

May 15, 2024



Adaptimmune Reports Q1 2024 Financial and Business Updates

Afami-cel commercial and regulatory update presented at Company's Investor Day (replay [HERE](#)); FDA review and inspections progressing with PDUFA date of August 4th, 2024

Commercial and manufacturing infrastructure in place to support afami-cel commercial launch upon approval

Data from SPEARHEAD-1 pivotal trial with afami-cel published in [The Lancet](#); data from a planned interim analysis of pivotal lete-cel IGNYTE-ESO trial to be presented at ASCO

Cash runway into late 2025

Conference call today at 8 a.m. EDT webcast link [HERE](#)

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - May 15, 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 first quarter ended March 31, 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: "Support from the sarcoma community continues to highlight the high unmet medical need for new therapies for synovial sarcoma and we are making great progress preparing for the commercial launch of afami-cel on approval. Behind afami-cel, we plan to launch lete-cel for synovial sarcoma and MRCLS in 2026 with projected peak US sales of \$400 million for our sarcoma franchise."

Sarcoma Franchise with afami-cel and lete-cel

- U.S. FDA accepted the BLA for afami-cel for the treatment of advanced synovial sarcoma with priority review and a PDUFA date of August 4th, 2024
- The BLA mid-cycle review meeting was held with FDA in April
- FDA GCP Bioresearch Monitoring Program (BIMO) inspections have been conducted at Adaptimmune and at selected clinical sites that participated in the pivotal SPEARHEAD-1 trial
- FDA GMP Pre-license inspections (PLI) have taken place at the Company's Navy Yard facility and at the lentiviral vector contract manufacturer's facility
- Preliminary plans for confirmatory evidence for afami-cel's full approval were previously agreed with FDA, including Cohort 2
- Adaptimmune expects to discuss post-marketing requirements and commitments at the late-cycle meeting which is scheduled for the second half of May
- To date, the FDA has not requested an Advisory Committee meeting or a REMS program
- The marketing application for the companion diagnostic for MAGE-A4 is currently

under FDA review and is expected to be approved contemporaneously with the BLA

- Adaptimmune is preparing to launch afami-cel on approval in the U.S. Initially, launch will be focused on 6-10 selected treatment centers ("Authorized Treatment Centers" or "ATCs") and will expand to up to ~30 ATCs.
- 100% of the customer facing commercial and medical affairs teams is now in place
- Company launched www.Tcrtcell.com: an unbranded website aimed at educating healthcare providers about TCR T-cell therapy in solid tumors, including synovial sarcoma, and the role of biomarkers and testing to determine future treatments
- The second product in Adaptimmune's sarcoma franchise, lete-cel, is being investigated in the pivotal IGNYTE-ESO trial (NCT03967223), which at a planned interim analysis exhibited response in 18/45 of patients (ORR 40%). The primary efficacy endpoint requires 16/60 patients have responses, so this trial has met its primary endpoint for efficacy. The full pivotal analyses are anticipated in late 2024.
- Lete-cel will enable Adaptimmune to expand its addressable synovial sarcoma patient population by targeting the NY-ESO cancer antigen, in addition to MAGE-A4 targeted by afami-cel, as well as treating Myxoid Round Cell Liposarcoma (MRCLS) patients.
- Sarcoma franchise of afami-cel and lete-cel leverages same development and commercial footprint with US peak year sales projected to be up to \$400 million
- **Data presentations**
 - Data from pivotal SPEARHEAD-1 trial with afami-cel published in [The Lancet](#): article entitled "*Afamitresgene autoleucel for advanced synovial sarcoma and myxoid round cell liposarcoma (SPEARHEAD-1): an international, open-label, phase 2 trial*"
 - Data from the planned interim analysis of the pivotal IGNYTE-ESO trial with lete-cel to be presented by Dr. Sandra P. D'Angelo, M.D., Sarcoma Medical Oncology, Memorial Sloan Kettering Cancer Center, in an oral presentation at ASCO entitled "*Lete-cel in patients with synovial sarcoma or myxoid/round cell liposarcoma: Planned interim analysis of the pivotal IGNYTE-ESO trial*" during the Developmental Therapeutics-Immunotherapy session in Hall D2 on June 3, 2024 at 11:30 a.m. CDT

Clinical pipeline

- Uzatresgene autoleucel ("uza-cel", formerly ADP-A2M4CD8) 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.
- Cohorts in the Phase 1 SURPASS trial are ongoing for people with head & neck and urothelial (bladder) cancers with uza-cel in combination with standard of care checkpoint inhibitor therapy.

