#### SECURITIES AND EXCHANGE COMMISSION

### FORM 6-K

Current report of foreign issuer pursuant to Rules 13a-16 and 15d-16 Amendments

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#### **FILER**

#### **AC Immune SA**

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM 6-K

# REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of August, 2024

Commission file number: 001-37891

#### **AC IMMUNE SA**

(Exact Name of Registrant as Specified in Its Charter)

EPFL Innovation Park
Building B
1015 Lausanne, Switzerland
(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F					
Form 20-F ⊠	Form 40-F □				

This Report on Form 6-K (excluding Exhibit 99.3 hereto) shall be deemed to be incorporated by reference into the registration statements on Form F-3 (File Nos. 333-227016, 333-249655, 333-255576 and 333-277940) and Form S-8 (File Nos. 333-213865, 333-216539 and 333-233019) of AC Immune SA and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

#### **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

#### AC IMMUNE SA

By: /s/ Andrea Pfeifer

Name: Andrea Pfeifer

Title: Chief Executive Officer

By: /s/ Christopher Roberts

Name: Christopher Roberts
Title: Chief Financial Officer

Date: August 6, 2024

#### EXHIBIT INDEX

Exhibit Number	Description
3.1	Articles of Association (incorporated herein by reference to Exhibit 3.1 to the Company's Registration
	Statement on Form F-3, filed with the U.S. Securities and Exchange Commission on July 26, 2024)
10.1‡	Option and License Agreement between AC Immune SA and Takeda Pharmaceuticals, USA, Inc., dated
	May 11, 2024
99.1	Interim Condensed Consolidated Financial Statements (Unaudited) (IFRS) as of and for the three and six
	months ended June 30, 2024
99.2	Management's Discussion and Analysis of Financial Condition and Results of Operations
99.3	Press Release dated August 6, 2024

 $<sup>\</sup>dagger$  Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.

#### **EXECUTION VERSION**

[\*\*\*] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and is the type that the registrant treats as private or confidential.

#### **OPTION AND LICENSE AGREEMENT**

between

#### **AC IMMUNE SA**

and

TAKEDA PHARMACEUTICALS, USA, INC.

Dated as of May 11, 2024

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#### **OPTION AND LICENSE AGREEMENT**

This Option and License Agreement (the "Agreement") is made and entered into as of May 11, 2024 (the "Effective Date") by and between AC Immune SA, a Swiss company ("ACI") and Takeda Pharmaceuticals, USA, Inc., a corporation organized under the laws of the State of Delaware ("Takeda"). ACI and Takeda are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

#### **RECITALS**

WHEREAS, ACI owns and controls certain intellectual property rights with respect to the Licensed Compounds (as defined herein) and Licensed Products (as defined herein) in the Territory (as defined herein); and

WHEREAS, ACI wishes to grant to Takeda, and Takeda wishes to take, an exclusive option to obtain an exclusive license under such intellectual property rights to develop, manufacture and commercialize Licensed Compounds and Licensed Products in the Territory, in each case, in accordance with the terms and conditions set forth below.

**NOW, THEREFORE**, in consideration of the premises and the mutual promises and conditions set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

### ARTICLE 1 DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

- **1.1.** [\*\*\*]
- **1.2.** "**Abeta**" means any of [\*\*\*]
- 1.3. "Accounting Standards" means, with respect to a Party or its Affiliates or its or their (sub)licensees/Sublicensees, International Financial Reporting Standards, generally accepted accounting principles as practiced in the United States, or such other internationally recognized accounting standards as may be used by such entity, in each case, as consistently applied.
  - **1.4.** [\*\*\*]
  - **1.5.** "ACI" has the meaning set forth in the preamble hereto.
  - **1.6.** "ACI Indemnitees" has the meaning set forth in Section 12.1.
  - 1.7. "ACI Ongoing Activities" has the meaning set forth in Section

- **1.8.** "ACI-24.060" means the Active Immunotherapy candidate referred to by ACI as of the Effective Date as ACI-24.060, as further described on **Schedule 1.8**.
- 1.9. "Acquirer Technology" means any Patents or Information Controlled (other than pursuant to an agreement with the Party undergoing a Change of Control or any of its Affiliates) by a Pre-Existing Entity in a Change of Control of a Party immediately prior to the effective date of such Change of Control.
- **1.10.** "Active Immunotherapy" means any compound, modality, process or construct that exposes an individual to an antigen to generate an adaptive immune response by stimulating the B-cells or T-cells of such individual.
  - **1.11.** [\*\*\*]
- **1.12.** "Additional Development Proposal" has the meaning set forth in Section 7.2.4.
- 1.13. "Adverse Event" means any untoward medical occurrence in a patient or human clinical investigation subject administered any Licensed Product pursuant to this Agreement, including occurrences which do not necessarily have a causal relationship with any Licensed Product.
- 1.14. "Affiliate" means, with respect to a Person, any Person that, whether now or in the future, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such first Person. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" mean: (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise; or (b) the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).
  - **1.15.** "Agreement" has the meaning set forth in the preamble hereto.
  - **1.16.** "Alliance Manager" has the meaning set forth in Section 2.9.
- 1.17. "Alzheimer's Disease Indication" means, with respect to a Licensed Product, the treatment, prevention, mitigation or cure of Alzheimer's disease, including prodromal and preclinical Alzheimer's disease, and including in subjects with Down's syndrome, in each case, as is reflected in the "Indications and Usage" section of labeling pursuant to 21 C.F.R. § 201.57(c)(2) if such Licensed Product is approved in the U.S. or, to the extent applicable, any comparable labeling section outside the U.S.
  - 1.18. "Amyloid Precursor Protein" means [\*\*\*]

	1.19.	"Antitrust	Authority"	means	any	Governmental	Authority
having power	or auth	ority with re	spect to antitu	ust matt	ers, in	cluding the Un	ited States
Federal Trade		-				_	
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Commission, the Antitrust Division of the United States Department of Justice, any attorney general of any state of the United States, the European Commission or any other equivalent competition authority of any jurisdiction.

- 1.20. "Antitrust Clearance" means the earlier of (a) notification to the Parties from each applicable Antitrust Authority of early termination of the applicable waiting period under the applicable Antitrust Laws with respect to an Antitrust Filing and (b) expiration of all applicable waiting periods under applicable Antitrust Laws with respect to any required Antitrust Filings; provided, however, that if any Antitrust Authority commences any investigation by means of a second request or otherwise, clause (b) shall be deemed to occur on the termination of such investigation without action to prevent the Parties from implementing the transactions contemplated by this Agreement.
- **1.21.** "Antitrust Filing" means any filings, notices, applications or other submissions by Takeda or ACI to any Antitrust Authority under applicable Antitrust Laws that are necessary or advisable in connection with exercise of the Option, including any such required filings under the HSR Act.
- **1.22.** "Antitrust Laws" means any Applicable Law with respect to antitrust, competition or trade regulations that are designed or intended to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade or lessening competition, including the HSR Act.
- 1.23. "Applicable Law" means, with respect to any Person, any transnational, domestic or foreign federal, state or local laws, rules, regulations, constitution, treaty, order, judgment or other similar requirement of any Regulatory Authorities or Governmental Authorities that may be in effect from time to time and applicable to such Person, including Good Laboratory Practices, Good Manufacturing Practices and Good Clinical Practices and, if and as appropriate under the circumstances, International Conference on Harmonization (ICH) guidance or other comparable regulation and guidance of any applicable Regulatory Authority in the Territory.
  - **1.24.** "Applicable Rate" has the meaning set forth in Section 8.11.
  - **1.25.** "Assigned IP" means [\*\*\*]
  - **1.26.** "Audit Decision" has the meaning set forth in Section 8.13.2.
  - **1.27.** "Audit Dispute" has the meaning set forth in Section 8.13.2.
  - **1.28.** "Auditor" has the meaning set forth in Section 8.13.2.
- **1.29.** "Biosimilar Competition" has the meaning set forth in Section 8.5.3(b).
- **1.30.** "Biosimilar Product" means, on a country-by-country basis, with respect to a Licensed Product, any product (a) whose licensing, approval or marketing authorization references or relies on, in whole or in part, (i) a prior

country to be a generic, follow-on, hybrid, biosimilar or interchangeable product of such Licensed Product; [\*\*\*]

- **1.31.** "Breaching Party" has the meaning set forth in Section 13.2.1.
- **1.32.** "Bring Down Updated Disclosure Schedule" has the meaning set forth in Section 11.3.2.
- **1.33.** "Business Day" means a day other than: a Saturday or Sunday or a day on which banking institutions in New York, New York, Lausanne, Switzerland or Tokyo, Japan are permitted or required to be closed.
- 1.34. "Calendar Quarter" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 or October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date and the last Calendar Quarter shall end on the last day of the Term.
- 1.35. "Calendar Year" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.
- 1.36. "Change of Control" means, with respect to a Party, any of the following events: (a) any Third Party becomes the beneficial owner, directly or indirectly, as a result of a single transaction or a series of related transactions, of fifty percent (50%) or more of the total voting power of all classes of shares of capital stock or other interests of such Party (or, if applicable, a controlling Affiliate of such Party) then outstanding and normally entitled to vote in the general election of directors of such Party ("Voting Stock"); (b) such Party (or, if applicable, a controlling Affiliate of such Party) consolidates with or merges into a Third Party, or any such Third Party consolidates with or merges into such Party (or, if applicable, a controlling Affiliate of such Party), in either event pursuant to a transaction in which fifty percent (50%) or more of the total voting power of all Voting Stock of the surviving entity then outstanding is not held by the Persons holding at least fifty percent (50%) of the total voting power of all Voting Stock of such Party (or, if applicable, a controlling Affiliate of such Party) outstanding immediately prior to such consolidation or merger; or (c) such Party and its Affiliates convey, transfer or lease all or substantially all of the assets relating to the subject matter of this Agreement to a Third Party. Notwithstanding the foregoing, Change of Control shall not include any of the following transactions: (x) the reincorporation of such Party in a different country or state or its change of name or reorganization in the same country or state; provided that such Party will continue to be owned by the then-current stockholders of such Party, which will hold all of the outstanding shares of capital stock of such Party in substantially the same proportion (with respect to both voting power and economics) as such stockholders held in such Party immediately prior to such reincorporation, change of name or reorganization; or

current stockholders of such Party, which will hold all of the outstanding shares capital stock of such Party in substantially the same proportion (with	эf
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(y) the formation of a holding company that will be owned exclusively by the then-

respect to both voting power and economics) as such stockholders held in such Party immediately prior to such formation.

- 1.37. "Clinical and Regulatory Working Group" or "CRWG" has the meaning set forth in Section 2.3.3.
- **1.38.** "CMC Development" means, with respect to any Licensed Product, all process development, product characterization, manufacturing scale-up, qualification and validation and quality assurance/quality control with respect to such Licensed Product or any part or component thereof.
- **1.39.** "CMC Development Plan" means the plan setting forth in reasonable detail the CMC Development activities to be performed by each Party or its Affiliates or designees with respect to the Licensed Compounds and Licensed Products. The initial CMC Development Plan is attached as **Schedule 1.39** to this Agreement.
  - 1.40. [\*\*\*]
- **1.41.** "CMC Working Group" has the meaning set forth in Section 2.3.2.
- 1.42. "Combination Product" means any pharmaceutical product that contains one (1) or more Licensed Compounds as an active ingredient(s) together with one (1) or more other active ingredients that are not Licensed Compounds ("Other Components") that are co-formulated or co-packaged or otherwise sold together for one (1) price. [\*\*\*]
- **1.43.** "Commercial Milestone Event" has the meaning set forth in Section 8.4.
- **1.44.** "Commercial Milestone Payment" has the meaning set forth in Section 8.4.
- **1.45.** "Commercial Process" means the process for the Manufacture of Licensed Compounds that satisfies all of the elements set forth on Schedule 1.40.
- **1.46.** "Commercialization" means any and all activities directed to the preparation for sale of, offering for sale of or sale of any product, including activities related to marketing, promoting, distributing and importing such product, and interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, "to Commercialize" or "Commercializing" means to engage in Commercialization and "Commercialized" has a corresponding meaning.
  - 1.47. "Commercially Reasonable Efforts" means, [\*\*\*]
  - **1.48.** [\*\*\*]
- **1.49.** "Competing Program" has the meaning set forth in Section 5.5.2.

Section 9.4.2(a)	"Competitive	Infringement"	has	the	meaning	set	forth	ın
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- 1.51. [\*\*\*]
- **1.52.** [\*\*\*]
- 1.53. [\*\*\*]
- **1.54.** "Confidential Information" has the meaning set forth in Section 10.1.
- **1.55.** "Confidentiality Agreement" has the meaning set forth in Section 10.1.
- 1.56. "Control" means, with respect to any item of Information, Regulatory Documentation, material, Patent or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise (other than by operation of the license grants in Section 5.1), to assign, grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent or other intellectual property right as provided for herein without [\*\*\*]
- 1.57. "Covered" or "Cover" means, with respect to a given subject matter (including any Licensed Product) and any claim of any Patent in any jurisdiction, that, in the absence of a license granted under, or ownership of, such Patent and in the absence of the benefit of the safe harbor provision under 35 U.S.C. Section 271(e)(1) or other Applicable Law, the making, use, offering for sale, sale or importation of such subject matter would infringe a Valid Claim (or, for any pending Valid Claim, infringe such Valid Claim as if it were issued) included in such Patent.
- **1.58.** "Data Package" means all Information (including clinical data) with respect to the Development (including CMC Development) of Licensed Compounds and Licensed Products as set forth on **Schedule 1.58**.
- 1.59. "Data Package Bring Down Date" has the meaning set forth in Section 11.3.1.
- **1.60.** "Data Package Updated Disclosure Schedule" has the meaning set forth in Section 11.3.1.
- 1.61. "Data Protection Law" means, to the extent applicable, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) as well as, if applicable, any and all Applicable Laws of the United States relating to data protection, privacy or data security and any and all other Applicable Laws relating to data protection, privacy or data security laws applicable to either Party in connection with this Agreement, including the United States Health Insurance Portability and Accountability Act of 1996 and its implementing regulations and the California Consumer Privacy Act. "Personal Data" as used in this Agreement shall be defined as in the General Data Protection Regulation.

9.3.1.	1.62.	"Defense	Proceeding"	has	the	meaning	set	forth	in	Section
7.5.1.										
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- **1.63.** "**Delivery System**" means any delivery system comprising equipment, instrumentation, one (1) or more devices or other components designed to assist in the administration of a Licensed Product.
- 1.64. "Development" means any and all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, translational (target engagement, biomarker) studies, CMC Development, clinical studies, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of applications for Regulatory Approval and regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. When used as a verb, "to Develop" or "Developing" means to engage in Development and "Developed" has a corresponding meaning.
- **1.65.** "Development Budget" has the meaning set forth in the definition of "Development Plan".
- **1.66.** "Development Milestone Event" has the meaning set forth in Section 8.3.
- **1.67.** "Development Milestone Payment" has the meaning set forth in Section 8.3.
- 1.68. "Development Plan" means the plan setting forth in reasonable detail the Development (excluding CMC Development) activities to be performed by or on behalf of ACI or its Affiliates with respect to the Licensed Compounds and Licensed Products, including a reasonably detailed budget of FTE Costs and Out-of-Pocket Costs to be incurred on a Fiscal Year basis with respect thereto (the "Development Budget"). The initial Development Plan (including the initial Development Budget) is attached as Schedule 1.68 to this Agreement. For clarity, the Development Plan shall not include any Development activities to be performed by or on behalf of Takeda from and after the Option Effective Date.
- **1.69.** "Directed" or "Directed To" means, with respect to any Active Immunotherapy and Abeta, that such Active Immunotherapy binds to, inhibits, modulates, reduces aggregation of or induces immunogenicity against aggregates of, in each case, Abeta.
  - **1.70.** "Dispute" has the meaning set forth in Section 14.5.1.
  - **1.71.** "Divest" has the meaning set forth in Section 5.5.2(c).
  - 1.72. "Dollars" or "\$" means United States Dollars.
- 1.73. "Drug Approval Application" means a New Drug Application or a Biologics License Application, each as defined in the FFDCA, or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a

country in Europe with respect to the mut procedure.	ual recognition or any other national approval
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- **1.74.** "**Drug Price Negotiation Program**" means the program described in 42 U.S.C. Part E (§§1320f et seq.).
  - **1.75.** "Effective Date" has the meaning set forth in the preamble.
- **1.76.** "EMA" means the European Medicines Agency and any successor agency thereto.
- 1.77. "European Union" or "EU" means the economic, scientific and political organization of member states of the European Union as its membership may be constituted from time to time.
  - **1.78.** "Exclusive License" has the meaning set forth in Section 5.1.1.
  - **1.79.** "Exclusivity Period" has the meaning set forth in Section 5.5.1.
- **1.80.** "Executive Officer" means, with respect to ACI, its Chief Executive Officer and with respect to Takeda, a senior executive officer responsible for research and discovery (or if the issue to be decided relates to Development or Commercialization, with responsibility for the applicable area), or, in either case, such executive officer's designee with appropriate responsibilities, seniority and decision-making authority with respect to the issue to be decided.
  - **1.81.** "Exercise Notice" has the meaning set forth in Section 4.1.3.
- **1.82.** "Existing Agreements" means any agreement existing as of the Effective Date, the Data Package Bring Down Date or the Option Effective Date, as applicable, by and between ACI or any of its Affiliates, on the one hand, and one (1) or more Third Parties, on the other hand, related to one (1) or more Licensed Compounds or Licensed Products or the Exploitation thereof.
  - **1.83.** "Existing Patents" has the meaning set forth in Section 11.2.1.
- **1.84.** "Existing Regulatory Documentation" means the Regulatory Documentation owned or controlled by ACI or any of its Affiliates as of the Effective Date, the Data Package Bring Down Date or the Option Effective Date, as applicable.
- **1.85.** "Exploit" means to make, have made, import, use, sell or offer for sale, including to research, Develop, Commercialize, register, Manufacture, have Manufactured, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of. "Exploitation" means the act of Exploiting.
- **1.86.** "FDA" means the United States Food and Drug Administration and any successor agency thereto.
- **1.87.** "FFDCA" means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

- 1.88. "Field" [\*\*\*]
- **1.89.** "Firewall Procedures" has the meaning set forth in Section 5.5.2(d).
- 1.90. "First Commercial Sale" means, with respect to a Licensed Product and a country, the first commercial sale for monetary value of such Licensed Product in such country by Takeda, its Affiliates or its or their respective Sublicensees to a Third Party after all Regulatory Approvals for such Licensed Product have been obtained in such country. [\*\*\*]
- 1.91. "Fiscal Year" means each successive period of twelve (12) calendar months commencing on April 1 and ending on March 31, except that the first Fiscal Year of the Term shall commence on the Effective Date and end on the following March 31 and the last Fiscal Year of the Term shall commence on the last April 1 before the Term ends and end on the last day of the Term.
- 1.92. "FTE" means the equivalent of the work of one (1) full time employee (i.e., one (1) fully-committed or multiple partially-committed employees aggregating to one (1) full-time employee but for clarity, excluding any contract personnel) for one (1) Calendar Year (consisting of [\*\*\*] hours per Calendar Year or such other number as may be agreed by the Parties in writing) employed by ACI (or its Affiliate) who directly performs activities under this Agreement. With respect to any employee who works fewer than [\*\*\*] hours per Calendar Year (or such other number as may be agreed by the Parties), such employee shall be treated as an FTE on a pro rata basis based upon the actual number of hours worked in a Calendar Year divided by [\*\*\*] hours; provided that in no event shall any employee count as more than one (1) FTE regardless of the number of hours worked by such employee. For clarity, sixty (60) minutes of work performed by one (1) employee (or aggregated across multiple employees) on a relevant activity shall be considered one (1) "FTE-hour." In no event shall FTEs include any indirect personnel, including support functions such as managerial, financial, legal and business development.
- 1.93. "FTE Costs" means, with respect to ACI for any period, the applicable FTE Rate multiplied by the applicable number of FTEs of ACI or any of its Affiliates performing the relevant activities under this Agreement.
- 1.94. "FTE Rate" means, as of the Effective Date, [\*\*\*] such rate to be adjusted annually (with the first of such adjustments to be made as of January 1, 2025 and each subsequent Calendar Year thereafter, but such adjustment determined no later than the preceding September 30) to correspond with the total percentage change in the Consumer Price Index for All Urban Consumers (CPI-U) for the U.S. City Average, 1982-84 = 100, calculated by the Bureau of Labor Statistics over the twelve (12)-month period preceding each such January 1. [\*\*\*]
- 1.95. "Good Clinical Practices" means the then-current standards for clinical trials for pharmaceuticals, as set forth in 21 C.F.R. Parts 50, 54, 56 and 312, and such standards of good clinical practice as are required by the Regulatory Authorities

of the United States and European Union and other organizations and Governmental Authorities in countries for which any
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Licensed Product is intended to be Developed, to the extent such standards are not less stringent than United States Good Clinical Practices.

- 1.96. "Good Laboratory Practices" means the then-current standards for nonclinical laboratory studies for pharmaceuticals, as set forth in the FDA's Good Laboratory Practice regulations as defined in 21 C.F.R. Part 58 or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development, and such standards of good laboratory practice as are required by the European Union and other organizations and Governmental Authorities in countries in which any Licensed Product is intended to be sold, to the extent such standards are not less stringent than United States Good Laboratory Practice.
- 1.97. "Good Manufacturing Practices" means all applicable current Good Manufacturing Practices including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 600 and 610, (b) Commission Delegated Regulation (EU) 2017/1569, Commission Directive (EU) 2017/1572 and the European Commission's Good Manufacturing Practice guidelines as set out in volume 4 of EudraLex, (c) the principles detailed in the ICH Q7 guidelines and (d) the equivalent applicable law in any relevant country, each as may be amended and applicable from time to time.
- 1.98. "Government Official" means (a) any person employed by or acting on behalf of a government, government-controlled agency or entity or public international organization, (b) any political party, party official or candidate or Person employed by or acting on behalf of any of the foregoing, (c) any person categorized as a government official under local law or (d) any person who holds themself out to be the authorized intermediary of any of the foregoing.
- 1.99. "Governmental Authority" means any national, international, federal, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, or any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.
- 1.100. "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as codified at 15 U.S.C. §18a, as may be amended from time to time, and the rules and regulations promulgated thereunder, or foreign equivalent thereof under Applicable Law (including all additions, supplements, extensions and modifications thereto).
- 1.101. "Improvements" means any invention, discovery, development or modification licensed, acquired, conceived, reduced to practice, discovered, developed or otherwise made by or on behalf of Takeda or any of its Affiliates or its or their Sublicensees with respect to a Licensed Compound or a Licensed Product or relating to the Exploitation thereof, whether or not patented or patentable, including any enhancement in the efficiency, operation, Manufacture, ingredients, preparation, presentation, formulation, means of delivery (including the development of any

Delivery	System	or en	hancemen	t thereto)	or	dosage	ot	such	Licensed	Compound	or
Licensec	l Product	, any c	discovery	or develo	pme	ent of ar	ıy r	new or	expanded	d	

indications for such Licensed Compound or Licensed Product, or any discovery or development that improves the stability, safety or efficacy of such Licensed Compound or Licensed Product.

- **1.102.** "IND" means (a) an investigational new drug application filed with the FDA for authorization to commence clinical studies and its equivalent in other countries or regulatory jurisdictions and (b) all supplements and amendments that may be filed with respect to the foregoing.
- **1.103.** "Indemnification Claim Notice" has the meaning set forth in Section 12.3.1.
- **1.104.** "Indemnified Party" has the meaning set forth in Section 12.3.1.
- 1.105. "Independent Expert" means an impartial and conflicts-free Third Party expert that (a) has no less than [\*\*\*] of relevant business, financial, scientific or other experience in the pharmaceutical or biotechnology industry, with substantial experience in valuing intellectual property rights for the commercialization of pharmaceutical and biotechnology products, (b) is not a current or former director, officer, employee or consultant of any Party or any of its Affiliates or its or their (sub)licensees/Sublicensees, (c) has no known personal financial interest or benefit in the outcome or resolution of the applicable dispute and (d) is a native English speaker.
- 1.106. "Information" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays and biological methodology, in each case (whether or not proprietary, patented or patentable), in written, electronic or any other form now known or hereafter developed and that is not generally known to the public.
- **1.107.** "Initial Disclosure Schedule" has the meaning set forth in Section 11.2.
- **1.108.** "Initiation" means, with respect to a clinical trial, the first dosing of the first human subject in such clinical trial. When used as a verb, "Initiate" means to engage in Initiation and "Initiated" has a corresponding meaning.
- 1.109. "Insolvency Event" means (a) the commencement of any bankruptcy, insolvency, moratorium, liquidation, judicial reorganization proceeding, dissolution, arrangement or proceeding under any creditors' rights law or other similar proceeding by or against either Party, (b) any applications for, consent by either Party or acquiescence by such Party in, the appointment of any trustee, receiver or other custodian for either Party or a substantial part of its property, (c) any appointment of a

trustee, receiver or other custodian for either Party or a substantial part of its property or (d) any assignment by either Party for the benefit of creditors.

**1.110.** "**IRA**" means 42 U.S.C. §§1320f *et seq.* and all its subsequent amendments and replacements and regulations promulgated thereunder.

- **1.111.** "IRA Reduction Event" has the meaning set forth in Section 8.5.3(c).
- **1.112.** "Joint Development Team" or "JDT" has the meaning set forth in Section 2.1.
- **1.113.** "Joint Intellectual Property Rights" has the meaning set forth in Section 9.1.2.
  - **1.114.** "Joint Know-How" has the meaning set forth in Section 9.1.2.
  - **1.115.** "Joint Patents" has the meaning set forth in Section 9.1.2.
- **1.116.** "Knowledge" means the actual knowledge after performing a diligent investigation with respect to such facts and information [\*\*\*]
  - 1.117. "Licensed Compound" means [\*\*\*]
- **1.118.** "Licensed Know-How" means all Information that is Controlled by ACI or its Affiliates as of the Effective Date or during the Term that is necessary or reasonably useful for the Development, Manufacture, Commercialization or other Exploitation of one (1) or more Licensed Compounds or Licensed Products in the Field in the Territory, but excluding ACI's interest in the Joint Know-How.
- **1.119.** "Licensed Patents" means all Patents that are Controlled by ACI or its Affiliates as of the Effective Date or during the Term that are necessary or reasonably useful for the Development, Manufacture, Commercialization or other Exploitation of one (1) or more Licensed Compounds or Licensed Products in the Field in the Territory, but excluding ACI's interest in the Joint Patents.
- **1.120.** "Licensed Product" means any product containing or comprising any Licensed Compound or any Improvement thereto, alone or in combination with one (1) or more other active ingredients, in any and all forms, presentations, Delivery Systems, dosages and formulations (including Improvements to any such forms, presentations, Delivery Systems, dosages and formulations), including any Combination Products.
  - **1.121.** "Losses" has the meaning set forth in Section 12.1.
  - 1.122. "Major Market" means each of [\*\*\*]
- 1.123. "Manufacture" or "Manufacturing" means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of a compound, product or any intermediate or component thereof, including pre-clinical, clinical and commercial manufacture, stability and shelf life assignment and manufacturing release. Manufacturing excludes activities that are CMC Development activities.
  - **1.124.** "Manufacturing Process" has the meaning set forth in Section

**1.125.** "Manufacturing Technology Transfer" has the meaning set forth in Section 6.2.

1.126. "Maximum Fair Price" means a maximum fair price under the Drug Price Negotiation Program as defined in 42 U.S.C. §1320f(c)(3) and all its subsequent amendments and replacements and guidance or regulations promulgated thereunder or any future Applicable Law in the United States that sets or imposes a cap on the price for a drug product that will be charged to, or reimbursed by, the United States (or any department or agency thereof) or any healthcare program administered by or on behalf thereof.

1.127. "Net Sales" means, with respect to a Licensed Product, the gross amount invoiced in a country in the Territory by or on behalf of Takeda or its Affiliates or its or their Sublicensees (each of the foregoing Persons, a "Selling Party") for the sale or other disposition of such Licensed Product in such country to Third Parties (including Third Party distributors), *less* the following deductions, consistently applied in such country in the Territory by the relevant Selling Party, [\*\*\*]

- (a) [\*\*\*]
- (b) [\*\*\*]
- (c) [\*\*\*]
- (d) [\*\*\*]
- (e) [\*\*\*]
- (f) [\*\*\*]
- (g) [\*\*\*]

Notwithstanding the foregoing, amounts received or invoiced by Takeda or its Affiliates or its or their Sublicensees for the sale of such Licensed Product among Takeda or its Affiliates or its or their Sublicensees for resale will not be included in the computation of Net Sales hereunder; [\*\*\*] For clarity, a particular deduction may only be accounted for once in the calculation of Net Sales. [\*\*\*]

For purposes of calculating Net Sales, all Net Sales shall be converted into Dollars in accordance with Section 8.9.

[***]
[***]
[***]
[***]

- 1.128. "Non-Breaching Party" has the meaning set forth in Section 13.2.1.
  - **1.129.** "Notice Period" has the meaning set forth in Section 13.2.1.
  - **1.130.** "Option" has the meaning set forth in Section 4.1.1.
- **1.131. "Option Effective Date"** has the meaning set forth in Section 11.3.2.
- **1.132.** "Option Exercise Date" means the date upon which Takeda delivers to ACI the Exercise Notice with respect to the Option in accordance with Section 4.1.3.
  - **1.133.** "Option Exercise Fee" has the meaning set forth in Section 8.2.
- **1.134.** "Option Period" means the period commencing on the Effective Date and ending on the date that is [\*\*\*]
  - **1.135.** "**Option Period IP**" means [\*\*\*]
- **1.136.** "Orange Book" means the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (which identifies drug products approved on the basis of safety and effectiveness by the FDA under the FFDCA) or any replacement thereof established or approved by the FDA.
- **1.137.** "Other Components" has the meaning set forth in the definition of "Combination Product".
- 1.138. "Other Licensed Patents" means the Patents set forth on Schedule 1.138.
  - 1.139. "Out-of-Pocket Costs" means [\*\*\*]
  - 1.140. [\*\*\*]
- **1.141.** "Party" and "Parties" have the meaning set forth in the preamble hereto.
- 1.142. "Patents" means (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the

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**1.143.** "Payment" has the meaning set forth in Section 8.10.

