

AC Immune Reports First Quarter 2021 Financial Results and Provides Corporate Update

- Reported potent interim immunogenicity results for anti-pTau Alzheimer's vaccine in ongoing Phase 1b/2a study, which support further development into Phase 2/3
- Initiated first-in-human clinical study for next-generation alpha-synuclein PET diagnostic with results expected in Q3 2021
- Advanced multiple candidates targeting the NLRP3 inflammasome pathway for CNS and non-CNS indications
- Strong financial position of CHF 216.1 million in cash ensures the Company is fully financed through at least Q1 2024

Lausanne, Switzerland, April 28, 2021 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today reported its financial results for the quarter ended March 31, 2021. The Company also provided an overview of its recent clinical and corporate highlights and anticipated milestones for 2021.

Prof. Andrea Pfeifer, CEO of AC Immune SA, commented: “Our clinical and R&D accomplishments over the last quarter serve to strengthen our leadership in precision medicine for neurodegenerative diseases. Encouraging clinical results from both of our Alzheimer's vaccine programs further reinforce our belief that early intervention, and ultimately prevention, using vaccines represents a key strategy in neurodegenerative diseases. To enable this strategy, we are advancing our suite of novel diagnostics, such as our alpha-synuclein imaging agent, which recently entered the clinic in Parkinson's disease. Our vision is to address the heterogeneity of neurodegenerative diseases by pairing earlier, more accurate diagnosis with highly selective treatments that address the right proteinopathy, in the right patient, at the right time.”

Prof. Pfeifer continued: “We are poised to achieve four additional clinical readouts in 2021, as we continue progressing our first-in-class preclinical programs addressing alpha-synuclein, TDP-43, and NLRP3-ASC towards the clinic, driving significant future value creation.

Q1 2021 Highlights

Clinical and R&D

- Reported encouraging [top line results](#) from a first-of-its-kind Phase 1b study of anti-Abeta vaccine candidate ACI-24 in people with Down syndrome (DS). These results support further development in Down syndrome-related Alzheimer's disease (AD). AC Immune also reported promising preclinical results for an [optimized anti-Abeta vaccine](#) formulation, for which it expects to file an investigational new drug application (IND) in Q4 2021.
- Reported [promising interim Phase 1b/2a results](#) for ACI-35.030, a novel anti-phospho-Tau (pTau) vaccine candidate, showing strong safety and high titers of antigen-specific antibodies in 100% of older patients with early Alzheimer's disease. The study is currently

enrolling patients into the highest dose group, with further clinical readouts expected this year.

- Advanced next-generation alpha-synuclein positron emission tomography (PET) tracer candidate, ACI-12589, into a [first-in-human clinical study](#), with an expected data readout in Q3 2021
- Identified and characterized the first biologically active small molecule Morphomer™ [alpha-synuclein aggregation inhibitors](#), which significantly decreased alpha-synuclein aggregate formation in cellular assays by interfering with the fibrillation process
- Reported key advancements for several [therapeutic programs targeting the \(NOD\)-like receptor protein 3 \(NLRP3\) inflammasome](#), including small molecule inhibitors, which showed the first evidence of *in vivo* activity in a model of peripheral inflammation, as well as high-affinity monoclonal antibodies that bind extracellular components of the NLRP3 pathway and inhibit inflammasome-mediated immune response *in vitro*

Thought leadership

- Co-sponsored a virtual [Global Down Syndrome Forum](#) that brought together thought leaders on Down syndrome and Down syndrome-related Alzheimer's disease to discuss the unmet need and underlying causes of this important health challenge, as well as the broader implications for clinical development in other Alzheimer's disease populations.
- Hosted a [comprehensive webinar](#) focusing on the Company's proprietary Morphomer™ platform underlying the generation of therapeutic and diagnostic small molecules, which featured presentations and a Q&A session with members of AC Immune's Management and R&D Teams.

