AC Immune Reports Second Quarter 2024 Financial Results and Provides a Corporate Update

August 6, 2024

AC Immune Reports Second Quarter 2024 Financial Results and Provides a Corporate Update

- Announced exclusive option and license agreement with Takeda for ACI-24.060 on May 13 for $100 million upfront and total potential milestones of up to approximately $2.1 billion
- ACI-24.060 ABATE Phase 2 trial in Alzheimer's disease (AD) on track with enrolment expectations
- ACI-7104.056 VacSYn Phase 2 trial of anti-a-syn active immunotherapy in Parkinson's disease (PD) on track for safety and immunogenicity interim data in H2 2024
- Potent inhibitor of the inflammatory NLRP3 pathway, ACI-19764, demonstrates promising preclinical results and may be broadly applicable to treat CNS and non-CNS diseases
- Cash balance of CHF 175.2 million at quarter end, including CHF 92.3 million from Takeda, provides sufficient runway for three years

Lausanne, Switzerland, August 6, 2024 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision therapeutics for neurodegenerative diseases, today reported results for the quarter ended June 30, 2024, and provided a corporate update.

Dr. Andrea Pfeifer, CEO of AC Immune SA, commented, "AC Immune is entering the second half of 2024 with tremendous momentum. We are excited about the recently announced partnership with Takeda for ACI-24.060 as a potential best-in-class Abeta-targeted active immunotherapy. Enrollment in the ABATE Phase 2 trial of ACI-24.060 in AD continues to progress as planned."

"We are also excited to be advancing our preclinical programs, some of which were recently featured in multiple presentations at the AAIC 2024 conference. Our novel morADC platform, a synergistic combination of our SupraAntigen® and Morphomer® platforms, has significant potential for enhanced targeted interventions for a variety of neurodegenerative diseases and also offers opportunities for simultaneous combination approaches. These morADCs are already showing promise in multiple preclinical models, and we look forward to sharing more details on this and on other preclinical development programs in an upcoming R&D day. Our solid financial position, enhanced by the Takeda partnership, enables us to drive clinical and preclinical development, leveraging the core competency of AC Immune that is anchored by our foundational expertise in neurodegenerative disease drug discovery."

Q2 2024 and Subsequent Highlights

- AC Immune and Takeda signed an exclusive option and license agreement for AC Immune's active immunotherapies targeting Abeta, including ACI-24.060 for AD. Under the terms of the agreement, AC Immune received an upfront payment of $100 million from Takeda and, if all related milestones are achieved over the course of the agreement, is eligible to receive payments of up to approximately $2.1 billion including an option exercise fee and additional potential development, commercial and sales-based milestones. Upon commercialization, AC Immune will be entitled to receive tiered double-digit royalties on worldwide net sales.
- Enrolment in the ACI-24.060 ABATE Phase 2 AD trial continues.
- We also completed the regulatory toxicology studies for the anti-TDP-43 monoclonal antibody candidate in Q2 which will enable us to proceed with IND filing.
- Our targeted NLRP3 inhibitor candidates continue to show excellent promise in preclinical results featured at the AD/PD™ 2024 conference:
  - ACI-19764 is a brain penetrant small molecule in preclinical development that directly binds and inhibits NLRP3. Its activity *in vitro* and *in vivo* was demonstrated in two models of neuroinflammation. In addition, ACI-19764 demonstrated an excellent safety profile and optimal exposure for sustained NLRP3 inhibition in the brain.
  - AC Immune intends to file an IND from the NLRP3 program in the near future.
- AC Immune's preclinical programs were featured in multiple presentations at the Alzheimer's Association International Conference (AAIC) 2024:
  - *A new class of neurodegenerative disease-fighting drugs: morADC (Morphomer®- antibody drug conjugates),* presented by Madiha Derouazi (Chief Scientific Officer, AC Immune), featured data from AC Immune's proprietary morADC platform. Results demonstrated the ability of morADCs to penetrate the blood brain barrier *in vivo* and produce potent catalytic activity *in vitro* compared to the parental monoclonal antibody or small molecule alone.
  - *Active immunotherapy, ACI-24.060, induces anti-Abeta antibodies with binding profiles mirroring clinically validated monoclonal antibodies,* presented by Emma Fiorini (AC Immune), featured results from non-human primates demonstrating that ACI-24.060 induced antibody responses in a similar range of levels of donanemab and lecanemab and with preferential oligomeric Abeta binding as compared to monomeric Abeta.
  - *Discovery and preclinical development of [^{18}F]ACI-19626, a first-in-class TDP-43 PET tracer,* presented by Tamara