- **1.145.** "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a Governmental Authority.
- **1.146.** "Personal Data" has the meaning set forth in the definition of "Data Protection Law".
- **1.147.** "Phase 1b/2 Trial" means the clinical trial entitled "A Study to Assess the Effects of ACI-24.060 in Alzheimer's Disease and in Down Syndrome (ABATE Study)," identified by ClinicalTrials.gov ID NCT05462106.
- **1.148.** "Phase 3 Process" means the process for the Manufacture of the Licensed Compounds that satisfies all of the elements set forth on Schedule 1.148.
- 1.149. "Phase 3 Trial" means, with respect to any Licensed Product, (a) a human pivotal clinical trial for such Licensed Product, the results of which, together with prior data and information concerning such Licensed Product, would [\*\*\*], including those trials described in 21 C.F.R. §312.21(c) or (b) a foreign clinical trial that is equivalent to the one described in the preceding clause (a), in each case ((a) and (b)), as acknowledged by the applicable Regulatory Authority; provided that, for clarity, data from prior studies and trials may additionally support the filing of a Drug Approval Application for such Licensed Product (including, for clarity, to establish that such Licensed Product is safe and efficacious for its intended use). For clarity, a human clinical trial that does not meet the foregoing criteria when it is Initiated, but later meets the foregoing criteria shall constitute a Phase 3 Trial for purposes of this Agreement only at the time the applicable Regulatory Authority acknowledges that such human clinical trial meets such criteria and, for purposes of Section 8.3, such Phase 3 Trial shall be deemed to be Initiated as of the date of such acknowledgement.
- **1.150.** "PMDA" means Pharmaceuticals and Medical Devices Agency of Japan and any successor agency thereto.

- 1.153. "Pre-Existing Entity" and "Pre-Existing Entities" has the meaning set forth in Section 5.5.2.
- **1.154.** "Price Applicability Period" has the meaning set forth in 42 U.S.C. §1320f(b)(2).
  - **1.155.** "Product Agreement" has the meaning set forth in Section 5.6.

- 1.156. "Product Information" means Confidential Information constituting Regulatory Documentation, Joint Know-How and any other Information, in each case, developed, owned or Controlled by ACI or any of its Affiliates (including Licensed Know-How) (a) relating to any Licensed Compound or any Licensed Product or any Improvements thereto or the Exploitation of any of the foregoing in the Field in the Territory or (b) specific to Abeta or vaccine products Directed to Abeta or the Exploitation thereof.
- 1.157. "Product Patents" means any and all Licensed Patents, including the Patents set forth on Schedule 1.157, but excluding the Other Licensed Patents.
- 1.158. "Product Trademarks" means the Trademark(s) used or to be used by Takeda or its Affiliates or its or their Sublicensees for the Commercialization of Licensed Products in the Territory and any registrations thereof or any pending applications relating thereto in the Territory, including any unregistered Trademark rights related to the Licensed Products as may exist through use before, on or after the Effective Date (excluding, in any event, any Trademarks that include the corporate name or logo of Takeda or its Affiliates or its or their Sublicensees and any Trademarks Controlled by ACI or any of its Affiliates and anything confusingly similar to such Trademarks).

1.159. [\*\*\*]

- **1.160.** "**Proprietary Information**" means, with respect to a Party, any Information that [\*\*\*]
- **1.161.** "Purple Book" means the FDA's Purple Book Database of FDA-licensed biological products or any replacement thereof established or approved by the FDA.

1.162. [\*\*\*]

- 1.163. "Regulatory Approval" means, with respect to a country in the Territory, any and all approvals (including accelerated or conditional approvals), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a Licensed Product in such country, including, where applicable, (a) pricing or reimbursement approval in such country, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (c) labeling approval.
- **1.164.** "Regulatory Authority" means any applicable Governmental Authority regulating or otherwise exercising authority with respect to the Exploitation of Licensed Compounds or Licensed Products in the Territory, including the FDA in the United States, the EMA in the European Union and the PMDA in Japan.
- **1.165.** "Regulatory Documentation" means: any and all (a) applications (including all INDs and Drug Approval Applications), registrations, licenses, authorizations and approvals (including Regulatory Approvals);

(b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all Adverse Event files and complaint files; and (c) clinical and other data

contained or referenced in any of the foregoing; in each case ((a), (b) and (c)), relating to any Licensed Compound or any Licensed Product.

1.166. "Regulatory Exclusivity" means, with respect to any Licensed Product in any country in the Territory, exclusive marketing or data exclusivity rights (other than Patent protection) granted by a Regulatory Authority in such country with respect to such Licensed Product [\*\*\*]

1.169. "Royalty Term" means, with respect to each Licensed Product and each country in the Territory, the period beginning on the date of the First Commercial Sale of such Licensed Product in such country and ending on the latest to occur of: [\*\*\*]

- **1.172.** "Selected Drug" has the meaning set forth in Section 1192(c)(1) of the Social Security Act.
- 1.173. "Selling Party" has the meaning set forth in the definition of "Net Sales".
- **1.174.** "Sublicensed Option Period IP" has the meaning set forth in Section 9.1.3(b).
- 1.175. "Sublicensee" means a Third Party that is granted a sublicense by Takeda or its Affiliate under the grants in Section 5.1, as provided in Section 5.2, and any further sublicenses of such license (regardless of the number of tiers, layers or levels of sublicense of such rights), except for a Third Party to which Takeda or its Affiliate or its or their Sublicensees grants a sublicense [\*\*\*] to settle or avoid litigation or any Patent claim or dispute with such Third Party related to (a) the alleged infringement by a Licensed Product or the Exploitation thereof of any Patents or other intellectual property of such Third Party or (b) the alleged non-infringement, invalidity or unenforceability of, or challenge against, any Patents Covering or claiming a Licensed Product or the Exploitation thereof; provided that any bona fide Third Party commercial distributor that pays to Takeda or its Affiliate a supply price for the Licensed Product ordered from Takeda or its Affiliate shall not be considered a "Sublicensee" hereunder, irrespective of whether a sublicense is granted by Takeda or its Affiliate to such Third Party.
  - **1.176.** "Supply Agreement" has the meaning set forth in Section 6.1.4.
  - **1.177.** "Takeda" has the meaning set forth in the preamble.
  - 1.178. [\*\*\*]

- **1.180.** "Takeda Indemnitees" has the meaning set forth in Section 12.2.
  - **1.181.** "Takeda Notice Date" has the meaning set forth in Section 13.6.
- **1.182.** "Tax" or "Taxes" means any form of tax or taxation, levy, duty, charge, social security charge, contribution or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, any Governmental Authority.
- **1.183.** "Technology Transfer Plan" has the meaning set forth in Section 4.5.
  - **1.184.** "Term" has the meaning set forth in Section 13.1.
- **1.185.** "Termination Notice" has the meaning set forth in Section 13.2.1.
- **1.186.** "**Territory**" means the entire world (except for any country that has been terminated in accordance with Section 13.2.2, subject to Section 13.5.2).
- **1.187.** "**Third Party**" means any Person other than ACI, Takeda and their respective Affiliates.
  - **1.188.** "Third Party Claims" has the meaning set forth in Section 12.1.
- **1.189.** "Third Party Infringement Claim" has the meaning set forth in Section 9.6.
- **1.190.** "Third Party Payments" has the meaning set forth in Section 8.6.
  - **1.191.** "Third Party Right" has the meaning set forth in Section 9.7.1.
- 1.192. "Trademark" means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design, business symbol, domain name, URL, social media tag or handle, that functions as an identifier of source or origin, whether or not registered and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.
- 1.193. "United States" or "U.S." means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).
- **1.194.** "UPC Opt-In" means, with respect to a Patent that has previously been opted out of the exclusive competence of the Unified Patent Court pursuant to Article 83(3) of the Agreement on a Unified Patent Court ((2013/C 175/

01), 20.6.2013, OJEU 175/1), withdrawing the UPC Opt-Out of such Patent pursuant to Article 83(4) of the Agreement on a Unified Patent Court.
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- **1.195.** "UPC Opt-Out" means, with respect to a Patent, opting such Patent out of the exclusive competence of the Unified Patent Court pursuant to Article 83(3) of the Agreement on a Unified Patent Court ((2013/C 175/01), 20.6.2013, OJEU 175/1).
- 1.196. "Valid Claim" means a claim of any (a) United States or foreign pending patent application that has not, in the country in question, been finally cancelled, finally rejected, withdrawn, expired or abandoned, without the opportunity for appeal or (b) issued and unexpired Patent, where the claim (i) has not been subject to irretrievable lapse, abandonment, permanent revocation, dedication to the public or disclaimer, (ii) is neither admitted to be invalid or unenforceable through reissue nor subject to ongoing reissue proceedings and (iii) has not been held permanently revoked, invalid or unenforceable by a holding, finding or decision of a court, national or regional patent office or other Governmental Authority that has competent jurisdiction, such holding, finding or decision being final and unappealable or unappealed within the time allowed for appeal; *provided* that Valid Claim shall exclude any such pending claim that has not been granted within [\*\*\*] following the earliest priority filing date for such application.
- **1.197.** "Voting Stock" has the meaning set forth in the definition of "Change of Control".
- **1.198.** "Withholding Tax Action" has the meaning set forth in Section 8.10.
  - **1.199.** "Withholding Taxes" has the meaning set forth in Section 8.10.
  - **1.200.** "Working Group" has the meaning set forth in Section 2.3.1.

# ARTICLE 2 JOINT DEVELOPMENT TEAM

- 2.1. Joint Development Team. Within [\*\*\*] after the Effective Date, the Parties shall establish a joint development team (the "Joint Development Team" or "JDT"), which shall consist of [\*\*\*] representatives from each of the Parties, each with the requisite experience and seniority to enable such representative to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JDT. From time to time, each Party may substitute one (1) or more of its representatives to the JDT on written notice to the other Party. [\*\*\*] The JDT shall have the overall responsibility for the oversight and coordination of Development activities (including any CMC Development activities) under this Agreement; provided that, for clarity, such responsibility shall not extend to oversight or coordination of Takeda's Development activities from and after the disbandment of the JDT.
- **2.2. Specific Responsibilities.** In addition to its overall responsibility for overseeing and coordinating Development activities under this Agreement as set forth in Section 2.1 and subject to the final decision-making authority of the Parties as set forth in Section 2.6, the JDT shall:

2.2.1. [\*\*\*]

2.2.2. [\*\*\*]

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- 2.2.3. [\*\*\*]
- 2.2.4. [\*\*\*]
- 2.2.5. [\*\*\*]
- 2.2.6. [\*\*\*]
- 2.2.7. [\*\*\*]
- 2.2.8. [\*\*\*]
- 2.2.9. [\*\*\*]
- 2.2.10. [\*\*\*]
- 2.2.11. [\*\*\*]

**2.2.12.** perform such other functions as are set forth herein, if and as applicable, or as the Parties may mutually agree in writing.

### 2.3. Working Groups.

2.3.1. Working Groups Generally. From time to time, the JDT may establish and delegate duties to other committees or directed teams (each, a "Working Group") on an "as-needed" basis to oversee particular projects or activities. Each such Working Group shall be constituted and shall operate as the JDT determines; provided that (a) unless otherwise agreed by the Parties in writing, each Working Group shall have [\*\*\*] with each representative having the requisite experience and seniority, and each Party may substitute one (1) or more of its representatives on each such Working Group upon written notice to the other Party, (b) unless otherwise determined by the JDT, Working Groups shall not have any decision-making authority and shall solely be responsible for coordination and information-sharing (but, for clarity, the CMC Working Group and the CRWG shall have the authority over dayto-day implementation of the CMC Development Plan and the Development Plan, respectively, and without limiting Section 2.6.2, ACI shall have authority over its dayto-day implementation of the Development Plan, and each Party shall have authority over its day-to-day implementation of its respective activities in the CMC Development Plan), (c) any dispute between the representatives of each Party on a Working Group shall be referred to the JDT for resolution in accordance with Section 2.6 and other terms and conditions of this Agreement and (d) the JDT shall have the discretion to disband any Working Groups. Working Groups may be established on an ad hoc basis for purposes of a specific project, for the term of the JDT or on such other basis as the JDT may determine. Alliance Managers or other employees or consultants of a Party who are not representatives of the Parties on a Working Group may attend meetings of such Working Group (other than the CMC Working Group, the meetings of which shall be limited to the members of the CMC Working Group unless otherwise agreed by the Parties); provided, however, that such attendees are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set

forth in Article 10. Each Working Group and its activities shall be subject to oversig review and	ξht,
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approval of the JDT. In no event shall the authority of any Working Group exceed that specified for the JDT in this Article 2.

**2.3.2. CMC Working Group.** Without limiting Section 2.3.1, within [\*\*\*] after its formation, the JDT shall establish a CMC working group (the "CMC Working Group") to coordinate the CMC Development and Manufacturing activities performed by or on behalf of the Parties in accordance with this Agreement. The CMC Working Group shall meet at least [\*\*\*] or as otherwise determined by the JDT; provided that the CMC Working Group, in its reasonable discretion, may decide to cancel or reschedule meetings. The CMC Working Group may meet in person, by videoconference or by teleconference as determined by the JDT. Subject to Section 2.3.1 and Section 3.3, the CMC Working Group shall (a) serve as a forum for discussing and coordinating the CMC Development and Manufacturing activities, including with respect to [\*\*\*] (b) encourage and facilitate ongoing communication and cooperation between the Parties with respect to the CMC Development and Manufacturing activities and the progress thereof; (c) seek to resolve any issues or delays with respect to the development of the Phase 3 Process and the Commercial Process; (d) periodically discuss the Parties' respective supply chains, plans and process development activities and coordinate to identify any efficiencies with respect thereto; and (e) perform such other functions as determined by the JDT.

2.3.3. Clinical and Regulatory Working Group. Without limiting Section 2.3.1, within [\*\*\*] after its formation, the JDT shall establish a clinical and regulatory working group (the "Clinical and Regulatory Working Group" or the "CRWG") to develop and oversee the overall clinical and regulatory strategy for Licensed Compounds and Licensed Products. The CRWG shall meet at least [\*\*\*] or as otherwise determined by the JDT; provided that the CRWG, in its reasonable discretion, may decide to cancel or reschedule meetings. The CRWG may meet in person, by videoconference or by teleconference as determined by the JDT. Subject to Section 2.3.1, the CRWG shall (a) serve as a forum for discussing and overseeing the clinical and regulatory activities of the Parties with respect to Licensed Compounds and Licensed Products; (b) encourage and facilitate ongoing communication and cooperation between the Parties with respect any Regulatory Documentation; and (c) perform such other functions as determined by the JDT.

**2.4. Meetings and Minutes.** The JDT shall meet at least [\*\*\*] or as otherwise agreed to by the Parties. The JDT may meet in person, by videoconference, by teleconference or similar means in which each participant can hear what is said by and be heard by the other participants as mutually agreed by the Parties; *provided* that such meetings shall be in-person at least [\*\*\*] unless otherwise agreed by the Parties. In-person meetings shall be held at locations alternating between locations designated by ACI and locations designated by Takeda, with Takeda designating the place of the first in-person meeting. The chairperson of the JDT shall be responsible for calling meetings on no less than [\*\*\*] notice unless exigent circumstances require shorter notice. Each Party shall make all proposals for agenda items at least [\*\*\*] in advance of the applicable meeting and shall provide all appropriate information with respect to such proposed items at least [\*\*\*] in advance of the applicable meeting; *provided* that under exigent circumstances requiring input by the JDT, a Party may provide its agenda

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items to the other Party within a shorter period of time in advance of the meeting or may

unreasonably withheld, conditioned or delayed). The chairperson of the JDT (or his or her designee) shall prepare and circulate for review and approval of the Parties minutes of each meeting within [\*\*\*] after the meeting. The Parties shall agree on the minutes of each meeting promptly, but in any event no later than the next meeting of the JDT, and such agreed minutes shall be converted to a finalized PDF version (which version shall constitute the official minutes for the applicable meeting).

2.5. Procedural Rules. The JDT shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the JDT shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. Representation by proxy shall be allowed. Alliance Managers or other employees or consultants of a Party who are not representatives of the Parties on the JDT may attend meetings of the JDT; provided, however, that such attendees (a) shall not vote or otherwise participate in the decision-making process of the JDT and (b) are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in Article 10.

## 2.6. Decision-Making.

**2.6.1. Generally.** [\*\*\*] The JDT shall review and discuss the matters before it in good faith such that the perspectives of each Party's representatives on the JDT are given due consideration. Any decision made by the Executive Officers in accordance with Section 2.6.2(a) or by a Party in accordance with Section 2.6.2(b) shall be considered a decision made by the JDT.

#### 2.6.2. Resolution of JDT Matters.

(a) **Executive Officers.** In the event that the JDT cannot reach a unanimous vote with respect to an issue within its jurisdiction and authority within [\*\*\*] after such issue is first presented to the JDT for consideration, the JDT shall refer such dispute to the Executive Officers, who shall confer in good faith on resolution of such dispute for a period of [\*\*\*] Any final decision mutually agreed to by such Executive Officers shall be conclusive and binding on the Parties.

(b) Unresolved Matters. If any such issue has not been resolved by Executive Officers pursuant to Section 2.6.2(a) in such [\*\*\*] period (or such longer period as the Executive Officers may agree) despite good faith negotiations, then:

- (i) [\*\*\*]
- (ii) [\*\*\*]

provided that, in each case ((i) and (ii)), neither Party shall exercise its final decision-making authority in a manner that is reasonably likely to cause the other Party to violate Applicable Law.

In participating in the JDT, and in exercising their rights under this Article 2, all representatives of both Parties shall consider reasonably and in good faith all input received from the other Party.

- 2.7. Limitations on Authority. Without limitation to the foregoing, the Parties hereby agree that (a) matters explicitly reserved to the consent, approval or other decision-making authority of one or both Parties, as expressly provided in this Agreement, are outside the jurisdiction and authority of the JDT, including (i) amendment, modification or waiver of compliance with this Agreement (which may only be amended or modified as provided in Section 14.8 or compliance with which may only be waived as provided in Section 14.11) and (ii) such other matters as are reserved to the consent, approval, agreement or other decision-making authority of either or both Parties in this Agreement that are not required by this Agreement to be considered by the JDT prior to the exercise of such consent, approval or other decision-making authority and (b) from and after the Option Effective Date, [\*\*\*]
- Discontinuation; Disbandment. The JDT and any Working 2.8. Groups shall continue to exist until the first to occur of (a) the Parties mutually agreeing in writing to disband the JDT or any such Working Group, as applicable, (b) [\*\*\*] and (c) either Party exercising its right to disband the JDT and Working Groups in the event of a Change of Control as set forth in Section 5.5.2(e), as applicable. Upon the occurrence of any of the foregoing, (i) the JDT and each Working Group shall disband, have no further responsibilities or authority under this Agreement and shall be considered dissolved by the Parties; (ii) any requirement of a Party to provide Information or other materials to the JDT or a Working Group shall be deemed a requirement to provide such Information or other materials to the other Party; (iii) prior to the Option Effective Date, decision-making authority over all matters that are subject to review or approval by the JDT hereunder shall be made in accordance with Section 2.6, mutatis mutandis; and (iv) following the Option Effective Date, Takeda shall have the right to solely decide all matters that are subject to review or approval by the JDT hereunder.
- 2.9. Alliance Managers. Each Party shall appoint one (1) of its employees to act as alliance manager for such Party under this Agreement (each, an "Alliance Manager"), which Alliance Manager may be replaced at any time by notice in writing to the other Party. The Alliance Managers shall work together to manage and facilitate the communication between the Parties under this Agreement, including the resolution (in accordance with the terms of this Agreement) of issues between the Parties that arise in connection with this Agreement and other responsibilities as the Parties may agree in writing. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement.

# ARTICLE 3 INITIAL DEVELOPMENT

3.1. Development Plan and CMC Development Plan. Attached hereto as Schedule 1.68 is the initial Development Plan (including the initial Development Budget) and attached hereto as Schedule 1.39 is the initial CMC Development Plan. [\*\*\*] For clarity, the Development Plan shall not include any

### 3.2. ACI Performance; Costs.

**3.2.1.** ACI shall perform (or cause to be performed) the Development activities set forth in the Development Plan as set forth therein and shall use Commercially Reasonable Efforts to do so in accordance with the timelines set forth therein. ACI shall perform, or cause to be performed, all Development activities in good scientific manner and in compliance with all Applicable Law and by allocating sufficient time, effort, equipment and skilled personnel to complete such Development activities in accordance with the Development Plan. Except as set forth in Section 7.2.4, ACI shall not initiate or perform any Development activity or any CMC Development activity with respect to a Licensed Compound or Licensed Product that is not set forth in the Development Plan or the CMC Development Plan, as applicable.

**3.2.2.** Each Party shall bear all costs and expenses incurred by or on behalf of such Party in the performance of the Development activities (including CMC Development activities) in the Territory.

## 3.3. CMC Development.

**3.3.1.** Without limiting Section 3.2.1, ACI shall perform (or cause to be performed) its CMC Development activities set forth in the CMC Development Plan as set forth therein and shall use Commercially Reasonable Efforts to do so in accordance with the timelines set forth therein. Any CMC Development activities performed by or on behalf of Takeda shall be performed in accordance with the CMC Development Plan. The Parties shall perform, or cause to be performed, all CMC Development activities in good scientific manner and in compliance with all Applicable Law and, with respect to ACI, by allocating sufficient time, effort, equipment and skilled personnel to complete such CMC Development activities in accordance with the CMC Development Plan. Each Party shall coordinate with the other Party with respect thereto, including that (a) subject to Section 5.5.2(e), at each meeting of the CMC Working Group, each Party shall share with the CMC Working Group the results of any CMC Development activities it has performed, or caused to be performed, since the preceding CMC Working Group meeting and (b) the CMC Working Group shall seek to resolve any delays, issues or other inefficiencies between the Parties' respective performance of any CMC Development activities.

**3.3.2.** Without limiting Section 6.2 but subject to Section 3.3.3, in order to enable Takeda's performance of CMC Development activities, ACI shall transfer and make available to Takeda the Licensed Know-How and other materials set forth in the CMC Development Plan (at the times specified therein) or as otherwise agreed by the CMC Working Group and shall provide such support as may be necessary or reasonably useful to Takeda or its designee to use and implement such Licensed Know-How and other materials in the performance of its CMC Development activities.

**3.4. Subcontracting.** ACI shall not have the right to subcontract its Development activities (including CMC Development activities) to a Third Party without the prior written approval of Takeda (it being understood that any Third Parties listed on **Schedule 3.4** shall be deemed approved by Takeda as of the Effective Date with respect to the performance of those activities listed in **Schedule 3.4** for each such Third Party). As between the Parties, ACI shall (a) be responsible for the acts and omissions of its subcontractors and (b) ensure that its Third Party subcontractors comply with the applicable terms and conditions of this Agreement, including Article 10. For the avoidance of doubt, (x) ACI shall remain directly responsible for all of its obligations under this Agreement, notwithstanding any subcontracting arrangement hereunder, and (y) use of a subcontractor shall not relieve or release ACI from, or modify, any obligations of ACI under this Agreement.

## **3.5. Regulatory.** Prior to the Option Effective Date:

- **3.5.1.** As between the Parties, subject to and without limiting the JDT's authority to approve any amendment to the protocol or statistical analysis plan for the Phase 1b/2 Trial, ACI shall have the sole right to prepare, obtain and maintain INDs and other Regulatory Documentation (including all Regulatory Approvals) and other submissions to Regulatory Authorities in the Territory and to conduct communications with the Regulatory Authorities in the Territory, in each case, for the Licensed Compounds and Licensed Products. Without limiting the remainder of this Section 3.5, in [\*\*\*]
- **3.5.2.** ACI shall provide Takeda with (a) its proposed engagement strategy for Regulatory Authorities in the Territory with respect to the Licensed Products and (b) all regulatory filings and documents (including INDs, Regulatory Authority meeting materials and core data sheets), in each case ((a) and (b)), sufficiently (but in any event at least [\*\*\*] in advance of the finalization or submission thereof for Takeda's review and comment and, if necessary, discussion with ACI. ACI shall incorporate all reasonable comments from Takeda except to the extent inconsistent with Applicable Law.
- 3.5.3. ACI shall provide Takeda with prior written notice of any scheduled meeting, conference or discussion (including any advisory committee meeting) with a Regulatory Authority within [\*\*\*] after ACI or its Affiliate first receives notice of the scheduling of such meeting, conference or discussion (or within such shorter period as may be necessary in order to give Takeda a reasonable opportunity to attend such meeting, conference or discussion). Upon Takeda's written request, Takeda shall have the right to have [\*\*\*] attend [\*\*\*] all such meetings, conferences and discussions (including by [\*\*\*]. ACI shall promptly provide Takeda with copies of preliminary feedback and meeting minutes from any Regulatory Authority.
- **3.5.4.** As between the Parties, all Regulatory Documentation (including all Regulatory Approvals) relating to the Licensed Compounds or Licensed Products in the Territory shall be owned by, and shall be the sole property and held in the name of, ACI.

**3.5.5.** Takeda shall support ACI, as may be reasonably requested by ACI in writing, in preparing any Regulatory Documentation (including all Regulatory Approvals), including providing any documents or other materials as may be reasonably necessary for ACI to obtain and maintain Regulatory Approvals, at Takeda's sole cost and expense.

#### 3.6. Records.

**3.6.1.** ACI shall maintain, in good scientific manner, complete and accurate books and records pertaining to its Development activities (including CMC Development activities), in sufficient detail to verify compliance with its obligations under this Agreement and which shall be appropriate for Patent and regulatory purposes, in compliance with Applicable Law and that properly reflect all work done and results achieved in the performance of such activities. Such books and records shall record only such activities and shall not include or be commingled with records of activities outside the scope of this Agreement. Such books and records shall be retained by ACI for at least [\*\*\*] after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law.

**3.6.2.** Prior to the Option Effective Date, Takeda shall maintain, in good scientific manner, complete and accurate books and records pertaining to its CMC Development activities, in sufficient detail to verify compliance with its obligations under this Agreement and which shall be appropriate for Patent and regulatory purposes, in compliance with Applicable Law and that properly reflect all work done and results achieved in the performance of such activities. Such books and records shall record only such activities and shall not include or be commingled with records of activities outside the scope of this Agreement. Such books and records shall be retained by Takeda for at least [\*\*\*] after the expiration of the Option Period or for such longer period as may be required by Applicable Law.

**3.6.3.** Takeda shall have the right to request any records of ACI maintained pursuant to this Section 3.6, and ACI shall provide such records as promptly as reasonably practicable; *provided* that Takeda shall maintain such records and the information disclosed therein in confidence in accordance with Article [\*\*\*]

### 3.7. Reports and Information Sharing.

3.7.1. Without limiting Section 3.3.2, Section 3.6 or Section 4.5, during each meeting of the JDT, ACI shall provide to the JDT a detailed report of Development activities it has performed, or caused to be performed, since the preceding report, its Development activities in process and the future Development activities it expects to initiate during [\*\*\*] including updates regarding regulatory activities conducted by or on behalf of ACI or any of its Affiliates or (sub)licensees), in each case with respect to the Licensed Compounds and Licensed Products. Without limiting the foregoing, (a) ACI shall promptly make available to Takeda, through the JDT, all results and data from Development activities performed under the Development Plan (including all raw data from the Phase 1b/2 Trial) and the CMC Development Plan, (b) without limiting clause (a), until the Option Effective Date, ACI shall provide to Takeda all material safety Information with respect to the Licensed Compounds and Licensed Products as promptly as practicable (and in any event within [\*\*\*] after ACI receives such Information) and (c) upon Takeda's request (not more than [\*\*\*]), ACI shall provide additional ad-hoc summary reports with respect to its Development activities.

it expects to initiate during [\*\*\*] (including updates regarding regulatory activities conducted by or on behalf of Takeda or any of its Affiliates or Sublicensees), in each case, with respect to the Licensed Products and Licensed Compounds. During each meeting of the JDT, the Parties shall further discuss in detail such Development activities of Takeda. Upon the disbandment of the JDT in accordance with Section 2.8, [\*\*\*]

# ARTICLE 4 GRANT OF OPTION; OPTION EXERCISE

#### 4.1. Option; Submission of Data Package.

**4.1.1. Grant of License Option.** Subject to the terms and conditions of this Agreement (including the remainder of this Section 4.1), ACI hereby grants to Takeda an exclusive option, exercisable by Takeda in its sole discretion solely during the Option Period, to obtain the Exclusive License (the "Option").

## 4.1.2. Delivery of Data Package.

(a) Within [\*\*\*] ACI shall deliver to Takeda the Data Package and shall provide Takeda with electronic access in the form and format as Takeda may reasonably request (including by providing copies thereof) [\*\*\*] (provided that, to the extent that Takeda reasonably requests that any Information in the Data Package be provided in a different format, the timeline for such provision of the complete Data Package shall be extended to the extent necessary to account for the reasonable time needed for such format conversion).

(b) If Takeda believes in good faith that any of the Information required to be included in the Data Package is missing, then Takeda shall have the right within [\*\*\*] after receipt of such Data Package to request in writing that ACI provide Takeda any such missing Information, and ACI shall deliver a revised and complete Data Package within [\*\*\*] after the receipt of such request from Takeda (or, if any additional activities are required to provide such Information to Takeda, within [\*\*\*] after completion of such activities) (provided that, for clarity, (i) ACI shall not have any obligation under this Section 4.1.2(b) to perform activities other than those required to satisfy clauses (i) and (ii) of Section 4.1.2(a) and (ii) if Takeda has not requested any additional Information in accordance with this Section 4.1.2(b) prior to the expiration of such [\*\*\*] period, the Data Package shall be deemed complete).

(c) In addition, ACI shall promptly make available to Takeda such additional Information with respect to the Licensed Compounds or Licensed Products (or Exploitation thereof) that is in the possession or control of ACI or any of its Affiliates (without performing additional Development activities) as Takeda may reasonably request in writing, to the extent not previously provided to Takeda (or not previously provided in the form or format reasonably requested by Takeda in writing). For clarity (and as further set forth in the definition of "Option Period"), such additional requests by Takeda shall not extend the duration of the Option Period so long as such additional Information is provided within [\*\*\*] after receipt of such request.

**4.1.3. Exercise of Option.** Takeda may, in its sole discretion, exercise the Option solely during the Option Period by, subject to Section 4.2, delivering a written notice thereof to ACI (the "**Exercise Notice**") at any time during the Option Period in accordance with

Section 14.7. Subject to Section 4.3, (a) upon issuing the Exercise Notice for the Option, the Exclusive License shall be automatically granted by ACI; *provided* that such Exclusive License shall not come into full force and effect unless and until the Option Effective Date occurs and (b) if Takeda exercises the Option and the Option Effective Date occurs, Takeda shall pay to ACI the Option Exercise Fee as set forth in Section 8.2.

#### 4.2. Antitrust Clearance.

**4.2.1. Antitrust Clearance Determination.** Prior to the delivery of the Exercise Notice for the Option, if Takeda intends to exercise the Option, it shall notify ACI in writing as to whether Takeda has determined that the transactions to be consummated upon the exercise of such Option require any Antitrust Filings. [\*\*\*] Takeda's Exercise Notice for such Option (if any) shall include Takeda's irrevocable binding commitment to complete the exercise of such Option, subject only to Antitrust Clearance and the terms of this Section 4.2 and Section 13.2.4. Neither Party may seek early termination (or early determination) of Antitrust Clearance without the other Party's prior written consent.

