



AC Immune Reports First Quarter 2024 Financial Results and Provides a Corporate Update

May 13, 2024

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- Landmark deal announced with Takeda for ACI-24.060 with \$100 million upfront and total potential payments for option exercise and milestones of up to approximately \$2.1 billion
- ACI-24.060 ABATE Phase 2 trial on track to report Abeta-PET imaging results in Q2 2024, evaluating amyloid plaque reduction after 6 months of anti-Abeta active immunotherapy
- ACI-7104.056 VacSYn Phase 2 trial of anti-a-syn active immunotherapy in Parkinson's disease (PD) on track for safety and immunogenicity interim data in H2 2024
- Three-year cash runway with CHF 104.8 million at quarter end, plus \$100 million upfront from Takeda and the anticipated ACI-35.030-related CHF 25 million milestone

Lausanne, Switzerland, May 13, 2024 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering the development of precision medicine approaches for the diagnosis, treatment, and prevention of neurodegenerative diseases, today reported results for the quarter ended March 31, 2024, and provided a corporate update.

Dr. Andrea Pfeifer, CEO of AC Immune SA, commented: “We are thrilled to have announced today our agreement with Takeda to advance ACI-24.060 anti-Abeta active immunotherapy in Alzheimer’s disease (AD). This landmark collaboration furthers our aim of pioneering Precision Prevention, establishing a powerful force in the neuroscience space that combines the neuroscience knowledge and expertise of AC Immune with the development and commercial experience of Takeda. We remain on track to report the first Phase 2 data this quarter on amyloid plaque reduction as assessed by PET scans after 6-months of treatment. This is a potentially de-risking event for ACI-24.060 that could enable advancement into a registrational study.”

“We continue to make strong progress elsewhere in our pipeline. Our partner Janssen continues to push ahead with the launch of the Phase 2b trial, ReTain, evaluating ACI-35.030 (JNJ-64042056), our anti-phospho-Tau active immunotherapy, in patients with pre-symptomatic AD. At the same time, our wholly-owned anti-alpha-synuclein active immunotherapy, ACI-7104.056, is advancing through Phase 2 testing to treat Parkinson’s disease, with safety and immunogenicity updates expected in the second half of 2024. Any of these three studies could be transformational for treatment of patients with neurodegenerative disease. With our significantly strengthened financial position, we are well-positioned to achieve our clinical development milestones across our pipeline through 2024 and beyond.”

Q1 2024 and Subsequent Highlights

- AC Immune and Takeda signed an exclusive Option and License agreement to develop and commercialize ACI-24.060 for AD. Under the terms of the agreement, AC Immune will receive an upfront payment of \$100 million from Takeda and, if all related milestones are achieved over the course of the agreement, is eligible to receive payments of up to approximately \$2.1 billion including an Option exercise fee in the low-to-mid hundred million range and additional potential development, commercial and sales-based milestones. Upon commercialization, AC Immune will be entitled to receive tiered mid-to-high teens percentages royalties on worldwide net sales.
- Enrolment in the ACI-24.060 ABATE Phase 2 AD trial continues, with cohorts 1 and 2 now fully enrolled and an expanded cohort 3 targeting completion of enrolment by year end.
- Six-month Abeta positron emission tomography (PET) imaging results continue to be expected in Q2 2024, and 12-month Abeta-PET data are expected in H2 2024.
- AC Immune’s therapeutic and diagnostic programs were featured in multiple presentations at the International Conference on Alzheimer’s & Parkinson’s Diseases (AD/PD™ 2024). In addition, Andrea Pfeifer, Ph.D., CEO of AC Immune, led an industry symposium exploring the latest clinical advances in the diagnosis and treatment of alpha-synuclein pathologies. To view a replay of the industry symposium, click [HERE](#).

