

AC Immune Reports Full Year 2022 Financial Results and Provides Corporate Update

- Clinical-stage vaccine programs targeting amyloid-beta (Abeta), phosphorylated-Tau (pTau), and alpha-synuclein (a-syn) are all on track to reach important milestones in 2023
- ACI-24.060 anti-amyloid-beta vaccine for Alzheimer's disease (AD) showed positive initial safety and immunogenicity in Phase 1b/2 ABATE trial; further interim data expected in H2 2023; first amyloid plaque PET imaging results anticipated in 2024
- ACI-35.030 anti-pTau vaccine for AD selected for further development by partner; anticipated H2 2023 initiation of next trial in AD to be followed by milestone payment
- 2022 cash burn of CHF 70.9 million was better than guidance (2022: CHF 75-80 million) resulting in strong end of year financial position of CHF 122.6 million providing runway into Q3 2024, excluding potential milestone payments

Lausanne, Switzerland, March 16, 2023 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today reported results for the year ended December 31, 2022, and provided a corporate update.

Dr. Andrea Pfeifer, CEO of AC Immune SA, commented: “Thanks to the strong progress by our experienced team over the past year, we now have highly innovative vaccines targeting neurotoxic species of Abeta, Tau or a-syn in mid- to late-stage development for Alzheimer's and Parkinson's disease, respectively. This progress was highlighted by ABATE's successful interim readout in AD, which is enabling the quick and informed transition to this adaptive trial's next cohorts. Importantly, ABATE remains on track for additional readouts on ACI-24.060's safety and immunogenicity this year, and for interim Abeta PET analyses in 2024 that will provide an opportunity for early de-risking and potentially a rapid transition to a pivotal program.”

“Together, our vaccines and the highly specific diagnostics we are developing against targets such as Tau and a-syn form the cornerstone of our strategy to enable precision medicine for neurodegenerative diseases. With this strategy, our long-term goal is to identify and treat the multifactorial pathologies of each patient at their earliest stages, so that we can minimize irreversible neuronal damage and enable disease prevention.”

2022 and Subsequent Highlights

Pipeline Progress

Vaccine Programs

- [Positive initial interim safety and immunogenicity data](#) from the first AD cohort of the Phase 1b/2 ABATE trial of ACI-24.060, AC Immune's wholly-owned anti-amyloid beta (Abeta) SupraAntigen® vaccine candidate. Based on these data, ABATE has been expanded, as planned, to begin screening of individuals with Down syndrome (DS) for participation in

part 2 of the trial and also to evaluate higher doses in patients with AD. Interim safety and immunogenicity data from AD and DS cohorts are expected in the second half of 2023.

- ACI-35.030, a potential first-in-class anti-pTau vaccine candidate, was [selected for further development](#), based on clinical data from a Phase 1b/2 trial in AD presented at CTAD 2022. These data showed that vaccination with ACI-35.030 was well tolerated and elicited a strong, durable, and boost-able antibody response against pathological forms of Tau such as pTau and its aggregated form, enriched paired helical filaments. ACI-35.030, generated using AC Immune's SupraAntigen® technology platform, is being developed in collaboration with Janssen Pharmaceuticals, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson.
- ACI-24.060 [preclinical data](#) published in the peer-reviewed journal *Brain Communications*, showed it was well tolerated and generated a broad polyclonal immune response with high titers of antibodies against neurotoxic pyroglutamate Abeta (pyroGlu-Abeta), a major component of Abeta plaques. Additional preclinical data demonstrated ACI-24.060's strong immunogenicity against another key neurotoxic Abeta species, oligomeric Abeta.
- A [peer-reviewed publication](#) in *JAMA Neurology* showed that the first generation formulation of ACI-24.060 was safe and elicited an immune response in the first-ever clinical study of an anti-Abeta vaccine in individuals with DS. Data from the Phase 1b study also provided evidence of target engagement by the polyclonal response to the studied vaccine.

