

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

Announced strategic acquisition of industry-leading Parkinson's disease vaccine and equity investment led by key investors in Covid-19 vaccine innovator BioNTech SE

ACI-24 full Phase 1b results presented at AAIC 2021 support the continued clinical development of anti-Abeta vaccine approaches in Down syndrome-related Alzheimer's disease

Expanded Phase 1b/2 anti-pTau Alzheimer's vaccine trial in collaboration with Janssen Pharmaceuticals, Inc. to support the program's continued development

Strong financial position of CHF 199.1 million in cash ensures the Company is fully financed through at least Q1 2024

Lausanne, Switzerland, August 4, 2021 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision medicine for neurodegenerative diseases, today reported its financial results for the guarter ended June 30, 2021, and provided a corporate update.

Prof. Andrea Pfeifer, CEO of AC Immune SA, commented: "AC Immune continues its expansion with the transformative acquisition of PD01, which significantly strengthens our active vaccines portfolio by adding a clinically validated candidate in Parkinson's disease, whilst maintaining a strong financial position of CHF 199.1 million in cash. In Q1, the Company released positive data on the safety and immunogenicity of ACI-24 and ACI-35.030, our anti-Abeta and anti-Tau vaccines in Alzheimer's disease. We firmly believe that a vaccine approach coupled with the right diagnostic tools can bring an alternative therapeutic approach to prevent neurodegenerative diseases in large populations, like for Covid-19."

Q2 2021 and Subsequent Highlights

- Announced an all-stock acquisition of Affiris' portfolio of therapeutics targeting alphasynuclein notably PD01, a clinically validated active vaccine candidate that places AC Immune at the forefront of Parkinson's disease drug development. Through the planned acquisition and a concurrent financing, AC Immune will also strengthen its cash position and add Athos Service GmbH (Strüngmann family office), First Capital Partner GmbH (Egger Family Office), and MIG Fonds, the three lead investors in Covid-19 vaccine innovator BioNTech SE, to its shareholder base.
- Presented the full results from the landmark Phase 1b clinical trial evaluating the anti-Abeta vaccine ACI-24 in subjects with Down syndrome at the Alzheimer's Association International Conference (AAIC) 2021, showing that ACI-24 generated evidence of immunogenicity along with a positive pharmacodynamic response and a favorable safety and tolerability profile. Based on these results, the Company plans to advance an optimized

- formulation of ACI-24 into mid-stage clinical testing to treat and prevent the progression of Down syndrome (DS)-related Alzheimer's disease (AD).
- Provided <u>key clinical and preclinical updates</u> for its AD vaccine candidates targeting pathological amyloid beta (Abeta). The 18 months treatment and additional six-months safety observation is completed for all participants. The study is currently under analysis and AC Immune plans to present the results at an international Alzheimer conference. Non-human primate data further highlight the strong immunogenicity of our optimized ACI-24 formulation against pathological Abeta species, including oligomeric and pyroglutamate Abeta.
- Expanded the Phase 1b/2a trial evaluating the first-in-class anti-phosphorylated-Tau (pTau) vaccine candidate <u>ACI-35.030 for the treatment of AD</u> in collaboration with Janssen Pharmaceuticals, Inc. The trial expansion, which was based on <u>encouraging interim safety</u>, <u>tolerability and immunogenicity results</u> to date, specifically includes vaccination of additional AD patients at the second highest dose to support continued development of ACI-35.030.

Achieved and Anticipated 2021 milestones

Clinical Milestones

- ACI-35.030 anti-pTau vaccine: reported Phase 1b/2a interim results in AD patients in Q1 (second highest dose); further Phase 1b/2a interim analysis in Q4 (highest dose)
- JACI-35.054 alternative anti-pTau vaccine: reported a Phase 1b/2a interim analysis in AD patients 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 topline results in Q1
- ACI-24 in AD: reported Phase 2, 12-month interim analysis in Q1; reported 18-month interim analysis in Q2
- Semorinemab anti-Tau antibody: Phase 2 trial primary completion (estimated last patient, last visit) in moderate AD in Q3
- ACI-3024 small molecule Morphomer[®] Tau aggregation inhibitor: select NeuroOrphan indication for further development in H2
- 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

Analysis of Financial Statements for the quarter ended June 30, 2021

- Cash Position: The Company had a total cash balance of CHF 199.1 million, composed of CHF 104.1 million in cash and cash equivalents and CHF 95.0 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 three months ended June 30, 2021, a decrease of CHF 1.1 million from the comparable period. The overall decrease is predominantly related to CHF 0.9 million of contract revenue 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 0.9 million for the three months ended June 30, 2021, to CHF 13.7 million.
 - O Discovery and preclinical expenses (+0.8 million): The Company increased expenditures across a variety of its discovery and preclinical programs. These include investments for the development of our anti-TDP-43 antibody with the initiation of IND-enabling studies, the expansion of our Morphomer® Tau program into NeuroOrphan indications and various other investments across our programs.
 - Clinical expenses (-0.6 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 of 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 (+0.4 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 June 30, 2021, G&A increased by CHF 1.1 million to 5.2 million. This increase is predominantly related transaction costs incurred in completing the asset acquisition for Affiris' alpha-synuclein portfolio and cash, the internal reallocation of certain employees' salaries and other administrative items.

