

August 12, 2024



Adaptimmune Reports Q2 2024 Financial and Business Updates

Adaptimmune received U.S. FDA accelerated approval of Tecelra® (afami-cel), the first approved engineered cell therapy for a solid tumor

Patients can begin treatment journey; biomarker testing available; Adaptimmune systems ready to receive orders

At the end of Q2, Adaptimmune had Total Liquidity^[1] of \$214.8 million

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - August 12, 2024) - Adaptimmune Therapeutics plc (Nasdaq: ADAP), a company redefining the treatment of solid tumor cancers with cell therapy, today reports financial results and business updates for the second quarter ended June 30, 2024. The Company will host a live webcast at 8:00 a.m. EDT (1:00 p.m. BST) today.

Adrian Rawcliffe, Adaptimmune's Chief Executive Officer: "On 1 August, we received US FDA approval for Tecelra, the first ever engineered cell therapy for a solid tumor and the first new treatment option for people with synovial sarcoma in more than a decade. We have hit the ground running to make Tecelra available to eligible patients. Patients can start their treatment journey now with healthcare providers able to begin testing and our ordering platform is up and running. Tecelra will be available in 6-10 US authorized treatment centers in the coming weeks. Tecelra is the first product in our sarcoma franchise, and we are planning to commence our rolling BLA submission for lete-cel in 2025 and commercial launch in 2026. We expect our sarcoma franchise to redefine the treatment landscape in advanced soft tissue sarcoma with projected peak US sales of \$400 million."

Sarcoma Franchise with Tecelra® and lete-cel

- U.S. Food and Drug Administration (FDA) approves Tecelra® for the treatment of advanced MAGE-A4+ synovial sarcoma in adults with certain HLA types who have received prior chemotherapy.
- Tecelra® is the first engineered cell therapy for solid tumors.
- Tecelra® is the first new treatment option for synovial sarcoma in more than a decade.
- Tecelra® is a single infusion treatment.
- No Risk Evaluation and Mitigation Strategies (REMS) program was required for BLA approval.
- Patients can start their treatment journey now, with testing approved and available in the United States.
- Sarcoma centers of excellence across the United States are being onboarded as Authorized Treatment Centers (ATCs) for Tecelra®.
- The approval of Tecelra® was based on results of the SPEARHEAD-1 (Cohort 1) trial. The major efficacy outcome was overall response rate (ORR) by independent review and supported by duration of response. Tecelra® treatment resulted in an ORR of 43%

with a complete response rate of 4.5%. The median duration of response was 6 months (95% CI: 4.6, not reached). Among patients who were responsive to the treatment, 39.0% had a duration of response of 12 months or longer. Data from the pivotal SPEARHEAD-1 trial were previously published in [The Lancet](#) earlier this year.

- **Data presentations:**

- Data from the pivotal IGNYTE-ESO trial of lete-cel (letetresgene autoleucel), an engineered cell therapy targeting NY-ESO-1, in synovial sarcoma (SyS) and myxoid/round cell liposarcoma (MRCLS) [was presented](#) at the American Society of Clinical Oncology's (ASCO) annual meeting. The overall response rate (ORR) of 40% was consistent across both SyS and MRCLS, meeting the primary endpoint success criterion for efficacy. Given the trial's success, Adaptimmune plans to initiate a rolling Biologics License Application (BLA) submission for lete-cel for the treatment of advanced or metastatic MRCLS and synovial sarcoma during 2025. Lete-cel will bolster Adaptimmune's sarcoma franchise by expanding the addressable patient population to NY-ESO-1 positive MRCLS and SyS solid tumors.

