

AC Immune Reports Full Year 2023 Financial Results and Provides a Corporate Update

- ACI-24.060 ABATE Phase 2 trial to report Abeta-PET imaging results in Q2 and H2
- ACI-7104.056 VacSYn Phase 2 trial in Parkinson's disease on track for interim data in H2
- ACI-24.060 for Alzheimer's disease (AD) received FDA Fast Track designation
- ACI-35.030 ReTain Phase 2b program in preclinical (pre-symptomatic) AD patients, initiated by collaboration partner
- Cash of CHF 103 million at year end, plus the CHF 15 million milestone payment received on February 1, 2024 and the next CHF 25 million ACI-35.030-related milestone, provides funding into 2026

Lausanne, Switzerland, March 14, 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 year ended December 31, 2023, and provided a corporate update.

Dr. Andrea Pfeifer, CEO of AC Immune SA, commented: “We made significant progress in 2023 advancing our three innovative active immunotherapy programs in Phase 2 clinical trials in Alzheimer's and Parkinson's diseases. This sets the stage for a number of important milestones in 2024, which have the potential to further enhance our understanding of how best to prevent neurodegeneration and to generate significant value for AC Immune. In the second quarter and second half of 2024, we will be reporting Phase 2 ACI-24.060 data on amyloid plaque reduction after 6- and 12-months treatment, respectively. Amyloid plaque is a clinically validated biomarker of efficacy, making these data announcements potentially de-risking and providing an opportunity to accelerate ACI-24.060 into a registrational program.

“We are also delighted that ACI-35.030 (JNJ-64042056), our anti-phospho-Tau active immunotherapy, has now entered the Phase 2b trial, conducted by our partner in pre-symptomatic AD patients. In addition, our ACI-7104.056 anti-alpha-synuclein active immunotherapy is advancing through Phase 2 testing for Parkinson's disease (PD) with initial safety and immunogenicity data expected in the second half of 2024.

“AC Immune's primary focus remains on these three active immunotherapy programs, each of which has the potential to transform how neurodegenerative diseases are treated and ultimately, to enable precision prevention of these diseases. Thanks to our strengthened leadership team and reinforced balance sheet, we are well-positioned to deliver de-risking clinical milestones, working towards our mission to shift the paradigm from disease treatment to disease prevention.”

2023 and Subsequent Highlights

Active Immunotherapy Programs

ACI-24.060 anti-Abeta active immunotherapy

- Received Fast Track Designation from the U.S. Food and Drug Administration for the treatment of AD
- The enrolment in the ABATE Phase 2 AD trial continues with cohort 3 now being expanded. Following data safety monitoring board (DSMB) review, no safety concerns have been raised to date, consistent with the previously observed safety profile.
- Initial interim ABATE safety and immunogenicity data from the first, low dose AD cohort were promising, with clear evidence of anti-Abeta antibody responses against toxic Abeta species observed in the blinded data.
- The first participant with Down syndrome (DS) was dosed in the Phase 2 ABATE trial.
- Six-month Abeta positron emission tomography (PET) imaging results are expected in Q2 2024, and 12-month Abeta-PET data are expected in H2 2024.

ACI-35.030 (JNJ-64042056) anti-phospho-Tau (anti-pTau) active immunotherapy

- Phase 2b ReTain clinical trial in participants with preclinical AD preparations are ongoing to initiate the study by H1 2024 by Janssen Pharmaceuticals, Inc., a Johnson & Johnson company (Janssen).
- ReTain will evaluate the effect of ACI-35.030 on cognition and Tau pathology in approximately 500 participants with preclinical AD. These will be randomized in a 1:1 ratio to a single dose level of ACI-35.030 or placebo, administered as intramuscular injections for a maximum of 4 years.
- Under the terms of the licensing agreement, AC Immune received a milestone payment of CHF 15 million on February 1, 2024 and expects to receive another milestone payment of CHF 25 million related to achieving an undisclosed enrolment target in 2025.

ACI-7104.056 anti-a-syn active immunotherapy

- Completed enrolment of cohort 1 in the VacSYn Phase 2 trial in Parkinson's disease (PD), with 16 patients randomized. Enrolment and randomization of cohort 2 is ongoing as planned.
- No safety concerns have been reported to date with no reports of moderate or severe adverse events. Safety and immunogenicity updates from the trial are expected in H2 2024.