- Other Operating Income: The Company recognized CHF 0.3 million in grant income for R&D activities performed under our Michael J. Fox Foundation for Parkinson's Research (MJFF) and Target ALS grants, 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 19.1 million for the three months ended June 30, 2021, compared with a net loss of CHF 15.8 million for the comparable period in 2020.

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.

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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. 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 June 30, 2021	As of December 31, 2020
ASSETS		
Non-current assets		
Property, plant and equipment	5,165	4,416
Right-of-use assets	2,699	2,223
Long-term accrued income	61	_
Long-term financial assets	363	334
Total non-current assets	8,288	6,973
Current assets		
Prepaid expenses	2,726	3,954
Short-term accrued income	659	1,591
Other current receivables	282	329
Short-term financial assets	95,000	65,000
Cash and cash equivalents	104,135	160,893
Total current assets	202,802	231,767
Total assets	211,090	238,740
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	1,539	1,538
Share premium	354,899	346,890
Treasury shares	(85)	(100)
Accumulated losses	(167,071)	(132,850)
Total shareholders' equity	189,282	215,478
Non-current liabilities		
Long-term deferred income	61	<u></u>
Long-term lease liabilities	2,126	1,780
Net employee defined-benefit liabilities	7,774	7,464
Total non-current liabilities	9,961	9,244
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Current liabilities		
Trade and other payables	317	2,184
Accrued expenses	10,611	11,085
Short-term deferred income	348	306
Short-term lease liabilities	571	443
Total current liabilities	11,847	14,018
Total liabilities	21,808	23,262
Total shareholders' equity and liabilities	211,090	238,740

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

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		For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020	
Revenue					
Contract revenue		1,083	_	13,365	
Total revenue	_	1,083	_	13,365	
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Operating expenses					
Research & development expenses	(13,710)	(12,809)	(27,040)	(28,018)	
General & administrative expenses	(5,235)	(4,156)	(9,573)	(8,660)	
Other operating income/(expense)	256	195	673	324	
Total operating expenses	(18,689)	(16,770)	(35,940)	(36,354)	
Operating loss	(18,689)	(15,687)	(35,940)	(22,989)	
Financial income	_	17		78	
Financial expense	(202)	(56)	(228)	(113)	
Exchange differences	(178)	(12)	365	(401)	
Finance result, net	(380)	(51)	137	(436)	
Loss before tax	(19,069)	(15,738)	(35,803)	(23,425)	
Income tax expense	_	_	_		
Loss for the period	(19,069)	(15,738)	(35,803)	(23,425)	
Loss per share:	(0.26)	(0.22)	(0.50)	(0.33)	
Basic and diluted loss for the period	70 715 700	71 075 100	70 440 504		
attributable to equity holders	12,110,100	71,875,102	12,113,581	71,869,658	
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Statements of Comprehensive Income/(Loss	5)				

(In CHF thousands)

(III CHE tilousalius)	For the Thre Ended Ju 2021			Six Months June 30, 2020
Loss for the period Other comprehensive loss not to be reclassified to income or loss in subsequent periods (net of tax):	(19,069)	(15,738)	(35,803)	(23,425)
Re-measurement losses on defined-benefit plans (net of tax)	_	_	_	_
Total comprehensive loss, net of tax	(19,069)	(15,738)	(35,803)	(23,425)

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
In CHF thousands, except for share and per share data	2021	2020	2021	2020
Loss	(19,069)	(15,738)	(35,803)	(23,425)
Adjustments				
Non-cash share-based payments ¹	836	995	1,694	1,847
Foreign currency (gains)/losses ²	258	43	(363)	498
Transaction costs ³	410	-	410	_
Adjusted Loss	(17,565)	(14,700)	(34,062)	(21,080)
Loss per share – basic and diluted	(0.26)	(0.22)	(0.50)	(0.33)
Adjustment to loss per share – basic and diluted	0.02	0.02	0.03	0.04
Adjusted loss per share – basic and diluted	(0.24)	(0.20)	(0.47)	(0.29)
Weighted-average number of shares outstanding Adjusted loss –basic and diluted	72,715,783	71,875,102	72,113,581	71,869,658

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.

Adjustments for the three and six months ended June 30, 2021, decreased net loss by CHF 1.5 million and CHF 1.7 million, respectively compared with a decrease to net loss of CHF 1.0 million and CHF 2.3 million for the comparable periods in 2020, respectively. The Company recorded CHF 0.8 million and CHF 1.7 million for share-based compensation expenses, respectively, in each of these periods. There were foreign currency re-measurement losses of CHF 0.3 million and gains of CHF 0.4 million, respectively, primarily related to movement in the USD-CHF exchange rate during the respective periods. Finally, the Company incurred CHF 0.4 million in transaction costs associated with its acquisition of a portfolio of therapeutics targeting alpha-synuclein in the three months ended June 30, 2021.

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.

³ Reflects transaction costs for the asset acquisition for a portfolio of therapeutics targeting alphasynuclein and cash.