Antibody Programs

- [Detailed results](#) from the Phase 2 Alzheimer's Prevention Initiative (API) study evaluating the anti-Abeta monoclonal antibody crenezumab in autosomal dominant Alzheimer's disease (ADAD) were presented at the 2022 Alzheimer's Association International Conference (AAIC) by AC Immune's partner Genentech, a member of the Roche group, and the Banner Alzheimer's Institute. Numerical differences favoring crenezumab were observed across both co-primary endpoints, as well as multiple secondary and exploratory endpoints, though none were statistically significant. All participants in the study were offered up to one year of continued treatment (crenezumab for all carriers and placebo for all non-carrier) following the end of the double-blind period while primary results and additional analyses were pending. Final efficacy visits have begun.
- Further biofluid biomarker data from the Phase 2 Lauriet trial of the anti-Tau antibody semorinemab in mild-to-moderate AD were presented in a poster at CTAD 2022. Results featured in the poster showed statistically significant post-treatment reductions in pTau and total Tau in the cerebrospinal fluid with semorinemab versus placebo, supporting target engagement and modulation in the central nervous system. The Lauriet open label extension study is ongoing.

Diagnostic Programs

- The [first live images of a-syn in human brains](#) were shown using ACI-12589, an a-syn PET tracer discovered using AC Immune's Morphomer® platform. Analyses from a clinical study of the tracer presented at AD/PD™ 2022 showed enhanced contrast and a-syn target specificity in patients with multiple system atrophy (MSA), as well as increased tracer

retention in brain areas affected by MSA disease processes, highlighting ACI-12589's potential as the first non-invasive diagnostic for alpha-synucleinopathies (e.g. MSA).

- AC Immune's partner, Life Molecular Imaging, [imaged the first patient](#) in the pivotal Phase 3 **ADvance** trial evaluating the Tau PET tracer, PI-2620, in AD. PI-2620 was discovered and developed using the Morphomer® platform as part of a research collaboration between AC Immune and LMI.

Management Team

- Expanded executive team with the appointment of [Howard Donovan as Chief HR Officer](#). Prior to joining AC Immune, Mr. Donovan led People Services at the World Economic Forum.
- Promoted Christopher Roberts to [Interim Chief Financial Officer and Vice President, Finance](#). Mr. Roberts previously held the title of Associate Vice President, Finance, and prior to joining AC Immune worked as a Senior Manager for Ernst and Young.
- Promoted [Julian Snow to Vice President, U.S. Finance & Corporate Development](#). Mr. Snow previously held the title of Associate Vice President, Financial Reporting and prior to joining AC Immune worked as a manager at BDO.

Thought Leadership and Collaborations

- Received a [follow-on grant](#) from The Michael J. Fox Foundation for Parkinson's Research (MJFF) to support enhanced clinical studies of ACI-12589.
- Received [new grants](#) from MJFF and the Target ALS Foundation 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).
- AC Immune Co-Founder and CEO Dr. Andrea Pfeifer [received the prestigious Aenne Burda Award for Creative Leadership](#) in recognition of her work in the field of neurodegenerative diseases.

Key Achieved and Anticipated 2023 Milestones

<p>ACI-24.060 anti-Abeta vaccine</p>	<ul style="list-style-type: none"> • Reported interim Phase 1b safety and immunogenicity data from first AD cohort of Phase 1b/2 ABATE study • Initiation of first DS cohort of ABATE study expected in H1 2023 • Submission of an Investigational New Drug (IND) application to enable expansion of ABATE study to the U.S. expected in H1 2023 • Additional interim safety and immunogenicity data from AD cohort of ABATE study expected in H2 2023 • Interim safety and immunogenicity data from DS cohort of ABATE study expected in H2 2023
<p>ACI-7104 anti-a-syn vaccine</p>	<ul style="list-style-type: none"> • Update from Phase 2 VACSYN study expected in H2 2023
<p>ACI-35.030 anti-pTau vaccine</p>	<ul style="list-style-type: none"> • Initiation of next trial in AD expected in H2 2023 (to be followed by milestone payment)

