

# AC Immune Reports Full Year 2024 Financial Results and Provides a Corporate Update

- Landmark exclusive option and license deal with Takeda for ACI-24.060 with \$100 million upfront and additional potential milestones of up to about \$2.1 billion plus royalties on sales upon commercialization
- ACI-24.060 ABATE Phase 1b/2 trial showed encouraging interim safety and tolerability data in Down syndrome (DS) cohort; further interim results in Alzheimer's disease (AD) and DS expected in 2025
- Enrollment progress in JNJ-2056 (ACI-35.030) ReTain Phase 2b trial in preclinical AD patients triggered second milestone payment of CHF 24.6 million; JNJ-2056 granted U.S. FDA Fast Track Designation in AD
- ACI-7104.056 VacSYn Phase 2 trial demonstrated positive interim safety and immunogenicity results in Parkinson's disease (PD); further interim results in H1 2025
- Cash resources of CHF 165.5 million at year end provides funding into Q1 2027, assuming no other milestones

**Lausanne, Switzerland, March 13, 2025 –** AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision therapeutics for neurodegenerative diseases, today reported results for the full year ended December 31, 2024, and provided a corporate update.

**Dr. Andrea Pfeifer, CEO of AC Immune SA, commented:** "We significantly advanced our leading position in the precision prevention of neurodegenerative diseases in 2024 through strong pipeline progress and the closing of a landmark deal with Takeda. Achievements across our portfolio of active immunotherapies, including encouraging clinical data from ACI-7104.056 and ACI-24.060 and U.S. FDA Fast Track designation for ACI-35.030, underscore the potential of this modality to treat patients earlier and to prevent or delay neurodegenerative diseases and their symptoms. We anticipate additional important evidence this year from the VacSYn trial of ACI-7104.056 and the ABATE trial of ACI-24.060, bringing us closer to redefining treatment with more convenient and better tolerated prevention options for these devastating conditions."

"The agreement with Takeda for ACI-24.060 includes potential milestone payments of up to \$2.1 billion and affirms our proven track record of securing high-value partnerships. In 2024, our partnership with Takeda included a \$100 million upfront payment, combined with a CHF 24.6 million milestone payment from Janssen, triggered by rapid prescreening rates in the ReTain trial of ACI-35.030. These payments ensure funding for currently planned operations into 2027 and reaffirm the value of our pipeline assets and differentiated discovery platforms."

"The ability to innovate is key to our future success. Driven by our two drug discovery platforms, in 2024, we advanced multiple early-stage assets, such as small molecule candidates targeting NLRP3 and Tau further into development."



#### 2024 and Subsequent Highlights

#### **Active Immunotherapy Programs**

ACI-24.060 anti-Abeta active immunotherapy

- AC Immune and Takeda signed an exclusive option and license agreement for AC Immune's
  active immunotherapies targeting Abeta, including ACI-24.060 for AD. AC Immune received
  an upfront payment of \$100 million and is eligible to receive total potential payments of up to
  approximately \$2.1 billion; these include an option exercise fee, development, commercial
  and sales milestones. Upon commercialization, AC Immune also is entitled to receive tiered
  double-digit royalties on worldwide net sales.
- Positive interim data from the ABATE Phase 1b/2 trial in individuals with DS showed that ACI-24.060 was generally safe and well tolerated with no serious adverse events related to the study drug and no cases of amyloid-related imaging abnormalities (ARIA). ABATE will now start to evaluate the high dose of ACI-24.060 in individuals with DS.
- Treatment of AD patients in the Phase 1b/2 ABATE trial continues.

#### ACI-35.030 (JNJ-2056) anti-phospho-Tau (anti-pTau) active immunotherapy

- AC Immune received the second ReTain-related milestone payment of CHF 24.6 million under its agreement with Janssen Pharmaceuticals, Inc. (Janssen), a Johnson & Johnson company. The payment was triggered by the rapid prescreening rate in the potentially registrational Phase 2b ReTain trial investigating JNJ-2056 (ACI-35.030) to treat preclinical (pre-symptomatic) AD. Phase 1b/2a clinical testing showed that ACI-35.030 induces an antibody response targeting pathologic phosphorylated Tau while sparing normal physiological forms of Tau.
- Johnson & Johnson received Fast Track designation for JNJ-2056 from the U.S. FDA for AD in July 2024.
- The UK Medicines and Healthcare products Regulatory Agency (MHRA) has awarded the innovative medicine designation, the Innovation Passport, for ACI-35.030/JNJ-2056 in the treatment of AD. This is the entry point to the Innovative Licensing and Access Pathway (ILAP) which aims to accelerate time to market and facilitate patient access.