Anticipated 2024 Milestones

ACI-24.060 anti-Abeta active immunotherapy	<ul style="list-style-type: none"> • 6-month Abeta-PET data in AD expected in Q2 2024 • Initial safety and immunogenicity data in Down syndrome cohort expected in H2 2024 • 12-month Abeta-PET data in AD expected in H2 2024
ACI-7104.056 anti-a-syn active immunotherapy	<ul style="list-style-type: none"> • Interim safety and immunogenicity update from the Phase 2 VacSYn study in Parkinson’s disease expected in H2 2024

ACI-35.030 anti-pTau active immunotherapy	<ul style="list-style-type: none"> • First patient treated in ReTain Phase 2b clinical trial expected in the coming months
Anti-TDP-43 antibody	<ul style="list-style-type: none"> • Completion of regulatory tox studies expected in H1 2024
TDP-43-PET tracer	<ul style="list-style-type: none"> • Phase 1 initiation expected in H2 2024
ACI-15916 a-syn-PET tracer	<ul style="list-style-type: none"> • IND-enabling studies in PD expected to be completed in H2 2024

Analysis of Financial Statements for the Quarter Ended March 31, 2024

- **Cash position:** The Company had a total cash balance of CHF 104.8 million (CHF 103.1 million as of December 31, 2023), composed of CHF 47.8 million in cash and cash equivalents and CHF 57.0 million in short-term financial assets. The Company's cash balance provides sufficient capital resources for at least three years, when including the upfront payment of \$100 million from Takeda, and assuming the potential milestone payment of CHF 24.6 million related to achieving an undisclosed enrolment target for our ACI-35.030, and no other milestones.
- **R&D expenditures:** R&D expenses in the period were CHF 15.2 million, compared with CHF 13.9 million for the comparable period in 2023, mainly driven by higher clinical expenses in our ACI-24.060 active immunotherapy as the ABATE study progresses.
- **Other operating income:** The Company recognized CHF 0.1 million in grant income from Michael J. Fox Foundation and Target ALS.
- **IFRS loss for the period:** The Company reported a net loss after taxes of CHF 17.9 million for the three months ended March 31, 2024, compared with a net loss of CHF 17.5 million for the comparable period in 2023.

About AC Immune SA

AC Immune SA is a clinical-stage biopharmaceutical company and a global leader in precision prevention for neurodegenerative diseases, including Alzheimer's disease, Parkinson's disease, and NeuroOrphan indications driven by misfolded proteins. The Company's two clinically validated technology platforms, SupraAntigen® and Morphomer®, fuel its broad and diversified pipeline of first- and best-in-class assets, which currently features sixteen therapeutic and diagnostic programs, including five in Phase 2 development and one in Phase 3. AC Immune has a strong track record of securing strategic partnerships with leading global pharmaceutical companies, resulting in substantial non-dilutive funding to advance its proprietary programs and >\$4.5 billion in potential milestone payments plus royalties.

SupraAntigen® is a registered trademark of AC Immune SA in the following territories: AU, EU, CH, GB, JP, RU, SG and USA. Morphomer® is a registered trademark of AC Immune SA in CN, CH, GB, JP, KR, NO and RU.

The information on our website and any other websites referenced herein is expressly not incorporated by reference into, and does not constitute a part of, this press release.

For further information, please contact:

SVP, Investor Relations & Corporate Communications

Gary Waanders, Ph.D., MBA
AC Immune
Phone: +41 21 345 91 91
Email: gary.waanders@acimmune.com

U.S. Investors

Corey Davis, Ph.D.
LifeSci Advisors
Phone: +1 212 915 2577
Email: cdavis@lifesciadvisors.com

U.S. and International Media

Chris Maggos
Cohesion Bureau
Phone: +41 79 367 6254 / +1 646 583 2369
Email: chris.maggos@cohesionbureau.com

