

AC Immune Reports Full Year 2021 Financial Results and Provides Corporate Update

Seven clinical data readouts expected in 2022

Three vaccines, targeting Tau, Abeta and alpha-synuclein, advancing in 2022

Semorinemab Phase 2 Lauriet trial: additional fluid biomarker data expected in H2 2022

Initiation of ACI-24 anti-Abeta vaccine Phase 1b/2 trial in patients with Alzheimer's disease (AD) and people living with Down syndrome (DS) expected in H1 2022

AD/PD™ Conference: ACI-12589 identified as a reliable and accurate PET tracer for alpha-synucleinopathies (e.g. MSA)

Strong financial position of CHF 198.2 million ensures the Company is fully financed through at least Q1 2024

Lausanne, Switzerland, March 22, 2022 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today reported its financial results for the year ended December 31, 2021, and provided a corporate update, highlighting progress in its broad pipeline of products to treat and diagnose neurodegenerative diseases.

Prof. Andrea Pfeifer, CEO of AC Immune SA, commented: “We are off to a strong start in 2022 with the second of seven clinical data readouts presented last week at the AD/PD™ 2022 conference. The first-in-human study of our alpha-synuclein diagnostic, ACI-12589, showed it has strong potential to become the first reliable and accurate PET tracer for alpha-synucleinopathies (e.g. multiple system atrophy, MSA).”

“Pairing cutting-edge diagnostics with highly targeted and selective therapeutic agents, such as our vaccines targeting alpha-synuclein, phosphorylated-Tau, and Abeta, which are all advancing into later-stage development this year, we aim to shift the therapeutic paradigm of neurodegenerative diseases towards earlier, more accurate diagnosis, treatment, and prevention,” Prof. Pfeifer said.

2021 and Subsequent Highlights

Pipeline progress

Tau

- Expanded the Phase 1b/2a trial evaluating the first-in-class anti-phosphorylated-Tau (pTau) vaccine candidate [ACI-35.030 for the treatment of AD](#) in collaboration with Janssen Pharmaceuticals, Inc. The decision to expand the trial, which was made to support plans to advance ACI-35.030 into late-stage development, was based on [encouraging interim safety, tolerability, and immunogenicity results](#). These showed that ACI-35.030 treatment

- was well tolerated and led to the strong induction of antibodies specific for pathological forms of Tau such as pTau and its aggregated form, enriched paired helical filaments (ePHF).
- Top line data from the Phase 2 Lauriet trial of semorinemab in mild-to-moderate AD [presented at CTAD 2021](#) showed a statistically significant (p=0.0008) 42.2% reduction in cognitive decline vs. placebo as measured by ADAS-Cog11 at week 49, one of the trial's co-primary endpoints. There were no statistically significant differences between semorinemab and placebo arms in the other co-primary endpoint, ADCS-ADL, or in the secondary endpoints (MMSE and CDR-SB). AC Immune's partner Genentech, a member of the Roche Group, is continuing with the trial's open-label extension. Additional fluid biomarker data are expected in H2 2022.

Abeta

- Presented [full results](#) from the landmark Phase 1b clinical trial evaluating the anti-Abeta vaccine ACI-24 in subjects living with Down syndrome (DS) at the Alzheimer's Association International Conference (AAIC) 2021. These results showed evidence of immunogenicity and pharmacodynamic response following ACI-24 treatment and demonstrated its favorable safety and tolerability profile.
- Presented at CTAD 2021 full results of the Phase 2 study evaluating ACI-24 in patients with mild AD. This assessment confirmed earlier results showing no safety concerns nor evidence of inflammation or ARIA (amyloid-related imaging abnormalities) related to ACI-24 in any subject.
- [New data on the optimized formulation of ACI-24](#) were published in a peer reviewed journal [Brain Communications](#). The optimized formulation was well tolerated in preclinical models and generated a broad polyclonal anti-Abeta response with high titers of antibodies against neurotoxic pyroglutamate Abeta (pyroGlu-Abeta), a major component of Abeta plaques. Additional preclinical data on optimized ACI-24 were presented at AD/PD™ 2022 confirming its enhanced and sustained immunogenicity against another key pathological Abeta species, oligomeric Abeta.

A-syn

- Clinical PET image analyses and preclinical studies were presented at AD/PD™ 2022 suggest that ACI-12589 was retained in brain areas affected by disease processes involving a-synuclein (a-syn) aggregation, indicating the product-candidate has potential as the first non-invasive diagnostic for alpha-synucleinopathies (e.g. MSA).
- Completed [all-stock acquisition of Affiris' portfolio of therapeutics targeting a-syn](#), notably PD01, a clinically validated active vaccine candidate that places AC Immune at the forefront of Parkinson's disease (PD) drug development. ACI-7104, the optimized formulation of PD01, is on track to enter Phase 2 testing in early PD patients in H2 2022.