**4.2.2. Antitrust Filing.** [\*\*\*] each of Takeda and ACI shall make an Antitrust Filing in such jurisdiction within [\*\*\*] (or within such other period as mutually agreed in writing by the Parties) after the Option Exercise Date for the activities and licenses contemplated under this Agreement. The Parties shall cooperate with one another to the extent necessary in the preparation of any such filings. Each Party shall be responsible for its own costs and expenses associated with any such filings.

Antitrust Clearance, Takeda and ACI shall use their respective commercially reasonable efforts to resolve as promptly as practicable any objections that may be asserted by any Antitrust Authority with respect to the transactions notified in the applicable Antitrust Filing. The term "commercially reasonable efforts" as used in this Section 4.2.3 shall not require Takeda or ACI to (a) agree to any remedy or consent decree with any Governmental Authority, including (i) any remedy to sell, divest (including through a license or a reversion of licensed or assigned rights), hold separate, transfer or dispose of any assets, operations, rights, product lines or businesses, or interests therein, of itself or any of its Affiliates (or consent to any of the foregoing actions) or (ii) any behavioral remedy or (b) litigate or otherwise formally oppose any determination (whether judicial or administrative in nature) by a Governmental Authority seeking to impose any of the restrictions referenced in clause (a) above.

**4.2.4.** Cooperation. In connection with obtaining Antitrust Clearance, each of Takeda and ACI shall (a) cooperate with each other in connection with any investigation or other inquiry relating to an Antitrust Filing and the transactions contemplated by this Agreement; (b) keep the other Party or its counsel informed of any communication received from or given to an Antitrust Authority where Antitrust Filings are required, relating to the applicable Antitrust Filing and the transactions contemplated by this Agreement (and provide a copy to the other Party if such communication is in writing); (c) reasonably consult with each other in

advance of any meeting or conference with an Antitrust Authority where Antitrust Filings are required, and, to the extent permitted by such Antitrust Authority, give the other Party or its counsel the opportunity to attend and participate in such meetings and conferences; and (d) permit the other

Party or its counsel to review in advance, and in good faith consider the views of the other Party or its counsel concerning, any submission, filing or communication (and documents submitted therewith) intended to be given to the applicable Antitrust Authority.

- **4.3. Tolling of Obligations.** Notwithstanding anything in this Agreement to the contrary, if Takeda provides an Exercise Notice, then, except with respect to the obligations of the Parties with respect to (a) Antitrust Filings and Antitrust Clearance pursuant to Section 4.2, (b) development of the Technology Transfer Plan pursuant to Section 4.5, (c) negotiation of the Supply Agreement pursuant to Section 6.1.4 and (d) negotiation of a clinical trial plan pursuant to Section 7.2.2(b), all rights and obligations related to the exercise of such Option (including payment of any Option Exercise Fee) and the granting of the Exclusive License shall be tolled unless and until the Option Effective Date occurs (*provided* that, for clarity, (i) in each case of clause (b), (c) and (d), no such agreements or plans shall be effective until the Option Effective Date and (ii) if this Agreement is terminated in accordance with Section 13.2.4, then such Option Exercise Fee shall not be payable, the Exclusive License shall not be granted and the Technology Transfer Plan, Supply Agreement and clinical trial plan shall not be effective).
- **4.4. No Exercise of Option.** Notwithstanding anything in this Agreement to the contrary, if Takeda does not provide an Exercise Notice on or before the end of the Option Period in accordance with Section 4.1.3, then this Agreement shall be automatically deemed to be terminated by Takeda pursuant to Section 13.2.2(b) (and the effective date of such termination shall be the first day after expiration of the Option Period).
- 4.5. Transfers at Option Effective Date. As soon as reasonably practicable after the Option Exercise Date, the Parties shall mutually agree on and submit to the JDT for review and approval a plan to operationalize the technology transfer obligations of ACI set forth in this Section 4.5 (excluding any technology transfer with respect to Manufacturing, which is set forth in Section 6.2) (the "Technology Transfer Plan"). After the Option Effective Date, the Parties shall perform each activity allocated to such Party under the Technology Transfer Plan and implement each transfer to Takeda or its designee in accordance with the Technology Transfer Plan. Notwithstanding the foregoing, after the Option Effective Date, ACI shall (and shall cause its Affiliates to) cooperate with Takeda (and its designees) and provide reasonable assistance and technology transfers to Takeda (and its designees) to enable Takeda (and its designees) to Develop, Commercialize and otherwise Exploit (other than Manufacture, which is addressed in Section 6.2) the Licensed Compounds and Licensed Products, including by (a) providing Takeda (and its designees) such assistance with respect to Development (including CMC Development and regulatory) matters related to such Licensed Compounds and Licensed Products as Takeda may reasonably request and (b) providing Takeda (and its designees) with reasonable access by teleconference or in person (as requested by Takeda) to ACI personnel (and personnel of its Affiliates and Third Party subcontractors) involved in the Exploitation of the Licensed Compounds or Licensed Products to assist Takeda (and its designees) with Development (including CMC Development and regulatory) matters and to answer

questions related to such Licensed Compounds and Licensed Products. Without limiting the foregoing:

# 4.5.1. Licensed Know-How and Regulatory Documentation.

ACI shall, and shall cause its Affiliates to, disclose or make available to Takeda, to the extent not previously provided, in such form and format as Takeda may reasonably request (including by

providing copies thereof), all (a) Licensed Know-How (other than Licensed Know-How relating to Manufacturing, which is addressed in Section 6.2) and (b) Regulatory Documentation in ACI's or its Affiliates' possession or control (including copies of all correspondence to and from any Regulatory Authority), in each case ((a) and (b)), (i) that is in existence as of the Option Effective Date, including Regulatory Documentation assigned in accordance with Section 7.3.1(b), promptly, but in no event more than [\*\*\*], after the Option Effective Date or (ii) that comes into existence after the Option Effective Date, promptly, but in no event more than [\*\*\*], after the earliest of the conception, discovery, development or other making of such Licensed Know-How or Regulatory Documentation.

**4.5.2. Product Agreements.** Promptly after the Option Effective Date, upon Takeda's written request, ACI shall reasonably facilitate, cooperate with and assist Takeda in entering into its own agreements with Third Parties (including any agreement with any Third Party manufacturer) to the extent relating to the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product.

**4.5.3.** Clinical Trials. Promptly after the Option Effective Date, with respect to any clinical trial related to any Licensed Product being conducted by or on behalf of ACI or its Affiliates as of the Option Effective Date (other than the Phase 1b/2 Trial, which is subject to Section 7.2.2), ACI shall, at Takeda's election in writing on a clinical trial-by-clinical trial basis, (a) unless expressly prohibited by any Regulatory Authority, transfer sponsorship and control to Takeda of such clinical trial and continue to conduct such clinical trial, at Takeda's sole cost and expense and under the direction of and in accordance with all written instructions of Takeda, for up to [\*\*\*] to enable such transfer to be completed without interruption of any such clinical trial; provided that with respect to each clinical trial for which such transfer is expressly prohibited by the applicable Regulatory Authority, if any, ACI or its Affiliates shall continue to conduct such clinical trial to completion, at Takeda's sole cost and expense, under the direction of and in accordance with all written instructions of Takeda or (b) wind down such clinical trial (with due regard for patient safety and the rights of any subjects that are participating in such clinical trial).

4.5.4. Global Safety Database. Promptly after the Option Effective Date, ACI shall transfer to Takeda the global safety database and datasets for the Licensed Products. Following such transfer, Takeda shall hold and maintain (at Takeda's sole cost and expense) the global safety database for Licensed Products. Following such transfer of such global safety database and datasets, ACI shall provide Takeda with all information necessary for Takeda to comply with its pharmacovigilance responsibilities in the Territory, including, as applicable, any adverse drug experiences (including those events or experiences that are required to be reported to the FDA under 21 C.F.R. sections 312.32 or 314.80 or to foreign Regulatory Authorities under corresponding Applicable Law outside the United States), from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies with a Licensed Product, in each case, in the form reasonably requested by Takeda. If, following the Option Effective Date, Takeda determines that a pharmacovigilance agreement is necessary, the Parties shall negotiate in good faith and execute a written pharmacovigilance agreement

with respect to the Licensed Products. Such agreement shall (a) provide that Takeda shall hold and be responsible for the maintenance of the global safety database for the Licensed Products and (b) include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication and exchange (as

between the Parties) of Adverse Event reports, pregnancy reports and any other information concerning the safety of the Licensed Products.

- 4.5.5. Transfer of Inventory. As promptly as reasonably practicable after the Option Effective Date, ACI shall (a) provide Takeda with a written summary of all of the inventory of Licensed Compounds and Licensed Products (including intermediates and components thereof and material therefor) in its or its Affiliates' possession as of the Option Effective Date and (b) at Takeda's election, deliver to Takeda on a FCA basis (Incoterms 2020) at a location designated by Takeda, all such inventory as Takeda may request. Title to the inventory shall pass to Takeda at the same time as risk of loss in accordance with the aforementioned Incoterm but no earlier than when the inventory has cleared customs for export by ACI. ACI shall package and ship inventory in accordance with ACI's customary practices, unless otherwise specified by Takeda in writing. Takeda shall bear all reasonable and verifiable Out-of-Pocket Costs for freight, handling, insurance, duties, taxes and shipping of such inventory.
- 4.5.6. Patents. Following the Option Effective Date, ACI shall assist and cooperate with Takeda, as Takeda may reasonably request in writing, in the transition of the prosecution, maintenance, enforcement and defense of the Product Patents and Joint Patents and the control of any Third Party Infringement Claim or challenge or negotiation related to any Third Party Right, in each case, from ACI to Takeda to the extent necessary or reasonably useful for Takeda to exercise its rights under and in accordance with Section 9.3, Section 9.4, Section 9.5, Section 9.6 and Section 9.7. Within [\*\*\*] after the Option Effective Date, ACI shall transfer to Takeda the image file wrappers (as that term is understood under U.S. law) relating to the prosecution, defense, maintenance, validity and enforceability of the Product Patents and Joint Patents to the extent necessary or reasonably useful for Takeda to exercise its rights under and in accordance with Section 9.3, Section 9.4 and Section 9.5; provided that ACI shall not be obligated hereunder to transfer any privileged communications between counsel and ACI related to such image file wrappers or other documents or materials until such time as the Parties put in place procedures to safeguard privilege, including if applicable, by entering into a common interest agreement or equivalent.
- **4.5.7. Costs and Expenses.** Except as otherwise set forth in Section 4.5.3 and Section 4.5.5, each Party shall be solely responsible for the costs and expenses it incurs in connection with its activities set forth in this Section 4.5.

# ARTICLE 5 GRANT OF RIGHTS

- **5.1. Grants to Takeda.** Subject to the terms and conditions of this Agreement, ACI (on behalf of itself and its Affiliates) grants to Takeda:
- **5.1.1.** subject to Section 4.3, effective on the Option Effective Date, an exclusive (including, subject to Section 5.3.2, with regard to ACI and its Affiliates), non-transferable (except in accordance with Section 14.3) license (or sublicense), with the right to grant sublicenses in accordance with Section 5.2, under the Licensed Patents, the Licensed Know-How and ACI's interests in the Joint Patents

and the	Joint 1	Know-How,	in each	case, to	o (a)	Exploit	the	Licensed	Compounds	and
Licensed	d Produ	ucts in the Fi	eld in th	e Territ	ory in	n accorda	ance	with the		

terms and conditions of this Agreement and (b) otherwise exercise Takeda's rights as set forth in and in accordance with Article 9; *provided* that, with respect to any Licensed Product that is a Combination Product, such license shall not include the right for Takeda to Exploit any Other Component that is owned or controlled by ACI or its Affiliates (the license in this Section 5.1.1, the "Exclusive License"); and

- **5.1.2.** (a) a non-exclusive, non-transferable (except in accordance with Section 14.3) license (or sublicense), with the right to grant sublicenses in accordance with Section 5.2, under the Licensed Patents and the Licensed Know-How, in each case, solely for Takeda to perform its CMC Development activities with respect to the Licensed Compounds and Licensed Products prior to the Option Effective Date, and (b) prior to the Option Effective Date, an exclusive (including with regard to ACI and its Affiliates), non-transferable (except in accordance with Section 14.3), non-sublicensable, license (or sublicense) under the Product Patents solely to the extent necessary to exercise Takeda's rights as set forth in and in accordance with Section 9.3.4 and Section 9.5.3(a) (and in no event for purposes of Exploiting any Licensed Compounds or Licensed Products).
- **5.2. Sublicenses.** Takeda shall have the right to grant sublicenses, through multiple tiers of Sublicensees, under the licenses granted in Section 5.1, to any of its Affiliates and other Persons; *provided* that each such sublicense shall be consistent with the terms and conditions of this Agreement. Any act or omission of any Sublicensee, to the extent such act or omission would constitute a breach of this Agreement by Takeda if such act or omission were taken or made by Takeda directly, shall be deemed a breach of this Agreement by Takeda. [\*\*\*] Takeda shall remain responsible to ACI for the performance of all of its obligations under this Agreement [\*\*\*]

### 5.3. Retention of Rights.

- **5.3.1.** Except as expressly set forth in this Agreement, neither Party shall acquire under this Agreement any license or other right, title or interest, by implication, estoppel or otherwise, under any intellectual property owned or controlled by the other Party or such other Party's Affiliates. For clarity, (a) prior the Option Effective Date, ACI does not grant any rights to Takeda under the Licensed Know-How, Licensed Patents or ACI's interest in the Joint Patents or Joint Know-How other than the rights granted to Takeda pursuant to Section 5.1.2 and (b) from and after the Option Effective Date, ACI does not grant any rights to Takeda under the Licensed Know-How, Licensed Patents or ACI's interest in the Joint Patents or Joint Know-How other than the rights granted to Takeda pursuant to Section 5.1.1.
- **5.3.2.** From and after the Option Effective Date, with respect to the rights granted to Takeda pursuant to Section 5.1.1, ACI shall retain the right under the Licensed Know-How, Licensed Patents and ACI's interest in the Joint Patents and the Joint Know-How solely to perform (a) the Development activities and CMC Development activities set forth in the Development Plan and CMC Development Plan in accordance with Section 7.2 (including conducting the Phase 1b/2 Trial as set forth in Section 7.2.2), (b) the transition and Development activities set forth in Section 4.5 and Section 6.2, (c) the Manufacturing activities set forth in Section 6.1.4, (d) any

5.4. Confirmatory Patent License. From and after the Option Effective Date, ACI shall, if requested to do so by Takeda in writing, immediately enter into confirmatory license agreements in such form as may be reasonably requested in writing by Takeda for purposes of recording the licenses granted under this Agreement with such patent offices in the Territory as may be required by Applicable Law or as is customary in the applicable country or jurisdiction; *provided* that such confirmatory license agreements are consistent with the terms and conditions herein. Until the execution of any such confirmatory licenses, so far as may be legally possible, ACI and Takeda shall have the same rights in respect of the Licensed Patents and be under the same obligations to each other in all respects as if the said confirmatory licenses had been executed.

### 5.5. Exclusivity; Change of Control.

- **5.5.1.** Exclusivity. In any country in the Territory, during the period [\*\*\*] (the "Exclusivity Period"), (a) neither Party shall, directly or indirectly, either by itself or with or through any of its Affiliates or any Third Party (including via any arrangement or series of arrangements with a Third Party, including by licensing authorizing, permitting, appointing or otherwise enabling a Third Party to), [\*\*\*]
- **5.5.2.** Change of Control. Notwithstanding Section 5.5.1, subject to the remainder of this Section 5.5.2, if during the Term, a Party or any of its Affiliates undergoes a Change of Control and the counterparty in such Change of Control or any of its Affiliates prior to such transaction (but for clarity, not such Party or any of its Affiliates prior to such Change of Control or any of their successors or assigns) (collectively, the "**Pre-Existing Entities**") is then engaged in activities that would otherwise constitute a breach of such Party's obligations under Section 5.5.1 (a "**Competing Program**"), then such Party shall not be in violation of Section 5.5.2 as a result of such Competing Program, unless and until such Party fails to comply with the following terms and conditions:
- (a) Such Party shall provide the other Party with written notice of (i) such Change of Control within [\*\*\*] to such transaction and the closing date of such transaction and (ii) within [\*\*\*] after the date of such Change of Control, whether it intends to: (x) terminate, or cause its relevant Affiliate to terminate, the Competing Program or (y) Divest, or cause its relevant Affiliate to Divest, the Competing Program.
- (b) If such Party notifies the other Party in writing within such [\*\*\*] period that it intends to terminate, or cause its relevant Affiliate to terminate, the Competing Program, such Party and its Affiliates, shall: (i) terminate such Competing Program as promptly as possible (but in any event within [\*\*\*] (other than clinical trials that a Regulatory Authority requires such Party to continue, which may be continued for no more than [\*\*\*])) after such Party's delivery of such written notice to the other Party in compliance with Applicable Law and with due regard for patient safety and the rights of any subjects that are participating in any clinical trials with respect to such Competing Program; and (ii) confirm to the other Party in writing when such termination has been completed.

	(c) If such	Party notifies the	other Party in	writing
within such [***] period that it	it intends to Div	est the Competing	Program, such	Party or
its relevant Affiliate shall use	all reasonable e	fforts to effect such	n Divestiture as	quickly
as possible, and in any event				

within [\*\*\*] after such Party's delivery of such written notice to the other Party, and shall confirm to the other Party in writing when such Divestiture has been completed; provided, however, that such [\*\*\*] shall be extended for an additional period not to exceed [\*\*\*] as is necessary to obtain any competition approvals required to complete such Divestiture so long as such Party or its relevant Affiliate is using good faith efforts to obtain such approvals. Such Party shall keep the other Party reasonably informed of its efforts and progress in effecting such Divestiture until it is completed. As used in this Section 5.5.2, "Divest" means the sale or transfer of all rights to the Competing Program to a Third Party such that neither such Party nor any of its Affiliates (including the Pre-Existing Entities) has any further right to perform or be involved in any Development, Manufacturing or Commercialization activities with respect to such Competing Program or receive a continuing share of profit or other economic interest in the success of such Competing Program; provided that if such transfer is effected by way of one (1) or more licenses or sublicenses, the licensor shall be entitled to receive license fees, milestones and royalties on sales of products in the Competing Program so Divested ("Divests", "Divested" and "Divestiture" have correlative meanings).

(d) During the time periods provided for in Section 5.5.2(b) or Section 5.5.2(c), as applicable, prior to the termination or Divestiture of the Competing Program, such Party shall, and shall cause its Affiliates to, implement reasonable internal safeguards to: (i) ensure that the Pre-Existing Entities (and any successor thereto) do not obtain any rights or access to, or employ or benefit from the services of any Person who has access to, the Confidential Information of the other Party or its Affiliates or any other Information generated under or in connection with this Agreement or in the Development or Manufacture of Licensed Compounds or Licensed Products; (ii) keep the Competing Program (and the personnel conducting the Competing Program) separate from such Party's activities under this Agreement; and (iii) ensure the Competing Program is not covered by or otherwise related to and does not incorporate, reference, infringe, access or use Confidential Information of the other Party or its Affiliates, Product Information, Licensed Know-How, Licensed Patents or Joint Intellectual Property Rights (clauses (i)-(iii), "Firewall Procedures").

(e) In the event of a Change of Control of ACI, Takeda shall have the right, in its sole and absolute discretion, by written notice delivered to ACI (or its successor) at any time prior to the first anniversary of the closing date of such transaction, to (i) disband the JDT and terminate the activities of the JDT, (ii) require ACI to adopt Firewall Procedures to prevent disclosure of Product Information to any Pre-Existing Entities and (iii) terminate its obligation to provide Development reports, results and information pursuant to Section 3.7.2 and Section 3.3.1 (but, for clarity, Takeda shall continue to provide royalty reports pursuant to Section 8.5.4).

**5.5.3.** Acknowledgement. Both Parties acknowledge and agree that (a) Section 5.5.1 has been negotiated by the Parties, (b) the geographical and time limitations on activities set forth in Section 5.5.1 are reasonable, valid and necessary in light of the Parties' circumstances and necessary for the adequate protection of the business of the Licensed Compounds and Licensed Products and (c)

neither Party would have entered into this Agreement without the protection afforded it by Section 5.5.1. If, notwithstanding the foregoing, a court of competent jurisdiction determines that the restrictions set forth in Section 5.5.1 are too broad or otherwise unreasonable (for example, due to a change in circumstance) under Applicable Law,

including with respect to duration, geographic scope or space, the court is hereby requested and authorized by the Parties to, and if the court cannot do so the Parties shall, revise Section 5.5.1 to include the maximum restrictions allowable under Applicable Law.

5.6. Existing Agreements; Product Agreements. ACI shall not, and shall cause its Affiliates not to, (a) enter into any subsequent agreement or understanding with any Third Party to an Existing Agreement that modifies, amends or terminates any such Existing Agreement, or waives any right or obligation thereunder, in each case, in any manner that would adversely affect in any respect Takeda's rights or interests under this Agreement or would impose any material obligation on Takeda (including in the event Takeda exercises the Option) or (b) enter into any new agreements with a Third Party (including any agreement with any Third Party manufacturer) to the extent relating to the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product (excluding any in-license agreements pursuant to which ACI solely obtains a license or other rights to a Third Party Right and does not otherwise collaborate with, or perform or receive services or goods from, such Third Party with respect to the Development, Manufacture or Commercialization of any Licensed Compound or Licensed Product under such agreement) (each, a "Product Agreement"), in each case ((a) and (b)), without Takeda's prior written consent. ACI shall not, and shall cause its Affiliates not to, commit any acts or permit the occurrence of any omissions that would cause breach or termination of any of its Existing Agreements or Product Agreements where such breach or termination would adversely affect in any respect Takeda's rights or interests under this Agreement or impose any material obligation on Takeda (including in the event Takeda exercises the Option). ACI shall promptly provide Takeda with notice of any alleged, threatened or actual breach of any Existing Agreement or Product Agreement. Prior to entering into a new Product Agreement, ACI shall consult with Takeda and provide a reasonably detailed explanation of the relevance of such agreement and the expected terms thereof, and ACI shall ensure that the terms of such agreement are consistent with this Agreement. Upon Takeda's written request, ACI shall promptly provide Takeda with notice and a true and complete copy of each such Product Agreement entered into by ACI or any of its Affiliates; provided that ACI shall be permitted to redact from such Product Agreement any information that is not required for Takeda to determine ACI's compliance with this Agreement.

# ARTICLE 6 MANUFACTURING AND SUPPLY

### 6.1. Supply of Licensed Products and Materials.

**6.1.1.** ACI shall be solely responsible, at its sole cost and expense (except as set forth in Section 6.1.2 and Section 6.1.3), for manufacturing or having manufactured quantities of Licensed Compounds and Licensed Products and placebo as may be required for ACI's performance of Development activities and CMC Development activities set forth in the Development Plan and CMC Development Plan.

**6.1.2.** Prior to the Option Effective Date, ACI shall provide to Takeda (a) the materials set forth on **Schedule 6.1.2** at ACI's sole cost and expense,

and (b) any other materials (including Licensed Compounds, Licensed Products and intermediates or components thereof) as Takeda may reasonably request in writing to complete Takeda's CMC Development activities in accordance with the CMC Development Plan, at Takeda's sole cost and expense,

solely to the extent such other materials are in ACI's possession or control, or that ACI has the right to request from a Third Party under a Product Agreement, at the time of such request.

**6.1.3.** If the Option Effective Date occurs, Takeda shall reimburse ACI for any quantities of ACI-24.060 Manufactured by or on behalf of ACI using the Phase 3 Process that are administered to patients in a Phase 3 Trial [\*\*\*] after the end of any Calendar Quarter in which any such quantities of ACI-24.060 are administered to patients in a Phase 3 Trial, Takeda shall provide written notice to ACI of such quantities, and ACI shall submit an invoice promptly, but no more than [\*\*\*], following receipt of such notice from Takeda, which amount shall be payable [\*\*\*] after the receipt by Takeda of a valid invoice.

**6.1.4.** From and after the Option Effective Date, until the earlier of (a) the date on which all of the following have occurred: [\*\*\*] and (b) the last dosing of the last patient in the Phase 3 Trial with any Licensed Product Manufactured using the Phase 3 Process, as and to the extent requested by Takeda in writing, ACI shall supply clinical quantities of the Licensed Compounds and Licensed Products Manufactured using the Phase 3 Process for use by Takeda in the Development of Licensed Products; provided that ACI shall not be responsible for any clinical supply in excess of [\*\*\*] Following the Option Exercise Date, Takeda and ACI shall negotiate in good faith the terms of an agreement for the Manufacture and supply to Takeda of the Licensed Compounds and Licensed Products (the "Supply Agreement"), which Supply Agreement shall include the terms set forth on Schedule 6.1.4 and [\*\*\*] and other customary terms for supply of material to a licensee for clinical trials, including a related quality agreement, if necessary. Takeda and ACI shall use good faith efforts to execute such Supply Agreement (and any quality agreement) within [\*\*\*] (which Supply Agreement would become effective on the Option Effective Date). The Supply Agreement (and any quality agreement) shall be subordinate to this Agreement.

6.1.5. During any period in which ACI is required to Manufacture (or have Manufactured) Licensed Compounds and Licensed Products pursuant to this Article 6, ACI shall Manufacture (or have Manufactured) all such Licensed Compounds and Licensed Products in accordance with Applicable Law and any applicable manufacturing and quality agreements and, for the purposes of supply to Takeda, shall only use Third Party contract manufacturers that are approved by Takeda in writing in advance (it being understood that those contract manufacturers set forth on Schedule 3.4 shall be deemed approved by Takeda as of the Effective Date). ACI represents and warrants that each Licensed Compound and Licensed Product supplied to Takeda (a) will be Manufactured in accordance with Applicable Law, including current Good Manufacturing Practices, (b) will not be adulterated or misbranded under the FFDCA and may be introduced into interstate commerce pursuant to the FFDCA and (c) complies with the applicable specifications with respect thereto in the thencurrent IND for the Licensed Product.

**6.2. Manufacturing Technology Transfer.** Without limiting Section 3.3.2 or the generality of the obligations in Section 4.5, promptly upon Takeda's written request after (a) the Effective Date (subject to Takeda's obligations in Section 3.3.3), (b) the Option Effective Date and (c) ACI's completion of the CMC

Development Plan where such completion has not occurred prior to the Option Effective Date, ACI shall transfer to Takeda or its designee all Licensed Know-How relating to the Manufacture of the Licensed Compounds and the Licensed Products and all intermediates and components thereof, including, for clarity, the then-current Phase 3 Process and

Commercial Process for the Manufacture of the Licensed Compounds and Licensed Products, as well as any improvements or enhancements to such process (the "Manufacturing Process"), and provide such support as may be necessary or reasonably useful to Takeda or its designee to use and practice the Manufacturing Process (such transfer and support, as more fully described in this Section 6.2, the "Manufacturing Technology Transfer"); provided that [\*\*\*] Notwithstanding anything in this Agreement to the contrary, prior to the Option Effective Date, the use and disclosure of any portion(s) of Licensed Know-How transferred to Takeda pursuant to this Section 6.2 that relate(s) to the Proprietary CMC Information shall be subject to Section 3.3.3. Without limitation to the foregoing, in connection with each Manufacturing Technology Transfer:

**6.2.1.** ACI shall make available, and shall use commercially reasonable efforts to cause its Third Party manufacturers to make available, to Takeda (or its Affiliate or designated Third Party manufacturer, as applicable) from time to time as Takeda may reasonably request in writing, all Manufacturing-related Licensed Know-How, Information and materials relating to the Manufacturing Process that arise during the Term, and all documentation constituting material support, performance advice, shop practice, standard operating procedures, specifications as to materials to be used and control methods, in each case, that are reasonably necessary or useful to enable Takeda (or its Affiliate or designated Third Party manufacturer, as applicable) to use and practice the Manufacturing Process;

**6.2.2.** Upon Takeda's reasonable written request, ACI shall cause all appropriate employees and representatives of ACI and its Affiliates to meet with, and shall use commercially reasonable efforts to cause all appropriate employees and representatives of its Third Party manufacturers to meet with, employees or representatives of Takeda (or its Affiliate or designated Third Party manufacturer, as applicable) at the applicable manufacturing facility at mutually convenient times to assist with the working up and use of the Manufacturing Process and with the training of the personnel of Takeda (or its Affiliate or designated Third Party manufacturer, as applicable) to the extent reasonably necessary or useful to enable Takeda (or its Affiliate or designated Third Party manufacturer, as applicable) to use and practice the Manufacturing Process;

6.2.3. Without limiting the generality of Section 6.2.2 above, upon Takeda's reasonable written request, ACI shall cause all appropriate analytical and quality control laboratory employees and representatives of ACI and its Affiliates to meet with, and shall use commercially reasonable efforts to cause all appropriate analytical and quality control employees and representatives of its Third Party manufacturers to meet with, employees or representatives of Takeda (or its Affiliate or designated Third Party manufacturer, as applicable) at the applicable manufacturing facility and make available all necessary equipment, at mutually convenient times, to support and execute the transfer of all applicable analytical methods and the validation thereof;

**6.2.4.** ACI shall take such steps, and shall use commercially reasonable efforts to cause its Third Party manufacturers to take such steps, as are reasonably necessary or useful to assist in reasonable respects Takeda (or its Affiliate or

designated Third Party manufacturer, as applicable) in obtaining any necessary licenses, permits or approvals from Regulatory Authorities with respect to the Manufacture of the Licensed Compounds and Licensed Products at the applicable facilities; and

- **6.2.5.** ACI shall provide, and shall use commercially reasonable efforts to cause its Third Party manufacturers to provide, such other assistance as Takeda (or its Affiliate or designated Third Party manufacturer, as applicable) may reasonably request in writing to enable Takeda (or its Affiliate or designated Third Party manufacturer, as applicable) to use and practice the Manufacturing Process and otherwise to Manufacture Licensed Compounds and Licensed Products.
- **6.3. Manufacturing Improvements.** Without limiting Section 6.2, in the event that, following the Option Effective Date, ACI or any of its Affiliates makes any invention, discovery or improvement that is Licensed Know-How and that relates to, or that is otherwise necessary or reasonably useful for, the Manufacture of a Licensed Compound or a Licensed Product during the Term, ACI shall promptly disclose such invention, discovery or improvement to Takeda and shall, at Takeda's written request, perform technology transfer with respect to such invention, discovery or improvement in the same manner as provided in Section 6.2.

