

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

Announced the first positive cognitive results for a Tau-targeting monoclonal antibody in mild-to-moderate Alzheimer's disease

Closed its strategic acquisition of an industry-leading Parkinson's disease vaccine and an equity financing led by key investors

Appointed Monica Shaw, M.D., and Prof. Monika Bütler, Dr. Oec., to the Board of Directors

Strong financial position of CHF 188.6 million¹ ensures the Company is fully financed through at least Q1 2024

Lausanne, Switzerland, November 8, 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 September 30, 2021 and provided a corporate update.

Prof. Andrea Pfeifer, CEO of AC Immune SA, commented: “AC Immune concluded an exceptional third quarter, highlighted by the acquisition of a clinical α -syn vaccine candidate in Parkinson's disease and topline Phase 2 Lauriet data showing that semorinemab was the first Tau antibody candidate to significantly slow cognitive decline in mild-to-moderate Alzheimer's disease patients. Our partner Genentech, a member of the Roche Group, will present the topline Lauriet data, later this week at the CTAD 2021 conference, where we will present new clinical data on our p-Tau and Abeta vaccine candidates, ACI-35 and ACI-24, respectively. These achievements show the commitment, progress and breadth of our leadership in discovering and developing impactful therapeutics for neurodegenerative diseases.”

Q3 2021 and Subsequent Highlights

- Announced the first [positive cognitive results for a Tau-targeting monoclonal antibody](#) in Alzheimer's disease (AD). Topline data from the Lauriet Phase 2 trial of semorinemab in mild-to-moderate AD showed a statistically significant ($p < 0.0025$) 43.6% reduction at week 49 in cognitive decline vs. placebo as measured by ADAS-Cog11, one of the trial's co-primary endpoints. The second co-primary endpoint, ADCS-ADL, was not met. AC Immune's partner Genentech is continuing with the trial's open label extension and is

¹ Total cash position does not include total gross proceeds of USD 30 million received in October 2021 from (i) USD 5 million as part of the Affiris asset acquisition and (ii) USD 25 million as part of a private placement with select group of Affiris investors.

scheduled to present the topline data from the Lauriet study at the CTAD (Clinical Trials on Alzheimer's Disease) conference on November 10, 2021, at 10:50am EST.

- Completed [an all-stock acquisition of Affiris' portfolio of therapeutics targeting alpha-synuclein](#), notably PD01/ACI-7104, a clinically validated active vaccine candidate that places AC Immune at the forefront of Parkinson's disease drug development. Through this acquisition and a concurrent financing, AC Immune has also strengthened its cash position and added Athos Service GmbH (Strüngmann family office), First Capital Partner GmbH (Egger Family Office), and MIG Fonds to its shareholder base.
- Presented [the full results](#) from the landmark Phase 1b clinical trial evaluating the wholly-owned anti-Abeta vaccine ACI-24 in subjects with Down syndrome (DS) at the Alzheimer's Association International Conference (AAIC) 2021. Data showed that ACI-24 generated 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 DS-related AD.
- Extended the Company's [research partnership](#) with leading scientists at the Center for Neurodegenerative Disease Research at the Perelman School of Medicine at the University of Pennsylvania (Penn). The goal of the collaboration is to further understand the role of distinct pathogenic TDP-43 species in the different TDP-43 proteinopathies. Through the development of novel experimental models, AC Immune and Penn hope to unravel the underlying mechanisms of cell-to-cell transmission of TDP-43 pathology that could provide new therapeutic strategies to target TDP-43-related proteinopathies.
- Welcomed [pharmaceutical industry expert Monica Shaw, M.D., and leading Swiss economist Prof. Monika Bütler, Dr. Oec.](#), to the Company's Board of Directors.
- Announced that the Swiss Economic Forum (SEF) awarded AC Immune Co-Founder and [CEO Prof. Andrea Pfeifer with the SEF Women Award 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.

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; data to be presented at upcoming scientific meeting
- 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; reporting full data set at CTAD in November 2021
- Semorinemab anti-Tau antibody partnered with Genentech: topline results reported in Q3

- Small molecule Morphomer® Tau aggregation inhibitor program: 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 Q4
- 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 central nervous system 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 September 30, 2021

- **Cash Position:** The Company had a total cash balance of CHF 188.6 million, composed of CHF 93.6 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 September 30, 2021, a decrease of CHF 1.1 million from the comparable period in 2020. The overall decrease is predominantly related to CHF 1.1 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 decreased by CHF 0.4 million for the three months ended September 30, 2021, to CHF 15.1 million.
 - **Discovery and preclinical expenses (-1.7 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 (+0.6 million):** The Company increased expenditures across multiple clinical programs, predominantly for ACI-35-030 driven by R&D cost sharing and increased patient enrollments into the Phase 1b/2a study. This increase was offset as the Company incurred less expense for ACI-24 for AD as the prior six-month safety period completed.
 - **Salary- and benefit-related costs (+0.5 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 three months ended September 30, 2021, G&A increased by CHF 0.5 million to CHF 5.4 million. This increase is predominantly related to transaction costs incurred to complete the asset acquisition for Affiris' alpha-synuclein portfolio as well as 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, a decrease of CHF 0.2 million compared to the prior period.
- **IFRS Loss for the Period:** The Company reported a net loss after taxes of CHF 15.9 million for the three months ended September 30, 2021, compared with a net loss of CHF 19.0 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.

