



AC Immune Reports Full-Year 2018 Financial Results and Provides Business Update

March 21, 2019

CHF 300 million cash position as of Q1 2019 funds operations through Q3 2023

Eli Lilly deal validates Morphomer™ platform

Initiation of second Phase 2 trial of Tau antibody by partner Genentech

Multiple other products progressing, key appointments made to executive team

LAUSANNE, Switzerland, March 21, 2019 (GLOBE NEWSWIRE) -- AC Immune SA (NASDAQ: ACIU), a Swiss-based, clinical-stage biopharmaceutical company with a broad pipeline focused on pioneering precision medicine in neuro-degenerative diseases, today announced financial results for the year ended December 31, 2018, and provided a business and clinical update detailing its corporate progress and anticipated milestones.

Prof. Andrea Pfeifer, Ph.D., CEO of AC Immune, commented: “Our two proprietary discovery platforms, SupraAntigen™ and Morphomer™, have generated multiple product-candidates utilizing different approaches to treating neuro-degenerative diseases. We are advancing five of these through various stages of clinical testing and expect multiple developments in 2019, including data on ACI-24 in Down syndrome and the initiation of a Phase 1 trial of Tau Morphomer™ as we advance our new partnership with Eli Lilly.”

“Our partnerships with the global leaders in neuro-degeneration are a testament to our approach and already have generated CHF 292 million in funds, not including potential future milestones and royalties. We are particularly pleased with the recent validation of the small molecule Morphomer discovery platform by Lilly, which licensed rights to Tau Morphomer in December in one of the biggest deals ever for such an early-stage asset. Our cash position, approximately CHF 300 million as of Q1 2019, funds the company through Q3 2023, allowing us to continue and accelerate implementation of our strategy.”

Anticipated 2019 Research & Development Outlook

AC Immune’s external collaborations and broad, [robust pipeline to treat neuro-degenerative diseases](#) are driven by its proprietary technology platforms, which are fueling sustained growth. Successful delivery of external and internal research & development strategies are expected to produce multiple near-term catalysts in FY 2019-2020.

Data read-outs	<ul style="list-style-type: none"> ■ ACI-24 Phase 1b in Down syndrome interim data in 2019 (low dose cohort) and H1 2019 (high dose cohort); potential decision to start Phase 2 ahead of plan ■ a-synuclein antibodies lead selection in 2019 ■ TDP-43 antibodies lead selection in 2019 ■ Anti-Tau antibody phase 2 read-out in 2020
Study initiations	<ul style="list-style-type: none"> ■ Tau-PET tracer longitudinal study, Phase 2 in 2018 ■ Second generation a-synuclein-PET tracer start of first-in-human trial in Q1 2019 ■ Morphomer Tau Phase 1 expected start in Q2 2019 by Lilly ■ ACI-35 to start Phase 2 testing in H1 19

2019 Financial Guidance

For the full year 2019, the company expects total operating expenses to range between CHF 65–80 million, up from CHF 56.8 million in 2018.

Financial Highlights 2018

- Enhanced cash position projected to be approximately CHF 300 million as of Q1 2019, following receipt of CHF 80 million upfront payment and USD 50 million convertible note as a result of license agreement with Lilly in December 2018. The Company’s cash position as of December 31, 2018 totaled CHF 186.5 million.
- Completed follow-on offering of 10 million common shares in Q3 2018 which raised gross proceeds of USD 117.5 million (CHF 116.3 million).
- Strategic R&D expenditures increased by CHF 11.6 million (+36%) supporting an ongoing ramp-up in R&D activities, primarily driven by investments in our AD and discovery programs as well as advancements in our proprietary and partnered key vaccine programs, most notably ACI-24.
- Addition of 19 FTE’s in R&D (+29%).
- IFRS net operating loss of CHF 50.9 million and Non-IFRS loss of CHF 47.2 million.