# ARTICLE 7 POST-OPTION DEVELOPMENT, REGULATORY AND COMMERCIALIZATION ACTIVITIES

7.1. Rights Generally. As between the Parties, from and after the Option Effective Date, subject to Takeda's obligations under Article 2, Section 3.7.2 and Section 7.4 and ACI's performance of the ACI Ongoing Activities, Takeda shall have the sole right, at its sole cost and expense, to perform all Development, Manufacture, Commercialization and other Exploitation of the Licensed Compounds and Licensed Products in the Field in the Territory and will have the sole authority and discretion to make any and all decisions (or take any and all actions) with respect thereto. Without limiting the generality of the foregoing, from and after the Option Effective Date, as between the Parties, Takeda shall have the sole right to (a) file all Regulatory Documentation for Regulatory Approval and make all other filings with the Regulatory Authorities, and to otherwise seek all Regulatory Approvals, for Licensed Products in the Territory, as well as to conduct all correspondence and communications with Regulatory Authorities regarding such matters (except as expressly set forth in Section 7.3), (b) report all Adverse Events to Regulatory Authorities if and to the extent required by Applicable Law and (c) invoice and book sales, establish all terms of sale (including pricing and discounts) and warehouse and distribute the Licensed Products in the Territory and perform or cause to be performed all related services.

## 7.2. Certain ACI Ongoing Activities.

**7.2.1. Development Plan and CMC Development Plan.** If ACI has not completed the Development Plan or CMC Development Plan as of the Option Effective Date, ACI shall continue to complete the Development activities set forth in the Development Plan or the CMC Development activities set forth in the CMC Development Plan, as applicable, in accordance with Section 3.2 and Section 3.3, as applicable, unless Takeda decides (in its sole discretion but subject to Section 7.2.2) to assume responsibility for such activities, in which case Takeda shall provide written notice thereof to ACI, and ACI shall transfer such activities to Takeda in accordance with Section 4.5.

#### 7.2.2. Phase 1b/2 Trial.

Subject to Section 7.3, from and after the Option (a) Effective Date, (i) ACI shall continue to conduct the Phase 1b/2 Trial globally, including in the U.S., in accordance with the Development Plan and the protocol and statistical analysis plan with respect thereto, at ACI's sole cost and expense (subject to Section 2.6.2(b)(ii), the remainder of this Section 7.2.2 and the penultimate paragraph of Section 8.3) through completion thereof (including any survival follow-up) and (ii) ACI shall conduct the Phase 1b/2 Trial under the direction of and in accordance with all written instructions of Takeda; provided that, in each case ((i) and (ii)), if (x) Takeda determines, in its reasonable discretion, that ACI is not going to complete the Phase 1b/2 Trial (globally or on a country-by-country basis) within the timelines set forth in the Development Plan, Takeda shall notify the JDT of such determination and the JDT shall determine whether Takeda should, on a country-by-country basis, assume control of such Phase 1b/2 Trial in the applicable country(ies) at Takeda's sole cost and expense or (y) Takeda requires control of the Phase 1b/2 Trial globally for regulatory reasons, Takeda shall have the right, on a country-by-country basis, unless expressly prohibited any Regulatory Authority in the applicable country, on written notice to ACI, to assume control of such Phase 1b/2 Trial in the applicable country(ies) at Takeda's sole cost and expense. In the event Takeda assumes control of the Phase 1b/2 Trial in accordance with this Section 7.2.2(a), ACI shall transfer to Takeda sponsorship and control of the Phase 1b/2 Trial in the applicable country(ies); provided that ACI shall continue to conduct such Phase 1b/2 Trial, at Takeda's sole cost and expense and under the direction of and in accordance with all written instructions of Takeda, for up to [\*\*\*] to enable such transfer to be completed without interruption; provided, further, that if any such transfer is expressly prohibited by the applicable Regulatory Authority, ACI or its Affiliates shall continue to conduct such clinical trial to completion, at Takeda's sole cost and expense, under the direction of and in accordance with all written instructions of Takeda.

(b) Without limiting the foregoing, (i) promptly after the Option Exercise Date, the Parties shall negotiate in good faith a clinical trial plan, consistent with Takeda's standard practices, pursuant to which ACI would, following the Option Effective Date, complete the Phase 1b/2 Trial on behalf of Takeda, and (ii) ACI shall not modify, amend or terminate any Product Agreement with respect to the conduct of the Phase 1b/2 Trial, or waive any right or obligation thereunder, without Takeda's prior written consent.

7.2.3. Additional Activities. If, at any point from and after the Option Effective Date until receipt of Regulatory Approval in the U.S. for the first Licensed Product, Takeda reasonably believes that (a) additional pre-clinical Development support is necessary or important for the success of a Licensed Compound or Licensed Product and (b) such pre-clinical Development would not require re-performance of phase 1 clinical trials with respect to the Licensed Products, at Takeda's written request, ACI shall perform such additional pre-clinical Development work. If Takeda requests any such support, the Parties shall promptly and in good faith negotiate a plan and budget of [\*\*\*] to be incurred by or on behalf of ACI

in the performance of such support without mark-up, and Takeda shall reimburse ACI for its [\*\*\*] incurred in accordance with such plan and budget.

**7.2.4. Future Non-Clinical Development.** From and after the Option Effective Date, if ACI desires to perform any non-clinical Development activities with respect to

the Licensed Compounds or Licensed Products in the Territory that are not set forth in the then-current Development Plan (if applicable), then ACI shall provide to the JDT (or, after disbandment of the JDT, to Takeda) a reasonably detailed written proposal with respect to such non-clinical Development activities, which proposal shall include (a) the non-clinical Development activities to be conducted, (b) an analysis of the scientific or business opportunity for such non-clinical Development activities and (c) any other information as may be necessary or reasonably useful to evaluate such proposal or as Takeda may otherwise reasonably request (an "Additional Development **Proposal**"). Within [\*\*\*] after the JDT's (or, after disbandment of the JDT, Takeda's) receipt of such Additional Development Proposal (including the budget and allocation of costs with respect to such proposal), the JDT (or Takeda, as applicable) shall review and discuss such Additional Development Proposal; provided that Takeda shall have the sole right to determine whether to approve ACI's conduct of such proposed nonclinical Development activities (and such determination, for clarity, shall not be a JDT determination or subject to Section 2.6). From and after the Option Effective Date, ACI shall have the right to conduct any such non-clinical Development activities approved by Takeda, and ACI shall conduct any such activities in accordance with the Additional Development Proposal and any changes to the Additional Development Proposal shall be submitted to the JDT (or, after disbandment of the JDT, to Takeda) for the JDT's (or Takeda's, as applicable) review and Takeda's approval. From and after the Option Effective Date, ACI shall perform, or cause to be performed, all non-clinical Development activities under any Additional Development Proposal in good scientific manner and in compliance with all Applicable Law and by allocating sufficient time, effort, equipment and skilled personnel to complete such non-clinical Development activities in accordance with the applicable Additional Development Proposal. From and after the Option Effective Date, ACI shall not initiate or perform any such non-clinical Development activities with respect to the Licensed Compounds or Licensed Products in the Territory unless and to the extent that Takeda approves an Additional Development Proposal with respect thereto in accordance with this Section 7.2.4 (it being understood that following the disbandment of the JDT such Additional Development Proposal shall be reviewed and discussed with Takeda and shall remain subject to Takeda approval).

**7.2.5. Performance.** For clarity, the provisions of Section 3.2.1, Section 3.4, Section 3.6 and Section 3.7 shall apply to ACI's performance of any activities under this Section 7.2.

## 7.3. Regulatory.

**7.3.1. Regulatory Documentation; Regulatory Support.** From and after the Option Effective Date:

(a) as between the Parties, except as expressly set forth in this Section 7.3, Takeda shall have the sole right to prepare, obtain and maintain all Regulatory Documentation (including the IND for the Phase 1b/2 Trial in the U.S., all Drug Approval Applications and Regulatory Approvals) and to prepare other submissions to, and conduct communications with, all Regulatory Authorities, in each case, for the Licensed Compounds and Licensed Products in the Territory, including the setting of the overall regulatory strategy therefor;

Drug Approval Compounds or	(b) Applications and	` ′	gulatory Doo Approvals)	`	_
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Licensed Products with respect to the Territory developed or granted after the Option Effective Date shall, as between the Parties, be owned by and shall be the sole property and held in the name of Takeda and (ii) without limiting Section 4.5, effective upon the Option Effective Date, ACI and its Affiliates hereby assign to Takeda all of their right, title and interest in and to all Regulatory Documentation (including such Regulatory Approvals) owned or controlled by ACI or its Affiliates that is in existence as of the Option Effective Date or that is developed or granted thereafter (including all Existing Regulatory Documentation (including any existing Regulatory Approvals)) with respect to the Territory; provided that until the earlier of completion of the Phase 1b/2 Trial in each country outside of the U.S. in which such trial is conducted and the date on which Takeda assumes control of the Phase 1b/2 Trial in such country in accordance with Section 7.2.2, on a country-by-country basis, ACI shall continue to hold the IND for the Phase 1b/2 Trial, and effective upon the earlier of such completion in a country and the date of Takeda so assuming control (which, for the avoidance of doubt, shall be no earlier than the Option Effective Date), ACI and its Affiliates shall, and hereby do, assign to Takeda all of their right, title and interest in and to such INDs. From and after the Option Effective Date, ACI shall duly execute and deliver such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements and instruments, as may be necessary or as Takeda may reasonably request in writing to confirm Takeda's rights under, this Section 7.3.1;

(c) solely with respect to the conduct of the Phase 1b/2 Trial in any country of the Territory outside of the U.S. (unless and until Takeda assumes control of the Phase 1b/2 Trial in such country pursuant to Section 7.2.2), (i) ACI shall have the right to maintain the IND(s) with respect to such Phase 1b/2 Trial and other Regulatory Documentation and other submissions to Regulatory Authorities in each country of the Territory outside of the U.S. in connection therewith; provided that ACI shall provide Takeda with all such Regulatory Documentation and submissions sufficiently (but in any event at [\*\*\*] in advance of the finalization or submission thereof for Takeda's review and approval and (ii) ACI shall provide Takeda with prior written notice of any scheduled meeting, conference or discussion (including any advisory committee meeting) with a Regulatory Authority with respect to such Phase 1b/2 Trial within [\*\*\*] after ACI or its Affiliate first receives notice of the scheduling of such meeting, conference or discussion (or, to the extent reasonably practicable, within such shorter period as may be necessary in order to give Takeda a reasonable opportunity to attend such meeting, conference or discussion), and Takeda shall have the right to have [\*\*\*] attend and participate in all such meetings, conferences and discussions (including by telephone) (and ACI shall promptly provide Takeda with copies of preliminary feedback and meeting minutes from any Regulatory Authority); and

(d) upon Takeda's written request, the Parties shall cooperate to discuss, prepare and review any regulatory filings in connection with the Licensed Compounds or Licensed Products. Without limiting the foregoing, from and after the Option Effective Date, ACI shall support Takeda, as may be reasonably requested by Takeda in writing, in obtaining Regulatory Approvals for the Licensed Products, including providing any documents or other materials as may be necessary or reasonably useful for Takeda to obtain and maintain Regulatory Approvals for the

thereto, at ACI's sole cost and expense.	
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Licensed Products and attending meetings with Regulatory Authorities with respect

- 7.3.2. Recalls, Suspensions or Withdrawals. As between the Parties, from and after the Option Effective Date, Takeda shall have the sole right to make all determinations with respect to, and to implement, any recall, market suspension or market withdrawal with respect to a Licensed Product in the Territory. ACI shall, and shall cause its Affiliates to, cooperate in any recalls, market suspensions or market withdrawals undertaken pursuant to this Section 7.3.2. Subject to Article 12, Takeda shall be solely responsible for any and all costs of any such recall, market suspension or market withdrawal in the Territory, except in the event and to the extent that a recall, market suspension or market withdrawal resulted from (a) any inventory of Licensed Compounds and Licensed Products (including intermediates and components thereof and material therefor) transferred or supplied by ACI to Takeda pursuant to Section 4.5.5 or Section 6.1; or (b) ACI's or its Affiliate's breach of its obligations hereunder or from ACI's or its Affiliate's fraud, negligence or willful misconduct, in which case ((a) and (b)), ACI shall bear the costs and expenses of such recall, market suspension or market withdrawal (for clarity, only to the extent resulting from clause (a) or clause (b)).
- **7.4. Diligence.** Takeda shall use Commercially Reasonable Efforts to [\*\*\*]
- 7.5. Subcontracting. Takeda shall have the right to subcontract any of its Development, Manufacturing or Commercialization activities to a Third Party. Takeda shall (a) be responsible for the acts and omissions of its subcontractors and (b) ensure that its Third Party subcontractors comply with the applicable terms and conditions of this Agreement, including Article 10. For the avoidance of doubt, (x) Takeda shall remain directly responsible for all of its obligations under this Agreement, notwithstanding any subcontracting arrangement hereunder, and (y) use of a subcontractor shall not relieve or release Takeda from, or modify, any obligations of Takeda under this Agreement.

# ARTICLE 8 PAYMENTS AND RECORDS

- **8.1. Upfront Payment.** In partial consideration of the rights granted by ACI to Takeda hereunder and subject to the terms and conditions of this Agreement, Takeda shall pay ACI, no later than [\*\*\*] a one-time, non-refundable, non-creditable upfront payment of One Hundred Million Dollars (\$100,000,000).
- **8.2. Option Exercise Fee.** In the event Takeda exercises the Option during the Option Period and the Option Effective Date occurs, subject to the terms and conditions of this Agreement, Takeda shall pay ACI, no later than [\*\*\*] (the "**Option Exercise Fee**").
- **8.3. Development Milestones.** In partial consideration of the rights granted by ACI to Takeda hereunder and subject to the terms and conditions of this Agreement, Takeda shall pay to ACI a one-time, non-refundable, non-creditable (subject to Section 8.6 and Section 14.15) milestone payment (each, a "**Development Milestone Payment**") following the first achievement of the corresponding milestone event (each, a "**Development Milestone Event**") with respect to a Licensed Product (a)

by or on behalf of ACI or its Affiliates (with respect to Development Milestone Event Nos. 1 and 2) or (b) by or on behalf of Takeda or its Affiliates or its or their Sublicensees (with respect to Development Milestone Event Nos. 3, 4, 5, 6 and 7), calculated as follows:

For clarity, Development Milestone Event No. 2 shall not apply, and Development Milestone Payment No. 2 shall not be due, if the Option Effective Date occurs and Takeda assumes control of the Phase 1b/2 Trial in accordance with Section 7.2.2 prior to achievement of Development Milestone Event No. 2.

Each Development Milestone Payment in this Section 8.3 shall be payable only upon the first achievement of the corresponding Development Milestone Event and no amounts shall be due for subsequent or repeated achievements of such Development Milestone Event, whether for the same or a different Licensed Product. If Development Milestone Event No. 4 is achieved and Development Milestone Event No. 3 has not been previously paid to ACI, then such unpaid Development Milestone Event No. 3 will be deemed achieved and the corresponding Development Milestone Payment shall be payable in addition to and concurrently with Development Milestone Event No. 4. If Development Milestone Event No. 5, Development Milestone Event No. 6 or Development Milestone Event No. 7 is achieved and Development Milestone Event No. 3 or Development Milestone Event No. 4 has not been previously paid to ACI, then such unpaid Development Milestone Event No. 3 or Development Milestone Event No. 4, as applicable, will be deemed achieved and the corresponding Development Milestone Payment shall be payable in addition to and concurrently with Development Milestone Event No. 5, Development Milestone Event No. 6 or Development Milestone Event No. 7, as applicable. The maximum aggregate [\*\*\*] for the full amount of the corresponding Development Milestone Payment, which amount shall be payable [\*\*\*] after the receipt by Takeda of a valid invoice.

**8.4.** Commercial Milestones. In partial consideration of the rights granted by ACI to Takeda hereunder and subject to the terms and conditions of this Agreement, Takeda shall pay to ACI a one-time, non-refundable, non-creditable (subject to Section 8.6 and Section 14.15) milestone payment (each, a "Commercial Milestone Payment") following the Fiscal Year in which the corresponding milestone event ("Commercial Milestone Event") is first achieved by or on behalf of Takeda or its Affiliates or its or their Sublicensees, as follows:

[\*\*\*]

Each Commercial Milestone Payment in this Section 8.4 shall be payable only upon the first achievement of the corresponding Commercial Milestone Event and no amounts shall be due for subsequent or repeated achievements of such Commercial Milestone Event in any given or subsequent Fiscal Year, whether for the same or a different Licensed Product. The maximum aggregate amount payable by Takeda pursuant to this Section 8.4 is [\*\*\*]

In the event that any of the Commercial Milestone Events set forth in this Section 8.4 occurs and any of the preceding Commercial Milestone Events set forth in this Section 8.4 have not occurred, then each such skipped Commercial Milestone Payment shall become due and payable concurrently with the Commercial Milestone Payment for the Commercial Milestone Event with respect to which payment is due.

Following the end of a Fiscal Year in which a given Commercial Milestone Event was
achieved, Takeda will send ACI written notice that such Commercial Milestone Even
is achieved under this
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Section 8.4, within [\*\*\*] following the end of such Fiscal Year. Following receipt of such notice, ACI shall submit an invoice promptly, but no more than [\*\*\*] after receipt of such notice, to Takeda for the full amount of the corresponding Commercial Milestone Payment, which amount shall be payable [\*\*\*] after the receipt of a valid invoice.

#### 8.5. Royalties.

**8.5.1.** As further consideration for the rights granted to Takeda hereunder, subject to Section 8.5.2, Section 8.5.3 and Section 8.6, commencing upon the First Commercial Sale of a given Licensed Product in the Territory, on a Licensed Product-by-Licensed Product and country-by-country basis, Takeda shall pay to ACI a royalty on Net Sales of each Licensed Product in the Field in the Territory during each Fiscal Year at the applicable following rates:

[\*\*\*]

8.5.2. Royalty Term. Following the expiration of the Royalty Term for any Licensed Product in any country, Takeda shall have no obligation to pay any royalty with respect to Net Sales for such Licensed Product in such country. With respect to any Licensed Product in any country in the Territory, from and after the expiration of the Royalty Term for such Licensed Product in such country, (a) the Exclusive License shall become fully-paid, royalty-free, perpetual and irrevocable with respect to such Licensed Product in such country and (b) Net Sales of such Licensed Product in such country shall be excluded for purposes of [\*\*\*].

- **8.5.3. Royalty Reductions.** Notwithstanding Section 8.5.1 and subject to Section 8.5.2 and Section 8.7:
- (a) in the event that, and in such case from and after the date on which, a Licensed Product is Commercialized in a country in the Territory and there is no Licensed [\*\*\*] 8.5.1 with respect to such Licensed Product each shall be reduced by [\*\*\*] in such country;
- (b) in the event that, and in such case from and after the date on which, a Biosimilar Product with respect to a Licensed Product is marketed and sold in a country by one or more Third Parties [\*\*\*] the royalty rates set forth in Section 8.5.1 with respect to such Licensed Product each shall be reduced by [\*\*\*] in such country; and
- (c) with respect to the U.S., in the event that (i) a Licensed Product is designated as a Selected Drug by the Secretary of the U.S. Department of Health and Human Services, and Takeda or any of its Affiliates or its or their Sublicensees is required to negotiate a Maximum Fair Price that will apply to sales of such Licensed Product during the Price Applicability Period and (ii) [\*\*\*] "IRA Reduction Event"), [\*\*\*] then the royalty rates set forth in Section 8.5.1 with respect to such Licensed Product in the U.S. shall be reduced by [\*\*\*] for the remainder of the Royalty Term in the in the U.S.

**8.5.4.** Royalty Payments and Reports. Following the First Commercial Sale of any Licensed Product in the Field in the Territory until expiration of the last Royalty Term for the last Licensed Product, Takeda shall furnish a written report to ACI within [\*\*\*] after the end of each Calendar Quarter showing Net Sales of each Licensed Product and the amounts payable to ACI pursuant to this Section 8.5 for such Calendar Quarter, which amounts shall be

converted to Dollars in accordance with Section 8.9. ACI shall submit an invoice promptly, but no more than [\*\*\*], following the receipt of such report from Takeda for the full amount of the corresponding royalty payment, which amount shall be payable [\*\*\*] after the receipt of a valid invoice.

# **8.6.** Offset for Third Party Payments. [\*\*\*]

- **8.7. Mechanics of Adjustments.** Any reductions set forth in Section 8.5.3 and offsets set forth in Section 8.6 shall be applied to the royalties payable to ACI under Section 8.5.1 in the order in which the event triggering such reduction or offset occurs; *provided* that the adjustments made pursuant to Section 8.5.3 and Section 8.6, in the aggregate, shall not reduce by more than [\*\*\*] the royalties that would otherwise be owed under Section 8.5.1 (the [\*\*\*] Any adjustments pursuant to Section 8.5.3 shall apply only to the relevant Licensed Product in the relevant country and, with respect to royalties under Section 8.5.1, shall be allocated pro rata across each of the royalty tiers in the relevant Calendar Quarter.
- **8.8.** Estimated Sales Levels; Diligence. ACI acknowledges and agrees that (a) the sales levels set forth in Section 8.4 and Section 8.5.1 shall not be construed as representing an estimate or projection of anticipated sales of the Licensed Products and (b) such sales levels and the Development Milestone Events set forth in Section 8.3 shall not be construed as implying any level of diligence or Commercially Reasonable Efforts in the Territory, and that such sales levels and Development Milestone Events are merely intended to define Takeda's payment obligations in the event such sales levels or such Development Milestone Events are achieved.
- 8.9. Mode of Payment. All payments to ACI under this Agreement shall be paid in Dollars in the requisite amount by wire transfer or electronic funds transfer in immediately available funds to such bank account as ACI may from time to time designate by written notice to Takeda. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), Takeda shall convert any amount expressed in a foreign currency into Dollar equivalents using its, its Affiliate's or its or their Sublicensee's standard conversion methodology consistent with Accounting Standards.
- **8.10.** Taxes. The milestones, royalties and other amounts payable by Takeda to ACI pursuant to this Agreement (each, a "Payment") shall be paid free and clear of any and all taxes, except for any Taxes required to be withheld by Applicable Law ("Withholding Taxes"). Takeda shall deduct or withhold from the Payments any Taxes that are required by Applicable Law to be deducted or withheld. ACI and Takeda agree to cooperate with one another and use reasonable efforts to reduce or eliminate Withholding Taxes or similar obligations in respect of any payments under this Agreement. In the event that Takeda determines that any such Withholding Tax is required, Takeda shall use good faith efforts to notify ACI in writing at least [\*\*\*] in advance of the relevant Payment in order to provide ACI a reasonable opportunity to provide any tax forms described in the immediately following sentence. ACI will provide Takeda any tax forms that may be reasonably necessary in order for Takeda

not to withhold Tax or to withhold Tax at a reduced rate, including under an applicable bilateral income tax treaty, and Takeda shall apply the reduced rate of withholding or dispense with withholding, as the case may be; *provided* that Takeda has received evidence, in a form reasonably satisfactory to Takeda, of

ACI's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization to reduce or dispense with withholding, as the case may be) at least [\*\*\*] prior to the time that the Payments are due. ACI and Takeda will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of Withholding Taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such Withholding Taxes. [\*\*\*]

For the purposes of this Section 8.10, "ACI" and "Takeda" include any assignees under Section 14.3 of such respective Party.

**8.11.** Interest on Late Payments. Any undisputed amount owed by one (1) Party to the other Party under this Agreement that is not paid on or before the date such payment is due shall bear interest at a rate per annum (but with interest accruing on a daily basis) equal [\*\*\*] and such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest. For the purposes of this Agreement, "Applicable Rate" means the thencurrent U.S. Prime Rate (PRIME:IND) quoted by Bloomberg or the maximum rate allowable by Applicable Laws, whichever is lower, as adjusted from time to time on the first New York Business Day of each month.

**8.12. Financial Records.** Each Party shall, and shall cause its Affiliates to, keep complete and accurate books and records pertaining to Net Sales and any reimbursable FTE Costs or Out-of-Pocket Costs hereunder in sufficient detail to calculate all amounts payable hereunder. Such books and records shall be retained by such Party and its Affiliates until the later of (a) [\*\*\*] after the end of the period to which such books and records pertain and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

#### 8.13. Audit.

**8.13.1. Procedures.** Each Party may request that the other Party permit and cause its Affiliates to permit an internationally-recognized, independent auditor designated by such first Party as the auditing Party and reasonably acceptable to the audited Party, at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 8.12 to ensure the accuracy of all reports and payments made hereunder. Such examinations may not (a) be conducted for any Calendar Quarter more than [\*\*\*] after the end of such Calendar Quarter, (b) be conducted more than [\*\*\*] (unless a previous audit during such [\*\*\*] period revealed a material discrepancy with respect to such period) or (c) be repeated for any Calendar Quarter. Except as provided below, the cost of this audit shall be borne by the auditing Party, unless the audit reveals a variance of more than [\*\*\*] in each case, from the reported amounts in the auditing Party's favor, in which case the audited Party shall bear the cost of the audit. Unless disputed pursuant to Section 8.13.2 below, if such audit concludes that (x) additional amounts were owed by the audited Party or excess payments were made by the auditing Party, the audited Party shall pay such additional amounts or refund such excess payments, as applicable, or (y) excess payments were made by the audited Party or additional amounts were owed by the auditing Party, the auditing Party shall refund such excess payments or pay such additional amounts, as applicable, in either case ((x) or (y)), within [\*\*\*] after the date on which such audit is completed by the auditing Party and if such additional amounts or excess payments were due to an error in an invoice

or report provided by the Party that is required to pay such additional amounts or refund such excess payments, with interest from the date originally due as provided in Section 8.11.

**8.13.2.** Audit Dispute. In the event of a dispute between the Parties with respect to any audit under Section 8.13.1 (an "Audit Dispute"), the Parties shall work in good faith to resolve the Audit Dispute. If the Parties are unable to reach a mutually acceptable resolution of any such Audit Dispute within [\*\*\*] from the date on which either Party notifies the other in writing of the existence of an Audit Dispute, the Audit Dispute shall be submitted for resolution to an internationally-recognized, certified public accounting firm jointly selected by both Parties (the "Auditor"). The decision of the Auditor (the "Audit Decision") shall be final and binding on the Parties, and the costs of the Auditor proceeding shall be borne between the Parties in such manner as the Auditor shall determine. If such Audit Decision concludes that (a) additional amounts were owed by the audited Party or excess payments were made by the auditing Party, the audited Party shall pay such additional amounts or refund such excess payments, as applicable or (b) excess payments were made by the audited Party or additional amounts were owed by the auditing Party, the auditing Party shall refund such excess payments or pay such additional amounts, as applicable, in either case ((a) or (b)), within [\*\*\*] from the date on which the Audit Decision is served on the Parties and if such additional amounts or excess payments were due to an error in an invoice or report provided by the Party that is required to pay such additional amounts or refund such excess payments, with interest from the date originally due as provided in Section 8.11.

**8.13.3.** Confidentiality. Each Party shall treat all information subject to review under this Article 8 in accordance with the confidentiality provisions of Article 10 and the Parties shall cause the Auditor to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

**8.14.** Third Party Obligations. ACI shall be responsible for all payments owed to Third Parties under the Existing Agreements and any other license or other agreements regarding any intellectual property rights licensed, acquired or otherwise obtained by ACI or its Affiliates, including any agreement pursuant to which ACI or any of its Affiliates has rights with respect to any Licensed Compound or Licensed Product.

8.15. Apportionment of Compulsory License Revenue. [\*\*\*]

# ARTICLE 9 INTELLECTUAL PROPERTY

### 9.1. Ownership of Intellectual Property.

**9.1.1.** Ownership of Technology. Subject to Section 7.3.1(b), Section 9.1.2 and Section 9.1.3, as between the Parties, each Party shall solely and exclusively own and retain all right, title and interest in and to any and all: (a)

Information and other inventions that are conceived, discovered, developed or otherwise made by or on behalf of such Party (or its Affiliates or its or their respective (sub)licensees/Sublicensees) under or in connection with this Agreement, whether or not patented or patentable and any and all Patents and other intellectual property rights with respect thereto, except to the extent that any such Information or other invention, or any Patent

or intellectual property rights with respect thereto, is Joint Intellectual Property Rights; and (b) other Information, inventions, Patents and other intellectual property rights that are owned or otherwise controlled (other than pursuant to the license grants set forth in Section 5.1) by such Party or any of its Affiliates or its or their respective (sub)licensees/Sublicensees outside of this Agreement. Subject to Section 3.3.3, each Party shall disclose to the other Party in writing and shall cause its Affiliates, and its and their (sub)licensees/Sublicensees to so disclose, the conception, discovery, development or making of any Information, Patents, inventions and other intellectual property rights described in clause (a) that are conceived, discovered, developed or otherwise made prior to the Option Effective Date promptly after becoming aware thereof, including any invention disclosures or other similar documents submitted to such Party by its employees, agents, consultants, independent contractors or Affiliates in connection therewith.

### 9.1.2. Ownership of Joint Patents and Joint Know-How.

Subject to Section 7.3.1(b) and Section 9.1.3, as between the Parties, the Parties shall each own an equal, undivided interest in any and all: (a) Information and other inventions that are conceived, discovered, developed or otherwise made jointly by or on behalf of ACI or its Affiliates or its or their (sub)licensees, on the one hand, and Takeda or its Affiliates or its or their Sublicensees, on the other hand, under or in connection with this Agreement, whether or not patented or patentable (the "Joint Know-How"); and (b) Patents with respect to the Information and other inventions described in clause (a) (the "Joint Patents") and (c) other intellectual property rights with respect to the Information and other inventions described in clause (a) (together with Joint Know-How and Joint Patents, the "Joint Intellectual Property Rights"). Each Party shall disclose to the other Party in writing and shall cause its Affiliates, and its and their (sub)licensees/Sublicensees to so disclose, the conception, discovery, development or making of any Joint Intellectual Property Rights. Subject to each Party's exclusivity obligations under Section 5.5 and confidentiality obligations under Article 10 and, with respect to ACI, the licenses granted under Section 5.1, (x) each Party shall have the right to practice, grant licenses under and transfer any Joint Intellectual Property Rights, (y) neither Party shall have any obligation to account to the other for profits or to obtain any approval of the other Party to license or Exploit any Joint Intellectual Property Rights by reason of joint ownership thereof, and (z) each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting.

## 9.1.3. Treatment of Certain IP if Option is not Exercised.

- (a) If (i) Takeda does not provide an Exercise Notice prior to the expiration of the Option Period, then upon expiration of the Option Period, or (ii) this Agreement is terminated prior to the Option Effective Date, then upon the effective date of such termination, in each case ((i) and (ii)), [\*\*\*]
- (b) If (i) Takeda does not provide an Exercise Notice prior to the expiration of the Option Period, then upon expiration of the Option Period, or (ii) this Agreement is terminated prior to the Option Effective Date, then upon the effective date of such termination, in each case ((i) and (ii)), [\*\*\*]

rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States as such law exists as of the Effective Date irrespective of where or when such conception, discovery, development or making occurs. In the event that such United States law does not apply to the conception, discovery, development or making of any Information or other inventions hereunder, each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their (sub)licensees/Sublicensees to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Information and other inventions as well as any intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, (a) the sole ownership provided for in Section 9.1.1 and Section 9.1.3 and (b) the joint ownership provided for in Section 9.1.2.

