AC Immune Reports Q1 2019 Financial Results and Business Update

May 15, 2019

LAUSANNE, Switzerland, May 15, 2019 (GLOBE NEWSWIRE) -- AC Immune SA (NASDAQ: ACIU), a Swiss-based, biopharmaceutical company with a broad clinical-stage pipeline focused on pioneering Precision Medicine in neurodegenerative diseases, today announced financial results for the first quarter ended March 31, 2019.

Prof. Andrea Pfeifer, Ph.D., CEO of AC Immune, commented: “Our CHF 300 million cash position, funds operations through Q3 2023, allowing us to achieve multiple potentially transformative goals. This is thanks to SupraAntigen™ and Morphomer™, our proprietary discovery platforms, which already have generated multiple clinical and preclinical product-candidates and about CHF 300 million in partnering revenues for rights to our industry-leading therapeutic candidates to treat neurodegenerative diseases. We expect multiple developments in 2019, including initiation of a Phase 1 trial of small molecule Tau Morphomer™, as we advance our new partnership with Eli Lilly, and the interim Phase 1b data on ACI-24 to treat Alzheimer’s disease (AD) in Down syndrome.”

“Our key near- to medium-term focus is on developing our Tau therapies to treat early and moderate AD based on the growing body of clinical evidence that Tau pathology drives disease progression,” added Dr Pfeifer. “As the key opinion leaders have advised, we also are continuing testing of Abeta therapeutics, like ACI-24 and crenezumab, in carefully selected more homogeneous populations for early treatment and prevention, such as AD in Down syndrome patients and familial AD, respectively. The Roadmap to successful therapies for neurodegenerative diseases like Alzheimer’s requires that we treat earlier in the course of disease and select more homogenous populations using Precision Medicine and, as soon as practical, combination therapies.”

Financial Highlights Q1 2019

- Enhanced cash position of more than CHF 300 million as of Q1 2019, following receipt of CHF 80 million upfront payment and USD 50 million convertible equity note as a result of license agreement with Eli Lilly, effective in January 2019.
- Strategic R&D expenditures increased by CHF 1.5 million (+15%) supporting an ongoing ramp-up in R&D activities, primarily driven by investments in our neurodegenerative disease therapeutics development and discovery programs, most notably ACI-35.
- IFRS net income of CHF 63.6 million and Non-IFRS income of CHF 60.7 million.

Research & Development Highlights Q1 2019

- License agreement signed with Lilly to research and develop Tau aggregation inhibitor small molecules for the potential treatment of Alzheimer’s disease and other neurodegenerative 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.
- Presented new data on alpha-synuclein PET Tracer at the Alzheimer’s and Parkinson’s Diseases Congress (AD/PD)™ Lisbon, Portugal, March 26–31, 2019.
- New clinical data on AC Immune's novel next generation Tau PET-Tracer presented by licensing partner, Life Molecular Imaging, at AD/PD™.
- 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 and presented an interim analysis of CREAD studies at AD/PD™ onMarch 27, 2019.
- The landmark Alzheimer's Prevention Initiative (API) trial of crenezumab, for which data are expected in Q1 of 2022, is continuing in cognitively healthy individuals in Colombia with an autosomal dominant mutation who are at high risk of developing familial AD.

Analysis of Financial Statements for the Three Months Ended March 31, 2019

Revenues

- Revenues for the first quarter of 2019 increased CHF 73.6 million compared to 2018, driven by recognition of CHF 73.9 million from the right-of-use license and research and development activities. Revenues fluctuate as a result of payments associated with our collaborations with current and potentially new partners, the timing of milestone achievements and the size of each milestone payment.

Research & Development (R&D) Expenses

- Total R&D expenditures increased CHF 1.5 million (+15%) for the three months ended March 31, 2019 compared to 2018.

General & Administrative (G&A) Expenses

- For the three months ended March 31, 2019, G&A increased CHF 0.6 million (+22%) to CHF 3.3 million. Increase driven by rental and personnel expenses.

IFRS Income/(Loss) for the period

- AC Immune had net income after taxes of CHF 63.6 million in 2019 compared with a net loss of CHF 11.6 million for the comparable period in 2018.

Balance Sheet

- The Company had a total cash balance of CHF 302.1 million comprised of CHF 222.1 million in cash and cash equivalents and CHF 80.0 million in short-term financial assets. This compares to CHF 186.5 million as of December 31, 2018. The increase of CHF 115.6 million is principally due to the CHF 80 million upfront payment and USD 50 million convertible equity note with Lilly. Further details are available in our Statements of Cash flows on the accompanying Form 6-K.
- 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 from December 31, 2018 to CHF 241.9 million from CHF 177.6 million. Further details are available in our corresponding Financial Statements filed on the accompanying Form 6-K.