Clinical pipeline

- Adaptimmune recently [announced](#) the company had entered into a clinical collaboration agreement with Galapagos to conduct a clinical proof-of-concept trial to evaluate the safety and efficacy of uza-cel (next-generation engineered TCR T-cell therapy, formerly ADP-A2M4CD8) using Galapagos' decentralized manufacturing platform in patients with head & neck cancer and potential future solid tumor cancer indications.
- Adaptimmune retains the right to develop, manufacture, commercialize, and otherwise exploit uza-cel for platinum-resistant ovarian cancer.
- Uza-cel is being investigated in the SURPASS-3 Phase 2 clinical trial (NCT05601752) for the treatment of platinum-resistant ovarian cancer. Uza-cel received FDA RMAT designation in 2022 for the treatment of patients with platinum resistant ovarian cancer. The SURPASS-3 trial is currently enrolling patients.
- Screening in the SURPASS Phase 1 trial has stopped and enrolment will cease shortly.

Preclinical pipeline

- Wholly owned allogeneic pipeline progressing; process optimization continues at Adaptimmune's facility in Milton Park, UK.
- IND-enabling activities continue for ADP-600 (PRAME) and ADP-520 (CD70) programs.

Business and corporate updates

- Under the terms of Adaptimmune and Galapagos' collaboration agreement, Adaptimmune will receive initial payments of \$100 million, comprising \$70 million upfront and \$30 million of R&D funding of which \$15m was received on signing, option exercise fees of up to \$100 million, additional development and sales milestone payments of up to a maximum of \$465 million, plus tiered royalties on net sales.
- Adaptimmune announced in May entry into a Loan and Security Agreement with Hercules Capital, Inc., for a term loan facility of up to \$125.0 million. Following the

receipt of FDA approval for Tecelra, the Company is eligible to draw down the Tranche 2 Advance of \$25.0 million and is in the process of requesting this Tranche 2 Advance.

Financial Results for the three and six months ended June 30, 2024

- **Cash / liquidity position:** As of June 30, 2024, Adaptimmune had cash and cash equivalents of \$211.8 million and Total Liquidity^[2] of \$214.8 million, compared to \$144.0 million and \$146.9 million respectively, as of December 31, 2023.
- **Revenue:** Revenue for the three and six months ended June 30, 2024, was \$128.2 million and \$133.9 million, respectively, compared to \$5.1 million and \$52.7 million for the same periods in 2023. Revenue has increased in 2024, compared to the same periods in 2023 primarily due to the termination of the Genentech collaboration in the second quarter of 2023, resulting in the majority of the remaining deferred income for the collaboration being recognized as revenue including a cumulative catch-up adjustment of \$101.3 million. This was significantly higher than the impact from the termination of the Astellas collaboration in 2023, which resulted in \$42.4 million of revenue being recognized in March 2023.
- **Research and development (R&D) expenses:** R&D expenses for the three and six months ended June 30, 2024, were \$40.4 million and \$75.7 million, respectively, compared to \$30.0 million and \$55.5 million for the same periods in 2023. R&D expenses increase due to an increase in the average number of employees engaged in research and development, increases in subcontracted expenditures, an increase in in-process research and development costs and a decrease in offsetting reimbursements receivable for research and development tax and expenditure credits.
- **General and administrative (G&A) expenses:** G&A expenses for the three and six months ended June 30, 2024, were \$19.1 million and \$38.8 million, respectively, compared to \$20.1 million and \$40.5 million for the same periods in 2023. G&A expenses decreased due to restructuring and charges recognised in the first quarter of 2023 that were not repeated in 2024 and an increase in offsetting reimbursements, offset by an increase in other corporate costs due to an increase in accounting, legal and professional fees in the second quarter of 2024 due to fees relating to business development work and preparation for commercialization.
- **Net profit/(loss):** Net profit attributable to holders of the Company's ordinary shares for the three and six months ended June 30, 2024, was \$69.5 million and \$21.0 million, respectively (\$0.05 and \$0.01 per ordinary share), compared to losses of \$21.3 million and \$20.4 million (\$0.02) and \$(0.02) per ordinary share), for the same periods in 2023.

Today's Webcast Details

A live webcast and replay can be accessed [HERE](#). Call in information is as follows: **+1-844-763-8274** (US or Canada) or **+1-647-484-8814** (International). Callers should dial in 5-10 minutes prior to the scheduled start time and simply ask to join the Adaptimmune call.