Semorinemab anti-Tau antibody	<ul style="list-style-type: none"> Results from the open-label extension of the Phase 2 Lauriet trial in mild-to-moderate AD expected in H2 2023
Anti-TDP-43 antibody	<ul style="list-style-type: none"> Advancement of candidate into preclinical development (tox) expected in H2 2023
a-syn-PET tracer	<ul style="list-style-type: none"> Declaration of next clinical candidate for development in Parkinson's disease expected in H2 2023
TDP-43-PET tracer	<ul style="list-style-type: none"> Clinical candidate declaration expected in H1 2023

Analysis of Financial Statements for the Year Ended December 31, 2022

- Cash Position:** The Company had a total cash balance of CHF 122.6 million, composed of CHF 31.6 million in cash and cash equivalents and CHF 91.0 million in short-term financial assets. This compares to a total cash balance of CHF 198.2 million as of December 31, 2021. The Company's cash balance provides sufficient capital resources to progress into at least Q3 2024 without consideration of potential income milestone payments.
- Contract Revenues:** The Company recorded CHF 3.9 million in contract revenues for the year end December 31, 2022 compared with no contract revenues in the prior year. The increase relates to the progression of PI-2620 into Phase 3 development in AD.
- R&D Expenditures:** R&D expenses decreased by CHF 1.9 million for the year ended December 31, 2022 to CHF 60.3 million, predominantly due to:
 - Discovery and preclinical expenses (- CHF 3.1 million):** The Company decreased expenditures across a variety of its discovery and preclinical programs. This decrease was predominantly due to the advancement of the Company's ACI-24.060 vaccine into clinical studies.
 - Clinical expenses (- CHF 1.8 million):** The Company had a net decrease in clinical expenditures largely due to the timing of activities across various cohorts and the completion of certain R&D cost sharing activities for our ACI-35.030 vaccine. We increased expenditures in other clinical programs, notably for the clinical development of ACI-7104.056 and the initiation of our Phase 1b/2a ABATE study for ACI-24.060.
 - Salary- and benefit-related costs (+ CHF 1.2 million):** Personnel expenses increased due to the net increase in FTEs in 2022 along with the annualization of 2021 hires.
- G&A Expenditures:** G&A expenses decreased by CHF 2.1 million for the year ended December 31, 2022 to CHF 15.8 million. This decrease is related to prior year transaction costs incurred to complete the asset acquisition of Affiris' a-syn portfolio and the reduction in personnel expenses.
- Other Operating Income:** The Company recorded CHF 1.3 million in grant income for R&D activities performed under our grants for the year ended December 31, 2022, an increase of CHF 0.1 million compared to the prior period.
- IFRS Loss for the Period:** The Company reported a net loss after taxes of CHF 70.8 million for the year ended December 31, 2022, compared with a net loss of CHF 73.0 million for the prior period.

2023 Financial Guidance

- AC Immune anticipates that its total cash burn will be in the range of CHF 65 to CHF 75 million for the full year 2023. The Company defines cash burn 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 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 ten therapeutic and three diagnostic candidates, 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. These include: the impact of Covid-19 on our business, suppliers, patients and employees and any other impact of Covid-19. 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, 2022	As of December 31, 2021
ASSETS		
Non-current assets		
Property, plant and equipment	4,259	5,116
Right-of-use assets	2,808	2,914
Intangible asset	50,416	50,416
Long-term financial assets	361	363
Total non-current assets	57,844	58,809
Current assets		
Prepaid expenses	4,708	3,015
Accrued income	408	975
Other current receivables	392	428
Short-term financial assets	91,000	116,000
Cash and cash equivalents	31,586	82,216
Total current assets	128,094	202,634
Total assets	185,938	261,443
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	1,797	1,794
Share premium	431,323	431,251
Treasury shares	(124)	(124)
Currency translation differences	10	—
Accumulated losses	(264,015)	(200,942)
Total shareholders' equity	168,991	231,979
Non-current liabilities		
Long-term lease liabilities	2,253	2,340
Net employee defined-benefit liabilities	3,213	7,098
Total non-current liabilities	5,466	9,438
Current liabilities		
Trade and other payables	929	2,003
Accrued expenses	9,417	16,736
Deferred income	587	717
Short-term lease liabilities	548	570
Total current liabilities	11,481	20,026
Total liabilities	16,947	29,464
Total shareholders' equity and liabilities	185,938	261,443