Strengthening of Board

- Welcomed [Dr. Alan Colowick](#), an experienced biotech and investment executive, to the Company's Board of Directors

Achieved and Anticipated 2021 milestones

Clinical Milestones

- ACI-35.030 anti-pTau vaccine: reported Phase 1b/2a in AD interim results in Q1 (second highest dose); further Phase 1b/2a interim analysis in Q4 (highest dose)
- JACI-35.054 alternative anti-pTau vaccine: Phase 1b/2a in AD interim analysis in Q2 (low dose)
- Alpha-synuclein PET imaging agent: advanced third-generation candidate to first-in-human clinical study in Q1; readout expected in Q3
- ACI-24 anti-Abeta vaccine in DS: reported Phase 1b top line results in Q1; to present further study results at the Alzheimer's Association International Conference® 2021 in Q3
- ACI-24 in AD: reported Phase 2, 12-month interim analysis in Q1; 18-month interim analysis in Q2

- Semorinemab anti-Tau antibody: Phase 2 trial primary completion (estimated last patient, last visit) in moderate AD in Q2
- ACI-3024 small molecule Morphomer™ Tau aggregation inhibitor: select NeuroOrphan indication for further development in Q2
- ACI-24 in DS: submit investigational new drug (IND) application for optimized vaccine formulation in Q4

Preclinical Milestones

- Alpha-synuclein small molecule inhibitor: identified first biologically active small molecule in Q1; start *in vivo* proof-of-concept studies in Q3
- TDP-43 imaging agent: initiate investigational new drug (IND)-enabling studies in Q3
- Morphomer™ NLRP3-ASC: report *in vivo* proof-of-concept results in a non-central nervous system (CNS) disease model and begin *in vivo* proof-of-concept studies with validated candidate in CNS in Q4
- Anti-NLRP3-ASC antibody: begin *in vivo* proof-of-concept studies in Q4
- Anti-TDP-43 antibody: initiate IND-enabling toxicology studies in Q4
- TDP-43 biofluid diagnostic: establish validation-ready assay in Q4

Therapeutic and Diagnostic Pipeline Overview

On March 23, 2021, the Company provided a comprehensive overview highlighting strong progress across its clinical and preclinical development pipeline. This [supplemental material](#) can be viewed and downloaded in the investor section of the Company's website.

Analysis of Financial Statements for the quarter ended March 31, 2021

- **Cash Position:** The Company had a total cash balance of CHF 216.1 million, composed of CHF 151.1 million in cash and cash equivalents and CHF 65 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 potential incoming milestone payments.
- **Contract Revenues:** The Company did not record contract revenues for the three months ended March 31, 2021, a decrease of CHF 12.3 million from the comparable period. The decrease is predominantly related to a CHF 10 million milestone payment as well as CHF 2.1 million in R&D activities recognized in 2020, which did not repeat.
- **R&D Expenditures:** R&D expenses decreased by CHF 1.9 million for the three months ended March 31, 2021 to CHF 13.3 million.
 - **Discovery and preclinical expenses (+1.2 million):** The Company increased expenditures across a variety of its discovery and preclinical programs. These include investments to advance the optimized formulation of our ACI-24 vaccine, the expansion of our Morphomer™ Tau program into NeuroOrphan indications and various other investments across our programs.

- **Clinical expenses (-4.1 million):** The Company decreased expenditures across multiple clinical programs, as certain clinical activities completed or incurred significant scaling up in the prior period. For example, the Company completed its clinical activities to complete the Phase 1 trial of our Morphomer™ Tau asset in partnership with Lilly. Additionally, the Company incurred less expense for ACI-24 for DS-related AD as a result of prior period scaling up activities for a Phase 2 clinical trial which were not repeated in the current period.
- **Salary- and benefit-related costs (+1.1 million):** The Company's salary- and benefit-related costs increased primarily due to the internal reallocation of certain employees' salaries and annualization of 2020 hires and increases in share-based compensation
- **G&A Expenditures:** For the three months ended March 31, 2021, G&A decreased by CHF 0.2 million to 4.3 million. This decrease is predominantly related to the internal reallocation of certain employees' salaries.
- **Other Operating Income:** The Company recognized CHF 0.4 million in grant income for R&D activities performed under our MJFF and Target ALS grants, an increase of CHF 0.3 million compared to the prior period
- **IFRS Loss for the Period:** The Company reported a net loss after taxes of CHF 16.7 million for the three months ended March 31, 2021, compared with net loss of CHF 7.7 million for the comparable period in 2020

2021 Financial Guidance

For the full year 2021, the Company expects its total cash burn to range between CHF 65 million – 75 million.

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 nine 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.