About Adaptimmune

Adaptimmune is a fully integrated cell therapy company working to redefine how cancer is treated. With its unique engineered T cell receptor (TCR) platform, the Company is developing personalized medicines designed to target and destroy difficult-to-treat solid tumor cancers and to radically improve the patient's cancer treatment experience.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the safe harbor provisions of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements address our expected future business, financial performance, financial condition, as well as the results of operations and often contain words such as "anticipate," "believe," "expect," "may," "plan," "potential," "will," and similar expressions. Such statements are based only upon current expectations of Adaptimmune. Reliance should not be placed on these forward-looking statements because they involve certain risks and uncertainties. Such risks and uncertainties could cause our actual results to differ materially from those indicated by such forward-looking statements, and include, without limitation: the success, cost and timing of our product development activities and clinical trials and our ability to successfully advance our TCR therapeutic candidates through the regulatory and commercialization processes. For a further description of the risks and uncertainties that could cause our actual results to differ materially from those expressed in these forward-looking statements, as well as risks relating to our business in general, we refer you to our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2023, our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other filings with the Securities and Exchange Commission. The forward-looking statements contained in this press release speak only as of the date the statements were made and we do not undertake any obligation to update such forward-looking statements to reflect subsequent events or circumstances.

Total Liquidity (a non-GAAP financial measure)

Total Liquidity (a non-GAAP financial measure) is the total of cash and cash equivalents and marketable securities (available-for-sale debt securities). Each of these components appears separately in the condensed consolidated balance sheet. The U.S. GAAP financial measure most directly comparable to Total Liquidity is cash and cash equivalents as reported in the condensed consolidated financial statements, which reconciles to Total Liquidity as follows (in thousands):

	June 30, 2024	December 31, 2023
Cash and cash equivalents	\$ 211,810	\$ 143,991
Marketable securities - available-for-sale debt securities	2,979	2,947
Total Liquidity	\$ 214,789	\$ 146,938

The Company believes that the presentation of Total Liquidity provides useful information to investors because management reviews Total Liquidity as part of its assessment of overall solvency and liquidity, financial flexibility, capital position and leverage.

Condensed Consolidated Statement of Operations

(unaudited, in thousands, except per share data)

Three months ended

Six months ended

	June 30,		June 30,	
	2024	2023	2024	2023
Revenue	\$ 128,231	\$ 5,130	\$ 133,909	\$ 52,731
Operating expenses				
Research and development	(40,448)	(29,965)	(75,655)	(55,513)
General and administrative	(19,083)	(20,073)	(38,815)	(40,470)
Total operating expenses	(59,531)	(50,038)	(114,470)	(95,983)
Operating profit/(loss)	68,700	(44,908)	19,439	(43,252)
Interest income	1,376	1,543	2,721	2,219
Interest expense	(526)	-	(526)	-
Gain on bargain purchase	-	22,155	-	22,155
Other income (expense), net	497	501	436	(170)
Profit/(loss) before income tax expense	70,047	(20,709)	22,070	(19,048)
Income tax expense	(526)	(680)	(1,052)	(1,305)
Net profit/(loss) attributable to ordinary shareholders	\$ 69,521	\$ (21,389)	\$ 21,018	\$ (20,353)
Net profit/(loss) per ordinary share				
Basic	\$ 0.05	\$ (0.02)	\$ 0.01	\$ (0.02)
Diluted	\$ 0.04	\$ (0.02)	\$ 0.01	\$ (0.02)

Weighted average shares outstanding:

Basic	1,533,531,837	1,108,166,960	1,492,386,749	1,050,071,434
Diluted	1,559,183,774	1,108,166,960	1,519,004,675	1,050,071,434

Condensed Consolidated Balance Sheets

(unaudited, in thousands, except share data)