For further information, please contact:

Media Relations

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

U.S. Media

Shani Lewis
LaVoie Health Science
Phone: +1 609 516 5761
Email: slewis@lavoiehealthscience.com

Investor Relations

Yves Kremer, Ph.D.
AC Immune
Phone: +41 21 345 91 90
Email: yves.kremer@acimmune.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.

Balance Sheets
(In CHF thousands)

	As of September 30, 2021	As of December 31, 2020
ASSETS		
Non-current assets		
Property, plant and equipment	5,054	4,416
Right-of-use assets	2,572	2,223
Long-term accrued income	31	—
Long-term financial assets	363	334
Total non-current assets	8,020	6,973
Current assets		
Prepaid expenses	1,935	3,954
Short-term accrued income	92	1,591
Other current receivables	341	329
Derivative financial assets	4,424	—
Short-term financial assets	95,000	65,000
Cash and cash equivalents	93,584	160,893
Total current assets	195,376	231,767
Total assets	203,396	238,740
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	1,589	1,538
Share premium	359,421	346,890
Treasury shares	(124)	(100)
Accumulated losses	(181,665)	(132,850)
Total shareholders' equity	179,221	215,478
Non-current liabilities		
Long-term deferred income	31	—
Long-term lease liabilities	1,992	1,780
Net employee defined-benefit liabilities	7,929	7,464
Total non-current liabilities	9,952	9,244
Current liabilities		
Trade and other payables	215	2,184
Accrued expenses	13,308	11,085
Short-term deferred income	123	306
Short-term lease liabilities	577	443
Total current liabilities	14,223	14,018
Total liabilities	24,175	23,262
Total shareholders' equity and liabilities	203,396	238,740

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue				
Contract revenue	—	1,123	—	14,487
Total revenue	—	1,123	—	14,487
Operating expenses				
Research & development expenses	(15,118)	(15,518)	(42,158)	(43,536)
General & administrative expenses	(5,420)	(4,892)	(14,993)	(13,553)
Other operating income/(expense)	255	482	928	807
Total operating expenses	(20,283)	(19,928)	(56,223)	(56,282)
Operating loss	(20,283)	(18,805)	(56,223)	(41,795)
Financial income	4,424	—	4,424	78
Financial expense	(181)	(46)	(408)	(159)
Exchange differences	122	(143)	487	(545)
Finance result, net	4,365	(189)	4,503	(626)
Loss before tax	(15,918)	(18,994)	(51,720)	(42,421)
Income tax expense	—	—	—	—
Loss for the period	(15,918)	(18,994)	(51,720)	(42,421)
Loss per share:	(0.22)	(0.26)	(0.71)	(0.59)
Basic and diluted loss for the period attributable to equity holders	72,887,967	71,925,009	72,638,698	71,888,273

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Loss for the period	(15,918)	(18,994)	(51,720)	(42,421)
Other comprehensive loss that may be reclassified to income or loss in subsequent periods (net of tax):				
Currency translation differences	—	—	—	—
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	(15,918)	(18,994)	(51,720)	(42,421)

**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 September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Loss	(15,918)	(18,994)	(51,720)	(42,421)
Adjustments				
Non-cash share-based payments ¹	1,388	1,233	3,081	3,079
Foreign currency (gains)/losses ²	(117)	187	(481)	686
Change in fair value of derivative financial assets ³	(4,424)	—	(4,424)	—
Transaction costs ⁴	335	—	745	—
Adjusted Loss	(18,736)	(17,574)	(52,799)	(38,656)
Loss per share – basic and diluted	(0.22)	(0.26)	(0.71)	(0.59)
Adjustment to loss per share – basic and diluted	(0.04)	0.02	(0.02)	0.05
Adjusted loss per share – basic and diluted	(0.26)	(0.24)	(0.73)	(0.54)
Weighted-average number of shares outstanding	72,887,967	71,925,009	72,638,698	71,888,273

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.

³ Reflects the change in the fair value of the derivative financial instruments associated with the convertible notes due to Investors.

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

Adjustments for the three and nine months ended September 30, 2021, increased net loss by CHF 2.8 million and CHF 1.1 million, respectively compared with a decrease to net loss of CHF 1.4 million and CHF 3.8 million for the comparable periods in 2020, respectively. The Company recorded CHF 1.4 million and CHF 3.1 million for share-based compensation expenses, respectively, in each of these periods. There were foreign currency re-measurement gains of CHF 0.1 million and CHF 0.5 million, respectively, primarily related to movement in the USD-CHF exchange rate during the respective periods. The Company also recognized a CHF 4.4 million gain on the change in fair value of the derivative financial assets associated with the convertible notes. This gain did not arise in the comparable prior periods. Finally, the Company incurred CHF 0.3 and CHF 0.7 million in transaction costs associated with its acquisition of a portfolio of therapeutics targeting alpha-synuclein in the three and nine months ended September 30, 2021.