#### 9.2. Control of Intellectual Property.

9.2.1. Neither Party shall enter into or amend any agreement with a Third Party, or include in any such agreement or amendment any restrictive provisions, with an intent to limit its Control of, or to not Control, any Information, Patent or other intellectual property right that would be subject to the license grants in Section 5.1 or Section 9.1.3(b), as applicable, in the absence of such agreement, amendment or restrictive provisions. Further, when entering into any agreement or amendment with a Third Party relating to any Information, Patents or other intellectual property rights that, if Controlled by either Party or its Affiliates, would be subject to the license grants in Section 5.1 or Section 9.1.3(b), as applicable, each Party shall use good faith efforts to obtain Control of such Information, Patents and other intellectual property rights.

9.2.2. (a) ACI shall cause all Persons who perform Development (including CMC Development), Manufacturing or regulatory activities for ACI under this Agreement or who conceive, discover, develop or otherwise make any Information by or on behalf of ACI or its Affiliates or its or their (sub)licensees under or in connection with this Agreement and (b) Takeda shall cause all Persons who are granted access to or otherwise provided with ACI's Proprietary CMC Information pursuant to and in accordance with Section 3.3.3 or perform the CMC Development activities or who, on behalf of Takeda or its Affiliates or its or their Sublicensees, in performing any activities under this Agreement, conceive, discover, develop or otherwise make any Information in and to which Takeda is required hereunder to assign to ACI its entire interest or a joint ownership interest, in each case ((a) and (b)) to be under an obligation to assign (or, if the applicable Party is unable to cause such Person to agree to such assignment obligation despite such Party using commercially reasonable efforts to negotiate such assignment obligation, provide an exclusive license under) their rights in any Information or other inventions resulting from such activities as set forth in clause (a) or (b), as applicable to such Party, except (x) where Applicable Law requires otherwise, (y) in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case a suitable license, or right to obtain such a license, shall be obtained), and (z) in the case of a Third Party subcontractor that performs activities under this Agreement, with respect to any Information or inventions that constitute (i) the background intellectual property of such Third Party or (ii) improvements to such background intellectual

property that are not specific to one (1) or more Licensed Compounds or Licensed Products or the Exploitation thereof and that do not incorporate any of a Party's Confidential Information (in which case, a license for rights to use any such intellectual property that is necessary to Exploit one (1) or more Licensed Compounds or Licensed Products shall be obtained from such Third Party (which license shall be consistent with this

Agreement and shall not adversely affect in any respect the other Party's rights or interests under this Agreement or impose any material obligation on the other Party)).

9.2.3. [\*\*\*]

#### 9.3. Maintenance and Prosecution of Patents.

9.3.1. Licensed Patents and Joint Patents Prior to Option Effective Date. As between the Parties, subject to Section 9.3.3 and Section 9.3.4, prior to the Option Effective Date, ACI shall have (a) the sole right, but not the obligation [\*\*\*] using counsel of its own choice, to prepare, file, prosecute and maintain, and to be responsible for any opposition, re-issuance, post-grant review, interpartes review, reexamination request, nullity action, interference or other similar post-grant proceedings and any appeals therefrom (each, a "Defense Proceeding") with respect to, the Other Licensed Patents in the Territory, at its sole cost and expense and (b) the first right, but not the obligation, using counsel of its own choice, to prepare, file, prosecute and maintain, and to be responsible for any Defense Proceeding with respect to, the Product Patents and Joint Patents in the Territory, at its sole cost and expense; provided that (x) ACI shall promptly notify Takeda upon becoming aware of any Defense Proceeding with respect to a Licensed Patent or Joint Patent and [\*\*\*]

9.3.2. Licensed Patents and Joint Patents After the Option Effective Date. As between the Parties, subject to Section 9.3.3 and Section 9.3.4, from and after the Option Effective Date:

(a) Takeda shall have the first right, but not the obligation, using counsel of its own choice, to prepare, file, prosecute and maintain the Product Patents and Joint Patents in the Territory and to be responsible for any Defense Proceeding with respect thereto, in each case, at its sole cost and expense. For clarity, Takeda shall have the first right to prepare, file, prosecute and maintain any application for a Licensed Patent that is a continuation or divisional of another Licensed Patent and that would result in the issuance of a Patent that solely and specifically claims one (1) or more Licensed Compounds or Licensed Products or the Exploitation thereof (it being understood that any such continuations or divisionals shall be considered to be Product Patents upon the filing of such continuation or divisional application with the applicable Governmental Authority in a country); and

(b) [\*\*\*] using counsel of its own choice, to prepare, file, prosecute and maintain the Other Licensed Patents in the Territory and to be responsible for any Defense Proceeding with respect thereto, in each case, at its sole cost and expense; [\*\*\*]

9.3.3. Cooperation. The non-prosecuting Party shall, and shall cause its Affiliates to, assist and cooperate with the prosecuting Party, as the prosecuting Party may reasonably request from time to time, in the preparation, filing, prosecution and maintenance of the Licensed Patents and Joint Patents (and any related Defense Proceedings) under this Agreement, including that the non-prosecuting Party shall, and shall cause its Affiliates to, (a) offer its comments, if any, promptly, (b) provide reasonable access to relevant documents and other evidence and make its employees

upon its request, with copies of any patentability search reports	
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reasonably available at reasonable business hours and (c) provide the prosecuting Party,

generated by its patent counsel with respect to the Licensed Patents or Joint Patents, including relevant Third Party patents and patent applications located (*provided* that neither Party shall be required to provide legally privileged information with respect to such intellectual property unless and until procedures reasonably acceptable to such Party are in place to protect such privilege); *provided*, *further*, that, except with respect to the Joint Patents, the prosecuting Party shall reimburse the non-prosecuting Party for its reasonable and verifiable Out-of-Pocket Costs incurred in connection therewith. For clarity, this Section 9.3.3 shall apply both before and after the Option Effective Date.

9.3.4. Procedures; Step-In. Each Party shall periodically inform the other Party of all material steps with regard to the preparation, filing, prosecution and maintenance of the Product Patents, Joint Patents and [\*\*\*] (or the related Defense Proceedings) in the Territory, including by providing the other Party with a copy of material communications to and from any patent authority in the Territory regarding such Patents (or such Defense Proceedings) and by providing the other Party drafts of any material filings or responses to be made to such patent authorities in the Territory in connection therewith sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for the other Party to review and comment thereon. Each Party shall consider in good faith the requests and suggestions of the other Party with respect to such drafts and with respect to strategies for filing and prosecuting such Patents (or the conduct of such Defense Proceedings) in the Territory. If, as between the Parties, the Party with the first right to prosecute a Product Patent or Joint Patent (or conduct a related Defense Proceeding) decides not to prepare, file, prosecute or maintain such Product Patent or Joint Patent (or conduct the related Defense Proceeding) in a country in the Territory, such Party shall provide reasonable prior written notice to the other Party of such intention, and the other Party shall thereupon have the option to assume the control and direction of the preparation, filing, prosecution and maintenance of such Product Patent or Joint Patent (or the conduct of such Defense Proceeding) at its sole cost and expense in such country; provided that with respect to any Product Patent or Joint Patent from and after the Option Effective Date, if Takeda decides not to file such a Patent or not to continue such prosecution or maintenance (or conduct such Defense Proceeding) for strategic reasons (including if, from and after the Option Effective Date, with respect to the Product Patents and Joint Patents, Takeda in good faith believes that such filing or continued prosecution or maintenance (or conduct of such Defense Proceeding) would likely have an adverse impact on the Development, Manufacture or Commercialization of the Licensed Compounds or Licensed Products or is reasonably likely to have a detrimental effect on the overall patent portfolio for the Licensed Compounds or Licensed Products or if Takeda desires to maintain certain Information that would be disclosed therein as a trade secret), then ACI shall not have the right to exercise such step-in right without Takeda's prior written consent. For clarity, this Section 9.3.4 shall apply both before and after the Option Effective Date (as set forth herein).

## 9.3.5. Patent Term Extension and Supplementary Protection Certificate.

(a) As between the Parties, prior to the Option Effective Date, ACI shall have the sole right to make decisions regarding, and to apply

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for, patent term extensions in the Territory, including the United States with respect to extensions pursuant to 35 U.S.C. §156 et seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now available or become available in the

future prior to the Option Effective Date, wherever applicable, for the Licensed Patents and any Joint Patents and with respect to the Licensed Compounds and the Licensed Products, in each case, including whether or not to do so; *provided* that ACI shall notify Takeda prior to applying for any such patent term extension, and in the event Takeda disagrees with any such decision of ACI, Takeda shall have the right to escalate such dispute to the Executive Officers for resolution; *provided*, *further*, that unless and until the Executive Officers or Parties resolve such dispute, such dispute shall remain deadlocked, and ACI shall not have the right to apply for such patent term extension. If ACI applies for a patent term extension in accordance with the foregoing, (i) ACI shall discuss such filing with Takeda in advance and shall consider in good faith the requests and suggestions of Takeda and (ii) Takeda shall, and shall cause its Affiliates to, provide prompt and reasonable assistance, as requested by ACI in writing.

(b) As between the Parties, from and after the Option Effective Date, Takeda shall have the sole right to make decisions regarding, and to apply for, patent term extensions in the Territory, including the United States with respect to extensions pursuant to 35 U.S.C. §156 et seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for the Product Patents, Joint Patents and [\*\*\*] ACI shall, and shall cause its Affiliates to, provide prompt and reasonable assistance, as requested by Takeda, including by taking such action as patent holder as is required under any Applicable Law to obtain such extension or supplementary protection certificate.

**9.3.6.** Common **Ownership** Under Joint Research Agreements. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 U.S.C. §100(h). Notwithstanding anything to the contrary in this Agreement, neither Party shall invoke this Agreement under 35 U.S.C. §102(c) to except any patent or patent application as prior art without the prior written consent of the other Party. If such written consent is granted, the Parties shall coordinate their activities with respect to all submissions under 35 U.S.C. §102(c). Without limiting the foregoing, at the request of a Party, the Parties shall amend the specification of any U.S. patent application or patent claiming any Information or other inventions that are conceived, discovered, developed or otherwise made under or in connection with this Agreement as appropriate and necessary so as to avail of the Joint Research Agreement provisions permitting the execution of a terminal disclaimer under 37 C.F.R. §1.321(d) or similar regulation.

9.3.7. Transfer of Inventions. With respect to any Patents claiming any invention conceived, discovered, developed or otherwise made by or on behalf of Takeda (solely or jointly with ACI) under or in connection with this Agreement, Takeda may elect, in its sole discretion, to assign all of its right, title and interest in and to such invention and such Patent to ACI by written notice to ACI. If Takeda makes such an election, ACI shall and hereby does grant to Takeda an exclusive (or with respect to Joint Intellectual Property Rights co-exclusive and subject to Section 9.1.2), royalty-free, transferable, irrevocable, perpetual license under such invention and such Patent for any and all purposes. Notwithstanding the foregoing, if Takeda makes such an election, for purposes of this Agreement, such Patent shall not constitute

a Licensed Patent and shall continue to be considered a Joint Patent or a Patent solely owned by Takeda, and ACI shall cooperate with Takeda to effect such assignment (including pursuant to Section 14.13) and to afford Takeda its rights with respect to such Patent as set forth in this Article 9 as if such assignment had not occurred. As between the Parties, any and all costs and expenses incurred in

connection with any such assignment of any Patent to ACI shall be borne solely by Takeda, and any and all costs incurred in connection with the preparation, filing, prosecution or maintenance of any such Patent shall be borne as set forth in this Article 9 as if such assignment had not occurred.

#### 9.3.8. Patent Listings.

As between the Parties, prior to the Option (a) Effective Date, ACI shall have the sole right to make all filings with Regulatory Authorities in the Territory with respect to the Licensed Patents and Joint Patents, including as required or allowed (i) in the United States, in the FDA's Orange Book or Purple Book, as applicable and (ii) in the European Union, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents; provided that ACI shall notify Takeda prior to making any such filing, and in the event Takeda disagrees with any such decision of ACI, Takeda shall have the right to escalate such dispute to the Executive Officers for resolution; provided, further, that unless and until the Executive Officers or Parties resolve such dispute, such dispute shall remain deadlocked, and ACI shall not have the right to make such filing. If ACI makes any such filing in accordance with the foregoing, ACI shall discuss such filing with Takeda in advance and shall consider in good faith the requests and suggestions of Takeda and Takeda shall provide prompt and reasonable assistance, as requested by ACI in writing, with respect to such filings.

(b) As between the Parties, from and after the Option Effective Date, Takeda shall have the sole right to make all filings with Regulatory Authorities in the Territory with respect to the Product Patents, Joint Patents and, [\*\*\*] including as required or allowed (i) in the United States, in the FDA's Orange Book or Purple Book, as applicable and (ii) in the European Union, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents. ACI shall provide prompt and reasonable assistance, as requested by Takeda in writing, with respect to such filings, including by taking such action as may be required of the Patent holder under any Applicable Law.

## 9.3.9. UPC Opt-Out and Opt-In.

(a) As between the Parties, prior to the Option Effective Date, ACI shall have the sole right to make decisions regarding any UPC Opt-Out with respect to any Licensed Patent or Joint Patent; *provided* that ACI will not UPC Opt-In any Patent that may be issued prior to the Option Effective Date without Takeda's prior written consent. Each Party shall provide prompt and reasonable assistance, as requested by the other Party in writing, with respect to such UPC Opt-Out or UPC Opt-In.

(b) From and after the Option Effective Date, Takeda shall have the sole right to make decisions regarding any UPC Opt-Out or UPC Opt-In with respect to any Product Patent or Joint Patent. ACI shall provide prompt and reasonable assistance, as requested by Takeda in writing, with respect to such UPC Opt-Out or UPC Opt-In, including by taking such action as may be required of the Patent holder under any Applicable Law. ACI shall have the sole right to make decisions

regarding any UPC Opt-Out or UPC Opt-In with respect to any Other Licensed Patent provided that [***]
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#### 9.4. Enforcement of Patents.

**9.4.1. Notice.** Each Party shall promptly notify the other Party in writing of any alleged or threatened infringement of the Licensed Patents or Joint Patents in the Territory of which such Party becomes aware.

9.4.2. Enforcement of Infringement Actions Prior to the Option Effective Date. As between the Parties, subject to Section 9.4.4, prior to the Option Effective Date:

(a) ACI shall have (i) the sole right, but not the obligation, to prosecute any infringement with respect to the Licensed Patents, including as a defense or counterclaim in connection with any Third Party Infringement Claim, using counsel of its own choice, at its sole cost and expense and (ii) the first right, but not the obligation, to prosecute any infringement with respect to the Joint Patents, including as a defense or counterclaim in connection with any Third Party Infringement Claim, using counsel of its own choice, at its sole cost and expense; provided that ACI shall not institute any action or discussions with respect to (x) an infringement of any Other Licensed Patent or Joint Patent based on the development, commercialization or an application to market a product containing a Licensed Compound or any Licensed Product or Competing Product (including any Biosimilar Product) or (y) an infringement of a Product Patent ((x) and (y), a "Competitive Infringement"), in each case ((x) and (y)), without Takeda's prior written consent.

(b) In the event ACI prosecutes any Competitive Infringement prior to the Option Effective Date, Takeda shall have the right to join as a party to such claim, suit or proceeding in the Territory and participate with its own counsel at its sole cost and expense; *provided* that ACI shall retain control of the prosecution of such claim, suit or proceeding, including the response to any defense or defense of any counterclaim raised in connection therewith. If ACI or its designee does not take commercially reasonable steps to prosecute or settle an infringement (including Competitive Infringement) with respect to the Joint Patents by the earlier of ([\*\*\*] before the time limit, if any, set forth in Applicable Law for filing of such actions, then Takeda shall have the right to prosecute such infringement at its sole cost and expense. ACI shall promptly notify Takeda if it determines not to prosecute or settle an infringement with respect to the Joint Patents.

# 9.4.3. Enforcement of Infringement Actions After the Option Effective Date.

Option Effective Date. As between the Parties, subject to Section 9.4.4, from and after the Option Effective Date, Takeda shall have the first right, but not the obligation, to prosecute any infringement (including Competitive Infringement) with respect to the Product Patents and Joint Patents, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at Takeda's sole cost and expense, using counsel of its own choice. If Takeda or its designee does not take commercially reasonable steps to prosecute or settle an infringement with respect to the Product Patents or Joint Patents by the earlier of ([\*\*\*] Competitive Infringement under 35

U.S.C. Applies	§271(e)(2), able	[***]	and	(ii) [***]	before	the	time	limit,	if	any,	set	forth	in
 					54								

Law for filing of such actions, then ACI may prosecute such infringement with respect to the Product Patents or Joint Patents, at its sole cost and expense; *provided* that if Takeda decides not to prosecute or settle any such infringement for strategic reasons (including if Takeda in good faith believes that such prosecution or settlement would likely have an adverse impact on the Development, Manufacture or Commercialization of the Licensed Compounds or Licensed Products or is reasonably likely to have a detrimental effect on the overall patent portfolio for the Licensed Compounds or Licensed Products), then ACI shall not have the right to exercise such step-in right. Takeda shall promptly notify ACI in writing if it determines not to prosecute or settle an infringement with respect to the Product Patents or Joint Patents.

(b) Other Licensed Patents After the Option Effective Date. As between the Parties, subject to Section 9.4.4, from and after the Option Effective Date, ACI shall have the sole right, but not the obligation, to prosecute any infringement with respect to the Other Licensed Patents, including as a defense or counterclaim in connection with any Third Party Infringement Claim, at ACI's sole cost and expense, using counsel of its own choice; provided that (i) if there is no valid and enforceable Product Patent that would be infringed by the Exploitation of the Licensed Compound, Licensed Product or Competing Product that is the subject of a Competitive Infringement, Takeda shall have the right to prosecute such Competitive Infringement with respect to the Other Licensed Patents at its sole cost and expense, [\*\*\*] and (iii) ACI shall not institute any action or discussions with respect to any Competitive Infringement without Takeda's prior written consent. In the event ACI prosecutes any Competitive Infringement, Takeda shall have the right to join as a party to such claim, suit or proceeding in the Territory and participate with its own counsel at its sole cost and expense; provided, further, that ACI shall retain control of the prosecution of such claim, suit or proceeding to the extent applicable to the Other Licensed Patents, including the response to any defense or defense of any counterclaim raised in connection therewith. [\*\*\*]

9.4.4. Cooperation; Settlement. Where a Party controls an infringement action under this Section 9.4, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may reasonably request from time to time, in connection with its activities set forth in this Section 9.4, including furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing reasonable access to relevant records, documents (including laboratory notebooks) and other evidence and making inventors and other of its employees reasonably available at reasonable business hours; provided that the controlling Party shall reimburse such other Party for its reasonable and verifiable Out-of-Pocket Costs incurred in connection therewith (which excludes, for the avoidance of doubt, outside attorneys' fees incurred by such Party). Unless otherwise set forth herein, the Party entitled to bring any infringement action in accordance with this Section 9.4 shall have the right to settle such claim; provided that (a) ACI shall not have the right to settle any Competitive Infringement under this Section 9.4 without the express written consent of Takeda (which consent shall not be unreasonably withheld, conditioned or delayed) and (b) neither Party shall have the right to settle an infringement under this Section 9.4 in a manner that [\*\*\*] without the express written consent of the other Party (which 55

taken and provide copies of all material documents filed, in connection with such claim, suit or proceeding. In the event that Takeda controls any Competitive Infringement claim, suit or proceeding pursuant to this Section 9.4, Takeda shall keep ACI reasonably informed of any material steps taken and provide ACI with high-level details regarding the status of such claim, suit or proceeding. For clarity, this Section 9.4.4 shall apply both before and after the Option Effective Date.

**9.4.5. Recovery.** Except as otherwise agreed by the Parties in connection with a written cost sharing arrangement and except with respect to costs incurred by a Party that joins and participates in litigation at its sole cost and expense as set forth in this Section 9.4, any recovery realized as a result of such litigation described above in this Section 9.4 (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the Party that has exercised its right to bring the enforcement action; *provided, however*, that to the extent that any award or settlement after the Option Effective Date (whether by judgment or otherwise) with respect to a Licensed Patent is attributable to loss of sales or profits with respect to a Licensed Product, such amount shall be paid to or retained by Takeda and treated as "Net Sales" in the Fiscal Year to which such loss of sales or profits are attributable [\*\*\*]

#### 9.5. Invalidity or Unenforceability Defenses or Actions.

**9.5.1. Notice.** Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Licensed Patents or Joint Patents by a Third Party of which such Party becomes aware.

#### 9.5.2. Defense Actions.

the Parties, subject to Section 9.5.3, prior to the Option Effective Date, (i) ACI shall have the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Other Licensed Patents; and (ii) ACI shall have the first right, but not the obligation to defend and control the defense of the validity and enforceability of the Product Patents and Joint Patents, in each case ((i) and (ii)), in the Territory, using counsel of its own choice, at its sole cost and expense; *provided* that if the assertion of invalidity or unenforceability of such Patents is brought as a defense or counterclaim in connection with an infringement action initiated pursuant to Section 9.4, the applicable enforcing Party shall have the first right, but not the obligation, to defend and control the validity and enforceability of such Patents at its sole cost and expense.

(b) After the Option Effective Date. As between the Parties, subject to Section 9.5.3, from and after the Option Effective Date, (i) Takeda shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the Product Patents and the Joint Patents in the Territory, using counsel of its own choice, at its sole cost and expense and (ii) ACI shall have

the sole right, but not the obligation, to defend and control the defense of the validity and enforceability of the Other Licensed Patents in the Territory, using counsel of its own choice, at its sole cost and expense; *provided* that, in each case ((i) and (ii)), if the

counterclaim in connection with an infringement action initiated pursuant to Section 9.4, the applicable enforcing Party shall have the first right, but not the obligation, to defend and control the validity and enforceability of such Patents at its sole cost and expense.

(c) For clarity, this Section 9.5 shall not apply to control of Defense Proceedings, which proceedings shall be governed by Section 9.3. Nothing in this Section 9.5 shall limit any indemnification rights or obligations of a Party under Article 12.

#### 9.5.3. Step-In; Cooperation.

(a) Prior to the Option Effective Date, if ACI elects not to defend or control the defense of the Product Patents or Joint Patents in a claim, suit or proceeding arising under this Section 9.5 brought in the Territory, or otherwise fails to initiate and maintain the defense of any such claim, suit or proceeding, and, in either case, has not settled and is not actively pursuing settlement of such claim, suit or proceeding, then Takeda may conduct and control the defense of any such claim, suit or proceeding at its own expense. The non-controlling Party may participate in any claim, suit or proceeding regarding the validity and enforceability of such Product Patents or Joint Patents in the Territory with counsel of its choice at its sole cost and expense; provided that the controlling Party shall retain control of the defense in such claim, suit or proceeding.

(b) From and after the Option Effective Date, if Takeda elects not to defend or control the defense of the Product Patents or Joint Patents in a claim, suit or proceeding arising under this Section 9.5 brought in the Territory, or otherwise fails to initiate and maintain the defense of any such claim, suit or proceeding, and, in either case, has not settled and is not actively pursuing settlement of such claim, suit or proceeding, then ACI may conduct and control the defense of any such claim, suit or proceeding at its own expense; *provided* that ACI shall obtain the written consent of Takeda prior to settling or compromising any such claim, suit or proceeding with respect to any Product Patent or Joint Patent. The non-controlling Party may participate in any claim, suit or proceeding regarding the validity and enforceability of such Product Patents or Joint Patents in the Territory with counsel of its choice at its sole cost and expense; *provided* that the controlling Party shall retain control of the defense in such claim, suit or proceeding.

(c) During the Term, where a Party controls a claim, suit or proceeding under this Section 9.5, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the controlling Party, as such controlling Party may reasonably request from time to time in connection with its activities set forth in this Section 9.5, including furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, the relevant action, providing reasonable access to relevant records, documents and other evidence (including laboratory notebooks) and making inventors and other of its employees reasonably available at reasonable business hours; *provided* that, except with respect to Joint Patents, the controlling Party shall reimburse the other Party for its reasonable and verifiable Out-of-Pocket Costs incurred in connection therewith. In connection with

any activities with respect to a defense, claim or counterclaim relating to the Product Patents or Joint Patents pursuant to this Section 9.5, the controlling Party shall (i) consult with the other Party as to the strategy for such activities, (ii) consider in good faith any comments from the other Party and (iii) keep the other Party reasonably

informed of any material steps taken and provide copies of all material documents filed, in connection with such defense, claim or counterclaim.

**Infringement Claims by Third Parties.** If the Exploitation of a Licensed Compound or Licensed Product in the Territory pursuant to this Agreement results in, or is reasonably expected to result in, any claim, suit or proceeding by a Third Party alleging infringement by a Party or any of its Affiliates or its or their (sub)licensees/Sublicensees, distributors or customers (a "Third Party Infringement Claim"), including any defense or counterclaim in connection with an enforcement action initiated pursuant to Section 9.4, the Party first becoming aware of such alleged Third Party Infringement Claim shall promptly notify the other Party thereof in writing. As between the Parties, (a) prior to the Option Effective Date, ACI shall have the first right, but not the obligation, to defend and control the defense of (including to settle) any such Third Party Infringement Claim at its sole cost and expense (but subject to Article 12), using counsel of its own choice, and (b) from and after the Option Effective Date, Takeda shall have the first right, but not the obligation, to defend and control the defense of (including to settle) any such Third Party Infringement Claim at its sole cost and expense (but subject to Section 8.6 and Article 12), using counsel of its own choice; provided that ACI shall provide written notice to, and discuss with, Takeda prior to settling or compromising any such Third Party Infringement Claim and shall consider any comments provided by Takeda in good faith. In each case, the non-controlling Party may participate in any such Third Party Infringement Claim with counsel of its choice at its sole cost and expense; provided that the controlling Party shall retain control of such Third Party Infringement Claim. If the controlling Party or its designee elects (in a written communication submitted to the non-controlling Party within a reasonable amount of time after notice of the alleged Third Party Infringement Claim) not to defend or control the defense of such Third Party Infringement Claim, the non-controlling Party may conduct and control the defense of such Third Party Infringement Claim at its sole cost and expense; provided that, in the case of ACI as the initial non-controlling Party, ACI shall obtain the written consent of Takeda prior to settling or compromising any such Third Party Infringement Claim. Where either Party controls such an action, the other Party shall, and shall cause its Affiliates to, assist and cooperate with such Party, as such Party may reasonably request from time to time, in connection with its activities set forth in this Section 9.6, including furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing reasonable access to relevant records, documents (including laboratory notebooks) and other evidence and making inventors and other of its employees reasonably available at reasonable business hours; provided that the controlling Party shall reimburse the other Party for its reasonable and verifiable Out-of-Pocket Costs incurred in connection therewith. Each Party shall keep the other Party reasonably informed of all material developments in connection with any such claim, suit or proceeding. Nothing in this Section 9.6 will limit any indemnification rights or obligations of a Party under Article 12.

## 9.7. Third Party Rights.

**9.7.1. Prior to the Option Effective Date.** Subject to Section 8.14, Section 9.2 and Section 9.6, prior to the Option Effective Date, if ACI determines

that any Patent, Information or other intellectual property right of a Third Party in any country in the Territory is necessary or reasonably useful for the Exploitation of a Licensed Compound or Licensed Product (such Patent, Information or other intellectual property right, a "Third Party Right"), then, as between the Parties, ACI shall have the sole right, but not the obligation, to challenge the

applicability, patentability, validity or enforceability of, or to enter into a license or other agreement with such Third Party pursuant to which ACI or its Affiliate would acquire a license or other right under, such Third Party Right as necessary or reasonably useful to Exploit a Licensed Compound and Licensed Products in such country. Prior to entering into any such license or other agreement with respect to a Third Party Right, ACI shall notify Takeda of such Third Party Right, including a reasonably detailed explanation of its relevance and the expected terms of any license or other agreement with respect thereto. ACI shall ensure that the terms of such license or agreement are consistent with this Agreement and do not adversely affect in any respect Takeda's rights or interests under this Agreement or impose any material obligation on Takeda (including in the event Takeda exercises the Option). ACI will promptly provide Takeda with notice and a true and complete copy of each such agreement entered into by ACI or any of its Affiliates.

9.7.2. After the Option Effective Date. Subject to Section 9.6, from and after the Option Effective Date, if Takeda determines that any Third Party Right is necessary or reasonably useful for the Exploitation of a Licensed Compound or Licensed Product by Takeda or any of its Affiliates or any of its or their Sublicensees, distributors or customers, then, as between the Parties, Takeda shall have the first right, but not the obligation, to challenge the applicability, patentability, validity or enforceability of, or to enter into a license or other agreement with such Third Party pursuant to which Takeda or its Affiliate would acquire a license or other right under, such Third Party Right as necessary or reasonably useful for Takeda or its Affiliates or its and their Sublicensees, distributors or customers to Exploit Licensed Compounds and Licensed Products in such country. In the event that Takeda or its Affiliate negotiates and obtains any such license or other agreement from a Third Party with respect to any Third Party Right that Takeda reasonably determines is necessary for Takeda or its Affiliates or its and their Sublicensees, distributors or customers to Exploit a Licensed Compound or Licensed Product, Takeda shall be entitled to deduct [\*\*\*]

9.8. Product Trademarks. As between the Parties, from and after the Option Effective Date, Takeda and its Affiliates shall have the sole right to use any Trademark it owns or controls for Licensed Products in the Territory at its sole discretion. Takeda shall have the sole right to determine, develop, prosecute, enforce and defend one (1) or more Product Trademark(s) for use by Takeda and its Affiliates and its or their Sublicensees to Commercialize Licensed Products in the Field in the Territory. As between the Parties, Takeda and its Affiliates shall own all rights to such Product Trademarks and all goodwill associated therewith, and the rights to any Internet domain names incorporating the applicable Product Trademarks or any variation or part of such Product Trademarks used as its URL address or any part of such address, throughout the Territory. ACI shall not, and shall cause its Affiliates and (sub)licensees not to, (a) use in their respective businesses, any Trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of the Product Trademarks and (b) do any act that endangers, destroys or similarly adversely affects, in any material respect, the value of the goodwill pertaining to the Product Trademarks. ACI shall not, and shall cause its Affiliates and (sub)licensees not to, attack, dispute or contest the validity of or ownership of any Product Trademark anywhere in the Territory or any registrations issued or issuing with respect thereto.

