



AC Immune Reports Third Quarter 2023 Financial Results and Provides a Corporate Update

November 3, 2023

AC Immune Reports Third Quarter 2023 Financial Results and Provides a Corporate Update

- Results from amyloid plaque reduction analysis (Abeta-PET) after 6 months of treatment with ACI-24.060 in ABATE Phase 1b/2 study on track for H1 2024
- ACI-24.060 ABATE interim safety and immunogenicity data in Alzheimer's disease (AD) expected by year-end
- ACI-7104.056 alpha-synuclein active immunotherapy in Phase 2 'VacSYn' Parkinson's disease (PD) trial to complete Cohort 1 enrollment and report initial safety findings by year-end
- Cash position of CHF 79.9 million finances the Company into Q4 2024, excluding the benefit of anticipated milestone payments

Lausanne, Switzerland, November 3, 2023 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today reported results for the third quarter ended September 30, 2023, and provided a corporate update.

Dr. Andrea Pfeifer, CEO of AC Immune SA, commented: "As we look to year-end and into 2024, AC Immune is poised to achieve multiple milestones across our clinical programs. We remain on track to report safety and immunogenicity data from the AD cohort of our ABATE trial of ACI-24.060 this year. Then, in the first half of 2024 results are anticipated from the important Abeta-PET imaging analyses on amyloid plaque reduction following 6 months of treatment. With amyloid clearance as measured by PET imaging now established as a reliable surrogate for efficacy, these results could significantly de-risk the program and enable advancement into a registrational study. We look forward to further discussing the clinical utility of PET imaging in AD at our KOL webinar on November 9, 2023."

"We continue to progress our pipeline, and are looking forward to the initiation of the next AD trial of anti-pTau (phosphorylated Tau) active immunotherapy ACI-35.030 later this year, which will be followed by a milestone payment. Taken together with ACI-24.060 and our a-syn active immunotherapy, ACI-7104.056, we will have three active immunotherapies in mid- to late-stage clinical testing for neurodegeneration. With further clinical readouts from our precision medicine pipeline ahead, we continue to work diligently towards earlier diagnosis and treatment to prevent progression of neurodegenerative diseases."

Q3 2023 and Subsequent Highlights

- A peer-reviewed paper featuring the first-in-human trial of AC Immune's wholly owned experimental alpha-synuclein (a-syn) positron emission tomography (PET) tracer ACI-12589 comparing healthy control subjects to patients with a-synucleinopathies and other neurological diagnoses was [published in Nature Communications](#).
- KOL webinar on PET imaging in AD featuring Victor Villemagne, M.D. (University of Pittsburgh) will be held on November 9, 2023 at 10:00 AM ET. To register for the event, [please click here](#).
- The first patient with PD was dosed in the Phase 2 VacSYn clinical trial evaluating ACI-7104.056, AC Immune's wholly-owned anti-a-syn active immunotherapy.
- Several programs were [showcased](#) at the annual Alzheimer's Association International Conference (AAIC 2023), including presentations on ABATE's trial design, TDP-43 proteinopathy in neurodegenerative diseases, and ACI-12589, a novel PET tracer targeting a-syn.
- [Announced](#) the appointment of new Chief Medical Officer, Dr Nuno Mendonça.
- 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.

Anticipated Milestones

ACI-24.060 anti-Abeta active immunotherapy	<ul style="list-style-type: none">• Additional interim safety and immunogenicity data from AD cohorts of ABATE study expected in Q4 2023• First Abeta-PET data on amyloid plaque reduction in AD following 6 months of treatment expected in H1 2024
ACI-7104.056 anti-a-syn active immunotherapy	<ul style="list-style-type: none">• Completion of cohort 1 enrollment and initial safety findings in the Phase 2 VacSYn study in PD expected by year-end
ACI-35.030 anti-pTau active immunotherapy	<ul style="list-style-type: none">• Initiation of next trial in AD expected in Q4 2023 (to be followed by a milestone payment)

Anti-TDP-43 antibody	<ul style="list-style-type: none"> • Advancement of candidate into preclinical development (tox) expected in Q4 2023
a-syn-PET tracer	<ul style="list-style-type: none"> • Declaration of next clinical candidate for development in PD expected in Q4 2023