Seredenina (AC Immune), described the selection of [^{18}F]ACI-19626 for evaluation as a potential PET tracer for detection and monitoring progression of TDP-43 aggregates based on its favorable affinity, selectivity and pharmacokinetic properties.

- Board and Management Share Purchases: Members of the Board of Directors and certain members of executive management purchased shares in AC Immune SA during Q2 2024, following the announcement of the exclusive option and license agreement with Takeda for ACI-24.060. As a foreign private issuer (FPI), individual shareholdings will be disclosed in the Annual Report on Form 20-F.

Anticipated 2024 Milestones

ACI-24.060 anti-Abeta active immunotherapy	• ABATE Phase 2 trial in AD on track with enrolment expectations
ACI-7104.056 anti-a-syn active immunotherapy	• Interim safety and immunogenicity update from the Phase 2 VacSYn study in Parkinson's disease expected in H2 2024
ACI-35.030 anti-pTau active immunotherapy	• First patient treated in ReTain Phase 2b clinical trial expected in the coming months
TDP-43-PET tracer	• Phase 1 initiation expected in H2 2024
ACI-15916 a-syn-PET tracer	• IND-enabling studies in PD expected to be completed in H2 2024

Analysis of Financial Statements for the Quarter Ended June 30, 2024

- **Cash Position:** The Company had a total cash balance of CHF 175.2 million (CHF 103.1 million as of December 31, 2023), composed of CHF 51.6 million in cash and cash equivalents and CHF 123.6 million in short-term financial assets. The Company's cash balance provides sufficient capital resources for three years, assuming the potential milestone payment of CHF 24.6 million related to achieving an undisclosed enrolment target for our ACI-35.030, and no other milestones.
- **Contract Revenues:** The Company recorded CHF 0.7 million in contract revenues for the three months ended June 30, 2024, compared to nil in the comparable prior period. For the three months ended June 30, 2024, our contract revenues of CHF 0.7 million were related to the efforts made under the agreement with Takeda.
- **R&D Expenditures:** R&D expenses for the three months ended June 30, 2024, were CHF 17.1 million compared to CHF 13.7 million in the comparable period in 2023. The increase was due mainly to higher clinical expenses, driven by the ramp-up activities for our Phase 2 VacSYn study evaluating ACI-7104.056 in early PD and for the expansion of the ABATE study in our ACI-24.060 active immunotherapy.
- **G&A Expenditures:** G&A increased by CHF 0.9 million to CHF 4.6 million, mostly due to an increase in legal fees related to business development and licensing activities, as well as salaries and related costs, largely attributable to the higher expenses from equity awards granted in 2024, which have a higher fair value based on our share price development.
- **Other Operating Income:** The Company recognized less than CHF 0.1 million in grant income from Target ALS grants.
- **IFRS Loss for the Period:** The Company reported a net loss after taxes of CHF 22.8 million for the three months ended June 30, 2024, compared with a net loss of CHF 16.8 million for the comparable period in 2023.

About AC Immune SA

AC Immune SA is a clinical-stage biopharmaceutical company and a global leader in precision prevention 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 sixteen therapeutic and diagnostic programs, including five in Phase 2 development and one in Phase 3. AC Immune has a strong track record of securing strategic partnerships with leading global pharmaceutical companies, resulting in substantial non-dilutive funding to advance its proprietary programs and >$4.5 billion in potential milestone payments plus royalties.