## ARTICLE 10 CONFIDENTIALITY AND NON-DISCLOSURE

10.1. Confidentiality Obligations. At all times during the Term and for a period of [\*\*\*] following termination or expiration of this Agreement in its entirety, each Party shall, and shall cause its Affiliates and each of its and their respective officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to any Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this [\*\*\*] "Confidential Information" means any technical, business or other information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic or otherwise) that is disclosed or otherwise provided by or on behalf of one (1) Party to the other Party in connection with this Agreement or that certain Confidentiality Agreement entered into by the Parties, dated February 20, 2023, as amended ("Confidentiality Agreement"), whether prior to, on or after the Effective Date, including the terms of this Agreement, information relating to any Licensed Compound or any Licensed Product (including the Regulatory Documentation), any Development, Manufacture or Commercialization of any Licensed Compound or any Licensed Product, any Information with respect thereto developed by or on behalf of the disclosing Party or its Affiliates or its or their respective (sub)licensees/Sublicensees (including Licensed Know-How) and the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, from and after the Option Effective Date until termination (but not expiration) of this Agreement, Product Information shall be deemed the Confidential Information of Takeda (and Takeda shall be deemed the disclosing Party and ACI shall be deemed the receiving Party with respect thereto) and from and after any such termination (but not expiration) of this Agreement, ACI shall be deemed the disclosing Party (and Takeda shall be deemed the receiving Party) with respect thereto. For the avoidance of doubt, any Joint Know-How (other than that which is Product Information) and the terms of this Agreement shall be deemed to be the Confidential Information of both Parties (and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto).

**10.2.** Exceptions. Notwithstanding the foregoing, Confidential Information shall not include any information that the receiving Party can demonstrate in its written records or with other competent evidence:

10.2.1. is or hereafter becomes generally available to the public by use, publication, general knowledge or the like other than through any act or omission of the receiving Party or any of its Affiliates in breach of this Agreement or, prior to the Effective Date, the Confidentiality Agreement by the receiving Party;

10.2.2. is subsequently disclosed to the receiving Party or any of its Affiliates, without obligation of confidentiality or non-use, by a Third Party (other than any representative of, or any Person that disclosed such information on behalf of, the disclosing Party or its Affiliates, without obligation of confidentiality or non-use) who may lawfully do so and who is not under an obligation of confidentiality to the disclosing Party or any of its Affiliates with respect to such information;

10.2.3. was already in the possession of the receiving Party or any of its Affiliates prior to receipt from the disclosing Party or any of its Affiliates, without any obligation of confidentiality with respect to such information; *provided* that the foregoing exception shall not apply with respect to Product Information or Joint Know-How; or

**10.2.4.** is or was independently developed by the receiving Party or any of its Affiliates without use or reference to Confidential Information of the disclosing Party; *provided* that the foregoing exception shall not apply with respect to Product Information or Joint Know-How.

Specific aspects or details of Confidential Information shall not become exempt from the obligations set forth in this Article 10 merely because the Confidential Information is embraced by more general information included in the exceptions set forth in this Section 10.2. Further, any combination of Confidential Information shall not become exempt from the obligations herein merely because individual elements of such Confidential Information are included in the exceptions set forth in this Section 10.2, unless the combination and its principles fall within one or more of such exceptions.

**10.3. Permitted Disclosures.** Notwithstanding anything to the contrary in Section 10.1, each Party may disclose Confidential Information of the other Party to the extent that such disclosure is:

10.3.1. made in response to a valid order of a court of competent jurisdiction or other Governmental Authority of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law (other than by reason of filing with securities regulators, which shall be governed by Section 10.7); provided, however, that the receiving Party shall first have given written notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order or required to be disclosed be held in confidence by such court or Governmental Authority or, if disclosed, be used only for the purposes for which the order was issued or such disclosure was required by law; and provided, further, that the Confidential Information disclosed in response to such order of a court or Governmental Authority or as required by Applicable Law shall be limited to the information that is legally required to be disclosed in response to such order or by such Applicable Law;

10.3.2. made by or on behalf of the receiving Party to a patent authority as may be reasonably determined by the receiving Party to be necessary for purposes of obtaining or enforcing a Patent pursuant to this Agreement; *provided*, *however*, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available;

10.3.3. to potential or actual investors, acquirers in connection with any actual or proposed Change of Control, lenders or other financial partners or financing sources, and their respective attorneys, accountants, banks, investors and advisors, in each case, solely as may be necessary in connection with their evaluation

of such potential or actual investment, acquisition, debt transaction or other acquisition or financial transaction; <i>provided</i> , <i>however</i> , that (a) the
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foregoing disclosure shall be limited to [\*\*\*] and (b) any further disclosure to such Persons of Confidential Information of the other Party beyond that set forth in clause (a) shall require the other Party's prior written consent (and such other Party shall consider any such request in good faith); *provided, further*, that such Persons must be bound by similar (or subject to ethical) obligations of confidentiality and non-use at least equivalent in scope to, and no less restrictive than, those set forth in this Article 10 (with a duration of confidentiality and non-use obligations as appropriate that is no less than [\*\*\*] the date of disclosure); or

**10.3.4.** in connection with a Party's performance of this Agreement, to any Affiliates of such Party; *provided* that, prior to disclosure, such Affiliates must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to, and no less restrictive than, those set forth in this Article 10 (with a duration of confidentiality and non-use obligations as appropriate that is no less [\*\*\*] from the date of disclosure).

10.4. Additional by Permitted **Disclosures** Takeda. Notwithstanding anything to the contrary in Section 10.1, subject to Section 3.3.3, Takeda and its Affiliates and its and their Sublicensees may disclose Confidential Information of ACI as may be necessary or reasonably useful in connection with the Exploitation of the Licensed Compounds or the Licensed Products (including in connection with any filing, application or request for Regulatory Approval by or on behalf of Takeda or any of its Affiliates or its or their Sublicensees) or otherwise in connection with the performance of Takeda's obligations or exercise of Takeda's rights as contemplated by this Agreement solely to the extent such Confidential Information is within the scope of the licenses granted to Takeda in Section 5.1, including to existing or potential distributors, Sublicensees, collaboration partners or acquirers; provided, however, that such distributors, Sublicensees, collaboration partners or acquirers shall be bound by similar obligations of confidentiality and non-use at least equivalent in scope to, and no less restrictive than, those set forth in this Article 10 (with a duration of confidentiality and non-use obligations as appropriate that is no less than [\*\*\*] from the date of disclosure).

anything to the contrary in Section 10.1, ACI shall have the right to disclose Confidential Information of Takeda to any permitted subcontractor appointed in accordance with Section 3.4 to the extent that such disclosure is necessary in connection with ACI's performance of its Development and Manufacturing obligations under this Agreement; *provided* that, prior to disclosure, such subcontractors must be bound by similar obligations of confidentiality and non-use at least equivalent in scope to, and no less restrictive than, those set forth in this Article 10 (with a duration of confidentiality and non-use obligations as appropriate that is no less than [\*\*\*] from the date of disclosure); *provided, further*, in the event the Option Effective Date does not occur or this Agreement is terminated after the Option Effective Date, [\*\*\*] shall be bound by similar obligations of confidentiality and non-use at least equivalent in scope to, and no less restrictive than, those set forth in this Article 10 (with a duration of confidentiality and non-use obligations as appropriate that is no less than [\*\*\*] from the date of disclosure).

<b>10.6.</b> Use of Name. Except as expressly provided herein, neither Part
shall mention or otherwise use the name, logo or Trademark of the other Party or an
of its Affiliates or any of its or their respective (sub)licensees/Sublicensees (or any
abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of

publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 10.6 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted).

10.7. Public Announcements. The Parties have agreed upon the content of one (1) or more press releases which shall be issued substantially in the form(s) attached hereto as Schedule 10.7, the release of which the Parties shall coordinate in order to accomplish such release promptly following the Effective Date. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted). In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [\*\*\*] prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon; provided that if such required disclosure includes a disclosure of this Agreement, the disclosing Party shall also submit a redacted form of this Agreement to the other Party and shall submit a confidential treatment request (or equivalent protection in a country other than the U.S.) in connection with such disclosure. The disclosing Party shall incorporate any reasonable comments received from the other Party with respect to such disclosure. Notwithstanding the foregoing, from and after the Option Effective Date, Takeda and its Affiliates and its and their Sublicensees shall have the right to publicly disclose research, development and commercial information (including with respect to regulatory matters) regarding the Licensed Compounds and Licensed Products; provided that such disclosure is subject to the other provisions of this Article 10 with respect to ACI's Confidential Information. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment hereto that has already been publicly disclosed by such Party or by the other Party, in accordance with this Section 10.7; provided that such information remains accurate as of such time and provided the frequency and form of such disclosure are reasonable.

10.8. Publications. The Parties recognize the desirability of publishing and publicly disclosing the results of, and information regarding, activities under this Agreement. Accordingly, (a) prior to the Option Effective Date, ACI and (b) from and after the Option Effective Date, Takeda, in each case ((a) and (b)), shall be free to publicly disclose the results of, and information regarding, activities under this Agreement, including research, development and commercial information (including with respect to regulatory matters) subject to prior review by the other Party of any disclosure of such Party's Confidential Information for issues of patentability and protection of such Confidential Information, in a manner consistent with Applicable Law and industry practices, as provided in this Section 10.8; provided that if Takeda

reasonably believes that a publication of ACI could cause competitive harm or have a detrimental effect on the value of the Licensed Compounds or Licensed Products or on the overall Patent portfolio for the Licensed Compounds or Licensed Products, Takeda shall notify ACI of such belief in writing, and such publication shall be subject to Takeda's prior written consent.

Accordingly, prior to publishing or disclosing the other Party's Confidential Information (or, in the case of ACI, publishing or disclosing information regarding the Licensed Compounds or Licensed Products), the publishing Party shall provide the other Party with drafts of such proposed publications and disclosures at least [\*\*\*] prior to submission for publication or presentation (except with respect to drafts of proposed abstracts, posters or summaries of presentations, which shall be provided at least [\*\*\*] prior to submission for publication or presentation). The publishing Party shall respond promptly through its designated representative and in any event no later than [\*\*\*] after the receipt of such proposed publication or presentation or such shorter period as may be required by the publication or presentation. If the other Party requests a delay in publication or presentation, the publishing Party shall delay such submission or presentation for a period (not to exceed [\*\*\*]) to permit filings for Patent protection and to otherwise address issues of Confidential Information or related competitive harm. For clarity, from and after the Option Effective Date, ACI shall not, and shall cause each of its Affiliates and its and their respective licensors and (sub)licensees not to, make any publications or public disclosures regarding the Licensed Compounds or Licensed Products or any Confidential Information of Takeda without Takeda's prior written consent.

10.9. Return of Confidential Information. If this Agreement is terminated for any reason, upon the written request of a Party, the non-requesting Party shall either, at the requesting Party's election: (a) promptly destroy all copies of the requesting Party's Confidential Information in the possession or control of the nonrequesting Party (other than Joint Know-How and the terms of this Agreement) and confirm such destruction in writing to the requesting Party or (b) promptly deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of the requesting Party's Confidential Information in the possession or control of the non-requesting Party (other than Joint Know-How and the terms of this Agreement); provided that in the event of a termination of this Agreement with respect to one (1) or more (but not all) Licensed Products or countries in the Territory, the foregoing obligation to return or destroy shall only apply to Confidential Information solely related to such terminated Licensed Products or countries, as applicable. Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain (x) such Confidential Information to the extent necessary or reasonably useful for purposes of performing any continuing obligations or exercising any ongoing rights under this Agreement (including with respect to any non-terminated Licensed Products and countries) and, in any event, a single copy of such Confidential Information for archival purposes and (y) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 10.1. Upon written request of the requesting Party, the non-requesting Party shall certify that all actions required to be taken pursuant to this Section 10.9 have been completed. For clarity, the foregoing provisions of this Section 10.9 shall apply if (i) Takeda does not provide an Exercise Notice prior to the expiration of the Option Period, upon expiration of the Option Period, and (ii) this Agreement is terminated prior to the Option Effective Date, then upon the effective date of such termination.

**10.10. Protection of Personal Data.** The Parties acknowledge and agree that each Party alone determines the purposes and means of the processing of Personal Data to be carried out by it, and thus that each Party is an independent Data Controller (as defined under the GDPR)

in respect of its own processing of Personal Data and not a processor which processes Personal Data on behalf of the other Party. Consequently, each Party is itself responsible to comply with the obligations as a controller under applicable Data Protection Law, including compliance with any requirements related to the transfer of Personal Data outside of the country of origin to a Party's Affiliates or subcontractors located in a third country. Each Party acknowledges that in respect of any data supplied to it by the other Party, it shall comply in all material respects with the applicable requirement of the protection of Personal Data including pseudonymized raw data and the Standard Contractual Clauses set forth on **Schedule 10.10** to the extent applicable to each Party's performance of its obligations under this Agreement. Without limiting the foregoing, each Party that conducts a clinical trial with respect to the Licensed Compounds and Licensed Products shall provide a data privacy notice to all persons participating in such clinical trial and, when required by applicable Data Protection Law, obtain appropriate consent from such persons, in each case, in accordance with applicable Data Protection Law and that allow for the use of Personal Data as set forth in this Agreement. If any Party becomes aware that it has provided Personal Data to the other Party that may not be shared pursuant to such a consent or notice, or such person participating in a clinical trial has withdrawn his or her consent, requested deletion of or opted-out of certain processing of Personal Data, such Party shall promptly notify the other Party so that the affected Personal Data can be removed or anonymized as, and when, required under applicable Data Protection Law. In the event of a Personal Data breach affecting the Personal Data that is the subject of this Agreement, the Party suffering said Personal Data breach shall notify the other Party without undue delay. The Parties shall reasonably assist one another in responding to a Personal Data breach and in meeting their notification obligations to data subjects or data protection regulators, as may be required by applicable Data Protection Law.

#### ARTICLE 11 REPRESENTATIONS AND WARRANTIES

- **11.1. Mutual Representations and Warranties.** ACI and Takeda each represents and warrants to the other as of the Effective Date that:
- 11.1.1. it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;
- 11.1.2. the execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (a) such Party's charter documents, bylaws or other organizational documents; (b) in any material respect, any agreement, instrument or contractual obligation to which such Party is bound; (c) any requirement of any Applicable Law; or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party;
- 11.1.3. this Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the

enforcement of creditor rights, judicial principles affecting the availability of speci-	fic
performance and general principles of equity (whether enforceability is considered	1 a
proceeding at law or equity); and	

11.1.4. it is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

11.2. Additional Representations and Warranties of ACI. ACI further represents and warrants to Takeda that (a) (i) except as set forth in Schedule 11.2 attached hereto (the "Initial Disclosure Schedule") and (ii) excluding Section 11.2.18, in each case ((i) and (ii)), as of the Effective Date, (b) subject to Section 11.3, except as set forth in the Data Package Updated Disclosure Schedule as of the Data Package Bring Down Date and (c) subject to Section 11.3 and except, solely with respect to the last two sentences of Section 11.2.2, Section 11.2.3, the last sentence of Section 11.2.6 and the last sentence of Section 11.2.10, as set forth in the Bring Down Updated Disclosure Schedule, as of the Option Effective Date, as follows:

11.2.1. All Licensed Patents existing as of the Effective Date, the Data Package Bring Down Date and the Option Effective Date, as applicable, are listed on Schedule 1.138 and Schedule 1.157 (the "Existing Patents"), and ACI is the sole and exclusive owner of the entire right, title and interest in the Existing Patents, free of any encumbrance, lien or claim of ownership by any Third Party. All such Existing Patents (a) are subsisting and are not invalid or unenforceable, in whole or in part, (b) are being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law and (c) have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment. With respect to pending applications in the Existing Patents, ACI and its Affiliates have presented all relevant references, documents and information of which it and the inventors are aware to the relevant patent examiner at the relevant patent office. ACI is entitled to grant the licenses specified herein.

11.2.2. All Existing Agreements are listed on Schedule 11.2.2. The rights and obligations of the Parties hereunder are fully consistent with, and are not limited in any material respect by, the Existing Agreements. None of ACI or its Affiliates (a) is in breach of any Existing Agreement or (b) has received any written notice of breach or termination under any Existing Agreement from the counterparty thereto. To the Knowledge of ACI, (i) no facts or circumstances exist that would reasonably be expected to give rise to any such breach or termination and (ii) no counterparty is in breach of any Existing Agreement.

11.2.3. There are no claims, judgments or settlements against, or amounts with respect thereto owed by, ACI or any of its Affiliates relating to the Existing Regulatory Documentation, the Existing Patents or the Licensed Know-How. No claim or litigation has been brought or, to ACI's Knowledge, threatened by any Person alleging, and ACI has no Knowledge of any claim, whether or not asserted, that (a) the Existing Patents or the Licensed Know-How are invalid or unenforceable or (b) the Existing Regulatory Documentation, the Existing Patents or the Licensed Know-How, or the disclosing, copying, making, assigning or licensing of the Existing Regulatory Documentation, the Existing Patents or the Licensed Know-How or the Development, Manufacture or Commercialization of the Licensed Compounds or Licensed Products (as such Licensed Compounds or Licensed Products exist as of the Effective Date, the Data Package Bring Down Date and the Option Effective Date) as

would reasonably be expected to give rise to any such claims. To ACI's Knowledge, no Person (i) has infringed or is infringing or threatening to infringe any Existing Patent or (ii) has misappropriated or is misappropriating or threatening to misappropriate the Licensed Know-How.

- 11.2.4. ACI Controls all Information and Patents in its or its Affiliates' ownership or control that are necessary or reasonably useful to Develop, Manufacture or Commercialize the Licensed Compounds and the Licensed Products as contemplated herein and such Information and Patents are not subject to any other license or agreement to which ACI or any of its Affiliates is a party other than the Existing Agreements. ACI Controls all Active Immunotherapies that are Directed To Abeta in its or its Affiliates ownership or control.
- 11.2.5. The Existing Patents represent all Patents within ACI's or its Affiliates' ownership or control relating to the Licensed Compounds or the Licensed Products or the Exploitation thereof. To ACI's Knowledge, there is no Information owned or controlled by ACI or any of its Affiliates as of the Effective Date, the Data Package Bring Down Date and the Option Effective Date, as applicable, that relates to the Licensed Compounds or the Licensed Products existing as of the Effective Date, the Data Package Bring Down Date and the Option Effective Date that is not within the Licensed Know-How that exists as of the Effective Date, the Data Package Bring Down Date and the Option Effective Date.
- any Existing Patents or any Licensed Know-How has assigned and has executed an agreement assigning its entire right, title and interest in and to such Existing Patents and Licensed Know-How to ACI. To ACI's Knowledge, no current officer, employee, agent or consultant of ACI or any of its Affiliates or its or their (sub)licensees is in violation of any term of any assignment or other agreement, including any employment contract, regarding the protection of Patents or other intellectual property or proprietary information of ACI or such Affiliate.
- 11.2.7. ACI has obtained the right (including under any Patents and other intellectual property rights) to use all Information and all other materials (including any formulations and manufacturing processes and procedures) developed or delivered by any Third Party under any agreements between ACI and any such Third Party with respect to the Licensed Compounds and Licensed Products existing as of the Effective Date, the Data Package Bring Down Date and the Option Effective Date, and ACI has the rights under each such agreement to transfer such Information or other materials to Takeda and its designees and to grant Takeda the right to use such Information or other materials in the Development, Manufacture or Commercialization of the Licensed Compounds or Licensed Products without restriction.
- 11.2.8. The inventions Covered by the Existing Patents (a) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof, (b) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e), (c) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C.

§§200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. Part 401 and (d) except as set forth on **Schedule 11.2.8**, are not the subject of any licenses, options or other rights of any other Governmental Authority, within or outside the United States, due to such Governmental Authority's funding of research and

development or otherwise (other than the right to receive payments or any law of general application that applies to personal property generally, e.g., takings laws).

11.2.9. The Licensed Know-How has been kept confidential or has been disclosed to Third Parties only under terms of confidentiality. To the Knowledge of ACI, no breach of such confidentiality has been committed by any Third Party.

Regulatory Documentation and all Existing Agreements; and (b) all material Licensed Know-How and other Information in its possession or Control regarding or related to the Licensed Compounds or Licensed Products, including all material adverse information with respect to the safety and efficacy of the Licensed Compounds known to ACI or its Affiliates (except, solely as of the Effective Date, for the Proprietary CMC Information), and in each case ((a) through (b)), to ACI's Knowledge, all such materials, Existing Regulatory Documentation, Existing Agreements, Licensed Know-How and other Information are true, complete and correct. Except as disclosed to Takeda in writing prior to the Effective Date, the Data Package Bring Down Date and the Option Effective Date, as applicable, ACI and its Affiliates have no Knowledge of any facts or circumstances that would be reasonably likely to adversely affect the scientific, therapeutic or commercial potential of the Licensed Compounds or Licensed Products (including the acceptance, or the subsequent approval, by any Regulatory Authority of any filing, application or request for any IND or Regulatory Approval).

11.2.11. Neither ACI nor any of its Affiliates or its or their (sub)licensees have applied for, registered or obtained any Trademarks with respect to the Licensed Products in the Territory.

11.2.12. Neither ACI nor any of its Affiliates or its or their (sub)licensees, nor any of its or their respective officers, employees or agents has made an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Development of the Licensed Compounds or Licensed Products, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority with respect to the Development of the Licensed Compounds or Licensed Products or committed an act, made a statement or failed to make a statement with respect to the Development of the Licensed Compounds or Licensed Products that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory.

11.2.13. ACI and its Affiliates and its and their (sub)licensees have conducted, and their respective contractors and consultants have conducted, all Development and Manufacture of the Licensed Compounds and Licensed Products (including the generation, preparation, maintenance and retention of all Regulatory Documentation) that they have conducted prior to the Effective Date, the Data Package Bring Down Date and Option Effective Date, as applicable, in accordance with Applicable Law (including Good Laboratory Practices, Good Manufacturing Practices and Good Clinical Practices).

- 11.2.14. Except as set forth on Schedule 11.2.14, there are no amounts that will be required to be paid to a Third Party as a result of the Development, Manufacture or Commercialization of the Licensed Compounds or Licensed Products that arise out of any agreement (other than the Existing Agreements) to which ACI or any of its Affiliates is a party or, to ACI's Knowledge, at all.
- 11.2.15. ACI and its Affiliates and its and their (sub)licensees have complied in all material respects with all Applicable Laws relating to the privacy, processing and security of Personal Data in all countries in connection with the Licensed Compounds and Licensed Products (including any transfer of Personal Data across national borders), all privacy related consents and notices that apply to the Licensed Compounds and Licensed Products and the requirements of any contract to which it is a party, in each case that were in effect at the time such Personal Data was collected, disclosed or otherwise processed and applicable to such collection, disclosure or processing at the time conducted. ACI, its Affiliates and its and their (sub)licensees has provided a data privacy notice to all persons participating in clinical trials with respect to the Licensed Compounds and Licensed Products and, when required by applicable Data Protection Law, obtained appropriate consent from such persons. Such notices and consents were made in accordance applicable Data Protection Law and allow for the disclosure and use of Personal Data by Takeda, its Affiliates and its and their Sublicensees as set forth in this Agreement.
- 11.2.16. Neither ACI nor any of its Affiliates nor its or their (sub)licensees has been debarred or is subject to debarment and neither it nor any of its Affiliates will use in any capacity, in connection with the Licensed Compounds or Licensed Products, any Person who has been debarred pursuant to Section 306 of the FFDCA or who is the subject of a conviction described in such section.
- (sub)licensees' officers, directors and employees, and to ACI's Knowledge, any other Person acting on its or their behalf, has directly or indirectly given, offered or promised to give money or anything of value to any Government Official in an effort to influence any Government Official or any other Person in a corrupt or improper effort to obtain or retain business or any commercial advantage, such as a permit or license to do business, and (b) all Persons acting on its or their behalf have materially complied with the U.S. Foreign Corrupt Practices Act, laws implementing the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions and applicable local laws prohibiting bribery, kickbacks or other unlawful or improper means of obtaining business or commercial advantages, in each case ((a) and (b)), with respect to the Licensed Compounds or Licensed Products.
- and the Option Effective Date, (a) the Data Package is complete in all material respects, (b) the Data Package has been prepared by employees of ACI who are qualified with appropriate skills, experience and expertise to accurately prepare such Information, and (c) if ACI has entered into any agreement with a Third Party in order to obtain a license or right under a Third Party Right pursuant to Section 9.7, (i) such agreement is in full force and effect and, by its terms, is sublicensable to Takeda as contemplated by this Agreement, (ii) the rights and obligations of the Parties hereunder are fully consistent

with, and are not limited in any material respect by, such agreement and (iii) ACI has made available to Takeda a copy of any such agreement.					
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11.3. Updated Disclosure Schedules. ACI shall provide to Takeda updated disclosure schedules (or statements that no such updates are required) in respect of the representations and warranties made in Section 11.2, as follows:

11.3.1. concurrently with ACI's delivery to Takeda of the Data Package in accordance with Section 4.1.2, ACI shall provide to Takeda either (a) an updated Schedule 11.2.1, an updated Schedule 11.2.2 and a list of any exceptions to Schedule 11.2 (any such list of exceptions provided under this Section 11.3.1, the "Data Package Updated Disclosure Schedule"); or (b) a written statement that no such updates are required and all such schedules and representations and warranties remain true and correct as of such date (the date that such updated schedules or such statement is provided, the "Data Package Bring Down Date"); and

11.3.2. if Takeda provides an Exercise Notice within the Option Period, within [\*\*\*] shall provide to Takeda either (x) an updated **Schedule 11.2.1**, an updated **Schedule 11.2.2** and, solely with respect to the last two sentences of Section 11.2.2, Section 11.2.3, the last sentence of Section 11.2.6 and the last sentence of Section 11.2.10, a list of any exceptions to **Schedule 11.2** (any such list of exceptions provided under this Section 11.3.2, a "**Bring Down Updated Disclosure Schedule**"); or (y) a written statement that no such updates are required and all such schedules and representations and warranties remain true and correct as of such [\*\*\*]

provided that, in each case, any update in a Data Package Updated Disclosure Schedule or a Bring Down Updated Disclosure Schedule (as applicable) shall not be deemed to amend or supplement the Initial Disclosure Schedule as it exists as of the Effective Date or Data Package Updated Disclosure Schedule as it exists as of the Data Package Bring Down Date or prior to such amendment for any purposes hereunder, including for the purposes of the indemnification provisions under Section 12.2 (and therefore shall not cure any prior failure to disclose). For all representations and warranties for which ACI does not provide an updated schedule pursuant to clause (a) of Section 11.3.1 or clause (x) of Section 11.3.2 (as applicable), or if ACI fails to provide any updated schedules or such statement in clause (b) of Section 11.3.1 or clause (y) Section 11.3.2 (as applicable) within the time periods set forth in each such Section, ACI shall be deemed to have made the representations and warranties in Section 11.2 to Takeda as of the Data Package Bring Down Date and the Option Effective Date (as applicable) without additional qualification. For the avoidance of doubt, an exception made by ACI in a Data Package Updated Disclosure Schedule or a Bring Down Updated Disclosure Schedule (as applicable) shall not cure a deficiency in the Initial Disclosure Schedule or Data Package Updated Disclosure Schedule (as applicable). ACI acknowledges and agrees that any disclosure made in a Data Package Updated Disclosure Schedule or a Bring Down Updated Disclosure Schedule (as applicable) cannot cure a breach of any covenant or obligation of ACI hereunder, including Section 11.5, and no disclosure made in a Data Package Updated Disclosure Schedule or a Bring Down Updated Disclosure Schedule (as applicable) that relates to or reflects any such breach by ACI shall be deemed to qualify any representation or warranty hereunder.

11.4. Anti-Bribery and Anti-Corruption Compliance. The Parties and its Affiliates have and undertake that they shall continue to update and maintain during the Term an internal compliance program under which each Party's (or its

Affiliates')	employees	are	required	to	comply	with	all	Applicable	Law,	including
applicable lo	ocal and into	ernat	ional anti	-br	ibery and	l anti-	corı	ruption laws	and re	gulations.
Without lin	niting the fo	rego	ing, each	Pa	rty shall,	and s	hall			

cause its Affiliates and its and their (sub)licensees/Sublicensees to, (a) not, directly or indirectly, give, offer or promise to give money or anything of value to any Government Official in an effort to influence any Government Official or any other Person in a corrupt or improper effort to obtain or retain business or any commercial advantage, such as a permit or license to do business and (b) materially comply with all Applicable Laws in connection with conducting its business operations, including the U.S. Foreign Corrupt Practices Act, laws implementing the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions and local laws prohibiting bribery, kickbacks, or other unlawful or improper means of obtaining business or commercial advantages, in each case ((a) and (b)), with respect to the Licensed Compounds and Licensed Products.

#### 11.5. Covenants.

11.5.1. During the Term, neither ACI nor any of its Affiliates shall encumber or diminish the rights granted (or to be granted as of the Option Effective Date) to Takeda hereunder with respect to the Licensed Patents.

11.5.2. During the Option Period, neither Party shall, and shall cause its Affiliates not to (a) misappropriate any know-how of a Third Party or infringe any published or issued Patent (or, with respect to any Patent application, take any action that would constitute infringement if such application were to issue as a published Patent) or, to the extent known, or reasonably knowable, by such Party or any of its Affiliates, any other intellectual property rights of a Third Party, in each case, in connection with the Development or Manufacture of the Licensed Compounds and Licensed Products and (b) use any funds from the federal government of the United States or any agency thereof to fund, directly or indirectly, any Development or Manufacturing activities hereunder, in whole or in part.

11.5.3. During the Term, each Party shall inform the other Party in writing promptly if it or any Person who is performing or has performed services with respect to the Licensed Compounds or Licensed Products is debarred or is the subject of a conviction described in Section 306 of the FFDCA or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to such Party's Knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing (or who has performed) services with respect to the Licensed Compounds or Licensed Products.

ACI shall, and shall cause its Affiliates to (a) refrain from taking any action or omitting to take any action that would have the effect of restricting or impairing the rights to be granted to Takeda hereunder or preventing either Party's ability to perform its obligations under this Agreement, including (i) licensing, transferring or otherwise disposing of any Licensed Know-How or Licensed Patent or (ii) entering into, modifying, extending, renewing or amending any contract related to the Licensed Compounds or Licensed Products or the intellectual property rights granted hereunder in a manner that would materially limit or impair Takeda's rights under this Agreement, (b) not commit any act or permit the occurrence of any omission that would cause any of the representations and warranties of ACI in Section 11.2 (as may be updated in

accordance with and pursuant to Section 11.3) to be untrue as of the Option Effective
Date and (c) promptly notify Takeda if it becomes aware that any of the representations
or warranties in Section 11.2 are untrue.

11.6. DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY REPRESENTATION AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY REPRESENTATION OR WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY REPRESENTATION OR WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

# ARTICLE 12 INDEMNITY

Indemnification of ACI. Takeda shall indemnify ACI, its Affiliates and its and their respective directors, officers, employees and agents ("ACI Indemnitees") and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "Third Party Claims") arising from or occurring as a result [\*\*\*], in each case ((a), (b) and (c)), to the extent that such Loss (x) in the case of Section 12.1(a) and Section 12.1(b), is based upon an action or omission for which ACI would have an obligation to indemnify a Takeda Indemnitee under Section 12.2(a) or Section 12.2(b) if such Loss were incurred by a Takeda Indemnitee, (y) in the case of Section 12.1(c), is based upon an action or omission for which ACI would have an obligation to indemnify a Takeda Indemnitee under Section 12.2 if such Loss were incurred by a Takeda Indemnitee, in each case ((x) and (y)), as to which Losses each Party shall indemnify the other to the extent of their respective liability or (z) arises from or occurs as a result of the negligence on the part of any ACI Indemnitee under this Agreement.