Diagnostic Programs

- A peer-reviewed paper published in Nature Communications (Smith *et al.*, Nat. Comm., 2023) showed that AC Immune's wholly-owned a-syn-PET tracer ACI-12589 can detect a-syn pathology in multiple system atrophy (MSA) and differentiate MSA from other a-synucleinopathies.
- The TDP-43-PET tracer program has progressed as planned and a clinical candidate has been selected. Further IND-enabling studies will be completed over the coming months to permit the initiation of a Phase 1 clinical trial in H2 2024.
- In the pivotal Phase 3 ADvance trial evaluating the Morphomer® derived Tau-PET tracer, PI-2620 in AD, the first participant was imaged and the study is progressing well. PI-2620 was

discovered and developed using the Morphomer® platform as part of a research collaboration between AC Immune and Life Molecular Imaging.

Corporate Updates

- Completed USD 50 million equity financing in December 2023, extending cash runway into Q1 2026. (This assumes the second ACI-35-related milestone payment of CHF 25 million is received in 2025)
- New grants that collectively provide more than USD 500,000 in additional non-dilutive capital to support the advancement of diagnostic programs targeting TDP-43 (TAR DNA-binding protein 43) were awarded to AC Immune by The Michael J. Fox Foundation for Parkinson’s Research (MJFF) and the Target ALS Foundation.
- Strengthened leadership team with appointments of Dr. Nuno Mendonça as Chief Medical Officer, Dr. Madiha Derouazi as Chief Scientific Officer, and Mr. Christopher Roberts as Chief Financial Officer.

Thought Leadership and Collaborations

- Initiated a research collaboration with Prof. Michael Heneka, director of the Luxembourg Centre for Systems Biomedicine, University of Luxembourg, to evaluate the therapeutic potential of AC Immune’s SupraAntigen®- and Morphomer®-derived inhibitors of the NLRP3-ASC inflammasome pathway in preclinical disease models.
- Hosted webinar on PET imaging in AD featuring key opinion leader (KOL) Victor Villemagne, M.D. (University of Pittsburg). To view a replay of the event, click [HERE](#).
- Hosted KOL webinar on early diagnosis and prevention of AD featuring presentations by Kaj Blennow, MD, PhD, of University of Gothenburg and Sahlgrenska University Hospital, and Giovanni Frisoni, MD, of University of Geneva and the Memory Clinic at Geneva University Hospital. To view a replay of the webinar, click [HERE](#).

Anticipated 2024 Milestones

ACI-24.060 anti-Abeta active immunotherapy	<ul style="list-style-type: none"> • 6-month and 12-month Abeta-PET data in AD expected in Q2 2024 and H2 2024, respectively • Initial safety and immunogenicity data in DS cohort 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 in ReTain Phase 2b clinical trial expected in H1 2024
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 Year Ended December 31, 2023

- **Cash Position:** The Company had a total cash balance of CHF 103.1 million as of December 31, 2023, compared to a total cash balance of CHF 122.6 million as of December 31, 2022. On February 1, 2024, the Company received the milestone payment of CHF 14.8 million from Janssen for the commencement of ReTain, the ACI-35.030 Phase 2b clinical study. The Company's cash balance provides sufficient capital resources to progress into at least Q1 2026, assuming potential milestone payment of CHF 24.6 million related to achieving an undisclosed enrolment target for our ACI-35.030 and no other milestones.
- **Contract Revenues:** The Company recorded CHF 14.8 million in contract revenues for the year end December 31, 2023 compared with CHF 3.9 million in contract revenues in the prior year. For the year ended December 31, 2023, our contract revenues of CHF 14.8 million were related to the commencement of the first Phase 2b clinical study of ACI-35.030 per our agreement with Janssen.
- **R&D Expenditures:** R&D expenses decreased by CHF 5.7 million for the year ended December 31, 2023 to CHF 54.6 million, predominantly due to:
 - **Discovery and preclinical expenses (- CHF 5.8 million):** The Company decreased expenditures across a variety of its discovery and preclinical programs.
 - **Clinical expenses (- CHF 2.0 million):** The Company had a net decrease in clinical expenditures largely due the completion of the Phase 1b/2a and the advancement into Phase 2b for our ACI-35.030 active immunotherapy. We increased expenditures for the continued clinical development of our Phase 1b/2 ABATE study for ACI-24.060.
 - **Salary- and benefit-related costs (+ CHF 2.2 million):** While the staffing position remained stable in 2023, personnel expenses increased due to the annualization of 2022 hires.
- **G&A Expenditures:** G&A expenses decreased by CHF 0.5 million for the year ended December 31, 2023 to CHF 15.3 million. This decrease is related to a decrease in operating expenses across various cost centers. This is partially offset by an increase in salaries and related costs.
- **Other Operating Income:** The Company recorded CHF 1.4 million in grant income for R&D activities performed under our grants for the year ended December 31, 2023.
- **IFRS Loss for the Period:** The Company reported a net loss after taxes of CHF 54.2 million for the year ended December 31, 2023, compared with a net loss of CHF 70.8 million for the prior period.

