

March 6, 2024



Adaptimmune Reports Q4/Full Year 2023 Financial Results and Business Updates

U.S. FDA accepted BLA for afami-cel for the treatment of advanced synovial sarcoma with priority review and a PDUFA date of August 4th, 2024

Confirmatory evidence for afami-cel full approval agreed with FDA; will use data from Cohort 2 of pivotal SPEARHEAD-1 trial, which is fully enrolled

Company is targeting launch of afami-cel upon receipt of FDA approval with commercial, manufacturing, and supply chain teams preparing for product delivery

Lete-cel program transitioned back to Adaptimmune and the Company is planning for US commercial launch in 2026

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

Cash runway into early 2026; with greater than \$300 million including current cash on hand, future expected income from partners and projected other non-dilutive capital sources

[Webcast](#) to be held today, March 6, 2024, at 8:00 a.m. EST. (1:00 p.m. GMT)

Company will hold an investor day at its Navy Yard facility on April 18th – more details to follow

Philadelphia, Pennsylvania and Oxford, United Kingdom--(Newsfile Corp. - March 6, 2024) - Adaptimmune Therapeutics plc (NASDAQ: ADAP), a company redefining the treatment of solid tumor cancers with cell therapy, today reported financial results for the fourth quarter and full year ended December 31, 2023, and provided a business update on the progress made in establishing its sarcoma franchise.

Adrian Rawcliffe, Adaptimmune's Chief Executive Officer: "Adaptimmune is poised to bring afami-cel to market – which will be the first ever engineered T-cell therapy for a solid tumor. Afami-cel is the first product in our sarcoma franchise, which, if approved, along with lete-cel, has the potential to redefine the landscape for the treatment of advanced synovial sarcoma and MRCLS. This franchise, which is only the beginning of our commercial ambitions, is projected to deliver up to \$400 million in U.S. peak year sales."

Sarcoma Franchise

Afami-cel

- Adaptimmune is preparing to launch the first product in its sarcoma franchise, afami-cel, for the treatment of advanced synovial sarcoma pending review and approval by the FDA with a PDUFA date of August 4, 2024.

- Synovial sarcoma is a solid tumor cancer with high unmet medical need for which there has been no new effective treatment since 2013. Synovial sarcoma represents 5%-10% of the ~13,000 soft tissue sarcoma cases in the United States each year.^a
- If approved, afami-cel would be the first engineered T-cell therapy for a solid tumor to receive commercial approval in the U.S.
- Data from Cohort 2 of the pivotal trial SPEARHEAD-1 will serve as confirmatory evidence for full approval. This cohort is fully enrolled.
- Adaptimmune does not anticipate an advisory committee meeting, at this time, based on feedback received from FDA.
- Adaptimmune is preparing to launch afami-cel in Q3 of 2024 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 additional ATCs. Field teams are being recruited and are engaging with ATCs.
- 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 a fully integrated cell therapy company and will deliver afami-cel's commercial supply from the Company's Navy Yard cell therapy manufacturing facility in Philadelphia. Adaptimmune's manufacturing and supply chain organization has delivered hundreds of clinical cell therapy batches to people enrolled in the Company's clinical trials, to date.

Lete-cel

- The second product in Adaptimmune's sarcoma franchise, lete-cel, is being investigated in the pivotal IGYTE-ESO trial (NCT03967223), which at an 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.
- Adaptimmune has received an upfront amount and will receive milestone-based payments totaling £30 million under the agreement with GSK.
- 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.
- Once approved and marketed, afami-cel and lete-cel have the potential to treat more than 1,000 people with soft tissue sarcomas annually in the United States^b

Clinical pipeline update

- [As reported in ESMO 2023](#), ADP-A2M4CD8, Adaptimmune's next-generation engineered T-cell therapy exhibited 35% response rate in a broad range of solid tumors; 50% response rate in 26 patients with ovarian, urothelial, and head & neck cancers.
- ADP-A2M4CD8 is being investigated in the SURPASS-3 Phase 2 clinical trial (NCT05601752) for the treatment of platinum-resistant ovarian cancer. ADP-A2M4CD8 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 ADP-A2M4CD8 in combination with standard of care checkpoint inhibitor therapy.

Preclinical pipeline update

- IND-enabling studies are underway for ADP-600 (PRAME) and ADP-520 (CD70) programs
- Genentech collaboration to research and develop allogeneic cell therapies continues as planned
- Wholly owned allogeneic pipeline advancing; process development in progress at Adaptimmune's allogeneic manufacturing facility in Milton Park, UK.

