended March 31, 2022, operating activities used \$35.0 million of cash, resulting from our net loss of \$37.1 million, and net cash used resulting from changes in our operating assets and liabilities of \$3.9 million, partially offset by non-cash charges of \$6.0 million. Net cash used in operating activities resulting from changes in our operating assets and liabilities for the three months ended March 31, 2022 consisted primarily of a \$5.2 million increase in prepaid expenses and other current and non-current assets and an increase in accrued expenses and other liabilities of \$1.9 million. This cash used was offset by a decrease in accounts payable of \$0.3 million and a \$0.4 million decrease in right of use assets from amortization and lease liabilities, net.

Net Cash Used in Investing Activities

During the three months ended March 31, 2023 and 2022, we used \$3.6 million and \$0.8 million, respectively, of cash in investing activities, all of which consisted of purchases of property and equipment. Property and equipment purchased during the three months ended March 31, 2023 related primarily to assets under construction associated with the fit-out of the Nucleus.

Net Cash used in Financing Activities

During the three months ended March 31, 2023 and March 31, 2022, net cash used in financing activities related to payments of issuance costs relating to the prior financings of \$0.7 million and \$1,000, respectively.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. Our expenses will increase as we:

- seek regulatory approvals for any product candidates that successfully complete preclinical and clinical trials;
- establish a sales, marketing and distribution infrastructure in anticipation of commercializing of any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- hire additional clinical, medical and development personnel;
- expand our infrastructure and facilities to accommodate our growing employee base; and
- maintain, expand and protect our intellectual property portfolio.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical costs, external research and development services, laboratory and related supplies, legal and other regulatory expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support the development of our product candidates.

Based on our current clinical development plans, we believe our current cash and cash equivalents will be sufficient to fund our current and planned operating expenses and capital expenditure requirements for at least the next twelve months from the date of the issuance of these unaudited condensed consolidated financial statements. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. If we receive regulatory approval for our other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, outcome and costs of our clinical trials and other research and development activities;
- the costs, timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs and timing of hiring new employees to support our continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the extent to which we in-license or acquire additional product candidates or technologies.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through equity offerings, reimbursable U.K. research and development tax credits and receipts from the U.K. RDEC Scheme, out-licensing arrangements, strategic collaboration agreements. To the extent that we raise additional capital through the sale of equity, the ownership interest of existing shareholders will be diluted. If we raise additional funds through other third-party funding, collaborations agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, "U.S. GAAP". The preparation of our unaudited condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our unaudited condensed consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report.

JOBS Act

The Jumpstart Our Business Startups Act, or the JOBS Act, provides that, among other things, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. As an emerging growth company, we have irrevocably elected not to take advantage of the extended transition period afforded by the JOBS Act for implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth public companies.

We also currently rely on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), or (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

These exemptions will apply until December 31, 2023 or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

Recent Accounting Pronouncements Not Yet Adopted

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2, "Summary of Significant Accounting Policies," to our unaudited condensed consolidated financial statements included in Exhibit 99.1 of this Report on Form 6-K.



Autolus Therapeutics Reports First Quarter 2023 Financial Results and Operational Progress

May 4, 2023

- Obe-cel, a potentially transformational treatment for relapsed/refractory (r/r) B-cell Acute Lymphoblastic Leukemia (ALL), on track for next data update at ASCO and EHA, with a Biologics License Application (BLA) submission to the US FDA planned by end of the year
- Establishing core distribution capabilities required to commercialize a CAR T-cell therapy in the US by selecting Cardinal Health as commercial distribution partner
- Purpose-built commercial manufacturing facility on track to commence Good Manufacturing Practice (GMP) operations in H2 2023
- Conference call to be held today at 8:30 am EDT/1:30 pm BST

LONDON, May 04, 2023 (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 quarter ended March 31, 2023.

"It has been a busy quarter as we continue to execute on delivering on our obe-cel strategy in order to bring this innovative and potentially transformative treatment to an underserved adult Acute Lymphoblastic Leukemia (ALL) patient population," said Dr. Christian Itin, Chief Executive Officer of Autolus. "We look forward to presenting data from all patients treated in the FELIX study in an oral presentation at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, as well as data at the European Hematology Association (EHA) 2023 Congress, both in June, with longer term follow up data expected at the American Society of Hematology (ASH) meeting at the end of the year."