Forward looking statements

This press release contains statements that constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are statements other than historical fact and may include statements that address future operating, financial or business performance or AC Immune's strategies or expectations. In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," "outlook" or "continue," and other comparable terminology. Forward-looking statements are based on management's current expectations and beliefs and involve significant risks and uncertainties that could cause actual results, developments and business decisions to differ materially from those contemplated by these statements. These risks and uncertainties include those described under the captions "Item 3. Key Information – Risk Factors" and "Item 5. Operating and Financial Review and Prospects" in AC Immune's Annual Report on Form 20-F and other filings with the Securities and Exchange Commission. Forward-looking statements speak only as of the date they are made, and AC Immune does not

undertake any obligation to update them in light of new information, future developments or otherwise, except as may be required under applicable law. All forward-looking statements are qualified in their entirety by this cautionary statement.

Condensed Consolidated Balance Sheets (Unaudited)
(In CHF thousands)

	As of	
	March 31, 2024	December 31, 2023
Assets		
Non-current assets		
Property, plant and equipment	3,236	3,376
Right-of-use assets	3,341	3,508
Intangible asset	50,416	50,416
Long-term financial assets	415	361
Total non-current assets	<u>57,408</u>	<u>57,661</u>
Current assets		
Prepaid expenses	3,917	6,437
Accrued income	267	246
Other current receivables	868	622
Accounts receivable	—	14,800
Short-term financial assets	47,812	24,554
Cash and cash equivalents	57,009	78,494
Total current assets	<u>109,873</u>	<u>125,153</u>
Total assets	<u>167,281</u>	<u>182,814</u>
Shareholders' equity and liabilities		
Shareholders' equity		
Share capital	2,093	2,089
Share premium	475,286	474,907
Treasury shares	(105)	(105)
Currency translation differences	(35)	(51)
Accumulated losses	(332,558)	(316,197)
Total shareholders' equity	<u>144,681</u>	<u>160,643</u>
Non-current liabilities		
Long-term lease liabilities	2,657	2,825
Net employee defined benefit liabilities	5,819	5,770
Total non-current liabilities	<u>8,476</u>	<u>8,595</u>
Current liabilities		
Trade and other payables	2,837	1,679
Accrued expenses	10,541	11,087
Deferred income	74	138
Short-term lease liabilities	672	672
Total current liabilities	<u>14,124</u>	<u>13,576</u>
Total liabilities	<u>22,600</u>	<u>22,171</u>
Total shareholders' equity and liabilities	<u>167,281</u>	<u>182,814</u>

Condensed Consolidated Statements of Income/(Loss) (Unaudited)
(In CHF thousands, except for per-share data)

	For the Three Months Ended March 31,	
	2024	2023
Revenue		
Contract revenue	—	—
Total revenue	<u>—</u>	<u>—</u>
Operating expenses		

Research & development expenses	(15,165)	(13,873)
General & administrative expenses	(4,971)	(4,106)
Other operating income/(expense), net	68	408
Total operating expenses	(20,068)	(17,571)
Operating loss	(20,068)	(17,571)
Financial income	629	209
Financial expense	(36)	(97)
Exchange differences	1,613	(51)
Finance result, net	2,206	61
Loss before tax	(17,862)	(17,510)
Income tax expense	—	(3)
Loss for the period	(17,862)	(17,513)
Loss per share:	(0.18)	(0.21)

Condensed Consolidated Statements of Comprehensive Income/(Loss) (Unaudited)
(In CHF thousands)

	For the Three Months	
	Ended March 31,	
	2024	2023
Loss for the period	(17,862)	(17,513)
Items that will be reclassified to income or loss in subsequent periods (net of tax):		
Currency translation differences:	16	(8)
Items that will not to be reclassified to income or loss in subsequent periods (net of tax):		
Remeasurement gains on defined-benefit plans (net of tax)	—	—
Total comprehensive loss, net of tax	(17,846)	(17,521)

Attachment

- [20240513_ACIU_Q1_Earnings_Final](#)



Source: AC Immune SA