SupraAntigen® is a registered trademark of AC Immune SA in the following territories: AU, EU, CH, GB, JP, RU, SG and USA. Morphomer® is a registered trademark of AC Immune SA in CN, CH, GB, JP, KR, NO and RU.

The information on our website and any other websites referenced herein is expressly not incorporated by reference into, and does not constitute a part of, this press release.

For further information, please contact:

SVP, Investor Relations & Corporate Communications
Gary Waanders, Ph.D., MBA
AC Immune

U.S. Investors
Corey Davis, Ph.D.
LifeSci Advisors

Phone: +41 21 345 91 91
Email: gary.waanders@acimmune.com

Phone: +1 212 915 2577
Email: cdavis@lifesciadvisors.com

International Media
Chris Maggos
Cohesion Bureau
Phone: +41 79 367 6254
Email: chris.maggos@cohesionbureau.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. 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.

Condensed Consolidated Balance Sheets (Unaudited)
(In CHF thousands)

	As of	
	June 30, 2024	**December 31, 2023**
Assets		
Non-current assets		
Property, plant and equipment	2,926	3,376
Right-of-use assets	3,235	3,508
Intangible asset	50,416	50,416
Long-term financial assets	415	361
Total non-current assets	56,992	57,661
Current assets		
Prepaid expenses	3,864	6,437
Accrued income	402	246
Other current receivables	1,153	622
Accounts receivable	—	14,800
Short-term financial assets	123,560	24,554
Cash and cash equivalents	51,564	78,494
Total current assets	180,543	125,153
Total assets	237,535	182,814
Shareholders' equity and liabilities		
Shareholders' equity		
Share capital	2,212	2,089
Share premium	476,074	474,907
Treasury shares	(218)	(105)
Currency translation differences	(35)	(51)
Accumulated losses	(354,608)	(316,197)
Total shareholders' equity	123,425	160,643
Non-current liabilities		
Long-term deferred contract revenue	5,170	—
Long-term lease liabilities	2,542	2,825
Net employee defined benefit liabilities	5,868	5,770
Total non-current liabilities	13,580	8,595
Current liabilities		
Trade and other payables	1,435	1,679
Accrued expenses	11,895	11,087

Short-term deferred income	45	138
Short-term deferred contract revenue	86,468	—
Short-term lease liabilities	687	672
Total current liabilities	100,530	13,576
Total liabilities	114,110	22,171
Total shareholders' equity and liabilities	237,535	182,814

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenue				
Contract revenue	687	—	687	—
Total revenue	687	—	687	—
Operating expenses				
Research & development expenses	(17,138)	(13,682)	(32,303)	(27,555)
General & administrative expenses	(4,551)	(3,681)	(9,522)	(7,787)
Other operating income/(expense), net	41	317	109	725
Total operating expenses	(21,648)	(17,046)	(41,716)	(34,617)
Operating loss	(20,961)	(17,046)	(41,029)	(34,617)
Financial income	739	259	1,368	468
Financial expense	(34)	(27)	(70)	(124)
Exchange differences	(2,504)	(16)	(891)	(67)
Finance result, net	(1,799)	216	407	277
Loss before tax	(22,760)	(16,830)	(40,622)	(34,340)
Income tax expense	—	(3)	—	(6)
Loss for the period	(22,760)	(16,833)	(40,622)	(34,346)
Loss per share:	(0.23)	(0.20)	(0.41)	(0.41)

Condensed Consolidated Statements of Comprehensive Income/(Loss) (Unaudited)
(In CHF thousands)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Loss for the period	(22,760)	(16,833)	(40,622)	(34,346)
Items that will be reclassified to income or loss in subsequent periods (net of tax):				
Currency translation differences	—	(8)	16	(16)
Items that will not to be reclassified to income or loss in subsequent periods (net of tax):				
Remeasurement gains on defined-benefit plans	—	—	—	—
Total comprehensive loss (net of tax)	(22,760)	(16,841)	(40,606)	(34,362)

Attachment

- 20240805_ACIU_Q2_Earnings_Final

Source: AC Immune SA