Research & Development Highlights 2018 and Beyond

- [License agreement](#) signed with Lilly to research and develop Tau aggregation inhibitor small molecules for the potential treatment of Alzheimer's disease and other neuro-degenerative diseases. The terms include upfront payment of CHF 80 million, USD 50 million convertible equity note, CHF 60 million in potential near-term milestones, as well as other milestones up to approximately CHF 1.68 billion, and tiered royalty payments in the low double digits.
- Genentech, a member of Roche Group, [commenced recruitment](#) for a second Phase 2 trial of AC Immune's anti-Tau monoclonal antibody, RG6100 (MTAAU9937A, RO7105705), in moderate AD supplementing a separate Phase 2 trial to evaluate its efficacy and safety in participants with prodromal to mild AD.
- [Roche discontinued](#) CREAD 1 and CREAD 2 Phase 3 studies of crenezumab. Further update on the interim analysis CREAD studies will be presented by Roche at Alzheimer's and Parkinson's Diseases Congress (AD/PD) Lisbon, Portugal on March 27 at 4:20 – 4:35 PM WET.
- The landmark Alzheimer's Prevention Initiative trial of crenezumab, for which data are expected in 2021/22, is continuing in cognitively healthy individuals in Colombia with an autosomal dominant mutation who are at high risk of developing familial AD.
- [Commenced a Phase 2 clinical trial](#) with an adaptive design for evaluation of ACI-24 (anti-Abeta vaccine) in patients with mild AD.
- [Completed recruitment](#) for the high-dose cohort of the ACI-24 Phase 1b study for the treatment of AD-like characteristics in adults with Down syndrome. Low-dose cohort was fully recruited in August 2017.
- [Awarded third follow-up grant](#) from The Michael J. Fox Foundation for first-in-human study of a potential alpha-synuclein Positron Emission Tomography (PET) tracer for Parkinson's disease anticipated to commence in H1 of 2019.
- [Hosted a Key Opinion Leader \(KOL\) event](#) addressing Abeta oligomers in AD and other neuro-degenerative diseases with top-level insights from KOLs Professor Michael W. Weiner, University of California San Francisco School of Medicine and Professor John Q. Trojanowski, Perelman School of Medicine, University of Pennsylvania.
- Established an [exclusive strategic partnership](#) with WuXi Biologics allowing ACIU to leverage WuXi Biologics' capacities and capabilities in the manufacturing and supply of biologics for CNS disorders.
- Announced appointments to ACIU executive management including [Dr. Marie Kosco-Vilbois](#), as Chief Scientific Officer, [Piergiorgio Donati](#) as Head of Technical Operations and Program Management, and [Dr. Sonia Poli](#) as Head of Translational Science.

Analysis of Financial Statements for the 12 months ended December 31, 2018

Key Financial Results¹

	For the year ended December 31,		Change
	2018	2017	
	(in CHF million except per share data)		
Revenues	7.2	20.3	(13.1)
R&D expenses	(44.3)	(32.7)	(11.6)
G&A expenses	(12.5)	(10.1)	(2.4)
IFRS loss for the period	(50.9)	(26.4)	(24.5)
IFRS EPS – basic and diluted	(0.82)	(0.46)	(0.36)
Non-IFRS loss for the period ¹	(47.2)	(20.6)	(26.6)
Non-IFRS EPS – basic and diluted ¹	(0.76)	(0.36)	(0.40)
	As of December 31,		
	2018	2017	Change
	(in CHF million)		
Cash and cash equivalents	156.5	124.4	32.1
Short-term financial assets	30.0	-	30.0
Total Liquidity²	186.5	124.4	62.1
Total shareholder's equity	177.6	116.8	60.8

¹ Non-IFRS (Loss) and Non-IFRS EPS are non-IFRS measures. See "Non-IFRS Financial Measures" below for further information

² Liquidity is defined as the cash and cash equivalents plus short-term financial assets. These short-term financial assets are comprised of cash held

in fixed-term deposits ranging in maturity from 3–12 months

Revenues

- Revenues for the 12-month period decreased CHF 13.1 million (-64%) compared to 2017. Revenues fluctuate as a result of our collaborations with current and potentially new partners, the timing of milestone achievements and the size of each milestone payment.
- CHF 14 million milestone payment received in 2017 for the Company's anti-Tau antibody moving into a Phase 2 trial for AD as part of the Company's collaboration with Genentech. No such milestone was received in 2018.
- Increase of CHF 0.9 million and CHF 0.1 million for Janssen and Biogen collaborations, respectively. For Janssen, this relates to an increase in cost sharing activities for the advancement of ACI-35 in the development plan.
- The Company also recorded an increase of CHF 0.6 million in its collaboration with Essex as this collaboration was in effect for the full year 2018.

Research & Development (R&D) Expenses

- Total R&D expenditures increased CHF 11.6 million (+36%) for the 12 months ended December 31, 2018 compared to 2017.
- The Company increased investments in each of its respective development category, led by a CHF 3.6 million (+34%) and CHF 3.9 million (+50%) increase in Alzheimer's disease and discovery programs, respectively.
- Alzheimer's disease expenses increased due to a CHF 3.0 million increase for investments related to the completion of the Phase 1b study for ACI-35 and advancement of the vaccine through the development plan. ACI-24 AD spend increased by CHF 1.4 million in set-up fees such as site selection, administration and related manufacturing costs associated with the Phase 2 study.
- Increase in discovery programs was led by a CHF 1.5 million increase related to continued proof-of-concept and manufacturing activities for studies related to our lead compounds in the anti-Tau Morphomer™ program and investments in new therapeutic and preventive vaccine technology, CHF 0.5 million increase related to manufacturing activities in our vaccine technology program and a CHF 0.8 million for our anti-a-Synuclein antibody. The Company also increased its investment by CHF 0.7 million in the area of neuroinflammation driven by additional costs related to medicinal chemistry and preclinical evaluation of the compounds.

