

AC Immune Reports Q3 2020 Financial Results and Provides Business Update

- Phase 1 trial completed in Lilly Morphomer™ Tau partnership program with plans to evaluate candidates in Alzheimer's disease and NeuroOrphan indications
- First-in-class TDP-43 therapeutic and diagnostic programs advance as the target's role in a newly defined form of age-related dementia, limbic-predominant age-related TDP-43 encephalopathy (LATE), gains prominence, with a highly competitive grant awarded
- All clinical and preclinical programs remain on track to meet all milestones expected in 2020
- CHF 246.6 million in cash ensures operations are fully financed through Q1 2024

Lausanne, Switzerland, November 13, 2020 – AC Immune SA (NASDAQ: ACIU), a Swiss-based, clinical-stage biopharmaceutical company with a broad pipeline focused on neurodegenerative diseases, today announced financial results for Q3 2020 and provided a business update. The Company ended the third quarter with CHF 246.6 million in cash, which ensures operations are fully financed through Q1 2024 allowing the Company to advance our clinical and preclinical projects to key value inflection points while investing further in our diverse pipeline.

Prof. Andrea Pfeifer, CEO of AC Immune SA, commented: “AC Immune continued to advance its world-leading pipeline in Q3 2020, underpinned by our proprietary discovery platforms SupraAntigen™ and Morphomer™ and solid financial position. Our proven business model of early development and partnering of validated therapeutic and diagnostic candidates has made us a global leader in precision medicine for neurodegenerative diseases. All clinical and preclinical milestones expected this year remain on track with key data across our Alzheimer's disease (AD) vaccines, alpha-synuclein and NLRP3-ASC inflammasome programs this year – with the latter becoming a focus for neurodegenerative diseases and non-CNS applications. Together these milestones highlight progress in our late stage clinical programs and focus in NeuroOrphan indications with multiple near and mid-term catalysts.”

The strength of the Company's diversified approach continues to be demonstrated with the announcement today that the Phase 1 study of the small molecule Morphomer™ Tau aggregation inhibitor, ACI-3024 in healthy young, elderly and Japanese volunteers, has been completed. In the study, which was conducted in partnership with Eli Lilly and Company, single and multiple dosing with the Morphomer™ Tau ACI-3024 resulted in a dose-dependent exposure and brain penetration by achieving the desired levels of ACI-3024 in the cerebrospinal fluid. The program will be expanded to NeuroOrphan indications and ACI-3024 will be further evaluated for efficacy in models of rare Tauopathies. Continued candidate characterization across the research program has also identified new and highly differentiated candidates with excellent cerebrospinal fluid exposure and selectivity for pathological aggregated Tau. These will be broadly developed in Tau-dependent neurodegenerative diseases.

Prof. Pfeifer commented: “The pharmacokinetic observations from the Phase 1 trial in our Lilly Morphomer™ Tau partnership program show the first evidence of a Morphomer™ Tau entity meeting the target CNS concentration in humans. Compared to other Tau-targeting molecules in development, the key potential differentiating factor is that our Morphomer™ Tau molecules have been shown to act intracellularly to address Tau pathology, potentially saving affected neurons that otherwise might die. Our Morphomer™ Tau program is the most advanced orally available small molecule therapeutic candidate of its kind in development.”

Q3 2020 Research & Development Updates and Highlights:

- [The next phase of the strategic partnership](#) between AC Immune and WuXi was unveiled with plans to accelerate advancement of AC Immune’s TDP-43 antibody into clinical development. A particular focus is developing the clinical antibody candidate to ensure it has high-affinity for TDP-43 and is capable of preventing the intercellular spread of toxic species. With no disease modifying therapies currently available that target TDP-43 there is significant unmet need and market potential
- [A highly competitive European Union grant was awarded](#) to support the partnership between AC Immune and the EU Joint Programme – Neurodegenerative Disease Research (JPND) ImageTDP-43 consortium to accelerate development of the Company’s first-in-class TDP-43 positron emission tomography (PET) tracer. Advancement of the tracer may enable the development of precision medicine approaches for the large and growing proportion of patients with TDP-43-related pathologies, such as patients with LATE and AD
- [Top line results from a Phase 2 trial of the anti-Tau antibody](#) in early (prodromal to mild) AD showed that semorinemab did not meet the co-primary efficacy endpoint or two secondary endpoints in the Tauriel study; the primary safety endpoint was met. Additional data presented at the CTAD 2020 Alzheimer Congress by our partner, Genentech, a member of the Roche group, confirm that semorinemab did not slow clinical progression or Tau accumulation relative to placebo with any of the three different doses tested. Dose-dependent increases were seen in serum pharmacokinetics and there was clear and consistent evidence of plasma target engagement. Preliminary analysis continues to suggest that semorinemab has an acceptable and well-tolerated safety profile. A second Phase 2 (Lauriet) study of semorinemab in patients with moderate AD remains ongoing
- [Initiation of investigational new drug \(IND\)-enabling studies](#) for AC Immune’s first-in-class therapeutic antibody targeting TDP-43. The anti-TDP-43 antibody is the first therapeutic candidate shown to mitigate TDP-43 neuropathology *in vivo* and the Company plans to develop the antibody for the treatment of NeuroOrphan indications. Effectively slowing or stopping the spread of TDP-43 pathology throughout the brain could provide the first antibody-based TDP-43 targeted therapeutic approach for treating conditions such as LATE, amyotrophic lateral sclerosis (ALS) and frontotemporal lobar degeneration with TDP-43 pathology, representing 50 per cent of all FTL cases.

Update on Covid-19

AC Immune remains in continuous contact with its partners and other important stakeholders, including the Swiss government, trial investigators and contractors, and at this stage the Company is not modifying guidance with respect to the multiple clinical and preclinical data readouts anticipated this year. AC Immune will continue to keep the market apprised of any new developments or information that may impact clinical timelines.

Analysis of Financial Statements for the Three and Nine Months Ended September 30, 2020

- **Revenues:** Revenues for the three and nine months ended September 30, 2020 totaled CHF 1.1 million and CHF 14.5 million, respectively. This represents a decrease of CHF 32.1 million and CHF 95.1 million over the comparable periods in 2019. The decrease for the three months ended September 30, 2020 relates to the prior recognition of CHF 30 million for the first installment of the first milestone achieved with Lilly and CHF 2.2 million for the initiation of a Phase 2 trial of Tau PET tracer with Life Molecular Imaging that did not repeat in the current quarter. The decrease for the nine months ended September 30, 2020 predominantly relates to CHF 104.5 million recognized in the prior period associated with our license agreement with Lilly offset by a recognition of a CHF 10 million milestone payment and CHF 4.1 million for research and development activities performed in the current period
- **R&D Expenditures:** For the three and nine months ended September 30, 2020, R&D expenses increased by CHF 4.0 million (+35.2%) and CHF 7.8 million (+21.7%) to CHF 15.5 million and CHF 43.5 million, respectively. For R&D expenses directly allocated to R&D programs, the Company increased investments in its non-AD programs predominantly led by increases in ACI-24 in Down syndrome related to scaling up activities for a Phase 2 clinical study, investments to advance our alpha-synuclein projects and the development of our anti-TDP-43 antibody with the initiation of IND-enabling studies. For AD, the Company's expenditures for ACI-24 in AD decreased due to completing the manufacturing process development. The Company also spent less for ACI-35 in the current period related to toxicology and manufacturing costs for clinical trial material in the prior period that did not repeat in the current period
Additionally, personnel costs in R&D increased by CHF 0.6 million and CHF 2.0 million for the three and nine months ended September 30, 2020, respectively driven by an increase of 11 FTEs during the year. The remaining increases of CHF 0.9 million and CHF 1.8 million relate to an increase in regulatory and quality assurance, intellectual property and other unallocated research and development costs
- **G&A Expenses:** For the three and nine months ended September 30, 2020, G&A expenses increased CHF 0.9 million (+23.7%) and CHF 2.7 million (+25.1%) to CHF 4.9 million and CHF 13.6 million, respectively. Increases were driven by an addition of 4 FTEs as well as an increase in professional services and depreciation expenses.
- **IFRS (Loss)/Income for the period:** The Company incurred a net loss after taxes of CHF 19.0 million and CHF 42.4 million for the three and nine months ended September 30, 2020, respectively, compared with net income of CHF 18.2 million and CHF 64.9 million for the comparable periods in 2019, predominantly related to the variance in revenues and operating expenses discussed above