#### ACI-7104.056 anti-a-syn active immunotherapy

- ACI-7104.056 demonstrated positive interim safety and immunogenicity in the Phase 2
   VacSYn clinical trial in early PD patients:
  - Positive antibody responses were induced against the target antigen at week 6 after 2 immunizations and were strongly boostable.
  - ACI-7104.056 induced an increase in anti-a-syn antibodies on average 16-fold higher than the placebo background level after three immunizations.



 To date, no clinically relevant safety issues have been reported and the most common adverse events were transient injection site reactions (49%) and headaches (18%).

#### **Small Molecule Programs**

- ACI-19764 small molecule NLRP3 inhibitor is undergoing in vivo proof of concept with results expected in 2025 anticipated to enable investigational new drug (IND) application.
- Our Morphomer Tau and Morphomer a-syn small molecule aggregation inhibitors have made steady progress with selection of lead candidates expected in 2025.

#### **Diagnostic Programs**

- AC Immune's partner Life Molecular Imaging (LMI) received FDA Fast Track Designation for the Tau positron emission tomography (PET) diagnostic PI-2620 in AD, progressive supranuclear palsy (PSP), and corticobasal degeneration (CBD).
- Phase 1 clinical trial of TDP-43-PET tracer ACI-19626 in genetic frontotemporal dementia
   (FTD) is ongoing with initial clinical data expected in 2025.
- Completed IND-enabling studies of a-syn-PET tracer ACI-15916 for the diagnosis of PD.

#### **Thought and Innovation Leadership**

- AC Immune's therapeutic and diagnostic programs were featured in multiple presentations at the International Conference on Alzheimer's & Parkinson's disease (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.
- AC Immune unveiled its novel therapeutic antibody drug conjugate technology morADC for improved efficacy in neurodegenerative diseases at the Alzheimer's Association International Conference (AAIC) 2024. morADC combines proprietary brain-penetrant small molecule Morphomers® with SupraAntigen® monoclonal antibodies and holds substantial promise in our fight against neurodegeneration.

#### **Anticipated 2025 Milestones**

Program	Milestone	Expected in
ACI-24.060	ABATE Phase 2 trial interim results in AD and DS	H2 2025
anti-Abeta active		
immunotherapy		



ACI-7104.056 anti-a-syn active immunotherapy	Further interim results from Part 1 of Phase 2 VacSYn trial in PD, including pharmacodynamics and biomarkers	H1 2025
	Initiation of Part 2 of VacSYn trial	H2 2025
TDP-43 monoclonal antibody	Validated pharmacodynamic assay for clinical readout	H2 2025
ACI-19764 Small molecule	Lead declaration and initiation of IND-enabling studies	H1 2025
NLRP3 inhibitor	IND/CTA filing	H2 2025
Morphomer-Tau aggregation inhibitors	Lead declaration and initiation of IND-enabling studies	H2 2025
Morphomer a-syn aggregation inhibitor	Lead declaration	H2 2025
morADC	In vivo PoC study of proprietary brain delivery platform	H1 2025
TDP-43-PET tracer	Initial Phase 1 readout in genetic FTD	H2 2025
ACI-15916 a-syn-PET tracer	Phase 1 readout	H2 2025

#### Analysis of Financial Statements for the Year Ended December 31, 2024

- Cash Position: The Company had total cash resources of CHF 165.5 million as of December 31, 2024, compared to total cash resources of CHF 103.1 million as of December 31, 2023.
   The Company's cash balance provides sufficient capital resources into Q1 2027, assuming no other milestones.
- Contract Revenues: The Company recorded CHF 27.3 million in contract revenues for the year ended December 31, 2024, compared with CHF 14.8 million in contract revenues in the prior year. For the year ended December 31, 2024, our contract revenues of CHF 27.3 million were related to:
  - The recognition of the second ReTain-related milestone payment of CHF 24.6 million under the agreement with Janssen. The milestone payment was triggered by the rapid rate of prescreening in the potentially registrational Phase 2b ReTain trial investigating active-immunotherapy candidate JNJ-2056 (ACI-35.030) to treat preclinical AD; and