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

	For the Year Ended December 31,		
	2022	2021	2020
Revenue			
Contract revenue	3,935	—	15,431
Total revenue	<u>3,935</u>	<u>—</u>	<u>15,431</u>
Operating expenses			
Research & development expenses	(60,336)	(62,282)	(59,487)
General & administrative expenses	(15,789)	(17,910)	(18,557)
Other operating income/(expense), net	1,343	1,182	1,353
Total operating expenses	<u>(74,782)</u>	<u>(79,010)</u>	<u>(76,691)</u>
Operating loss	(70,847)	(79,010)	(61,260)
Financial income	69	6,485	78
Financial expense	(355)	(581)	(184)
Exchange differences	393	113	(555)
Finance result, net	<u>107</u>	<u>6,017</u>	<u>(661)</u>
Loss before tax	(70,740)	(72,993)	(61,921)
Income tax expense	(13)	(3)	—
Loss for the period	<u>(70,753)</u>	<u>(72,996)</u>	<u>(61,921)</u>
Loss per share:			
Basic and diluted loss for the period attributable to equity holders	(0.85)	(0.97)	(0.86)

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

	For the Year Ended December 31,		
	2022	2021	2020
Loss for the period	(70,753)	(72,996)	(61,921)
Items that may be reclassified to income or loss in subsequent periods (net of tax):			
Currency translation differences	10	—	—
Items that will not be reclassified to income or loss in subsequent periods (net of tax):			
Remeasurement gains on defined-benefit plans (net of tax)	4,426	956	726
Other comprehensive income	4,436	956	726
Total comprehensive loss, net of tax	<u>(66,317)</u>	<u>(72,040)</u>	<u>(61,195)</u>

**Reconciliation of loss to adjusted loss and
loss per share to adjusted loss per share**

(In CHF thousands, except for share and per share data)	For the Year Ended December 31,		
	2022	2021	2020
Loss	(70,753)	(72,996)	(61,921)
Adjustments:			
Non-cash share-based payments ¹	3,330	4,126	4,088
Foreign currency (gains)/losses ²	(521)	70	703
Change in fair value of derivative financial assets ³	—	(6,459)	—
Transaction costs ⁴	—	1,144	—
Adjusted loss	(67,944)	(74,115)	(57,130)
Loss per share – basic and diluted	(0.85)	(0.97)	(0.86)
Adjustment to loss per share – basic and diluted	0.04	(0.02)	0.07
Adjusted loss per share – basic and diluted	(0.81)	(0.99)	(0.79)
Weighted-average number of shares used to compute adjusted loss per share – basic and diluted	83,554,412	74,951,833	71,900,212

¹Reflects non-cash expenses associated with share-based compensation for equity awards issued to directors, management and employees of the Company. This expense reflects the awards' fair value recognized for the portion of the equity award which is vesting over the period.

²Reflects foreign currency re-measurement gains and losses for the period, predominantly impacted by the change in the exchange rate between the U.S. Dollar and the Swiss Franc.

³Reflects the change in the fair value of the derivative financial instruments associated with two convertible notes sold to certain Affiris affiliated entities.

⁴Reflects transaction costs associated with our asset acquisition for a portfolio of therapeutics targeting alpha-synuclein.