AC Immune Reports Q2 2019 Financial Results, Business and Clinical Update

August 14, 2019

Company Outlines Roadmap to Develop Successful Therapies for Neurodegenerative Diseases Based on its Broad Anti-Tau Clinical Pipeline

LAUSANNE, Switzerland, Aug. 14, 2019 (GLOBE NEWSWIRE) -- AC Immune SA (NASDAQ: ACIU), a Swiss-based, biopharmaceutical company with a broad clinical-stage pipeline focused on neurodegenerative diseases, today announced its business and clinical plan and strategy, reported consolidated financial results for the second quarter of 2019 and its revised cash guidance.

Prof. Andrea Pfeifer, Ph.D., CEO of AC Immune, commented: "Our business strategy is based on a three-pillar approach in the development of treatments for Alzheimer's disease, NeuroOrphan therapeutics and diagnostics. Our *Roadmap to Successful Therapies for Neurodegenerative Diseases* is based on treating earlier, targeting Tau, incorporating homogeneous populations, applying precision medicine and targeting neuroinflammation."

There is a growing body of clinical evidence that Tau drives disease progression. AC Immune has one of the broadest anti-Tau pipelines with antibodies, small molecules, vaccines and diagnostics, covering five clinical trials and partnerships with four major pharmaceutical companies.

"SupraAntigen™ and Morphomer™, our proprietary discovery platforms are the foundation for multiple product candidates," added Dr. Pfeifer. "The productivity of these platforms has recently demonstrated significant clinical, value-creating milestones."

Research & Development Highlights Q2 2019 and Beyond

- Dosing of the first subject in a Phase 1 study of ACI-3024, a first-in-class investigational oral small molecule Tau Morphomer™ inhibitor that will be studied in neurodegenerative diseases that are characterized by the presence of pathological Tau aggregates. This is the first significant advancement in AC Immune's collaboration with Eli Lilly and Company
- Initiation of a Phase 1b/2a clinical trial to evaluate ACI-35.030, a clinically advanced anti-phospho-Tau designed to reduce and to prevent the spread and development of Tau pathology to treat early and moderate Alzheimer's disease (AD)
- Initial interim data from an ongoing Phase 1b trial of AC Immune's ACI-24 anti-Abeta vaccine, to treat AD like symptoms in subjects with Down syndrome (DS), demonstrated strong safety and preliminary immunogenicity results
- Hosted a Key Opinion Leader (KOL) event, where presentations underscored the significant need and opportunity for studying AD-like symptoms in DS, a high-risk and genetically homogeneous population
- Initiation of a substudy by Genentech, a member of the Roche Group, in the ongoing Phase 2 Alzheimer's Prevention Initiative (API) trial of AC Immune's investigational candidate, crenezumab. The substudy, which measures Tau burden using Positron Emission Tomography (PET), aims to increase the understanding of disease progression in the preclinical stage of autosomal dominantly inherited, or familiar, AD
- Initiation of a research partnership with leading scientists in the Perelman School of Medicine at the University of Pennsylvania (Penn) focused on studying the pathological mechanisms of TDP-43 misfolding and aggregation

Anticipated Near-Term Milestones

- H2:2019: Proof-of-concept data from three NeuroOrphan indications from our SupraAntigen™ platform
- H2:2020: Read out from a Phase 2 clinical trial in prodromal/mild AD patients from the SupraAntigen™ platform
- Multiple clinical trial readouts from collaboration partners in 2020/2021 confirming Tau antibodies as a viable approach to halting the progression of AD and other neurodegenerative conditions

Analysis of Financial Statements for the Three and Six Months Ended June 30, 2019