Preclinical pipeline

- IND-enabling studies are underway for ADP-600 (PRAME) and ADP-520 (CD70) programs.
- Wholly owned allogeneic pipeline advancing; process development in progress at Adaptimmune's allogeneic manufacturing facility in Milton Park, UK.
- **Data presentation**

- Poster presented by George Pope, Ph.D., Associate Director Preclinical Safety at Adaptimmune, entitled "*Development and Preclinical Characterization of an Engineered T-Cell Therapy Targeting PRAME-Expressing Solid Tumors*" at the American Society of Gene & Cell Therapy (ASGCT) Annual meeting

Corporate news

- As announced earlier today, Adaptimmune has secured up to \$125 million in debt financing with Hercules Capital with the first tranche of \$25 million available upon closing; and an additional \$25 million available upon afami-cel approval
- Cash runway into late 2025 which includes current cash on hand, anticipated revenues from the launch of afami-cel, expected future income from partners and other non-dilutive capital sources including the Company's new debt facility with Hercules Capital
- [Company announced](#) that its strategic collaboration with Genentech was terminated

Financial Results for the three months ended March 31, 2024

- **Cash / liquidity position:** As of March 31, 2024, Adaptimmune had cash and cash equivalents of \$140.7 million and Total Liquidity^[1] of \$143.7 million, compared to \$144.0 million and \$146.9 million respectively, as of December 31, 2023.
- **Revenue:** Revenue for the three months ended March 31, 2024, was \$5.7 million compared to \$47.6 million for the same period in 2023. Revenue has decreased in 2024, compared to the same period in 2023 primarily due to the termination of the Astellas collaboration in the first quarter of 2023, resulting in the remaining deferred income for the collaboration being recognized as revenue in March 2023.
- **Research and development (R&D) expenses:** R&D expenses for the three months ended March 31, 2024, were \$35.2 million compared to \$25.5 million for the same period in 2023. R&D expenses in the three months ended March 31, 2024 increased in employee-related costs and additional costs associated with lease properties following the acquisition of TCR² in June 2023 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 months ended March 31, 2024, were \$19.7 million compared to \$20.4 million for the same period in 2023. G&A expenses in the three months ended March 31, 2024 decreased due to restructuring and charges recognised in the first quarter of 2023 and a decrease in other corporate costs due to an increase in accounting, legal and professional fees incurred in relation to the TCR² Therapeutics, Inc merger agreement that were not repeated in 2024, offset by an increase in depreciation due to leasehold improvements capitalised in 2023.
- **Net loss/profit:** Net loss attributable to holders of the Company's ordinary shares for the three months March 31, 2024, was \$48.5 million (\$0.03 per ordinary share), compared to a profit of \$1.0 million (\$0.00 per ordinary share), for the same periods in 2023.

Financial Guidance

The Company believes that its existing cash, cash equivalents and marketable securities, together with anticipated revenues from the launch of afami-cel, expected future income from partners and other non-dilutive capital sources including the Company's new debt facility with Hercules Capital announced earlier today, will fund the Company's current

operations into late 2025, as further detailed in the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2024, to be filed with the Securities and Exchange Commission following this earnings release.

Today's Webcast Details

A live webcast and replay can be accessed at <https://www.gowebcasting.com/13334>. Call in information is as follows: **1-800-806-5484** (US or Canada) or **+416-340-2217** (International and additional options available [HERE](#)) and the passcode is **3025919#**. 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 clinical-stage biopharmaceutical company focused on designing, developing, and delivering cell therapies to transform the lives of people with cancer. The Company's unique engineered T-cell receptor (TCR) platform enables the engineering of T-cells to target and destroy cancers across multiple solid tumor types.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). These forward-looking statements 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 31 December, 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):