For further information, please contact:

Head of Investor Relations and Corporate Communications

Joshua Drumm, Ph.D.
AC Immune
Phone : +1 917 809 0814
Email: joshua.drumm@acimmune.com

U.S. Media

Katie Gallagher
LaVoie Health Science
Phone: +1 617 792 3937
Email: kgallagher@lavoiehealthscience.com

European Investors & Media
Chris Maggos
LifeSci Advisors
Phone : +41 79 367 6254
Email : chris@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.

Balance Sheets
(In CHF thousands)

	As of March 31, 2021	As of December 31, 2020
ASSETS		
Non-current assets		
Property, plant and equipment	4,896	4,416
Right-of-use assets	2,147	2,223
Long-term accrued income	93	—
Long-term financial assets	334	334
Total non-current assets	7,470	6,973
Current assets		
Prepaid expenses	3,330	3,954
Short-term accrued income	688	1,591
Other current receivables	379	329
Short-term financial assets	65,000	65,000
Cash and cash equivalents	151,092	160,893
Total current assets	220,489	231,767
Total assets	227,959	238,740
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	1,539	1,538
Share premium	354,736	346,890
Treasury shares	(85)	(100)
Accumulated losses	(148,774)	(132,850)
Total shareholders' equity	207,416	215,478
Non-current liabilities		
Long-term deferred income	93	—
Long-term lease liabilities	1,706	1,780
Net employee defined-benefit liabilities	7,619	7,464
Total non-current liabilities	9,418	9,244
Current liabilities		
Trade and other payables	370	2,184
Accrued expenses	9,734	11,085
Short-term deferred income	580	306
Short-term lease liabilities	441	443
Total current liabilities	11,125	14,018
Total liabilities	20,543	23,262
Total shareholders' equity and liabilities	227,959	238,740

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

	For the Three Months Ended March 31,	
	2021	2020
Revenue		
Contract revenue	—	12,281
Total revenue	<u>—</u>	<u>12,281</u>
Operating expenses		
Research & development expenses	(13,329)	(15,209)
General & administrative expenses	(4,338)	(4,504)
Other operating income/(expense)	416	130
Total operating expenses	<u>(17,251)</u>	<u>(19,583)</u>
Operating loss	<u>(17,251)</u>	<u>(7,302)</u>
Financial income	—	59
Financial expense	(26)	(57)
Exchange differences	543	(389)
Finance result, net	<u>517</u>	<u>(387)</u>
Loss before tax	<u>(16,734)</u>	<u>(7,689)</u>
Income tax expense	—	—
Loss for the period	<u>(16,734)</u>	<u>(7,689)</u>
Loss per share:		
Basic and diluted loss for the period attributable to equity holders	(0.23)	(0.11)

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

	For the Three Months Ended March 31,	
	2021	2020
Loss for the period	(16,734)	(7,689)
Other comprehensive loss not to be reclassified to income or loss in subsequent periods (net of tax):		
Re-measurement losses on defined-benefit plans (net of tax)	—	—
Total comprehensive loss, net of tax	<u>(16,734)</u>	<u>(7,689)</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 Three Months Ended March 31,	
	2021	2020
Loss	(16,734)	(7,689)
Adjustments		
Non-cash share-based payments ¹	857	852
Foreign currency (gains)/losses ²	(621)	454
Adjusted Loss	(16,498)	(6,383)
Loss per share – basic	(0.23)	(0.11)
Loss per share – diluted	(0.23)	(0.11)
Adjustment to loss per share – basic	0.00	0.02
Adjustment to loss per share – diluted	0.00	0.02
Adjusted loss per share – basic	(0.23)	(0.09)
Adjusted loss per share – diluted	(0.23)	(0.09)
Weighted-average number of shares outstanding Adjusted loss –basic	72,305,949	71,864,213
Weighted-average number of shares outstanding Adjusted loss –diluted	72,305,949	71,882,607

¹ Reflects 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.

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

Adjustments for the three months ended March 31, 2021 and March 31, 2020 decreased net loss by CHF 0.2 million and CHF 1.3 million, respectively. The Company recorded CHF 0.9 million for share-based compensation expenses, respectively. There were foreign currency re-measurement gains of CHF 0.6 million compared to foreign currency re-measurement losses of CHF 0.5 million, respectively, primarily related to a favorable movement in the USD-CHF exchange rate during the period as well as the non-repetition of a CHF 0.1 million loss on a forward contract.