General & Administrative (G&A) Expenses

- For the year ended December 31, 2018 G&A increased CHF 2.4 million (+23%) to CHF 12.5 million. Increase driven by personnel expenses including share-based compensation and professional services.

IFRS Loss for the period

- AC Immune had a net loss after taxes of CHF 50.9 million in 2018 compared with net loss of CHF 26.4 million in 2017.

Balance Sheet

- The Company had a total cash balance of CHF 186.5 million comprised of CHF 156.5 million in cash and cash equivalents and CHF 30.0 million short-term financial assets. This compares to CHF 124.4 million as of December 31, 2017. The increase of CHF 62.1 million is principally due to the follow-on financing in 2018 offset by the Company's net loss. Further details are available in our Statements of Cash flows on the accompanying Form 20-F.
- The Company's strong cash balance provides enough capital resources to progress through at least Q3 2023, not considering any incoming milestones.
- The total shareholders' equity position increased year-over-year to CHF 177.6 million as of December 31, 2018 from CHF 116.8 million as of December 31, 2017. Further details are available in our corresponding Financial Statements filed on the accompanying Form 20-F.

Non-IFRS Financial Measures

The Company's operating results, as calculated in accordance with International Financial Reporting Standards, or IFRS, as adopted by the International Accounting Standards Board, we use non-IFRS Loss and non-IFRS Loss per share when monitoring and evaluating our operational performance. Non-IFRS Loss is defined as loss for the relevant period, as adjusted for certain items that we believe are not indicative of our ongoing operating performance. Non-IFRS Loss per share is defined as non-IFRS Loss for the relevant period divided by the weighted-average number of shares for such period.

The Company believes that these measures assist shareholders because they enhance comparability and provide more useful insight into operational results for the period. The Company's executive management uses these non-IFRS measures to evaluate operational performance. These non-IFRS financial measures are not meant to be considered alone or substitute for IFRS financial measures and should be read in conjunction with AC Immune's financial statements prepared in accordance with IFRS. The most directly comparable IFRS measure to these non-IFRS measures is net loss and loss per share. The following table reconciles IFRS net loss and IFRS loss per share to non-IFRS net loss and non-IFRS net loss per share for the periods presented:

Reconciliation of Loss to Adjusted Loss and Loss per Share to Adjusted Loss per Share (unaudited)

	For the year ended December 31		Change
	2018	2017	CHF
	(in CHF millions except per share data)		
IFRS loss	(50.9)	(26.4)	(24.5)
Adjustments:			
Non-Cash share-based compensation	2.5	1.6	(0.9)
Foreign currency remeasurement losses	1.2	4.2	3.0
Non-IFRS loss	(47.2)	(20.6)	(26.6)
IFRS EPS – basic and diluted	(0.82)	(0.46)	(0.36)
Adjustment to EPS – basic and diluted	0.06	0.10	(0.04)
Non-IFRS EPS – basic and diluted	(0.76)	(0.36)	(0.40)
Weighted-average number of shares used to compute Adjusted Earnings (Loss) per share – basic and diluted	61,838,228	57,084,295	4,753,933

Non-IFRS Expenditures

Adjustments for the years ended December 31, 2018 and 2017 were CHF 3.7 million and CHF 5.8 million in net losses, respectively. These were largely due to foreign currency remeasurement losses of CHF 1.2 million and CHF 4.2 million for the years ended December 31, 2018 and 2017, 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 also recorded CHF 2.5 million and CHF 1.6 million for the years ended December 31, 2018 and 2017, respectively, for share-based compensation expenses.

About AC Immune

AC Immune SA is a Nasdaq-listed clinical-stage biopharmaceutical company, which aims to become a global leader in precision medicine for neuro-degenerative diseases. The Company designs, discovers and develops therapeutic as well as diagnostic products intended to prevent and modify diseases caused by misfolding proteins. AC Immune's two proprietary technology platforms create antibodies, small molecules and vaccines designed to address a broad spectrum of neuro-degenerative indications, such as Alzheimer's disease (AD). The Company's pipeline features nine therapeutic and three diagnostic product candidates, with five currently in clinical trials. It has collaborations with major pharmaceutical companies including Roche/Genentech, Lilly, Biogen, Janssen Pharmaceuticals, Nestlé Institute of Health Sciences, Life Molecular Imaging (formerly Piramal Imaging) and Essex Bio-Technology.

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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. 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.



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