	March 31, 2024	December 31, 2023
Cash and cash equivalents	\$ 140,670	\$ 143,991
Marketable securities - available-for-sale debt securities	2,982	2,947
Total Liquidity	\$ 143,652	\$ 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 March 31,	
	2024	2023
Revenue	\$ 5,678	\$ 47,601
Operating expenses		
Research and development	(35,207)	(25,548)
General and administrative	(19,732)	(20,397)
Total operating expenses	(54,939)	(45,945)
Operating (loss)/profit	(49,261)	1,656
Interest income	1,345	676
Other income (expense), net	(61)	(671)
(Loss)/profit before income tax expense	(47,977)	1,661
Income tax expense	(526)	(625)
Net (loss)/profit attributable to ordinary shareholders	\$ (48,503)	\$ 1,036
Net (loss)/profit per ordinary share		
Basic	\$ (0.03)	\$ 0.00
Diluted	\$ (0.03)	\$ 0.00
Weighted average shares outstanding:		
Basic	1,451,241,661	991,330,402
Diluted	1,451,241,661	1,000,276,615

Condensed Consolidated Balance Sheets

(unaudited, in thousands, except share data)

	March 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	\$ 140,670	\$ 143,991
Marketable securities - available-for-sale debt securities (amortized cost of \$2,981 and \$2,940) net of allowance for expected credit losses of \$0 and \$0	2,982	2,947
Accounts receivable, net of allowance for expected credit losses of \$0 and \$0	8,404	821
Other current assets and prepaid expenses	34,847	59,793
Total current assets	186,903	207,552
Restricted cash	2,858	3,026
Operating lease right-of-use assets, net of accumulated amortization of \$14,381 and \$13,220	19,434	20,762
Property, plant and equipment, net of accumulated depreciation of \$48,445 and \$46,020	48,291	50,946
Intangible assets, net of accumulated amortization of \$5,198 and \$5,155	524	330
Total assets	\$ 258,010	\$ 282,616

Liabilities and stockholders' equity**Current liabilities**

Accounts payable	\$ 6,587	\$ 8,128
Operating lease liabilities, current	5,250	5,384
Accrued expenses and other current liabilities	23,050	30,303
Deferred revenue, current	31,524	28,973
Total current liabilities	66,411	72,788

Operating lease liabilities, non-current	18,442	19,851
Deferred revenue, non-current	147,365	149,060
Other liabilities, non-current	1,417	1,404
Total liabilities	233,635	243,103

Stockholders' equity

Common stock - Ordinary shares par value £0.001, 1,702,760,280 authorized and 1,532,974,878 issued and outstanding (2023: 1,702,760,280 authorized and 1,363,008,102 issued and outstanding)	2,081	1,865
Additional paid in capital	1,096,690	1,064,569
Accumulated other comprehensive loss	(2,720)	(3,748)
Accumulated deficit	(1,071,676)	(1,023,173)
Total stockholders' equity	24,375	39,513

Total liabilities and stockholders' equity	\$ 258,010	\$ 282,616
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Condensed Consolidated Cash Flow Statement

(unaudited, in thousands)

	Three months ended	
	March 31,	
	2024	2023
Cash flows from operating activities		
Net (loss)/profit	\$ (48,503)	\$ 1,036
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>		
Depreciation	2,771	1,659
Amortization	59	186
Share-based compensation expense	3,102	1,676
Unrealized foreign exchange losses	305	563
(Accretion)/amortization on available-for-sale debt securities	(23)	112
Other	(19)	134
<i>Changes in operating assets and liabilities:</i>		
Increase in receivables and other operating assets	15,620	3,683
(Decrease)/increase in payables and other current liabilities	(7,650)	21
Decrease/(increase) in deferred revenue	2,388	(46,353)
Net cash used in operating activities	(31,950)	(37,283)
Cash flows from investing activities		
Acquisition of property, plant and equipment	(102)	(2,349)
Acquisition of intangible assets	(256)	(173)
Maturity or redemption of marketable securities	—	50,863
Net cash (used in)/provided by investing activities	(358)	48,341

Cash flows from financing activities

Proceeds from issuance of common stock from offerings, net of commissions and issuance costs	29,161	188
Proceeds from exercise of stock options	74	8
Net cash provided by financing activities	29,235	196
Effect of currency exchange rate changes on cash, cash equivalents and restricted cash	(416)	588
Net (decrease)/increase in cash, cash equivalents and restricted cash	(3,489)	11,842
Cash, cash equivalents and restricted cash at start of period	147,017	109,602
Cash, cash equivalents and restricted cash at end of period	\$ 143,528	\$ 121,444

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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



To view the source version of this press release, please visit

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