	June 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	\$ 211,810	\$ 143,991
Marketable securities - available-for-sale debt securities (amortized cost of \$2,979 and \$2,940) net of allowance for expected credit losses of \$0 and \$0	2,979	2,947
Accounts receivable, net of allowance for expected credit losses of \$0 and \$0	2,335	821
Other current assets and prepaid expenses	36,646	59,793
Total current assets	253,770	207,552
Restricted cash	2,866	3,026
Operating lease right-of-use assets, net of accumulated amortization of \$15,645 and \$13,220	18,203	20,762
Property, plant and equipment, net of accumulated depreciation of \$51,182 and \$46,020	45,867	50,946
Intangible assets, net of accumulated amortization of \$5,257 and \$5,155	996	330
Total assets	\$ 321,702	\$ 282,616
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 7,513	\$ 8,128
Operating lease liabilities, current	5,293	5,384

Accrued expenses and other current liabilities	30,850	30,303
Deferred revenue, current	38,417	28,973
Total current liabilities	82,073	72,788
Operating lease liabilities, non-current	17,101	19,851
Deferred revenue, non-current	99,860	149,060
Borrowings, non-current	24,954	-
Other liabilities, non-current	1,440	1,404
Total liabilities	225,428	243,103
Stockholders' equity		
Common stock - Ordinary shares par value £0.001, 2,039,252,874 authorized and 1,534,220,604 issued and outstanding (2023: 1,702,760,280 authorized and 1,363,008,102 issued and outstanding)	2,083	1,865
Additional paid in capital	1,099,758	1,064,569
Accumulated other comprehensive loss	(3,412)	(3,748)
Accumulated deficit	(1,002,155)	(1,023,173)
Total stockholders' equity	96,274	39,513
Total liabilities and stockholders' equity	\$ 321,702	\$ 282,616

Condensed Consolidated Cash Flow Statement (unaudited, in thousands)

	Six months ended June 30,	
	2024	2023
Cash flows from operating activities		
Net profit/(loss)	\$ 21,018	\$ (20,353)
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>		
Depreciation	5,457	3,824
Amortization	115	253
Gain on bargain purchase	-	(22,155)
Share-based compensation expense	6,160	5,513
Unrealized foreign exchange (gains)/losses	(266)	377
Accretion on available-for-sale debt securities	(42)	(633)
Other	2	663
<i>Changes in operating assets and liabilities:</i>		
Decrease in receivables and other operating assets	20,788	1,971
Increase/(decrease) in payables and other current liabilities	1,012	(8,801)
Increase in borrowings	454	-
Decrease in deferred revenue	(39,249)	(41,704)
Net cash provided by/(used in) operating activities	15,449	(81,045)
Cash flows from investing activities		
Acquisition of property, plant and equipment	(524)	(3,565)
Acquisition of intangible assets	(588)	(199)
Cash from acquisition of TCR2 Therapeutics Inc.	-	45,264
Maturity or redemption of marketable securities	-	76,119
Investment in marketable securities	-	(67,121)

Other	11	537
Net cash (used in)/provided by investing activities	(1,101)	51,035
Cash flows from financing activities		
Proceeds from issuance of borrowings, net of discount	24,500	-
Proceeds from issuance of common stock from offerings, net of commissions and issuance costs	29,171	188
Proceeds from exercise of stock options	76	22
Net cash provided by financing activities	53,747	210
Effect of currency exchange rate changes on cash, cash equivalents and restricted cash	(436)	398
Net increase/(decrease) in cash, cash equivalents and restricted cash	67,659	(29,402)
Cash, cash equivalents and restricted cash at start of period	147,017	109,602
Cash, cash equivalents and restricted cash at end of period	\$ 214,676	\$ 80,200

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[1] Total liquidity is a non-GAAP financial measure, which is explained and reconciled to the most directly comparable financial measures prepared in accordance with GAAP below

[2] Total liquidity is a non-GAAP financial measure, which is explained and reconciled to the most directly comparable financial measures prepared in accordance with GAAP below



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