- The efforts made under the agreement with Takeda for the development, CMC, and regulatory activities.
- R&D Expenditures: R&D expense increased by CHF 8.0 million for the year ended December 31, 2024 to CHF 62.6 million, predominantly due to:
  - Discovery and preclinical expenses: Decrease of CHF 1.8 million, primarily due to the completion of certain pre-clinical studies and our strategic focus on advancing clinical-stage programs. As a result, a greater proportion of our resources was allocated to clinical development activities rather than discovery and pre-clinical activities.
  - Clinical expenses: Increase of CHF 8.8 million, primarily due to an increase of activities in our Phase 1b/2 ABATE study of ACI-24.060, and our Phase 2 VacSYn study of ACI-7104.056. This was partially offset by a decrease of CHF 0.8 million for the clinical development of ACI-35.030, driven by the completion of the prior Phase 1b/2a trial and its progression into the Phase 2b ReTain trial, where the costs are borne by Janssen.
  - Salary- and benefit-related costs: Increase of CHF 1.0 million, primarily due to the annualization of 2023 hires and additional new hires during the year, which resulted in an increase in salary- and benefit-related costs of CHF 0.7 million, and CHF 0.3 million in share-based compensation expense.
- G&A Expenditures: G&A expenses increased by CHF 2.0 million for the year ended
  December 31, 2024, to CHF 17.3 million. This increase is due to legal fees related to
  business development and licensing activities, as well as salaries and related costs, largely
  attributable to the higher expenses from equity awards granted in 2024, which have a higher
  fair value based on our share price development.
- IFRS Loss for the Period: The Company reported a net loss after taxes of CHF 50.9 million for the year ended December 31, 2024, compared with a net loss of CHF 54.2 million for the prior period.

#### 2025 Financial Guidance

For the full year 2025, the Company expects its total cash expenditure to be in the range
of CHF 75–85 million. The Company defines total cash expenditure as operating expenditures
adjusted to include capital expenditures and offset by significant non-cash items (including
share-based compensation and depreciation expense).

#### **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.

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#### 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.



### Consolidated Balance Sheets (In CHF thousands)

(In CHF thousands)			
		As of December 31,	
	2024	2023	
Assets			
Non-current assets			
Property, plant and equipment	2,651	3,376	
Right-of-use assets	5,437	3,508	
Intangible asset	50,416	50,416	
Long-term financial assets	415	361	
Total non-current assets	58,919	57,661	
Current assets	4 202	6 427	
Prepaid expenses	4,302	6,437	
Accrued income	1,099	246	
Other current receivables	1,104	622	
Accounts receivable		14,800	
Short-term financial assets	129,214	24,554	
Cash and cash equivalents	36,275	78,494	
Total current assets	171,994	125,153	
Total assets	230,913	182,814	
Shareholders' equity and liabilities			
Shareholders' equity			
Share capital	2,226	2,089	
Share premium	478,506	474,907	
Treasury shares	(218)	(105)	
Currency translation differences	(5)	(51)	
Accumulated losses	(368,239)	(316,197)	
Total shareholders' equity	112,270	160,643	
		,	
Non-current liabilities			
Long-term deferred contract revenue	4,560		
Long-term lease liabilities	4,401	2,825	
Net employee defined benefit liabilities	8,844	5,770	
Total non-current liabilities	17,805	8,595	
Current liabilities			
Trade and other payables	2,658	1,679	
Accrued expenses	12,098	11,087	
Short-term deferred income		138	
Short-term deferred contract revenue	85,056		
Short-term lease liabilities	1,026	672	
Total current liabilities	100,838	13,576	
Total liabilities	118,643	22,171	
Total shareholders' equity and liabilities	230,913	182,814	
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## Consolidated Statements of Income/(Loss) (In CHF thousands, except for per-share data)

	For the Year Ended December 31,		
	2024	2023	2022
Revenue			
Contract revenue	27,309	14,801	3,935
Total revenue	27,309	14,801	3,935
Operating expenses			
Research & development expenses	(62,570)	(54,606)	(60,336)
General & administrative expenses	(17,259)	(15,305)	(15,789)
Other operating income/(expense), net	142	1,486	1,343
Total operating expenses	(79,687)	(68,425)	(74,782)
Operating loss	(52,378)	(53,624)	(70,847)
Financial income	3,196	1,044	69
Financial expense	(133)	(176)	(355)
Exchange differences	(1,598)	(1,467)	393
Finance result, net	1,465	(599)	107
Loss before tax	(50,913)	(54,223)	(70,740)
Income tax expense	(3)	(10)	(13)
Loss for the period	(50,916)	(54,233)	(70,753)
Loss per share:			
Basic and diluted loss for the period attributable to equity holders	(0.51)	(0.64)	(0.85)

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

	For the Year Ended December 31,		
	2024	2023	2022
Loss for the period	(50,916)	(54,233)	(70,753)
Items that may be reclassified to income or loss in subsequent periods			
(net of tax):			
Currency translation differences	46	(61)	10
Items that will not to be reclassified to income or loss in subsequent			
periods (net of tax):			
Remeasurement gains/(losses) on defined-benefit plans (net of tax)	(3,084)	(1,669)	4,426
Other comprehensive income/(loss)	(3,038)	(1,730)	4,436
Total comprehensive loss, net of tax	(53,954)	(55,963)	(66,317)