- **Cash Position**: The Company had a total cash balance of CHF 285.7 million, comprised of CHF 205.7 million in cash and cash equivalents and CHF 80.0 million in short-term financial assets. This compares to a total cash balance of CHF 186.5 million as of December 31, 2018. The increase of CHF 99.2 million is principally due to the CHF 80 million upfront payment and USD 50 million convertible equity note related to the agreement with Lilly. Further details are available in our Statements of Cash Flows in the accompanying Form 6-K.
  The total shareholders' equity position increased from December 31, 2018 to CHF 273.3 million from CHF 177.6 million. Further details are available in our corresponding Financial Statements filed on the accompanying Form 6-K.
- **Revenues:** Revenues for the three and six months ended June 30, 2019 totaled CHF 1.5 million and CHF 76.6 million, respectively. This represents a decrease of CHF 0.5 million and increase of CHF 73.1 million compared to the respective periods in 2018. The decrease for the three-month period relates to 2018 Biogen revenues not repeated in 2019, as this contract concluded in April. The increase for the six-month period is driven by the recognition of CHF 74.3 million from the

right-of-use license and research and development activities linked to the 2018 Lilly agreement. Revenues fluctuate as a result of payments associated with our collaborations with current and potential new partners, the timing of milestone achievements and the size of each milestone payment.

- **R&D Expenditures:** R&D expenditures increased by CHF 2.2 million (+21%) and CHF 3.7 million (+18%) for the three and six months ended June 30, 2019 compared to the comparable periods in 2018, respectively. The Company largely increased its investments in AD, non-AD and new discovery programs. For AD, the Company prepared activities for its Phase 1b/2a and Phase 2 studies for ACI-35 and ACI-24 AD, respectively. For non-AD, the Company increased investment in its Morphomer™ alpha-synuclein programs and continued to advance ACI-24 DS through clinical development. Finally, in new discovery, the Company continues to focus on its neuroinflammation discovery programs.
- **G&A Expenses**: For the three and six months ended June 30, 2019, G&A increased CHF 0.5 million (+17%) and CHF 1.1 million (+19%) to CHF 3.6 million and CHF 6.9 million, respectively. Increases are driven by rental, personnel and IT expenses.
- **IFRS Income/(Loss) for the period:** The Company incurred net loss and net income after taxes of CHF 16.9 million and CHF 46.7 million for the three and six months ended June 30, 2019, respectively, compared with net losses of CHF 11.1 million and CHF 22.8 million for the comparable periods in 2018.

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 neurodegenerative diseases. The Company is utilizing two proprietary discovery 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 five currently in clinical trials. It has collaborations with major pharmaceutical companies including Roche/Genentech, Lilly and Janssen Pharmaceuticals Inc.

As a strategic leader in the field of neurodegenerative diseases, AC Immune has developed a five point *Roadmap to Successful Therapies for Neurodegenerative Diseases* that recognizes the importance of treating earlier, targeting Tau, focusing on more homogeneous populations, precision medicine and exploring neuroinflammation as a target.

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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.

Balance Sheets

in CHF thousands	As of June 30, 2019	As of December 31, 2018
ASSETS		

Non-current assets		
Property, plant and equipment	3,594	3,324
Right-of-use assets	1,978	-
Long-term financial assets	304	304
Total non-current assets	**5,876**	**3,628**
Current assets		
Prepaid expenses	2,917	2,364
Accrued income	547	3,667
Finance receivable	98	199
Other current receivables	1,049	236
Short-term financial assets	80,000	30,000
Cash and cash equivalents	205,735	156,462
Total current assets	**290,346**	**192,928**
Total assets	**296,222**	**196,556**
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	1,436	1,351
Share premium	346,024	298,149
Accumulated losses	(74,170)	(121,877)
Total shareholders' equity	**273,290**	**177,623**
Non-current liabilities		
Long-term financing obligation	256	186
Long-term lease liabilities	1,559	-
Long-term deferred income	1,903	-
Net employee defined benefit liabilities	5,954	5,665
Total non-current liabilities	**9,672**	**5,851**
Current liabilities		
Trade and other payables	156	1,979
Accrued expenses	8,414	10,420
Short-term deferred income	3,941	351
Short-term debt obligation	329	332
Short-term lease liabilities	420	-
Total current liabilities	**13,260**	**13,082**
Total liabilities	**22,932**	**18,933**
Total shareholders' equity and liabilities	**296,222**	**196,556**