- Identified and characterized the first biologically active small molecule Morphomer® [a-syn aggregation inhibitors](#), showing that they significantly decreased a-syn aggregate formation in cellular assays by interfering with the fibrillation process.

NLRP3

- Reported key advancements for several [therapeutic discovery programs targeting the \(NOD\)-like receptor protein 3 \(NLRP3\) inflammasome](#). Small molecule Morphomer® inhibitors of NLRP3 showed the first evidence of *in vivo* activity in a model of peripheral inflammation, while high-affinity SupraAntigen® monoclonal antibodies were shown to bind extracellular components (ASC) of the NLRP3 pathway and inhibit inflammasome-mediated immune responses *in vitro*.

Strengthening Financial Position and Extend Shareholder Base

- Strengthened cash position via an equity financing, adding the three lead investors in Covid-19 vaccine innovator BioNTech SE, Athos Service GmbH (Strüngmann family office), First Capital Partner GmbH (Egger Family Office), and MIG Fonds, as part of the [Affiris deal](#).

Strengthening of Board

- Appointed [Alan Colowick, M.D.](#), [Monica Shaw, M.D.](#), and [Prof. Monika Büttler, Dr. oec.](#), to the Company's Board of Directors. Dr. Colowick is a biotech and investment executive with more than 20 years of experience in large and emerging biotech companies. Dr. Shaw is a pharmaceutical industry expert who has been involved in advancing more than 15 therapeutic products from first-in-human studies through commercialization. Prof. Büttler is a leading Swiss economist and former Vice President of the independent Swiss COVID-19 Science Taskforce.

Thought Leadership and Collaborations

- Swiss Economic Forum (SEF) awarded AC Immune Co-Founder and CEO Prof. Andrea Pfeifer with the first [SEF.WomenAward for CEO of the Year](#). This award recognizes women with an excellent entrepreneurial track record, giving greater prominence to role models who can inspire the next generation of businesswomen.
- Expanded the Company's [research collaboration](#) with leading scientists at the Center for Neurodegenerative Disease Research at the Perelman School of Medicine at the University of Pennsylvania. This partnership aims to advance therapeutic strategies targeting TAR DNA-binding protein 43 (TDP-43), a major driver of neurodegenerative diseases.
- Received two [Michael J. Fox Foundation grants](#) to accelerate the development of first-in-class brain penetrant small molecules to inhibit alpha-synuclein aggregation and NLRP3 inflammasome activation in PD.

Our strategy for 2022

AC Immune's execution strategy is to advance late-stage AD programs with partners, accelerate its non-AD and NeuroOrphan programs in-house, and advance development of its suite of potentially best-in-class diagnostics to enable precision medicine. The Company intends to maintain program leadership over its wholly-owned AD and PD vaccine programs until Phase 3 or beyond, and expects to initiate two mid-stage clinical trials in 2022:

- ACI-7104 anti-a-syn vaccine candidate is on track to enter an adaptive, placebo-controlled, and biomarker-based Phase 2 study in patients with early PD in H2 2022. The two part study will evaluate safety, immunogenicity, and measure biomarkers of pathological alpha-synuclein in Part 1, with a seamless transition to Part 2, which will aim to establish clinical proof-of-concept by monitoring progression of PD symptoms and biomarkers.
- Optimized ACI-24 Abeta vaccine is on track to enter a placebo-controlled Phase 1b/2 study evaluating different dosing regimens vs. placebo in up to four cohorts of patients with AD before being expanded to a separate cohort of people living with DS to address DS-related AD. Key outcome measures for the study will include assessments of safety, immunogenicity, pharmacodynamics, target engagement, Abeta-PET and clinical outcomes.

2022 Clinical Milestones

ACI-12589 a-syn-PET tracer	Reported results from first-in-human study at AD/PD™ 2022 conference
ACI-35.030 anti-pTau vaccine	Reported Phase 1b/2a interim analysis from highest dose group in Q1; disclose future late-stage development plans in H2
ACI-24 (optimized) anti-Abeta vaccine	ACI-24 (optimized vaccine formulation) Phase 1b/2a First-Patient-In (AD) in H1 Phase 1b in AD readout and decision to move into DS in H2
Crenezumab anti-Abeta antibody	Top line Phase 2 results from AD prevention trial in patients with autosomal dominant AD in H1
Semorinemab anti-Tau antibody	Additional fluid biomarker data from the Phase 2 Lauriet study in mild-to-moderate AD in H2
PI-2620 Tau-PET tracer	Phase 2 and Phase 1 results in AD and progressive supranuclear palsy (PSP) respectively, in H2
ACI-7104 anti-a-syn vaccine	Initiate Phase 2 trial in early PD in H2

Analysis of Financial Statements for the year ended December 31, 2021

- **Cash Position:** The Company had a total cash balance of CHF 198.2 million, composed of CHF 82.2 million in cash and cash equivalents and CHF 116.0 million in short-term financial assets. This compares to a total cash balance of CHF 225.9 million as of December 31, 2020. The Company's cash balance provides enough capital resources to

progress through at least Q1 2024 without consideration of potential incoming milestone payments.