Analysis of Financial Statements for the Quarter Ended September 30, 2023

- **Cash Position:** The Company ended Q3 with a total cash balance of CHF 79.9 million (CHF 122.6 million as of December 31, 2022), composed of CHF 31.9 million in cash and cash equivalents and CHF 48.0 million in short-term financial assets. The Company's cash balance provides sufficient capital resources to progress into Q4 2024 without considering receipt of potential future milestone payments.
- **R&D Expenditures:** R&D expenses for the three months ended September 30, 2023, were CHF 12.4 million compared to CHF 14.4 million in the comparable period in 2022, due to lower expenses in our preclinical portfolio and reduced clinical expenses.
- **G&A Expenditures:** For the three months ended September 30, 2023, G&A increased by CHF 0.2 million, which is materially consistent with the comparable period.
- **Other Operating Income:** The Company recognized CHF 0.3 million in grant income from Michael J. Fox Foundation and Target ALS grants.
- **IFRS Loss for the Period:** The Company reported a net loss after taxes of CHF 15.1 million for the three months ended September 30, 2023, compared with a net loss of CHF 13.5 million for the comparable period in 2022.

About AC Immune SA

AC Immune SA is a clinical-stage biopharmaceutical company that aims to become a global leader in precision medicine 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 including Genentech, a member of the Roche Group, Eli Lilly and Company, and others, resulting in substantial non-dilutive funding to advance its proprietary programs and >\$3 billion in potential milestone payments.

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:

Head of 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

International Media

Chris Maggos

Cohesion Bureau

Phone: +41 79 367 6254

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	
	September 30, 2023	December 31, 2022
Assets		
Non-current assets		
Property, plant and equipment	3,627	4,259
Right-of-use assets	2,403	2,808
Intangible asset	50,416	50,416
Long-term financial assets	361	361
Total non-current assets	56,807	57,844
Current assets		
Prepaid expenses	5,534	4,708
Accrued income	312	408
Other current receivables	406	392
Short-term financial assets	48,000	91,000
Cash and cash equivalents	31,927	31,586
Total current assets	86,179	128,094
Total assets	142,986	185,938
Shareholders' equity and liabilities		
Shareholders' equity		
Share capital	1,802	1,797
Share premium	434,451	431,323
Treasury shares	(106)	(124)
Currency translation differences	5	10
Accumulated losses	(310,488)	(264,015)
Total shareholders' equity	125,664	168,991
Non-current liabilities		
Long-term lease liabilities	1,838	2,253
Net employee defined-benefit liabilities	3,774	3,213
Total non-current liabilities	5,612	5,466
Current liabilities		
Trade and other payables	1,479	929
Accrued expenses	9,338	9,417
Deferred income	338	587
Short-term lease liabilities	555	548
Total current liabilities	11,710	11,481
Total liabilities	17,322	16,947
Total shareholders' equity and liabilities	142,986	185,938

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue				
Contract revenue	—	3,934	—	3,934
Total revenue	—	3,934	—	3,934
Operating expenses				
Research & development expenses	(12,407)	(14,385)	(39,962)	(45,200)
General & administrative expenses	(3,465)	(3,274)	(11,252)	(11,828)
Other operating income/(expense), net	406	262	1,131	944

Total operating expenses	(15,466)	(17,397)	(50,083)	(56,084)
Operating loss	<u>(15,466)</u>	<u>(13,463)</u>	<u>(50,083)</u>	<u>(52,150)</u>
Financial income	285	11	753	11
Financial expense	(26)	(77)	(150)	(356)
Exchange differences	67	17	—	502
Finance result, net	<u>326</u>	<u>(49)</u>	<u>603</u>	<u>157</u>
Loss before tax	<u>(15,140)</u>	<u>(13,512)</u>	<u>(49,480)</u>	<u>(51,993)</u>
Income tax expense	(3)	(4)	(9)	(11)
Loss for the period	<u>(15,143)</u>	<u>(13,516)</u>	<u>(49,489)</u>	<u>(52,004)</u>
Loss per share:	(0.18)	(0.16)	(0.59)	(0.62)

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Loss for the period	(15,143)	(13,516)	(49,489)	(52,004)
Items that will be reclassified to income or loss in subsequent periods (net of tax):				
Currency translation differences	11	23	(5)	72
Items that will not to be reclassified to income or loss in subsequent periods (net of tax):				
Remeasurement gains on defined-benefit plans	—	178	—	7,559
Total comprehensive loss (net of tax)	<u>(15,132)</u>	<u>(13,315)</u>	<u>(49,494)</u>	<u>(44,373)</u>

Attachment

- [20231103 ACIU Q3 Earnings_Final](#)



Source: AC Immune SA