"Meanwhile, we continue to advance plans for the submission of a BLA for obe-cel at the end of the year and working towards commercial launch in 2024, subject to required regulatory approval. Post period end we selected Cardinal Health as the US commercial distribution partner for obe-cel and we continue to build out our own commercial infrastructure as we look to on-board centers over the course of this year. Our purpose-built commercial manufacturing facility is on track for the commencement of Good Manufacturing Practice (GMP) operations in H2 2023 with an initial capacity of up to 2,000 batches per year, which we predict will be sufficient to serve global demand in adult ALL."

Key obe-cel Updates:

- Obecabtagene autoleucl (obe-cel) in relapsed / refractory (r/r) adult ALL – The FELIX Study
 - Oral presentations of the FELIX pivotal study to be presented at ASCO and EHA. The Company expects data from the FELIX study to form the basis of a BLA submission for obe-cel to the FDA at the end of 2023 and plans to present longer term follow up data and subgroup analysis data at the American Society of Hematology (ASH) meeting in late 2023, as well as at medical conferences in H1 2024.

Obe-cel trials in collaboration with University College London

- Obe-cel in r/r adult B-ALL patients – Phase 1 ALLCAR19 Study
 - Long term follow-up data were presented at the Tandem Meetings: Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR). The data demonstrated that 35% of adult B-ALL patients remained in complete remission at a median follow up of 36 months without the need for additional anti-leukemia therapy.
- Obe-cel in r/r B-NHL and CLL patients – Phase 1 ALLCAR19 Extension Study
 - Data presented at the ASH meeting in December 2022 demonstrated the potentially best-in-class profile of obe-cel supported by the data observed in B-cell non-Hodgkin lymphoma (NHL), with continued high levels of clinical activity paired with an encouraging tolerability profile across diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma (MCL), follicular lymphoma (FL) and chronic lymphocytic leukemia (CLL). Patients continue to be enrolled into the study and the Company expects to publish the full results in a peer-reviewed journal.
- Obe-cel in Primary CNS Lymphoma patients – Phase 1 CAROUSEL Study
 - Data presented at the EHA meeting in June 2022 demonstrated first activity in primary CNS lymphoma. The study is fully enrolled, and the Company expects to publish the full results in a peer-reviewed journal.

- AUTO1/22 in pediatric B-ALL patients – Phase 1 CARPALL Study
 - Data presented at the European Society for Blood and Marrow Transplantation (EBMT) Annual Meeting in April 2023 by the Company's UCL collaborators, showed favorable safety profile and good efficacy in a heavily pre-treated cohort of patients. Importantly, there were no observed antigen negative relapses observed as of the data cut-off date, indicating that the combining of our optimized CD22 CAR design with the CD19 CAR used in obe-cel may be effective in preventing antigen-loss driven relapse in pediatric B-ALL. The preclinical data supporting this program was published in Molecular Therapy in March 2023.

Early-stage pipeline – leveraging academic collaborations to generate opportunity for non-dilutive funding

- AUTO4 in T Cell Lymphoma patients – Phase 1/2 LibRA T1 Study
 - Autolus has optimized the manufacturing process for AUTO4 and is enrolling additional patients into the trial to evaluate this manufacturing change. The next update is planned as an oral presentation at the International Conference on Malignant Lymphoma in June 2023.
- AUTO8 in Multiple Myeloma – Phase 1 MCARTY Study
 - AUTO8 is a next-generation product candidate for multiple myeloma, which comprises two independent CARs for the multiple myeloma targets, BCMA and CD19. In collaboration with UCL, the Company initiated a study in Q1 2022. Patients continue to be enrolled and initial data is expected in 2023.
- AUTO6NG in Neuroblastoma
 - AUTO6NG contains a CAR that targets GD2 alongside additional programming modules to enhance the activity and persistence. In collaboration with UCL, the Company is planning on initiating a clinical trial of AUTO6NG in 2023.

Key Operational Updates during Q1 2023

- The Company's new 70,000 square foot commercial manufacturing facility in Stevenage, UK has continued to progress on track. Key equipment installation and validation were completed by Autolus in Q1 2023 enabling operational qualifications commencing in Q2 2023. Activities are on track for the commencement of GMP operations in H2 2023. The 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 is on track for submission of a BLA by the end of 2023.
- Announced a collaboration with Cabaletta Bio in January 2023. Autolus received an upfront payment for non-exclusive access to the RQR8 safety switch for use in Cabaletta's CD19-CAR T cell therapy program for the treatment of autoimmune disease, with the potential for near term option exercise fees and development and regulatory milestone payments. In addition, Autolus is entitled to receive royalties on net sales of all Cabaletta cell therapy products that incorporate the RQR8 safety switch.
- Announced two changes to the Board of Directors. The Company's non-executive Chairman, John H. Johnson, who has held the role since September 2021, will not stand for re-election at Autolus' upcoming annual shareholder meeting. Additionally, Dr. Jay T. Backstrom, who has served on Autolus' Board of Directors since August 2020, stepped down from Autolus' Board of Directors at the end of February 2023.
- Dr. Lucinda Crabtree will step down as CFO in August 2023. A search for a successor is under way.