- **Cash Position:** The Company had a total cash balance of CHF 246.6 million, comprised of CHF 176.6 million in cash and cash equivalents and CHF 70 million in short-term financial assets. This compares to a total cash balance of CHF 288.6 million as of December 31, 2019. This decrease of CHF 42 million is principally due to the factors noted above in the income statement which resulted in a CHF 42.4 million net loss for the period and changes in our working capital. Further details are available in our Statements of Cash Flows on the accompanying Form 6-K

About AC Immune SA

AC Immune SA is a Nasdaq-listed clinical-stage biopharmaceutical company, which aims to become a global leader in precision medicine for neurodegenerative diseases. The Company utilizes two proprietary platforms, SupraAntigen™ and Morphomer™, to design, discover and develop small molecule and biological therapeutics as well as diagnostic products intended to diagnose, prevent and modify neurodegenerative diseases caused by misfolding proteins. The Company's pipeline features nine therapeutic and three diagnostic product candidates, with six currently in clinical trials. It has collaborations with major pharmaceutical companies including Genentech, a member of the Roche group, Eli Lilly and Company, and Janssen Pharmaceuticals.

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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 September 30, 2020	As of December 31, 2019
ASSETS		
Non-current assets		
Property, plant and equipment	3,785	3,917
Right-of-use assets	1,932	2,255
Long-term financial assets	304	304
Total non-current assets	6,021	6,476
Current assets		
Prepaid expenses	2,764	2,788
Accrued income	944	1,095
Other current receivables	314	304
Short-term financial assets	70,000	95,000
Cash and cash equivalents	176,567	193,587
Total current assets	250,589	292,774
Total assets	256,610	299,250
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	1,539	1,437
Share premium	346,842	346,526
Treasury shares	(100)	—
Accumulated losses	(115,038)	(75,521)
Total shareholders' equity	233,243	272,442
Non-current liabilities		
Long-term lease liabilities	1,491	1,813
Net employee defined benefit liabilities	8,029	7,485
Total non-current liabilities	9,520	9,298
Current liabilities		
Trade and other payables	1,020	142
Accrued expenses	10,996	11,797
Short-term deferred income	1,080	4,477
Short-term financing obligation	310	652
Short-term lease liabilities	441	442
Total current liabilities	13,847	17,510
Total liabilities	23,367	26,808
Total shareholders' equity and liabilities	256,610	299,250

Statements of Income/(Loss)
(in CHF thousands except per share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue				
Contract revenue	1,123	33,208	14,487	109,596
Total revenue	1,123	33,208	14,487	109,596
Operating expenses				
Research & development expenses	(15,518)	(11,478)	(43,536)	(35,770)
General & administrative expenses	(4,892)	(3,956)	(13,553)	(10,835)
Other operating income/(expenses)	482	203	807	368
Total operating expenses	(19,928)	(15,231)	(56,282)	(46,237)
Operating income/(loss)	(18,805)	17,977	(41,795)	63,359
Finance expense, net	(146)	249	(552)	(1,564)
Change in fair value of conversion feature	—	—	—	4,542
Interest income	—	73	78	237
Interest expense	(43)	(86)	(152)	(1,686)
Finance result, net	(189)	236	(626)	1,529
Income/(loss) before tax	(18,994)	18,213	(42,421)	64,888
Income tax expense	—	—	—	—
Income/(loss) for the period	(18,994)	18,213	(42,421)	64,888
Earnings/(loss) per share (EPS):				
Basic income/(loss) for the period attributable to equity holders	(0.26)	0.25	(0.59)	0.92
Diluted income/(loss) for the period attributable to equity holders	(0.26)	0.25	(0.59)	0.92