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, five of which are currently in Phase 2 clinical trials and one of which is 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 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)

	As of December 31,	
	2023	2022
Assets		
Non-current assets		
Property, plant and equipment	3,376	4,259
Right-of-use assets	3,508	2,808
Intangible asset	50,416	50,416
Long-term financial assets	361	361
Total non-current assets	<u>57,661</u>	<u>57,844</u>
Current assets		
Prepaid expenses	6,437	4,708
Accrued income	246	408
Other current receivables	622	392
Accounts receivable	14,800	—
Short-term financial assets	24,554	91,000
Cash and cash equivalents	78,494	31,586
Total current assets	<u>125,153</u>	<u>128,094</u>
Total assets	<u>182,814</u>	<u>185,938</u>
Shareholders' equity and liabilities		
Shareholders' equity		
Share capital	2,089	1,797
Share premium	474,907	431,323
Treasury shares	(105)	(124)
Currency translation differences	(51)	10
Accumulated losses	(316,197)	(264,015)
Total shareholders' equity	<u>160,643</u>	<u>168,991</u>
Non-current liabilities		
Long-term lease liabilities	2,825	2,253
Net employee defined benefit liabilities	5,770	3,213
Total non-current liabilities	<u>8,595</u>	<u>5,466</u>
Current liabilities		
Trade and other payables	1,679	929
Accrued expenses	11,087	9,417
Deferred income	138	587
Short-term lease liabilities	672	548
Total current liabilities	<u>13,576</u>	<u>11,481</u>
Total liabilities	<u>22,171</u>	<u>16,947</u>
Total shareholders' equity and liabilities	<u>182,814</u>	<u>185,938</u>

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

	For the Year Ended December 31,		
	2023	2022	2021
Revenue			
Contract revenue	14,801	3,935	—
Total revenue	<u>14,801</u>	<u>3,935</u>	<u>—</u>
Operating expenses			
Research & development expenses	(54,606)	(60,336)	(62,282)
General & administrative expenses	(15,305)	(15,789)	(17,910)
Other operating income/(expense), net	1,486	1,343	1,182
Total operating expenses	<u>(68,425)</u>	<u>(74,782)</u>	<u>(79,010)</u>
Operating loss	<u>(53,624)</u>	<u>(70,847)</u>	<u>(79,010)</u>
Financial income	1,044	69	6,485
Financial expense	(176)	(355)	(581)
Exchange differences	(1,467)	393	113
Finance result, net	<u>(599)</u>	<u>107</u>	<u>6,017</u>
Loss before tax	<u>(54,223)</u>	<u>(70,740)</u>	<u>(72,993)</u>
Income tax expense	(10)	(13)	(3)
Loss for the period	<u>(54,233)</u>	<u>(70,753)</u>	<u>(72,996)</u>
Loss per share:			
Basic and diluted loss for the period attributable to equity holders	(0.64)	(0.85)	(0.97)

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

	For the Year Ended December 31,		
	2023	2022	2021
Loss for the period	(54,233)	(70,753)	(72,996)
Items that may be reclassified to income or loss in subsequent periods (net of tax):			
Currency translation differences	(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)	(1,669)	4,426	956
Other comprehensive income/(loss)	<u>(1,730)</u>	<u>4,436</u>	<u>956</u>
Total comprehensive loss, net of tax	<u>(55,963)</u>	<u>(66,317)</u>	<u>(72,040)</u>