Post Period End:

- Autolus selected Cardinal Health to provide core distribution capabilities required for U.S. commercialization of CAR T-cell therapies. Under the proposed agreement, Cardinal Health 3PL Services will establish essential capabilities for Autolus to commercialize a CAR T-cell therapy in the US, including a depot model that allows Autolus to maintain custody and physically position product closer to treatment sites during finalization of product release, with the goal of shortening vein-to-delivery times. In addition, Cardinal Health will help provide seamless order-to-cash capabilities.
- Autolus hosted a Virtual Capital Markets Day on Thursday, April 27, 2023, where members of the Executive Management Team and Key Opinion Leaders presented on the obe-cel commercial opportunity and positioning. A [replay](#) of the event is available on the Autolus website.
- In April 2023 Autolus announced data from the AUTO1/22 in a clinical trial of pediatric ALL patients at the EBMT Annual Meeting. This followed the publication of the preclinical work supporting this program in March in Molecular Therapy, 'Dual

targeting of CD19 and CD22 against B-ALL using a novel high sensitivity aCD22 CAR.'

- In April 2023 Autolus announced the publication of a paper in Molecular Therapy Nucleic Acids, 'Novel Fas-TNFR chimeras that prevent Fas ligand-mediated kill and signal synergistically to enhance CAR T-cell efficacy. The paper outlined how Fas-CD40 chimera can render T cell therapies resistant to FasL-mediated cell death and improve their effectiveness against solid tumors.
- In April 2023, Autolus moved funds to additional highly rated liquid money market funds. The limit to any one counterparty is less than 25% of the Company's total cash and cash equivalents balance.

Financial Results for the First Quarter Ended March 31, 2023

Cash and cash equivalents and restricted cash at March 31, 2023, totaled \$343.4 million, as compared to cash of \$382.8 million at December 31, 2022.

Net total operating expenses for the three months ended March 31, 2023, were \$43.1 million, which included license revenue income of \$1.3 million, as compared to net total operating expenses of \$41.8 million, which included grant income of \$0.2 million, for the same period in 2022.

Research and development expenses decreased by \$2.7 million to \$31.3 million for the three months ended March 31, 2023 from \$34.0 million for the three months ended March 31, 2022 primarily due to:

- a decrease of \$5.5 million in clinical trial and manufacturing costs which is offset by an increase of \$0.8 million in manufacturing material costs due to increased validation activities undertaken, primarily relating to our obe-cel clinical product candidate,
- a decrease of \$0.2 million in depreciation and amortization related to property, plant and equipment and intangible assets due to the reduction in our depreciable asset base,
- a decrease of \$0.1 million in legal fees and professional consulting fees in relation to our research and development activities,
- an increase of \$1.4 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 \$0.7 million related to information technology infrastructure and support for information systems related to the conduct of clinical trials and manufacturing operations, and
- an increase of \$0.2 million in facilities costs related to our new manufacturing facility, the "Nucleus", in Stevenage, United Kingdom as well increase in costs related to maintaining our current leased properties.

General and administrative expenses increased by \$1.3 million to \$9.3 million for the three months ended March 31, 2023 from \$8.0 million for the three months ended March 31, 2022 primarily due to:

- an increase of \$0.7 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 \$0.7 million in commercial readiness costs due to increased commercial readiness activities being undertaken,
- an increase of \$0.1 in general office supplies and expenses facilities costs due to the increase in space utilized for general and administrative activities,
- a decrease of \$0.2 million primarily related to a reduction in directors' and officers' liability insurance premiums, legal and professional fees.

For the three months ended March 31, 2023, we recognized a loss on disposal of property and equipment of \$3.8 million related to fixed assets no longer being utilized in the manufacturing facility exited in Stevenage, United Kingdom. There were no such disposals for the three months ended March 31, 2022.