Statements of Income/(Loss)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
	(in CHF thousands except for per share data)			
Revenue				

Contract revenue	1,511	2,028	76,553	3,486
Total revenue	**1,511**	**2,028**	**76,553**	**3,486**
Operating expenses				
Research & development expenses	(12,700)	(10,533)	(24,293)	(20,604)
General & administrative expenses	(3,585)	(3,065)	(6,879)	(5,770)
Total operating expenses	**(16,285)**	**(13,598)**	**(31,172)**	**(26,374)**
Operating income/(loss)	**(14,774)**	**(11,570)**	**45,381**	**(22,888)**
Finance income / (expense), net	(1,732)	447	(1,812)	165
Change in fair value of conversion feature	36	—	4,542	—
Interest income	75	2	164	3
Interest expense	(504)	(22)	(1,601)	(35)
Finance result, net.	**(2,125)**	**427**	**1,293**	**133**
Income/(loss) before tax	**(16,899)**	**(11,143)**	**46,674**	**(22,755)**
Income tax expense	—	—	—	—
Income/(loss) for the period	**(16,899)**	**(11,143)**	**46,674**	**(22,755)**
Income/(loss) per share (EPS):				
Basic income/(loss) for the period attributable to equity holders	(0.24)	(0.19)	0.67	(0.40)
Diluted income/(loss) for the period attributable to equity holders	(0.24)	(0.19)	0.67	(0.40)

Statements of Comprehensive Income/(Loss)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
			(in CHF thousands)	
Income/(loss) for the period	(16,899)	(11,143)	46,674	(22,755)
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	**(16,899)**	**(11,143)**	**46,674**	**(22,755)**

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
			(in CHF thousands except for share and per share data)	
Income/(Loss)	**(16,899)**	**(11,143)**	**46,674**	**(22,755)**
Adjustments:				
Non-cash share-based payments (a)	561	712	1,146	1,314
Foreign currency losses (b)	513	(397)	558	(195)
Effective interest expense (c)	364	—	1,355	—
Change in fair value of conversion feature (d)	(36)	—	(4,542)	—
Adjusted Income/(Loss)	**(15,497)**	**(10,828)**	**45,191**	**(21,636)**

Earnings/(Loss) per share – basic	(0.24)	(0.19)	0.67	(0.40)
Earnings/(Loss) per share – diluted	(0.24)	(0.19)	0.67	(0.40)
Adjustment to earnings/(loss) per share – basic	0.02	0.00	(0.02)	0.02
Adjustment to earnings/(loss) per share – diluted	0.02	0.00	(0.02)	0.02
Adjusted earnings/(loss) per share – basic	**(0.22)**	**(0.19)**	**0.65**	**(0.38)**
Adjusted earnings/(loss) per share – diluted.	**(0.22)**	**(0.19)**	**0.65**	**(0.38)**
Weighted-average number of shares used to compute Adjusted earnings/(loss) per share – basic	70,764,091	57,423,650	69,351,363	57,395,987
Weighted-average number of shares used to compute Adjusted earnings/(loss) per share – diluted	70,764,091	57,423,650	69,845,858	57,395,987

(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.

For the three and six months ended June 30, 2019, adjustments decreased net loss and net income by CHF 1.4 million and CHF 1.5 million compared with decreases to the net losses by CHF 0.3 million and CHF 1.1 million for the comparable periods in 2018, respectively. The Company recorded CHF 0.6 million and CHF 1.1 million for the three and six months, respectively, for share-based compensation expenses. There were foreign currency remeasurement losses of CHF 0.5 million and 0.6 million, respectively, predominantly related to foreign currency fluctuations. The Company recorded CHF 0.4 million and CHF 1.4 million for amortization of effective interest for the three and six months ended June 30, 2019, respectively. Finally, the Company recognized less than a CHF 0.1 million and a CHF 4.5 million gain for the change in fair value of the liability related to the conversion feature.

Source: AC Immune SA