12.2. Indemnification of Takeda. ACI shall indemnify Takeda, its Affiliates, its and their Sublicensees and distributors and its and their respective directors, officers, employees and agents ("Takeda Indemnitees") and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims arising from or occurring as a result [\*\*\*] except to the extent that such Loss, (x) in the case of Section 12.2(a) and Section 12.2(b), is based upon an action or omission for which Takeda would have an obligation to indemnify an ACI Indemnitee under Section 12.1(a) or Section 12.1(b) if such Loss were incurred by an ACI Indemnitee, and (y) in the case of Section 12.2(c), is based upon an action or omission for which Takeda would have an obligation to indemnify an ACI Indemnitee under Section 12.1 if such Loss were incurred by an ACI Indemnitee, in each case ((x) and (y)), as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses, or (z) arises from or occurs as a result of the negligence on the part of any Takeda Indemnitee under this Agreement.

#### 12.3. Indemnification Procedures.

12.3.1. Notice of Claim. All indemnification claims in respect of an ACI Indemnitee or Takeda Indemnitee, as applicable, shall be made solely by such Party to this Agreement (the "Indemnified Party"). The Indemnified Party shall give the indemnifying Party written notice as soon as reasonably practicable (an "Indemnification Claim Notice") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article 12, but in no event shall the indemnifying Party be liable for any Losses to the extent resulting from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

**12.3.2.** Control of Defense. Subject to the provisions of Section 9.4, Section 9.5 and Section 9.6, at its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [\*\*\*] after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 12.3.3, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any Losses incurred by the indemnifying Party in its defense of the Third Party Claim.

12.3.3. Right to Participate in Defense. Without limiting Section 12.3.2, any Indemnified Party shall be entitled to participate in, but not control (except as provided in Section 9.4, Section 9.5 and Section 9.6), the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided* that such employment shall be at the Indemnified Party's own expense unless (a) the employment thereof, and the assumption by the indemnifying Party of such expense, has been specifically authorized by the indemnifying Party in writing, (b) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 12.3.2 (in which case the Indemnified Party shall control the defense)

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or (c) the interests of the Indemnified Party and the indemnifying Party with respect

right to control the defense of a Third Party Claim pursuant to Section 9.4, Section 9.5 or Section 9.6, the Indemnified Party shall be entitled to control such Third Party Claim, without limiting the indemnifying Party's responsibility for Losses under Section 12.1 or Section 12.2, as applicable.

**12.3.4. Settlement.** With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the Indemnified Party's becoming subject to injunctive or other relief and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 12.3.2, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim. Without limiting the rights and obligations of the Parties under Article 9, regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or dispose of, any Third Party Claim without the prior written consent of the indemnifying Party. Except as provided in Article 9, the indemnifying Party shall not be liable for any settlement, compromise or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the indemnifying Party. For clarity, if a Third Party Claim, or the events giving rise to or resulting in such Third Party Claim, are subject to Article 9 and Section 12.1 or Section 12.2, then Article 9 shall apply with respect to the defense of such Third Party Claim and Section 12.1 or Section 12.2, as applicable, shall apply with respect to the allocation of financial responsibility for the related Losses.

Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable Out-of-Pocket Costs in connection therewith.

12.4. Special, Indirect and Other Losses. EXCEPT [\*\*\*] PARTY NOR ANY OF ITS AFFILIATES OR ITS OR THEIR SUBLICENSEES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS

AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THE USE OF THE LICENSED COMPOUNDS OR LICENSED PRODUCTS, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

**12.5. Insurance.** Each Party shall have and maintain such types and amounts of insurance covering its Exploitation of the Licensed Compounds and Licensed Products as is (a) normal and customary in the biopharmaceutical industry generally for parties similarly situated and (b) otherwise required by Applicable Law, but in each case ((a) and (b)), not less than:

**12.5.1.** Workers Compensation or Employers Liability to limits required by local law or jurisdiction;

**12.5.2.** General liability insurance in [\*\*\*]; and

**12.5.3.** Clinical studies insurance to limits required under Applicable Law.

All insurances maintained by a Party as required hereunder will be provided by a company having a financial rating of not less than A-Viii in the most current edition of Best's Key Rating Guide. Upon request by a Party, each Party shall provide to the requesting Party evidence of its insurance coverage. Each Party will provide a minimum of [\*\*\*] notice of any cancellation, with no replacement policy, to the other Party. The insurance policies shall be under an occurrence form, but if only a claims-made form is available to a Party, then such Party shall continue to maintain such insurance after the expiration or termination of this Agreement in its entirety for a period of [\*\*\*] the foregoing, Takeda may self-insure in whole or in part the insurance requirements described above.

# ARTICLE 13 TERM AND TERMINATION

13.1. Term and Expiration. This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance with Section 13.2 (including any automatic termination of this Agreement pursuant to Section 4.4 and Section 13.2.2), shall continue in force and effect until the date of expiration of the last Royalty Term for the last Licensed Product (such period, the "Term") (it being understood that, notwithstanding the foregoing, certain rights and obligations of the Parties contained herein that expressly commence upon the Option Effective Date shall commence thereon and not be effective unless and until the Option Effective Date occurs). Upon the expiration of the Term as set forth in this Section 13.1, the Exclusive License shall become fully-paid, royalty-free, perpetual and irrevocable in its entirety.

#### 13.2. Termination.

13.2.1. Termination for Material Breach. In the event that either Party (the "Breaching Party") materially breaches any of its material obligations under this Agreement, in addition to any other right and remedy the other Party (the "Non-Breaching Party") may have, the Non-Breaching Party may terminate this

Agreement by providing terminate; <i>provided</i> that:	 specifying	the	breach	and	its	claim	of	right	to
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- (a) to the extent that such material breach involves a failure to make a payment when due, the Notice Period shall be [\*\*\*] after the Termination Notice is given to the Breaching Party;
- (b) the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach specified in the Termination Notice during the Notice Period (or, other than any material breach involving a failure to make a payment when due, if such breach cannot be cured within the Notice Period, if the Breaching Party commences actions to cure such breach within the Notice Period and diligently continues such actions, such termination shall not become effective for so long as the Breaching Party diligently continues such actions);
- (c) with respect to any alleged breach by Takeda of its diligence obligations set forth in Section 7.4, ACI shall first provide written notice to Takeda and the Parties shall meet within [\*\*\*] after delivery of such notice to Takeda to discuss in good faith such alleged breach and Takeda's Development and Commercialization plans with respect to the applicable Licensed Product(s), which discussions shall be concluded before ACI may issue any Termination Notice with respect to such alleged breach (for clarity, the Notice Period shall not commence prior to the conclusion of such good faith discussions and the subsequent issuance of a Termination Notice by ACI); and
- (d) if either Party initiates a dispute resolution procedure under Section 14.5.1 as permitted under this Agreement during the Notice Period to resolve the dispute for which termination is being sought and is pursuing such procedure in good faith, the Notice Period set forth in this Section 13.2.1 shall be suspended and the termination shall become effective only if such breach remains uncured for [\*\*\*] after the final resolution of the dispute through such dispute resolution procedure (or, if the breach cannot be cured within such [\*\*\*] period, if the Breaching Party commences actions to cure such breach within such period and thereafter diligently continues such actions, such termination shall not become effective for so long as the Breaching Party diligently continues such actions).

It is understood that termination pursuant to this Section 13.2.1 shall be a remedy of last resort and may be invoked only in the case where the breach cannot be reasonably remedied by the payment of money damages.

## **13.2.2.** Termination by [\*\*\*]

Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [\*\*\*] after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within [\*\*\*] of the filing or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may

terminate this Agreement in its essuch Party.	ntirety effective in	nmediately upon written notice to
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## 13.2.4. Termination for Failure or Delay to Obtain Antitrust

Clearance. If an Antitrust Filing is made pursuant to Section 4.2.2, this Agreement shall terminate upon written notice given by Takeda to ACI if (a) Takeda receives a second request with respect to an Antitrust Filing with respect to the activities and licenses contemplated under this Agreement and Takeda delivers written notice of termination within [\*\*\*] after receipt of such second request; or (b) Antitrust Clearance has not been obtained within [\*\*\*] after the date on which the last Antitrust Filing is made and Takeda delivers written notice of termination within [\*\*\*] the end of such [\*\*\*] period.

13.3. Rights in Bankruptcy. The Parties intend to take advantage of the protections of Section 365(n) (or any successor provision) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction to the maximum extent permitted by Applicable Law. All rights and licenses granted under or pursuant to this Agreement, but only to the extent they constitute licenses of a right to "intellectual property" as defined in Section 101 of the U.S. Bankruptcy Code, shall be deemed to be "intellectual property" for the purposes of Section 365(n) or any analogous provisions in any other country or jurisdiction. Each Party shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, including the right to obtain the intellectual property from another entity.

13.3.1. Each Party will, during the Term, create and maintain current and updated copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all intellectual property licensed to the other Party under this Agreement. Each Party acknowledges and agrees that "embodiments" of intellectual property within the meaning of Section 365(n) include (a) copies of research data; (b) laboratory samples; (c) product samples and inventory; (d) formulas; (e) laboratory notes and notebooks; (f) data and results related to clinical trials; (g) Regulatory Documentation (including Regulatory Approvals); (h) rights of reference in respect of Regulatory Documentation (including Regulatory Approvals); (i) pre-clinical research data and results; (j) tangible Information (including Licensed Know-How and Joint Know-How); and (k) marketing, advertising and promotional materials that relate to such intellectual property. Upon the occurrence of an Insolvency Event by or against either Party, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) all such intellectual property (including all embodiments of such intellectual property), which, if not already in such Party's possession, shall be promptly delivered to it upon such Party's written request (x) upon commencement of a bankruptcy proceeding, unless the Party experiencing the Insolvency Event continues to perform all of its obligations under this Agreement, or (y) if not delivered pursuant to clause (x) above because the Party experiencing the Insolvency Event continues to perform, upon the rejection of this Agreement by or on behalf of such Party. Unless and until the Party experiencing the Insolvency Event rejects this Agreement, such Party shall perform all of its obligations under this Agreement or provide the intellectual property (including all embodiments of such intellectual property) to the other Party, and shall not interfere with the rights of the other Party to intellectual property as set forth in this Section 13.3, including the right to obtain the intellectual property from another entity.

13.3.2. The Parties intend and agree that any sale of either Party's assets under Section 363 of the Bankruptcy Code shall be subject to the other Party's rights under Section 365(n), that the other Party cannot be compelled to accept a money satisfaction of its interests in

the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser "free and clear" of the other Party's rights under this Agreement and Section 365(n) without the express, contemporaneous written consent of the other Party.

13.3.3. All rights, powers and remedies each Party provided in this Section 13.3 are not in substitution for any other rights, powers and remedies now or hereafter existing at law or in equity (including the U.S. Bankruptcy Code). The Parties intend the following rights to extend to the maximum extent permitted by Applicable Law, and to be enforceable under U.S. Bankruptcy Code Section 365(n):

- (a) the right of access to any intellectual property rights (including all embodiments thereof) of the Party experiencing the Insolvency Event, or any Third Party with whom such Party contracts to perform an obligation of such Party under this Agreement, and, in the case of any such Third Party, that is necessary or reasonably useful for the Exploitation of any Licensed Compounds or Licensed Products or the exercise of any other rights granted to the other Party under this Agreement;
- (b) the right to contract directly with any Third Party to complete the contracted work; and
- (c) the right to cure any default under any such agreement with a Third Party and set off the costs thereof against amounts payable to the other Party under this Agreement.
- 13.4. Consequences of Termination Prior to Option Effective Date. In the event of any termination of this Agreement prior to the Option Effective Date by a Party pursuant to Section 13.2, all rights and licenses granted by one Party to the other Party shall immediately terminate (it being understood that all rights and licenses granted to Takeda hereunder shall immediately revert to ACI); *provided* that Section 9.1.3 shall survive.

## 13.5. Consequences of Termination After Option Effective Date.

- 13.5.1. Termination in its Entirety. In the event of a termination of this Agreement in its entirety by a Party after the Option Effective Date pursuant to Section 13.2 (but, for clarity, not if this Agreement expires pursuant to Section 13.1 or if this Agreement is terminated prior to the Option Effective Date), subject to Section 13.5.2, the following shall apply:
- (a) The Parties shall use good faith efforts to negotiate and enter into a termination transition plan to wind-down, cease and, except in connection with a termination by Takeda pursuant to Section 13.2.2(a), transition to ACI any ongoing clinical Development and Commercialization activities with respect to any terminated Licensed Product(s) in any terminated country(ies) in accordance with appropriate professional and ethical standards and Applicable Law. Each Party shall bear its own costs and expenses in connection with the foregoing transition and

wind-down and otherwise incurred in the performance of activities under this Section 13.5; *provided* that [\*\*\*].

(b) Takeda's licenses under Section 5.1 shall immediately terminate with respect to any terminated Licensed Product(s) in any terminated country(ies);

provided that, notwithstanding such termination, Takeda may perform activities in accordance with this Section 13.5 and Takeda shall have, to the extent permissible pursuant to Applicable Law, the right [\*\*\*] the effective date of such termination with respect to each Licensed Product and each country with respect to which such termination applies to sell or otherwise dispose of all Licensed Product then in its inventory and any in-progress inventory, as though this Agreement had not terminated with respect to such Licensed Product or such country, as applicable, and such sale or disposition shall not constitute infringement of ACI's or its Affiliates' Patent or other intellectual property or proprietary rights; provided, further, that (i) any and all such sales shall be included in the Net Sales for purposes of this Agreement, (ii) Takeda shall continue to make payments on such Licensed Product [\*\*\*] (as if this Agreement had not terminated with respect to such Licensed Product(s) in any terminated country(ies) remaining following the foregoing sell-off period shall be [\*\*\*]

(c) except as expressly set forth in this Section 13.5, as between the Parties, ACI shall be solely responsible for all ongoing and future Development, Manufacture, Commercialization and other Exploitation of terminated Licensed Compounds and Licensed Products in the Field with respect to each country with respect to which such termination applies, at its sole cost and expense, including regulatory reporting and long-term monitoring (for safety and efficacy) of patients who were or are administered a Licensed Product before, on or after the effective date of termination;

(d) to the extent permitted by Applicable Law, Takeda shall [\*\*\*] with respect to each Licensed Product and each country with respect to which such termination applies; *provided* that Takeda may [\*\*\*]

(e) except in the event of termination by Takeda pursuant to Section 13.2.2(a), [\*\*\*]

(f) [\*\*\*]

(g) if ACI desires (i) a license [\*\*\*] conceived, discovered, developed or otherwise made by or on behalf of Takeda or its Affiliates or its Sublicensees under this Agreement (and that is Controlled by Takeda or its Affiliates or its or their Sublicensees) that relates to any Licensed Product(s) that are the subject of such termination, (ii) a license or reversion to terminated Licensed Product(s) that are not Reversion Products or (iii) a license or reversion from Takeda in the event of termination by Takeda pursuant to Section 13.2.2(a), in each case ((i), (ii) and (iii)), then ACI may notify Takeda within [\*\*\*] of the applicable notice of termination and the Parties shall use good faith efforts to negotiate for a period up to [\*\*\*] (or such longer period as mutually agreed by the Parties) such license or reversion, as applicable, from Takeda to ACI (but, for clarity, Takeda shall not be required to agree to any such license or reversion);

(h) to the extent that Takeda owns any Product Trademarks that pertain specifically to any terminated Licensed Product in a terminated country that is necessary for the Commercialization of such Licensed Product in such

country (as then currently marketed, but not including any Trademarks that include, in whole or part, any corporate name or logo of Takeda), [***] and
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(i) if Takeda and ACI cannot agree on [\*\*\*] in each case, within [\*\*\*] following the effective date of termination, Takeda and ACI will, as soon as reasonably practicable and in no event later than [\*\*\*] following the expiration of such [\*\*\*] period, mutually decide upon an Independent Expert to engage in determining the [\*\*\*] Each of Takeda and ACI shall submit to the Independent Expert and the other Party (i) its final proposal with respect to [\*\*\*] within [\*\*\*] after the retention of the Independent Expert and (ii) such other information as the Independent Expert may request within [\*\*\*] of such request. The Independent Expert shall determine [\*\*\*], as applicable, by selecting one or the other of the two final proposals submitted by Takeda and ACI, and, with respect [\*\*\*] Such determination by the Independent Expert shall be final and binding on the Parties.

## 13.5.2. Termination of this Agreement with respect to one (1)

or more Licensed Products or Countries. If this Agreement is terminated pursuant to Section 13.2.2 with respect to one (1) or more Licensed Products but not all Licensed Products or with respect to one (1) or more countries but not the entire Territory, (a) Section 13.5 shall apply solely with respect to the terminated Licensed Products in the terminated countries and (b) except for the surviving Sections and Articles set forth in Section 13.8.1, the provisions of this Agreement shall not apply to any such terminated Licensed Products or terminated country(ies); provided that, in the event of a termination with respect to one (1) or more countries but not the entire Territory, the termination of Takeda's licenses pursuant to Section 13.5.1(b) shall not apply, and instead the rights and licenses granted to Takeda under this Agreement shall automatically be deemed to be amended with respect to the terminated country(ies) to be non-exclusive and only to include the right to Develop and Manufacture Licensed Compounds and Licensed Products in the terminated country(ies) solely for the purposes of supporting Regulatory Approval or Commercialization of the Licensed Products in the surviving countries in the Territory.

- 13.7. Remedies. Except as otherwise expressly provided herein, termination of this Agreement (either in its entirety or with respect to one (1) or more Licensed Products or country(ies)) shall not limit remedies that may otherwise be available in law or equity.
- 13.8. Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement (either in its entirety or with respect to one (1) or more Licensed Products or country(ies)) for any reason shall be without prejudice to any rights that have accrued to the benefit of a Party prior to such termination or expiration; provided that in no event shall ACI accrue any rights to, and Takeda shall have no

obligation to make, any milestone payment under Section 8.3 or Section 8.4 based on any milestone event with respect to a Licensed Product that occurs on or after the date of delivery by either Party of any termination notice with respect to such Licensed Product pursuant to Section 13.2. Such termination or expiration shall not relieve a Party from

obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing:

13.8.1. Sections 3.6.1 (for the period provided therein), 3.6.2 (for the period provided therein), 5.2 (third sentence), 5.3.1 (first sentence), 5.5.3, 8.3 through 8.12 (for final accounting for any payment obligations accrued prior to the date of termination of this Agreement, subject to the proviso in Section 13.8), 8.13 (for final accounting for any payment obligations accrued prior to the date of termination of this Agreement, except that Section 8.13.3 shall survive generally for the period set forth in Section 10.1), 9.1, 10.1 (for the period provided therein), 10.2, 10.3 (except for Section 10.3.4), 10.5, 10.6, 10.7 (except for the penultimate sentence), 10.9, 10.10, 11.6, 12.1 through 12.4, 12.5 (for the period provided therein), 13.3, 13.4 (as applicable), 13.5 (as applicable), 13.7 and this Section 13.8.1 and Article 1 (to the extent required to give effect to the provisions set forth in this Section 13.8.1) and Article 14 of this Agreement shall survive the termination of this Agreement for any reason; and

13.8.2. Sections 3.6 (for the period provided therein), 4.5.4 (second sentence), 5.1.1, 5.2 (solely the first two sentences and *provided* that such sentences are limited to the applicable terms and conditions of this Agreement that survive expiration), 5.3.1, 5.4, 5.5.3, 7.1, 7.3, 7.5, 8.3 through 8.12 (for final accounting for any payment obligations accrued prior to the date of expiration of this Agreement), 8.13 (for final accounting for any payment obligations accrued prior to the date of termination of this Agreement, except that Section 8.13.3 shall survive generally for the period set forth in Section 10.1), 8.14, 9.1 (other than Section 9.1.3), 9.2.1, 9.3 through 9.8, 10.1 (for the period provided therein), 10.2, 10.3, 10.4, 10.6, 10.7, 10.8, 10.10, 11.6, 12.1 through 12.4, 12.5 (for the period provided therein), 13.1, 13.3, 13.7 and this Section 13.8.2 and Article 1 (to the extent required to give effect to the provisions set forth in this Section 13.8.2) and Article 14 of this Agreement shall survive the expiration of this Agreement for any reason.

If this Agreement is terminated with respect to one (1) or more Licensed Products or one (1) or more countries but not in its entirety, then following such termination, the foregoing provisions of this Agreement set forth in Section 13.8.1 shall remain in effect with respect to the terminated Licensed Product(s) in the terminated country(ies) (to the extent they would survive and apply in the event this Agreement is terminated in its entirety or as otherwise necessary for any of Takeda and its Affiliates and its and their Sublicensees to exercise their rights for the other Licensed Products or other countries) and all provisions not surviving in accordance with the foregoing shall terminate upon termination of this Agreement and be of no further force and effect with respect to the terminated Licensed Product(s) for the terminated country(ies) (and for the avoidance of doubt all provisions of this Agreement shall remain in effect with respect to all non-terminated Licensed Products and non-terminated countries).

## ARTICLE 14 MISCELLANEOUS

14.1. Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such

failure or delay is caused by or results from events beyond the reasonable control of
the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes,
shortages, pandemics, epidemics, quarantines, war,

acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any Governmental Authority (including any Regulatory Authority) (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The non-performing Party shall notify the other Party of such force majeure within [\*\*\*] after such occurrence by providing a written notice to the other Party stating the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

- 14.2. Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other Governmental Authority in accordance with Applicable Law.
- **14.3. Assignment.** Neither Party may, directly or indirectly, assign or otherwise transfer this Agreement or its rights or, except as provided in Section 3.4 and Section 7.5, delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; *provided*, *however*, that:
- 14.3.1. Takeda shall have the right, without ACI's consent, (a) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates, distributors or its or their Sublicensees or distributors, and (b) to assign any or all of its rights and delegate any or all of its obligations to any of its Affiliates; *provided* that [\*\*\*]
- 14.3.2. except as set forth in Section 14.3.1 and Section 14.3.3, Takeda shall not assign or otherwise transfer this Agreement or any of its rights or obligations under this Agreement, in whole or in part, without ACI's prior written consent (not to be unreasonably withheld, conditioned or delayed), to any Third Party; provided that Takeda may assign or transfer this Agreement to a Third Party that, [\*\*\*]
- 14.3.3. each Party shall have the right, without such consent, to assign this Agreement and all of its rights and obligations to any successor in interest in connection with a Change of Control of such Party;

provided that, in each case in which this Agreement is assigned in its entirety to an Affiliate or Third Party, the assigning Party shall provide written notice to the other Party within [\*\*\*] such assignment. Any permitted successor of a Party or any

permitted assignee of all of a Party's rights under this Agreement that has also assumed
all of such Party's obligations hereunder in writing shall, upon any such succession or
assignment and assumption, be deemed to be a party to this
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Agreement as though named herein in substitution for the assigning Party, whereupon the assigning Party shall cease to be a party to this Agreement and shall cease to have any rights or obligations under this Agreement; [\*\*\*]

All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party. Any attempted assignment or delegation in violation of this Section 14.3 shall be void and of no effect *ab initio*.

**Severability.** If, under Applicable Law, any one (1) or more of the provisions of this Agreement is held to be invalid, illegal or unenforceable at law or in equity in any court of competent jurisdiction and the rights of the Parties will not be materially and adversely affected thereby, (a) such invalid, illegal or unenforceable provision(s) shall be considered severed from this Agreement with respect to such jurisdiction, (b) this Agreement shall be construed and enforced as if such invalid, illegal or unenforceable provision(s) had never comprised a part hereof and (c) the Parties shall make a good faith effort to replace any invalid, illegal or unenforceable provision(s) with a valid, legal and enforceable provision(s) such that the objectives contemplated by the Parties when entering this Agreement may be realized (and, to the extent the Parties agree to a replacement provision, the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the invalid, illegal or unenforceable provision(s) or by its or their severance herefrom). To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof invalid, illegal or unenforceable in any respect.

### 14.5. Dispute Resolution.

14.5.1. Executive Officers; Litigation. Except as provided in Section 2.6.2, Section 8.13.2, Section 13.5.1(i), Section 14.5.2 or Section 14.10, any disputes arising out of or in connection with this Agreement, including any questions regarding its existence, validity, interpretation, breach or termination (a "Dispute") shall first be referred to the Executive Officers of the Parties, who shall confer in good faith on the resolution of such Dispute. Any final decision mutually agreed to by the Executive Officers shall be conclusive and binding on the Parties. If the Executive Officers are not able to agree on the resolution of any such issue within [\*\*\*] (or such other period of time as mutually agreed by the Executive Officers) after such issue was first referred to them, then either Party may initiate litigation pursuant to Section 14.6.

14.5.2. Intellectual Property Disputes. In the event that a Dispute arises with respect the validity, scope, enforceability, inventorship or ownership of any Patent, Trademark or other intellectual property rights, unless otherwise agreed by the Parties in writing, either Party may initiate litigation in a court of competent jurisdiction, notwithstanding Section 14.6, in any country or other jurisdiction in which such rights apply.

**14.5.3. Adverse Ruling.** Any determination pursuant to Section 14.5.1 or Section 14.6 that a Party is in material breach of its material obligations

breach, if feasible.	
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hereunder shall specify a (non-exclusive) set of actions to be taken to cure such material

14.5.4. Interim Relief. Notwithstanding anything herein to the contrary, nothing in this Section 14.5 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, if necessary to protect the interests of such Party.

**14.5.5. Specific Enforcement.** This Section 14.5 shall be specifically enforceable.

## 14.6. Governing Law, Jurisdiction and Service.

14.6.1. Governing Law. This Agreement and the performance, enforcement, breach or termination hereof shall be governed by and construed in accordance with the laws of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

**14.6.2. Jurisdiction.** Subject to Section 14.5 and Section 14.10, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial.

14.6.3. Venue. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the Southern District of New York and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

14.6.4. Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 14.7.2 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

#### 14.7. Notices.

14.7.1. Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 14.7.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 14.7.1. Such notice shall be deemed to have been given as of the date delivered

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by hand or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. A copy of any notice shall be provided via electronic mail to the email addresses specified in Section 14.7.2, if any

(which copies, for

clarity, shall not constitute notice). This Section 14.7.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

#### 14.7.2. Address for Notice.

If to Takeda, to:

Takeda Pharmaceuticals, USA, Inc. 95 Hayden Avenue Lexington, MA 02421 Attention: Regional General Counsel [\*\*\*]

with a copy (which shall not constitute notice) to:

Takeda Pharmaceutical Company Limited 1-1 Doshomachi 4-chomeChuo-ku, Osaka 540-8645, Japan Attention: Head of Center for External Innovation [\*\*\*]

If to ACI, to:

AC Immune SA
EPFL Innovation Park, Building B
CH-1015 Lausanne, Switzerland
[\*\*\*]
[\*\*\*]

with a copy (which shall not constitute notice) to:

AC Immune SA EPFL Innovation Park, Building B CH-1015 Lausanne, Switzerland Attention: General Counsel, Legal Department

14.8. Entire Agreement; Amendments. This Agreement, together with the attached Schedules, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter of this Agreement and all prior agreements, understandings and representations, whether written or oral, with respect thereto, including the Confidentiality Agreement, are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

14.9. English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English

language. Any translation into any other language shall not be an official version and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

14.10. Equitable Relief. Each Party acknowledges and agrees that the provisions of Section 4.5, Section 5.5 and Articles 9 and 10 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such provisions and that any breach or threatened breach of any provision of such Section or Articles will result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Section or Articles, the non-breaching Party shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Both Parties agree to waive any requirement that the other Party (a) post a bond or other security as a condition for obtaining any such relief and (b) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 14.10 is intended or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

14.11. Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided in this Agreement are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available, except as expressly provided herein.

14.12. No Benefit to Third Parties. The Contracts (Rights of Third Parties) Act 1999 shall not apply to this Agreement except with respect to Article 12. Except as provided in Article 12, subject to the foregoing, the covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns and they shall not be construed as conferring any rights on any other Persons (including any Third Party beneficiary rights) (whether under the Contracts (Rights of Third Parties) Act 1999 or otherwise).

14.13. Further Assurance. Each Party shall duly execute and deliver or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement.

Neither ACI, on the one hand, nor Takeda, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action that will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.

**14.15. Right to Offset.** Takeda shall have the right to offset any amount owed by ACI to Takeda under or in connection with this Agreement against any payments owed by Takeda to ACI under this Agreement. Such offsets shall be in addition to any other rights or remedies available under this Agreement and Applicable Law.

14.16. References. Unless otherwise specified, (a) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto.

14.17. Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include" or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term. All references to "will" are interchangeable with the word "shall" and shall be understood to be imperative or mandatory in nature. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

14.18. Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were original signatures.

[SIGNATURE PAGE FOLLOWS.]

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Effective Date.

TAKEDA PHARMACEUTICALS, USA, INC.	AC IMMUNE SA	
By:	By:	
Name:	Name:	
Title:	Title:	
	By:	
	Name:	
	Title:	
[Signature Page to Option and License Agreement]		





#### News Release

# AC Immune and Takeda Sign Exclusive Option and License Agreement for Active Immunotherapy Targeting Amyloid Beta for Alzheimer's Disease

- Takeda to receive exclusive option to license global rights to ACI-24.060, a potential first-in-class active immunotherapy designed to delay or slow Alzheimer's disease progression
- AC Immune to receive upfront payment of \$100 million upon closing and be eligible for an option exercise fee and additional potential milestones of up to approximately \$2.1 billion
- AC Immune to host conference call and webcast today at 8:30 a.m. ET

OSAKA, Japan, CAMBRIDGE, Massachusetts, and LAUSANNE, Switzerland, May 13, 2024 – Takeda (TSE:4502/NYSE:TAK) and AC Immune SA (NASDAQ: ACIU) today announced an exclusive, worldwide option and license agreement for AC Immune's active immunotherapies targeting toxic forms of amyloid beta (Abeta), including ACI-24.060 for the treatment of Alzheimer's disease.

ACI-24.060 is an anti-Abeta active immunotherapy candidate designed to induce a robust antibody response against the toxic forms of Abeta believed to drive plaque formation and Alzheimer's disease progression. By inducing plaque clearance and efficiently inhibiting plaque formation in the brain, ACI-24.060 has the potential to delay or slow Alzheimer's disease progression. ACI-24.060 is being investigated in the ongoing ABATE randomized, double-blind, placebo-controlled Phase 1b/2 trial to assess the safety, tolerability, immunogenicity and pharmacodynamic effects of the investigational immunotherapy in subjects with prodromal Alzheimer's disease and in adults with Down syndrome.