Other income, net decreased to \$0.8 million from \$0.9 million for the three months ended March 31, 2023 and 2022, respectively. The decrease of \$0.1 million is primarily due to the recognition of a lease termination loss arising from the termination and exit of one of our manufacturing suites in Stevenage, United Kingdom.

Interest income increased to \$3.4 million for the three months ended March 31, 2023, as compared to \$28,000 for the three months ended March 31, 2022. The increase in interest income of \$3.4 million primarily relates to the increase in interest rates on our interest-bearing bank accounts and short-term investments during the three months ended March 31, 2023 as compared to the three months ended March 31, 2022.

Interest expense increased to \$4.9 million for the three months ended March 31, 2023 as compared to \$1.8 million for the three months ended March 31, 2022. Interest expense is primarily related to the liability for future royalties and sales milestones, net associated with our strategic collaboration agreement with Blackstone.

Net loss attributable to ordinary shareholders was \$39.8 million for the three months ended March 31, 2023, compared to \$37.1 million for the same period in 2022. The basic and diluted net loss per ordinary share for the three months ended March 31, 2023, totaled \$(0.23) compared to a basic and diluted net loss per ordinary share of \$(0.41) for the three months ended March 31, 2022.

Autolus estimates that its current cash and cash equivalents on hand and anticipated future milestone payment from Blackstone will extend the Company's runway into 2025.

Unaudited Financial Results for the Quarter Ended March 31, 2023
Condensed Consolidated Balance Sheet
(In thousands, except share and per share amounts)

	March 31 2023	December 31 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 343,027	\$ 382,436
Restricted cash	328	325
Prepaid expenses and other current assets	50,530	43,010
Total current assets	393,885	425,771
Non-current assets:		
Property and equipment, net	34,667	35,209
Prepaid expenses and other non-current assets	465	2,176
Operating lease right-of-use assets, net	26,861	23,210
Long-term deposits	1,821	1,832
Deferred tax asset	2,272	2,076
Total assets	<u>459,971</u>	<u>490,274</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	353	531
Accrued expenses and other liabilities	34,463	40,797
Operating lease liabilities, current	4,821	5,038
Total current liabilities	39,637	46,366
Non-current liabilities:		
Operating lease liabilities, non-current	22,495	19,218
Liability related to future royalties and sales milestones, net	130,805	125,900
Other long-term payables	114	116
Total liabilities	193,051	191,600
Shareholders' equity:		
Ordinary shares, \$0.000042 par value; 290,909,783 authorized as of March 31, 2023 and December 31, 2022; 173,074,510 shares issued and outstanding at March 31, 2023 and December 31, 2022	8	8
Deferred shares, £0.00001 par value; 34,425 shares authorized, issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Deferred B shares, £0.00099 par value; 88,893,548 shares authorized, issued and outstanding at March 31, 2023 and December 31, 2022	118	118
Deferred C shares, £0.000008 par value; 1 share authorized, issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Additional paid-in capital	1,010,041	1,007,625
Accumulated other comprehensive loss	(33,257)	(38,898)
Accumulated deficit	(709,990)	(670,179)
Total shareholders' equity	266,920	298,674
Total liabilities and shareholders' equity	<u>\$ 459,971</u>	<u>\$ 490,274</u>

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

	Three Months Ended March 31, 2023	2022
Grant income	\$ —	\$ 166

License revenue	1,292	—
Operating expenses:		
Research and development	(31,344)	(33,963)
General and administrative	(9,284)	(7,987)
Loss on disposal of property and equipment	(3,768)	—
Total operating expenses, net	(43,104)	(41,784)
Other income, net	782	860
Interest income	3,446	28
Interest expense	(4,905)	(1,790)
Total other expense, net	(677)	(902)
Net loss before income tax	(43,781)	(42,686)
Income tax benefit	3,970	5,624
Net loss attributable to ordinary shareholders	(39,811)	(37,062)
Other comprehensive loss:		
Foreign currency exchange translation adjustment	5,641	(7,455)
Total comprehensive loss	<u>\$ (34,170)</u>	<u>\$ (44,517)</u>
Basic and diluted net loss per ordinary share	\$ (0.23)	\$ (0.41)
Weighted-average basic and diluted ordinary shares	173,825,825	90,914,175

Conference Call

Management will host a conference call and webcast at 8:30 am EDT/1:30 pm BST 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. 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 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 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 continued development of Autolus' AUTO1/22 program; the status of clinical trials (including, without limitation, expectations regarding the data that is being presented, the expected timing of data releases and development, as well as completion of clinical trials) and development timelines for the Company's product candidates. 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 7, 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.

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