Corporate and other news

- Strategic combination with TCR² Therapeutics completed in June of 2023
- Cintia Piccina appointed as Chief Commercial Officer
- The Company received R&D tax credits from the UK government in January 2024 of \$30.8m

Financial Results for the three months and year ended December 31, 2023

- **Cash / liquidity position:** As of December 31, 2023, Adaptimmune had cash and cash equivalents of \$143.9 million and Total Liquidity¹ of \$146.9 million, compared to \$108.0 million and \$204.6 million, respectively, as of December 31, 2022.
- **Revenue:** Revenue for the three months and year ended December 31, 2023, was \$0.2 million and \$60.3 million, respectively, compared to \$11.0 million and \$27.1 million for the same periods in 2022. Revenue has increased in 2023, compared to the same period in 2022 primarily due to the termination of the Astellas collaboration, 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 and year ended December 31, 2023, were \$33.2 million and \$126.5 million, respectively, compared to \$23.1 million and \$127.7 million for the same periods in 2022. R&D expenses in the three months ended December 31, 2023 increased due to a decrease in offsetting reimbursements receivable for research and development tax and expenditure credits. R&D expenses in the year ended December 31, 2023 decreased due to a decrease in the average number of employees engaged in research and development following the restructuring completed in the first quarter of 2023, decreases in subcontracted expenditures, a decrease in share-based compensation expenses and a decrease in in-process research and development costs, which was mostly offset by 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 and year ended December 31, 2023, were \$16.9 million and \$73.5 million, respectively, compared to \$15.2 million and \$63.4 million for the same periods in 2022. G&A expenses in the year ended December 31, 2023 increased due to restructuring and charges recognised in the first quarter of 2023, an increase in other corporate costs due to an increase in accounting, legal and professional fees incurred in relation to the TCR² Therapeutics, Inc merger agreement and severance and other related costs for former TCR² Therapeutics leadership, offset by a decrease in share-based compensation expenses.
- **Gain on bargain purchase:** a \$22.0 million gain on bargain purchase was recognised

in the year ended December 31, 2023, from the strategic combination with TCR² Therapeutics, Inc.

- **Net loss:** Net loss attributable to holders of the Company's ordinary shares for the three months and year ended December 31, 2023, was \$47.9 million and \$113.9 million, respectively (\$0.04) and \$(0.09) per ordinary share), compared to \$29.3 million and \$165.5 million, respectively (\$0.03) and \$(0.17) per ordinary share), for the same periods in 2022.

Financial Guidance

The Company believes that its existing cash, cash equivalents and marketable securities, together with the additional payments under the Strategic Collaboration and License Agreement with Genentech and payments under the Termination and Transfer Agreement with GSK, will fund the Company's current operations into early 2026, as further detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, to be filed with the Securities and Exchange Commission following this earnings release.

Webcast Information

The Company will host a live webcast to provide additional details at 8:00 a.m. EST (1:00 p.m. GMT) today, March 6, 2024. A live webcast of the conference call and replay can be accessed at <https://www.gowebcasting.com/13137>. Call in information is as follows: **1-800-319-4610** (US or Canada) or **+1-416-915-3239** (International and additional options available [HERE](#)).

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 December 31, 2022, 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):

	December 31, 2023	December 31, 2022
Cash and cash equivalents	\$ 143,991	\$ 108,033
Marketable securities - available-for-sale debt securities	2,947	96,572
Total Liquidity	\$ 146,938	\$ 204,605

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 December 31,		Year ended December 31,	
	2023	2022	2023	2022
Development revenue	231	11,028	60,281	27,148
Revenue	\$ 231	\$ 11,028	\$ 60,281	\$ 27,148
Research and development	(33,208)	(23,052)	(126,509)	(127,726)
General and administrative	(16,879)	(15,218)	(73,513)	(63,387)
Total operating expenses	(50,087)	(38,270)	(200,022)	(191,113)
Operating loss	(49,856)	(27,242)	(139,741)	(163,965)
Interest income	1,596	523	5,964	1,542
Gain on bargain purchase	—	—	22,049	—
Other income (expense), net	(313)	(1,537)	(807)	(536)
Loss before income tax expense	(48,573)	(28,256)	(112,535)	(162,959)
Income tax credit/(expense)	656	(994)	(1,336)	(2,497)
Net loss attributable to ordinary shareholders	\$ (47,917)	\$ (29,250)	\$ (113,871)	\$ (165,456)

Net loss per ordinary share

Basic and diluted	\$ (0.04)	\$ (0.03)	\$ (0.09)	\$ (0.17)
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Weighted average shares outstanding:

Basic and diluted	1,362,672,380	984,715,238	1,206,440,978	967,242,403
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Condensed Consolidated Balance Sheets

(unaudited, in thousands, except share data)