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.

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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 March 31, 2019	As of December 31, 2018
ASSETS		
Non-current assets		
Property, plant and equipment	3,570	3,324
Right-of-use assets	2,082	-
Long-term financial assets	304	304
Total non-current assets	**5,956**	**3,628**
Current assets		
Prepaid expenses	3,000	2,364
Accrued income	813	3,667
Finance receivable	201	199
Other current receivables	784	236
Short-term financial assets	80,000	30,000
Cash and cash equivalents	222,138	156,462
Total current assets	**306,936**	**192,928**

Total assets	**312,892**	**196,556**
SHAREHOLDERS' EQUITY AND LIABILITIES		
Shareholders' equity		
Share capital	1,361	1,351
Share premium	298,259	298,149
Accumulated losses	(57,766)	(121,877)
Total shareholders' equity	**241,854**	**177,623**
Non-current liabilities		
Long-term financing obligation	225	186
Long-term lease liabilities	1,666	-
Long-term deferred income	2,628	-
Net employee defined benefit liabilities	5,809	5,665
Total non-current liabilities	**10,328**	**5,851**
Current liabilities		
Trade and other payables	829	1,979
Accrued expenses	8,800	10,420
Short-term deferred income	3,546	351
Convertible loan	46,740	-
Liability related to conversion feature	43	-
Short-term debt obligation	336	332
Short-term lease liabilities	416	-
Total current liabilities	**60,710**	**13,082**
Total liabilities	**71,038**	**18,933**
Total shareholders' equity and liabilities	**312,892**	**196,556**

Statement of Income/(Loss)

	For the Three Months Ended March 31,	
	2019	**2018**
in CHF thousands except for share and per share data		
Revenue		
Contract revenue	75,042	1,458
Total revenue	**75,042**	**1,458**
Operating expenses		
Research & development expenses	(11,592)	(10,069)
General & administrative expenses	(3,294)	(2,711)
Total operating expenses	**(14,886)**	**(12,780)**
Operating income/(loss)	**60,156**	**(11,322)**
Finance expense, net	(80)	(281)
Change in fair value of conversion feature	4,505	-
Interest income	89	1
Interest expense	(1,096)	(12)
Finance result, net	**3,418**	**(292)**
Income/(loss) before tax	**63,574**	**(11,614)**

Income tax expense	-	-
Income/(loss) for the period	**63,574**	**(11,614)**
Income/(loss) per share (EPS):		
Basic income/(loss) for the period attributable to equity holders	0.94	(0.20)
Diluted income/(loss) for the period attributable to equity holders	0.91	(0.20)

Statements of Comprehensive Income/(Loss)	**For the Three Months ended March 31,**	
	2019	**2018**
in CHF thousands		
Income/(loss) for the period	**63,574**	**(11,614)**
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	**63,574**	**(11,614)**

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

	For the Three Months Ended March 31,	
	2019	**2018**
in CHF thousands except for share and per share data		
Income/(Loss)	**63,574**	**(11,614)**
Adjustments:		
Non-cash share-based payments (a)	584	602
Foreign currency losses (b)	45	202
Effective interest expense (c)	991	**-**
Change in fair value of conversion feature (d)	(4,505)	**-**
Adjusted Income/(Loss)	**60,689**	**(10,810)**
Earnings/(Loss) per share – basic	0.94	(0.20)
Earnings/(Loss) per share – diluted	0.91	(0.20)
Adjustment to earnings/(loss) per share – basic	(0.05)	0.01
Adjustment to earnings/(loss) per share – diluted	(0.06)	0.01
Adjusted earnings/(loss) per share – basic	**0.89**	**(0.19)**
Adjusted earnings/(loss) per share – diluted	**0.85**	**(0.19)**
Weighted-average number of shares used to compute Adjusted earnings/(loss) per share – basic	67,922,939	57,368,015
Weighted-average number of shares used to compute Adjusted earnings/(loss) per share – diluted	71,276,000	57,368,015

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 months ended March 31, 2019 and March 31, 2018 were CHF 2.9 million in net gains compared to CHF 0.8 million in net losses. The Company recorded CHF 0.6 million for the three months, respectively, for share-based compensation expenses. There were foreign currency remeasurement losses of CHF 45 thousand and CHF 0.2 million, respectively, predominantly related to the reduced foreign currency cash balance of the Company and reduced exposure to foreign currency fluctuations. The Company recorded CHF 1.0 million for amortization of effective interest for the three months ended March 31, 2019. Finally, the Company recognized a CHF 4.5 million gain for the change in fair value of the liability related to the conversion feature.



Source: AC Immune SA