- **Contract Revenues:** The Company did not record contract revenues for the year ended December 31, 2021, a decrease of CHF 15.4 million from the comparable period in 2020. The overall decrease is predominantly related to a CHF 10 million milestone payment as well as CHF 4.3 million associated with R&D activities in our agreement with Lilly that were recognized in 2020 and did not repeat in the current period.
- **R&D Expenditures:** R&D expenses increased by CHF 2.8 million for the year ended December 31, 2021, to CHF 62.3 million.
 - **Discovery and preclinical expenses (- CHF 0.4 million):** The Company decreased expenditures across a variety of its discovery and preclinical programs. This was predominantly led by a decrease in investment for the research of alpha-synuclein antibodies and other discovery programs.
 - **Clinical expenses (- CHF 2.3 million):** The Company decreased expenditures across multiple clinical programs, notably for Phase 1 activities associated with our Morphomer Tau compound and expenses. These decreases were offset predominantly by ACI-35.030, which was driven by R&D cost sharing and increased patient enrollments into the Phase 1b/2a study.
 - **Salary- and benefit-related costs (+ CHF 2.3 million):** The Company's salary- and benefit-related costs increased primarily due to the internal reallocation of certain employees' salaries and the annualization of 2020 hires.
- **G&A Expenditures:** For the year December 31, 2021, G&A decreased by CHF 0.6 million to CHF 17.9 million. This decrease is predominantly related to a reallocation of CHF 2.8 million of certain IT and facilities costs offset by transaction costs incurred to complete the asset acquisition for Affiris' alpha-synuclein portfolio.
- **Other Operating Income:** The Company recognized CHF 1.2 million in grant income for R&D activities performed under our Michael J. Fox Foundation for Parkinson's Research (MJFF) and Target ALS grants, a decrease 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 73.0 million for the year ended December 31, 2021, compared with a net loss of CHF 61.9 million for the comparable period in 2020.

2022 Financial Guidance

- For the full year 2022, the Company expects its total cash burn to be in the range, CHF 75 million to CHF 80 million. 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 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, six of which are currently in clinical trials. 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 Janssen Pharmaceuticals, Inc., 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 and RU. Morphomer[®] is a registered trademark of AC Immune SA in CN, CH, GB, JP, and NO.

For further information, please contact:

Media Relations

Saoyuth Nidh
AC Immune
Phone: +41 21 345 91 34
Email: saoyuth.nidh@acimmune.com

Investor Relations

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

U.S. Media

Shani Lewis
LaVoieHealthScience
Phone: +1 609 516 5761
Email: slewis@lavoiehealthscience.com

U.S. Investors

Corey Davis, Ph.D.
LifeSci Advisors
Phone: +1 212 915 2577
Email: cdavis@lifesciadvisors.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, 2021	As of December 31, 2020
ASSETS		
Non-current assets		
Property, plant and equipment	5,116	4,416
Right-of-use assets	2,914	2,223
Intangible asset	50,416	—
Long-term financial assets	363	334
Total non-current assets	58,809	6,973
Current assets		
Prepaid expenses	3,015	3,954
Accrued income	975	1,591
Other current receivables	428	329
Short-term financial assets	116,000	65,000
Cash and cash equivalents	82,216	160,893
Total current assets	202,634	231,767
Total assets	261,443	238,740
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	1,794	1,538
Share premium	431,251	346,890
Treasury shares	(124)	(100)
Accumulated losses	(200,942)	(132,850)
Total shareholders' equity	231,979	215,478
Non-current liabilities		
Long-term lease liabilities	2,340	1,780
Net employee defined-benefit liabilities	7,098	7,464
Total non-current liabilities	9,438	9,244
Current liabilities		
Trade and other payables	2,003	2,184
Accrued expenses	16,736	11,085
Deferred income	717	306
Short-term lease liabilities	570	443
Total current liabilities	20,026	14,018
Total liabilities	29,464	23,262
Total shareholders' equity and liabilities	261,443	238,740