December 31,	December 31,
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	2023	2022
Assets		
Current assets		
Cash and cash equivalents	\$ 143,991	\$ 108,033
Marketable securities - available-for-sale debt securities (amortized cost of \$2,940 and \$97,501) net of allowance for expected credit losses of \$0 and \$0	2,947	96,572
Accounts receivable, net of allowance for expected credit losses of \$0 and \$0	821	7,435
Other current assets and prepaid expenses	59,793	43,330
Total current assets	207,552	255,370
Restricted cash	3,026	1,569
Operating lease right-of-use assets, net of accumulated amortization of \$13,220 and \$9,470	20,762	18,019
Property, plant and equipment, net of accumulated depreciation of \$46,020 and \$38,588	50,946	53,516
Intangible assets, net of accumulated amortization of \$5,155 and \$4,676	330	442
Total assets	\$ 282,616	\$ 328,916
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 8,128	\$ 4,753
Operating lease liabilities, current	5,384	2,728
Accrued expenses and other current liabilities	30,303	31,215
Restructuring provision	—	2,285
Deferred revenue, current	28,973	23,520
Total current liabilities	72,788	64,501
Operating lease liabilities, non-current	19,851	20,349
Deferred revenue, non-current	149,060	160,892
Other liabilities, non-current	1,404	1,296
Total liabilities	243,103	247,038
Stockholders' equity		
Common stock - Ordinary shares par value £0.001, 1,702,760,280 authorized and 1,363,008,102 issued and outstanding (2022: 1,282,773,750 authorized and 987,109,890 issued and outstanding)	1,865	1,399
Additional paid in capital	1,064,569	990,656
Accumulated other comprehensive loss	(3,748)	(875)
Accumulated deficit	(1,023,173)	(909,302)
Total stockholders' equity	39,513	81,878
Total liabilities and stockholders' equity	\$ 282,616	\$ 328,916

Condensed Consolidated Cash Flow Statement

(unaudited, in thousands)

	Year ended December 31, 2023	Year ended December 31, 2022
Cash flows from operating activities		
Net loss	\$ (113,871)	\$ (165,456)
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>		
Depreciation	9,453	5,266
Amortization	387	809

Gain on bargain purchase	(22,049)	—
Share-based compensation expense	11,773	18,240
Unrealized foreign exchange losses/(gains)	198	(2,438)
(Accretion)/amortization on available-for-sale debt securities	(1,986)	2,525
Other	167	816
<i>Changes in operating assets and liabilities:</i>		
Increase in receivables and other operating assets	(1,291)	(9,813)
(Decrease)/increase in payables and other current liabilities	(9,087)	4,408
(Increase)/decrease in deferred revenue	(14,574)	3,874
Net cash used in operating activities	(140,880)	(141,769)
Cash flows from investing activities		
Acquisition of property, plant and equipment	(4,681)	(29,496)
Acquisition of intangible assets	(199)	(244)
Cash from acquisition of TCR ² Therapeutics Inc.	45,264	—
Maturity or redemption of marketable securities	210,983	166,994
Investment in marketable securities	(75,953)	(48,117)
Other	1,124	—
Net cash provided by investing activities	176,538	89,137
Cash flows from financing activities		
Proceeds from issuance of common stock from offerings, net of commissions and issuance costs	624	12,817
Proceeds from exercise of stock options	256	50
Net cash provided by financing activities	880	12,867
Effect of currency exchange rate changes on cash, cash equivalents and restricted cash	877	(2,299)
Net increase/(decrease) in cash, cash equivalents and restricted cash	37,415	(42,064)
Cash, cash equivalents and restricted cash at start of period	109,602	151,666
Cash, cash equivalents and restricted cash at end of period	\$ 147,017	\$ 109,602
Supplemental cash flow information		
Interest received	\$ 4,748	\$ 5,149
Accretion/(amortization) on available-for-sale debt securities	1,986	(2,525)
Income taxes paid	(4,000)	(630)

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a - "Synovial Sarcoma." National Cancer Institute. Accessed 11 December 2023.

b - 1: Aytekin MN, et al. J Orthop Surg (Hong Kong). 2020;28(2) 2: Disease-specific survival from Hoffman et al. (2013), Localized and metastatic 3: 67% of synovial sarcoma tumors express MAGE-A4. MAGE-A4 expression based on ADAP samples and expression cut off criteria of $\geq 30\%$ tumor cells at $\geq 2+$ intensity. Synovial sarcoma and MRCLS MAGE-A4 expression based on 1,043 patient samples at November 20, 2020 data cut-off and expression of all other tumor types on 6,167 patients, 1,543 tumor samples at November 19, 2021 data cut-off 4: 70-90% of SyS and MRCLS tumors express NY-ESO-1 Endo M, de Graaff MA, Ingram DR, et al. NY-ESO-1 (CTAG1B) expression in mesenchymal tumors. Mod Pathol 2015; 28: 587-95. Jungbluth AA, Chen YT, Stockert E, Busam KJ, Kolb D, Iversen K, et al. Immunohistochemical analysis of NY-ESO-1 antigen expression in normal and malignant human tissues. Int J Cancer 2001;92:856-60. 5: HLA A2 expression based on ADAP samples of 41% for synovial sarcoma and MRCLS (1,043 patient samples; data cut-off November 20, 2020)

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



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