Statements of Comprehensive Income/(Loss) (in CHF thousands)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Income/(loss) for the period	(18,994)	18,213	(42,421)	64,888
Other comprehensive income/(loss) not to be reclassified to income or loss in subsequent periods (net of tax):				
Re-measurement losses on defined benefit plans	—	—	—	—
Total comprehensive income/(loss), net of tax	(18,994)	18,213	(42,421)	64,888

**Reconciliation of Income/(Loss) to Adjusted Income/(Loss) and
Earnings/(Loss) Per Share to Adjusted Earnings/(Loss) Per Share**

	For the Three Months Ended September 30		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in CHF thousands except for share and per share data)			
Income/(Loss)	(18,994)	18,213	(42,421)	64,888
Adjustments:				
Non-cash share-based payments (a)	1,233	882	3,079	2,027
Foreign currency losses (b)	187	(272)	686	286
Effective interest expense (c)	—	—	—	1,355
Change in fair value of conversion feature (d)	—	—	—	(4,542)
Adjusted Income/(Loss)	(17,574)	18,823	(38,656)	64,014
Earnings/(Loss) per share – basic	(0.26)	0.25	(0.59)	0.92
Earnings/(Loss) per share – diluted	(0.26)	0.25	(0.59)	0.92
Adjustment to earnings/(loss) per share – basic	0.02	0.01	0.05	(0.01)
Adjustment to earnings/(loss) per share – diluted	0.02	0.01	0.05	(0.01)
Adjusted earnings/(loss) per share – basic	(0.24)	0.26	(0.54)	0.91
Adjusted earnings/(loss) per share – diluted	(0.24)	0.26	(0.54)	0.91
Weighted-average number of shares outstanding				
Adjusted earnings/(loss)–basic	71,925,009	71,822,884	71,888,273	70,184,257
Weighted-average number of shares outstanding				
Adjusted earnings/(loss)–diluted	71,925,009	72,281,264	71,888,273	70,700,690

- (a) 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.
- (b) Reflects foreign currency remeasurement gains and losses for the period, predominantly impacted by the change in the exchange rate between the US Dollar and the Swiss Franc.
- (c) Effective interest expense for the period relates to the accretion of the Company's convertible loan in accordance with the effective interest method.
- (d) Change in fair value of conversion feature that is bifurcated from the convertible loan host debt with Lilly.

Adjustments for the three and nine months ended September 30, 2020, were CHF 1.4 million and CHF 3.8 million decreases in net losses compared with an increase to net income and a decrease to net income of CHF 0.6 million and CHF 0.9 million for the comparable periods in 2019, respectively. The Company recorded CHF 1.2 million and CHF 3.1 million for the three and nine months, respectively, for share-based compensation expenses. There were foreign currency remeasurement losses of less than CHF 0.2 million and CHF 0.7 million, respectively, predominantly related to the movement in our forward contract settled in Q2 2020. For the three months ended September 30, 2019, the Company recorded CHF 0.9 million for share-based compensation expenses. For the nine months ended September 30, 2019, the Company recorded CHF 2.0 million for share-based compensation expense. Additionally, the Company recorded CHF 1.4 million for amortization of effective interest and a CHF 4.5 million gain for the change in fair value of the liability related to the conversion feature for the nine months ended September 30, 2019. These were not repeated in the current period.