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

	For the Years Ended December 31,		
	2021	2020	2019
Revenues			
Contract revenue	—	15,431	110,456
Total revenue	<u>—</u>	<u>15,431</u>	<u>110,456</u>
Operating expenses			
Research & development expenses	(62,282)	(59,487)	(50,432)
General & administrative expenses	(17,910)	(18,557)	(16,058)
Other operating income/(expense)	1,182	1,353	570
Total operating expenses	<u>(79,010)</u>	<u>(76,691)</u>	<u>(65,920)</u>
Operating income/(loss)	(79,010)	(61,260)	44,536
Financial income	6,485	78	303
Financial expense	(581)	(184)	(1,926)
Change in fair value of conversion feature	—	—	4,542
Exchange differences	113	(555)	(2,013)
Finance result, net	<u>6,017</u>	<u>(661)</u>	<u>906</u>
Income/(loss) before tax	(72,993)	(61,921)	45,442
Income tax expense	(3)	—	—
Income/(loss) for the period	<u>(72,996)</u>	<u>(61,921)</u>	<u>45,442</u>
Earnings/(loss) per share:			
Basic income/(loss) for the period attributable to equity holders	(0.97)	(0.86)	0.64
Diluted income/(loss) for the period attributable to equity holders	(0.97)	(0.86)	0.64

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

	For the Years Ended December 31,		
	2021	2020	2019
Income/(loss) for the period	(72,996)	(61,921)	45,442
Items that may be reclassified to income or loss in subsequent periods (net of tax):			
Currency translation differences	—	—	—
Items that will not be reclassified to income or loss in subsequent periods (net of tax):			
Re-measurement gains/(losses) on defined-benefit plans	956	726	(1,304)
Other comprehensive income/(loss)	956	726	(1,304)
Total comprehensive income/(loss), net of tax	<u>(72,040)</u>	<u>(61,195)</u>	<u>44,138</u>

Reconciliation of income/(loss) to adjusted income/(loss) and earnings/(loss) per share to adjusted earnings/(loss) per share

(In CHF thousands, except for share and per share data)	For the Years Ended December 31,		
	2021	2020	2019
Income/(loss)	(72,996)	(61,921)	45,442
Adjustments:			
Non-cash share-based payments ¹	4,126	4,088	2,834
Foreign currency (gains)/losses ²	70	703	826
Change in fair value of derivative financial assets ³	(6,459)	—	—
Transaction costs ⁴	1,144	—	—
Effective interest expenses ⁵	—	—	1,355
Change in fair value of conversion feature ⁶	—	—	(4,542)
Adjusted income/(loss)	(74,115)	(57,130)	45,915
Earnings/(loss) per share – basic	(0.97)	(0.86)	0.64
Earnings/(loss) per share – diluted	(0.97)	(0.86)	0.64
Adjustment to earnings/(loss) per share – basic	(0.02)	0.07	0.01
Adjustment to earnings/(loss) per share – diluted	(0.02)	0.07	0.00
Adjusted earnings/(loss) per share – basic	(0.99)	(0.79)	0.65
Adjusted earnings/(loss) per share – diluted	(0.99)	(0.79)	0.64
Weighted-average number of shares used to compute adjusted loss per share – basic	74,951,833	71,900,212	70,603,611
Weighted-average number of shares used to compute adjusted loss per share – diluted	74,951,833	71,900,212	71,103,341

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 US Dollar and the Swiss Franc.

³ Reflects 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.

⁵Effective interest expense for the period relates to the accretion of the Company's convertible loan in accordance with the effective interest method.

⁶Change in fair value of conversion feature that is bifurcated from the convertible loan host debt with Lilly.

Adjustments for the years ended December 31, 2021, 2020 and 2019 increased net loss by CHF 1.1 million, decreased net loss by CHF 4.8 million and increased net income by CHF 0.5 million, respectively. The Company recorded share-based compensation expenses of CHF 4.1 million, CHF 4.1 million and CHF 2.8 million for the years ended December 31, 2021, 2020 and 2019, respectively. There were foreign currency re-measurement losses of CHF 0.1 million, CHF 0.7 million and CHF 0.8 million for the years ended December 31, 2021, 2020 and 2019, respectively, predominantly related to the cash balance of the Company as a result of fluctuations of the US Dollar against the Swiss Franc. The Company recognized a CHF 6.5 million gain on the change in fair value of the derivative financial assets associated with two convertible notes with Affiris affiliated entities in 2021. This gain did not arise in the comparable prior periods. The Company also incurred CHF 1.1 million in transaction costs associated with its acquisition of a portfolio of therapeutics targeting alpha-synuclein, which did not arise in the comparable prior periods. Finally, related to the Company's convertible note settled with Lilly in 2019, we recorded CHF 1.4 million for amortization of effective interest for the year ended December 31, 2019 and recognized a CHF 4.5

million gain for the change in fair value of the liability related to the conversion feature in 2019.
There were no comparable expenses or gains in 2021 nor 2020.