"As pioneers in the field of active immunotherapy, we are developing an innovative approach that could change the treatment paradigm for Alzheimer's disease and address the multifaceted burden that patients and the broader community face. We believe the maximum impact of ACI-24.060 can best be realized by partnering with Takeda at this critical juncture in its development, which will help us move rapidly into Phase 3," said Dr. Andrea Pfeifer, CEO of AC Immune. "This agreement allows us to leverage the developmental expertise, strategic vision and financial capacity of an accomplished organization that has demonstrated its ability to execute the type of comprehensive global program required for Phase 3 trials in Alzheimer's disease while allowing us to focus on completing Phase 1b/2 development and accelerating our efforts to replicate this success with enhanced funding for our early-stage pipeline."

AC Immune will be responsible for completing the ABATE trial. Following option exercise, Takeda would conduct and fund all further clinical development and be responsible for all global regulatory activities as well as worldwide commercialization.

"At Takeda, we are committed to tackling some of society's most debilitating illnesses, including Alzheimer's disease. We are excited to partner with AC Immune on this ground-breaking treatment

approach, which leverages novel technology with the potential to offer patients a treatment with differentiated efficacy, safety and ease of administration," said Sarah Sheikh, M.Sc., B.M., B.Ch, MRCP, Head, Neuroscience Therapeutic Area Unit and Head, Global Development at Takeda. "Combining AC Immune's deep experience with active immunotherapy approaches with Takeda's expertise in neuroscience drug development and commercialization, we have an incredible opportunity to deliver real impact to the Alzheimer's community."

Under the terms of the agreement, AC Immune will receive an upfront payment of \$100 million and be eligible to receive an option exercise fee and additional potential development, commercial and sales-based milestones of up to approximately \$2.1 billion if all related milestones are achieved over the course of the agreement. Upon commercialization, AC Immune will be entitled to receive tiered double-digit royalties on worldwide net sales.

Further details related to the agreement are available in the Form 6-K filed today by AC Immune with the U.S. Securities and Exchange Commission (SEC). The effectiveness of Takeda's license following option exercise is subject to the termination or expiration of any applicable waiting periods under the Hart-Scott-Rodino Act.

#### **Conference Call and Webcast Information**

AC Immune management will host a conference call and webcast today at 8:30 a.m. ET to provide a brief overview of the agreement.

Monday, May 13 at 8:30 a.m. ET

Participants wishing to ask questions or to join the event via phone may call the following numbers 10 - 15 minutes before conference start:

United States	+1 (1) 631 570 56 13
Switzerland / Europe	+41 (0) 58 310 50 00
United Kingdom	+44 (0) 207 107 06 13
Other international numbers available	HERE

#### Webcast:

https://event.choruscall.com/mediaframe/webcast.html?webcastid=YteAZhdg

Please note that there is a function to type in your questions via webcast.

A live and archived webcast will also be accessible in the Investors section of the Company's website at https://www.acimmune.com/.

#### About ACI-24.060

This product is AC Immune's anti-Abeta active immunotherapy candidate. The ABATE randomized, double-blind, placebo-controlled Phase 1b/2 trial of ACI-24.060 for treatment of Alzheimer's disease (AD) continues fully blinded (NCT05462106). Enrolled patients are required to have a diagnosis of prodromal AD: MCI due to AD according to the National Institute on Aging Alzheimer's Association (NIA-AA) criteria, and a PET scan at screening must be consistent with the presence of amyloid pathology. Patients will be randomized to one of several doses of ACI-24.060 or placebo. Following multiple data safety monitoring board (DSMB) reviews, no safety concerns have been raised to date, consistent with previous results. Immunogenicity of the immunotherapy is very encouraging with clear evidence of anti-Abeta antibody responses against toxic Abeta species observed in the blinded data. The six-month Abeta positron emission tomography (PET) imaging results are expected in Q2 2024, and the 12-month Abeta PET data are expected in Q4 2024.

#### About Takeda

Takeda is focused on creating better health for people and a brighter future for the world. We aim to discover and deliver life-transforming treatments in our core therapeutic and business areas, including gastrointestinal and inflammation, rare diseases, plasma-derived therapies, oncology, neuroscience and vaccines. Together with our partners, we aim to improve the patient experience and advance a new frontier of treatment options through our dynamic and diverse pipeline. As a leading values-based, R&D-driven biopharmaceutical company headquartered in Japan, we are guided by our commitment to patients, our people and the planet. Our employees in approximately 80 countries and regions are driven by our purpose and are grounded in the values that have defined us for more than two centuries. For more information, visit www.takeda.com.

#### **About AC Immune SA**

AC Immune SA is a clinical-stage biopharmaceutical company that aims to become a global leader in precision medicine 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, five of which are currently in Phase 2 clinical trials and one of which is 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.

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.

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#### **Takeda Important Notice**

For the purposes of this notice, "press release" means this document, any oral presentation, any question and answer session and any written or oral material discussed or distributed by Takeda Pharmaceutical Company Limited ("Takeda") regarding this release. This press release (including any oral briefing and any question-and-answer in connection with it) is not intended to, and does not constitute, represent or form part of any offer, invitation or solicitation of any offer to purchase, otherwise acquire, subscribe for, exchange, sell or otherwise dispose of, any securities or the solicitation of any vote or approval in any jurisdiction. No shares or other securities are being offered to the public by means of this press release. No offering of securities shall be made in the United States except pursuant to registration under the U.S. Securities Act of 1933, as amended, or an exemption therefrom. This press release is being given (together with any further information which may be provided to the recipient) on the condition that it is for use by the recipient for information purposes only (and not for the evaluation of any investment, acquisition, disposal or any other transaction). Any failure to comply with these restrictions may constitute a violation of applicable securities laws.

The companies in which Takeda directly and indirectly owns investments are separate entities. In this press release, "Takeda" is sometimes used for convenience where references are made to Takeda and its subsidiaries in general. Likewise, the words "we", "us" and "our" are also used to refer to subsidiaries in general or to those who work for them. These expressions are also used where no useful purpose is served by identifying the particular company or companies.

#### **Takeda Forward-Looking Statements**

This press release and any materials distributed in connection with this press release may contain forward-looking statements, beliefs or opinions regarding Takeda's future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation,

forward-looking statements often include words such as "targets", "plans", "believes", "hopes", "continues", "expects", "aims", "intends", "ensures", "will", "may", "should", "would", "could", "anticipates", "estimates", "projects", "forecasts", "outlook" or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding Takeda's global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations; challenges inherent in new product development, including uncertainty of clinical success and decisions of regulatory authorities and the timing thereof; uncertainty of commercial success for new and existing products; manufacturing difficulties or delays; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic; the success of our environmental sustainability efforts, in enabling us to reduce our greenhouse gas emissions or meet our other environmental goals; the extent to which our efforts to increase efficiency, productivity or cost-savings, such as the integration of digital technologies, including artificial intelligence, in our business or other initiatives to restructure our operations will lead to the expected benefits; and other factors identified in Takeda's most recent Annual Report on Form 20-F and Takeda's other reports filed with the U.S. Securities and Exchange Commission, available on Takeda's website at: https://www.takeda.com/investors/sec-filings-and-security-reports/ or at www.sec.gov. Takeda does not undertake to update any of the forward-looking statements contained in this press release or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this press release may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda's future results.

#### **AC Immune 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.

# Schedule 10.10 Standard Contractual Clauses

#### **Module 1: Controller to Controller Transfers**

Takeda has entered into the Option and License Agreement ("Agreement") with AC Immune SA ("Company"), under which the Parties will share Personal Data for the purpose of effectuating the rights granted within the Agreement.

The Parties agree that if a Party will store, have access to or otherwise process Personal Data of individuals residing in the European Economic Area ("EEA"), United Kingdom ("UK") or Switzerland from any location other than (i) the "Safe Cluster" which comprises: countries in the EEA or adequate countries (Andorra, Argentina, Canada (commercial organisations), Faroe Islands, Guernsey, Israel, Isle of Man, Japan, Jersey, New Zealand, Republic of Korea, Switzerland, the UK, Uruguay, or as otherwise provided by the European Commission (at <a href="https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions\_en">https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions\_en</a>)) and (ii) specifically for transfers from the UK or Switzerland, any additional countries identified as adequate by the UK or Swiss authorities, then the Parties will comply with the terms set forth in this Module 1 of the European Commission Standard Contractual Clauses ("SCCs") under which each Party acts as a controller of the EEA, UK or Swiss Personal Data. In the event of a conflict between the SCCs and the Agreement, the SCCs shall prevail.

**UK and Swiss transfers**. For any storage, access to or processing of Personal Data of individuals residing in the UK or Switzerland, the following amendments to the SCCs shall apply:

- UK Personal Data: For storage, access to or processing of Personal Data of individuals residing in the UK, the SCCs shall be modified in accordance with the "International Data Transfer Addendum to the EU Commission Standard Contractual Clauses" ("UK Addendum") in Annex III;
- Swiss Personal Data: For storage, access to or processing of Personal Data of individuals residing in Switzerland, the SCCs shall be modified in accordance with the statement of the Swiss Federal Data Protection and Information Commissioner ("FDPIC") of 27 August 2021 (available at: <a href="https://www.edoeb.admin.ch/dam/edoeb/en/dokumente/2021/Paper%20SCC%20def.en%2024082021.pdf.download.pdf/">https://www.edoeb.admin.ch/dam/edoeb/en/dokumente/2021/Paper%20SCC%20def.en%2024082021.pdf.download.pdf/</a>
  Paper%20SCC%20def.en%2024082021.pdf). In particular: the FDPIC shall be the competent

supervisory authority insofar as the data transfer is governed by the Swiss Federal Act on Data Protection ("FADP") (Clause 13); the law of the EEA country specified by Takeda in the SCCs shall be the governing law (Clause 17); the courts of the EEA country as specified by Takeda in the SCCs shall be the choice of forum (Clause 18), but this shall not exclude individuals in Switzerland from the possibility of bringing a claim in their place of habitual residence in Switzerland, in accordance with Clause 18(c).

## STANDARD CONTRACTUAL CLAUSES

# **SECTION I**

#### Clause 1

#### Purpose and scope

- (a) The purpose of these standard contractual clauses is to ensure compliance with the requirements of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) for the transfer of personal data to a third country.
- (b) The Parties:
  - (i) the natural or legal person(s), public authority/ies, agency/ies or other body/ies (hereinafter "entity/ies") transferring the personal data, as listed in Annex I.A. (hereinafter each "data exporter"), and
  - (ii) the entity/ies in a third country receiving the personal data from the data exporter, directly or indirectly via another entity also Party to these Clauses, as listed in Annex I.A. (hereinafter each "data importer")

have agreed to these standard contractual clauses (hereinafter: "Clauses").

- (c) These Clauses apply with respect to the transfer of personal data as specified in Annex I.B.
- (d) The Appendix to these Clauses containing the Annexes referred to therein forms an integral part of these Clauses.

#### Clause 2

# Effect and invariability of the Clauses

(a) These Clauses set out appropriate safeguards, including enforceable data subject rights and effective legal remedies, pursuant to Article 46(1) and Article 46 (2)(c) of Regulation (EU) 2016/679 and, with respect to data transfers from controllers to processors and/or processors to processors, standard contractual clauses pursuant to Article 28(7) of Regulation (EU) 2016/679, provided they are not modified, except to select the appropriate Module(s) or to add or update information in the Appendix. This does not prevent the Parties from including the standard contractual clauses laid down in these Clauses in a wider contract and/or to add other clauses or additional safeguards, provided that they do not contradict, directly or indirectly, these Clauses or prejudice the fundamental rights or freedoms of data subjects.

These Clauses are without prejudice to obligations to which the data exporter is subject by virtue of Regulation (EU) 2016/679.

(b)

#### Clause 3

# Third-party beneficiaries

- (a) Data subjects may invoke and enforce these Clauses, as third-party beneficiaries, against the data exporter and/or data importer, with the following exceptions:
  - (i) Clause 1, Clause 2, Clause 3, Clause 6, Clause 7;
  - (ii) Clause 8 Clause 8.5(e) and Clause 8.9(b);
  - (iii) Clause 12 Clause 12(a) and (d);
  - (iv) Clause 13;
  - (v) Clause 15.1(c), (d) and (e);
  - (vi) Clause 16(e);
  - (vii) Clause 18 Clause 18(a) and (b).
- (b) Paragraph (a) is without prejudice to rights of data subjects under Regulation (EU) 2016/679.

#### Clause 4

# Interpretation

- (a) Where these Clauses use terms that are defined in Regulation (EU) 2016/679, those terms shall have the same meaning as in that Regulation.
- (b) These Clauses shall be read and interpreted in the light of the provisions of Regulation (EU) 2016/679.
- (c) These Clauses shall not be interpreted in a way that conflicts with rights and obligations provided for in Regulation (EU) 2016/679.

# Clause 5

# Hierarchy

In the event of a contradiction between these Clauses and the provisions of related agreements between the Parties, existing at the time these Clauses are agreed or entered into thereafter, these Clauses shall prevail.

#### Clause 6

# Description of the transfer(s)

The details of the transfer(s), and in particular the categories of personal data that are transferred and the purpose(s) for which they are transferred, are specified in Annex I.B.

# Clause 7 – Optional

## Docking clause

- (a) An entity that is not a Party to these Clauses may, with the agreement of the Parties, accede to these Clauses at any time, either as a data exporter or as a data importer, by completing the Appendix and signing Annex I.A.
- (b) Once it has completed the Appendix and signed Annex I.A, the acceding entity shall become a Party to these Clauses and have the rights and obligations of a data exporter or data importer in accordance with its designation in Annex I.A.
- (c) The acceding entity shall have no rights or obligations arising under these Clauses from the period prior to becoming a Party.

#### **SECTION II – OBLIGATIONS OF THE PARTIES**

#### Clause 8

# Data protection safeguards

The data exporter warrants that it has used reasonable efforts to determine that the data importer is able, through the implementation of appropriate technical and organisational measures, to satisfy its obligations under these Clauses.

# **8.1** Purpose limitation

- 1. The data importer shall process the personal data only for the specific purpose(s) of the transfer, as set out in Annex I. B. It may only process the personal data for another purpose:
  - (i) where it has obtained the data subject's prior consent;
  - (ii) where necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings; or
  - (iii) where necessary in order to protect the vital interests of the data subject or of another natural person.

# **8.2** Transparency

- (a) In order to enable data subjects to effectively exercise their rights pursuant to Clause 10, the data importer shall inform them, either directly or through the data exporter:
  - (i) of its identity and contact details;
  - (ii) of the categories of personal data processed;
  - (iii) of the right to obtain a copy of these Clauses;
  - (iv) where it intends to onward transfer the personal data to any third party/ ies, of the recipient or categories of recipients (as appropriate with a view to providing meaningful information), the purpose of such onward transfer and the ground therefore pursuant to Clause 8.7.
- (b) Paragraph (a) shall not apply where the data subject already has the information, including when such information has already been provided by the data exporter, or providing the information proves impossible or would involve a disproportionate effort for the data importer. In the latter case, the data importer shall, to the extent possible, make the information publicly available.
- (c) On request, the Parties shall make a copy of these Clauses, including the Appendix as completed by them, available to the data subject free of charge. To the extent necessary to protect business secrets or other confidential information, including personal data, the Parties may redact part of the text of the Appendix prior to sharing a copy, but shall provide a meaningful summary where the data subject would otherwise not be able to understand its content or exercise his/her rights. On request, the Parties shall provide the data subject with the reasons for the redactions, to the extent possible without revealing the redacted information.
- (d) Paragraphs (a) to (c) are without prejudice to the obligations of the data exporter under Articles 13 and 14 of Regulation (EU) 2016/679.
- **8.3** Accuracy and data minimisation
- (a) Each Party shall ensure that the personal data is accurate and, where necessary, kept up to date. The data importer shall take every reasonable step to ensure that personal data that

- is inaccurate, having regard to the purpose(s) of processing, is erased or rectified without delay.
- (b) If one of the Parties becomes aware that the personal data it has transferred or received is inaccurate, or has become outdated, it shall inform the other Party without undue delay.
- (c) The data importer shall ensure that the personal data is adequate, relevant and limited to what is necessary in relation to the purpose(s) of processing.

# **8.4** Storage limitation

The data importer shall retain the personal data for no longer than necessary for the purpose(s) for which it is processed. It shall put in place appropriate technical or organisational measures to ensure compliance with this obligation, including erasure or anonymisation of the data and all back-ups at the end of the retention period.

# **8.5** Security of processing

- (a) The data importer and, during transmission, also the data exporter shall implement appropriate technical and organisational measures to ensure the security of the personal data, including protection against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access (hereinafter "personal data breach"). In assessing the appropriate level of security, they shall take due account of the state of the art, the costs of implementation, the nature, scope, context and purpose(s) of processing and the risks involved in the processing for the data subject. The Parties shall in particular consider having recourse to encryption or pseudonymisation, including during transmission, where the purpose of processing can be fulfilled in that manner.
- (b) The Parties have agreed on the technical and organisational measures set out in Annex II. The data importer shall carry out regular checks to ensure that these measures continue to provide an appropriate level of security.
- (c) The data importer shall ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.
- (d) In the event of a personal data breach concerning personal data processed by the data importer under these Clauses, the data importer shall take appropriate measures to address the personal data breach, including measures to mitigate its possible adverse effects.
- (e) In case of a personal data breach that is likely to result in a risk to the rights and freedoms of natural persons, the data importer shall without undue delay notify both the data exporter and the competent supervisory authority pursuant to Clause 13. Such notification shall contain i) a description of the nature of the

breach (including, where possible, categories and approximate number of data subjects and personal data records concerned), ii) its likely consequences, iii) the measures taken or proposed to address the breach, and iv) the details of a contact point from whom more information can be

- obtained. To the extent it is not possible for the data importer to provide all the information at the same time, it may do so in phases without undue further delay.
- (f) In case of a personal data breach that is likely to result in a high risk to the rights and freedoms of natural persons, the data importer shall also notify without undue delay the data subjects concerned of the personal data breach and its nature, if necessary in cooperation with the data exporter, together with the information referred to in paragraph (e), points ii) to iv), unless the data importer has implemented measures to significantly reduce the risk to the rights or freedoms of natural persons, or notification would involve disproportionate efforts. In the latter case, the data importer shall instead issue a public communication or take a similar measure to inform the public of the personal data breach.
- (g) The data importer shall document all relevant facts relating to the personal data breach, including its effects and any remedial action taken, and keep a record thereof.

#### **8.6** Sensitive data

Where the transfer involves personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, or biometric data for the purpose of uniquely identifying a natural person, data concerning health or a person's sex life or sexual orientation, or data relating to criminal convictions or offences (hereinafter "sensitive data"), the data importer shall apply specific restrictions and/or additional safeguards adapted to the specific nature of the data and the risks involved. This may include restricting the personnel permitted to access the personal data, additional security measures (such as pseudonymisation) and/or additional restrictions with respect to further disclosure.

#### **8.7** Onward transfers

The data importer shall not disclose the personal data to a third party located outside the European Union (in the same country as the data importer or in another third country, hereinafter "onward transfer") unless the third party is or agrees to be bound by these Clauses, under the appropriate Module. Otherwise, an onward transfer by the data importer may only take place if:

- (i) it is to a country benefitting from an adequacy decision pursuant to Article 45 of Regulation (EU) 2016/679 that covers the onward transfer;
- (ii) the third party otherwise ensures appropriate safeguards pursuant to Articles 46 or 47 of Regulation (EU) 2016/679 with respect to the processing in question;

- (iii) the third party enters into a binding instrument with the data importer ensuring the same level of data protection as under these Clauses, and the data importer provides a copy of these safeguards to the data exporter;
- (iv) it is necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings;

- (v) it is necessary in order to protect the vital interests of the data subject or of another natural person; or
- (vi) where none of the other conditions apply, the data importer has obtained the explicit consent of the data subject for an onward transfer in a specific situation, after having informed him/her of its purpose(s), the identity of the recipient and the possible risks of such transfer to him/her due to the lack of appropriate data protection safeguards. In this case, the data importer shall inform the data exporter and, at the request of the latter, shall transmit to it a copy of the information provided to the data subject.

Any onward transfer is subject to compliance by the data importer with all the other safeguards under these Clauses, in particular purpose limitation.

**8.8** Processing under the authority of the data importer

The data importer shall ensure that any person acting under its authority, including a processor, processes the data only on its instructions.

- **8.9** Documentation and compliance
- (a) Each Party shall be able to demonstrate compliance with its obligations under these Clauses. In particular, the data importer shall keep appropriate documentation of the processing activities carried out under its responsibility.
- (b) The data importer shall make such documentation available to the competent supervisory authority on request.

# Clause 9

#### Use of sub-processors

(a) Intentionally omitted.

#### Clause 10

# Data subject rights

(a) The data importer, where relevant with the assistance of the data exporter, shall deal with any enquiries and requests it receives from a data subject relating to the processing of his/her personal data and the exercise of his/her rights under these Clauses without undue delay and at the latest within one month of the receipt of the enquiry or request. The data importer shall take appropriate measures to facilitate such enquiries, requests and the exercise of data subject rights. Any information provided to the data subject shall be in an intelligible and easily accessible form, using clear and plain language.

In particular, upon request by the data subject the data importer shall, free of

(b)

charge:

- (i) provide confirmation to the data subject as to whether personal data concerning him/her is being processed and, where this is the case, a copy of the data relating to him/her and the information in Annex I; if personal data has been or will be onward transferred, provide information on recipients or categories of recipients (as appropriate with a view to providing meaningful information) to which the personal data has been or will be onward transferred, the purpose of such onward transfers and their ground pursuant to Clause 8.7; and provide information on the right to lodge a complaint with a supervisory authority in accordance with Clause 12(c)(i);
- (ii) rectify inaccurate or incomplete data concerning the data subject;
- (iii) erase personal data concerning the data subject if such data is being or has been processed in violation of any of these Clauses ensuring third-party beneficiary rights, or if the data subject withdraws the consent on which the processing is based.
- (c) Where the data importer processes the personal data for direct marketing purposes, it shall cease processing for such purposes if the data subject objects to it.
- (d) The data importer shall not make a decision based solely on the automated processing of the personal data transferred (hereinafter "automated decision"), which would produce legal effects concerning the data subject or similarly significantly affect him/her, unless with the explicit consent of the data subject or if authorised to do so under the laws of the country of destination, provided that such laws lays down suitable measures to safeguard the data subject's rights and legitimate interests. In this case, the data importer shall, where necessary in cooperation with the data exporter:
  - (i) inform the data subject about the envisaged automated decision, the envisaged consequences and the logic involved; and
  - (ii) implement suitable safeguards, at least by enabling the data subject to contest the decision, express his/her point of view and obtain review by a human being.
- (e) Where requests from a data subject are excessive, in particular because of their repetitive character, the data importer may either charge a reasonable fee taking into account the administrative costs of granting the request or refuse to act on the request.
- (f) The data importer may refuse a data subject's request if such refusal is allowed under the laws of the country of destination and is necessary and proportionate in a democratic society to protect one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679.

(g)	If the data importer intends to refuse a data subject's request, it shall inform the data subject of the reasons for the refusal and the possibility of lodging a complaint with the competent supervisory authority and/or seeking judicial redress.							

#### Clause 11

#### Redress

- (a) The data importer shall inform data subjects in a transparent and easily accessible format, through individual notice or on its website, of a contact point authorised to handle complaints. It shall deal promptly with any complaints it receives from a data subject.
- (b) In case of a dispute between a data subject and one of the Parties as regards compliance with these Clauses, that Party shall use its best efforts to resolve the issue amicably in a timely fashion. The Parties shall keep each other informed about such disputes and, where appropriate, cooperate in resolving them.
- (c) Where the data subject invokes a third-party beneficiary right pursuant to Clause 3, the data importer shall accept the decision of the data subject to:
  - (i) lodge a complaint with the supervisory authority in the Member State of his/her habitual residence or place of work, or the competent supervisory authority pursuant to Clause 13;
  - (ii) refer the dispute to the competent courts within the meaning of Clause 18.
- (d) The Parties accept that the data subject may be represented by a not-for-profit body, organisation or association under the conditions set out in Article 80(1) of Regulation (EU) 2016/679.
- (e) The data importer shall abide by a decision that is binding under the applicable EU or Member State law.
- (f) The data importer agrees that the choice made by the data subject will not prejudice his/her substantive and procedural rights to seek remedies in accordance with applicable laws.

#### Clause 12

### Liability

- (a) Each Party shall be liable to the other Party/ies for any damages it causes the other Party/ies by any breach of these Clauses.
- (b) Each Party shall be liable to the data subject, and the data subject shall be entitled to receive compensation, for any material or non-material damages that the Party causes the data subject by breaching the third-party beneficiary rights under these Clauses. This is without prejudice to the liability of the data exporter under Regulation (EU) 2016/679.

(c)	Where more than one Party is responsible for any damage caused to the data subject as a result of a breach of these Clauses, all responsible Parties shall be jointly and severally liable and the data subject is entitled to bring an action in court against any of these Parties.							

- (d) The Parties agree that if one Party is held liable under paragraph (c), it shall be entitled to claim back from the other Party/ies that part of the compensation corresponding to its/their responsibility for the damage.
- (e) The data importer may not invoke the conduct of a processor or sub-processor to avoid its own liability.

#### Clause 13

# Supervision

(a) [[Where the data exporter is established in an EU Member State:] The supervisory authority with responsibility for ensuring compliance by the data exporter with Regulation (EU) 2016/679 as regards the data transfer, as indicated in Annex I.C, shall act as competent supervisory authority.

[Where the data exporter is not established in an EU Member State, but falls within the territorial scope of application of Regulation (EU) 2016/679 in accordance with its Article 3(2) and has appointed a representative pursuant to Article 27(1) of Regulation (EU) 2016/679:] The supervisory authority of the Member State in which the representative within the meaning of Article 27(1) of Regulation (EU) 2016/679 is established, as indicated in Annex I.C, shall act as competent supervisory authority.

[Where the data exporter is not established in an EU Member State, but falls within the territorial scope of application of Regulation (EU) 2016/679 in accordance with its Article 3(2) without however having to appoint a representative pursuant to Article 27(2) of Regulation (EU) 2016/679:] The supervisory authority of one of the Member States in which the data subjects whose personal data is transferred under these Clauses in relation to the offering of goods or services to them, or whose behaviour is monitored, are located, as indicated in Annex I.C, shall act as competent supervisory authority.]

(b) The data importer agrees to submit itself to the jurisdiction of and cooperate with the competent supervisory authority in any procedures aimed at ensuring compliance with these Clauses. In particular, the data importer agrees to respond to enquiries, submit to audits and comply with the measures adopted by the supervisory authority, including remedial and compensatory measures. It shall provide the supervisory authority with written confirmation that the necessary actions have been taken.

# SECTION III – LOCAL LAWS AND OBLIGATIONS IN CASE OF ACCESS BY PUBLIC AUTHORITIES

#### Clause 14

Local laws and practices affecting compliance with the Clauses

- (a) The Parties warrant that they have no reason to believe that the laws and practices in the third country of destination applicable to the processing of the personal data by the data importer, including any requirements to disclose personal data or measures authorising access by public authorities, prevent the data importer from fulfilling its obligations under these Clauses. This is based on the understanding that laws and practices that respect the essence of the fundamental rights and freedoms and do not exceed what is necessary and proportionate in a democratic society to safeguard one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679, are not in contradiction with these Clauses.
- (b) The Parties declare that in providing the warranty in paragraph (a), they have taken due account in particular of the following elements:
  - (i) the specific circumstances of the transfer, including the length of the processing chain, the number of actors involved and the transmission channels used; intended onward transfers; the type of recipient; the purpose of processing; the categories and format of the transferred personal data; the economic sector in which the transfer occurs; the storage location of the data transferred;
  - (ii) the laws and practices of the third country of destination including those requiring the disclosure of data to public authorities or authorising access by such authorities relevant in light of the specific circumstances of the transfer, and the applicable limitations and safeguards;
  - (iii) any relevant contractual, technical or organisational safeguards put in place to supplement the safeguards under these Clauses, including measures applied during transmission and to the processing of the personal data in the country of destination.
- (c) The data importer warrants that, in carrying out the assessment under paragraph (b), it has made its best efforts to provide the data exporter with relevant information and agrees that it will continue to cooperate with the data exporter in ensuring compliance with these Clauses.
- (d) The Parties agree to document the assessment under paragraph (b) and make it available to the competent supervisory authority on request.

(e)	The data importer agrees to notify the data exporter promptly if, after having agreed to these Clauses and for the duration of the contract, it has reason to believe that it is or has become subject to laws or practices not in line with the requirements under paragraph (a), including following a change in the laws of the third country or a measure (such as a

- disclosure request) indicating an application of such laws in practice that is not in line with the requirements in paragraph (a).
- (f) Following a notification pursuant to paragraph (e), or if the data exporter otherwise has reason to believe that the data importer can no longer fulfil its obligations under these Clauses, the data exporter shall promptly identify appropriate measures (e.g. technical or organisational measures to ensure security and confidentiality) to be adopted by the data exporter and/or data importer to address the situation. The data exporter shall suspend the data transfer if it considers that no appropriate safeguards for such transfer can be ensured, or if instructed by the competent supervisory authority to do so. In this case, the data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses. If the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise. Where the contract is terminated pursuant to this Clause, Clause 16(d) and (e) shall apply.

#### Clause 15

Obligations of the data importer in case of access by public authorities

#### 15.1 Notification

- (a) The data importer agrees to notify the data exporter and, where possible, the data subject promptly (if necessary with the help of the data exporter) if it:
  - (i) receives a legally binding request from a public authority, including judicial authorities, under the laws of the country of destination for the disclosure of personal data transferred pursuant to these Clauses; such notification shall include information about the personal data requested, the requesting authority, the legal basis for the request and the response provided; or
  - (ii) becomes aware of any direct access by public authorities to personal data transferred pursuant to these Clauses in accordance with the laws of the country of destination; such notification shall include all information available to the importer.
- (b) If the data importer is prohibited from notifying the data exporter and/or the data subject under the laws of the country of destination, the data importer agrees to use its best efforts to obtain a waiver of the prohibition, with a view to communicating as much information as possible, as soon as possible. The data importer agrees to document its best efforts in order to be able to demonstrate them on request of the data exporter.
- (c) Where permissible under the laws of the country of destination, the data importer agrees to provide the data exporter, at regular intervals for the

duration of the contract, with as much relevant information as possible on the requests received (in particular, number of requests, type of data requested, requesting authority/ies, whether requests have been challenged and the outcome of such challenges, etc.).

- (d) The data importer agrees to preserve the information pursuant to paragraphs (a) to (c) for the duration of the contract and make it available to the competent supervisory authority on request.
- (e) Paragraphs (a) to (c) are without prejudice to the obligation of the data importer pursuant to Clause 14(e) and Clause 16 to inform the data exporter promptly where it is unable to comply with these Clauses.

# **15.2** Review of legality and data minimisation

- (a) The data importer agrees to review the legality of the request for disclosure, in particular whether it remains within the powers granted to the requesting public authority, and to challenge the request if, after careful assessment, it concludes that there are reasonable grounds to consider that the request is unlawful under the laws of the country of destination, applicable obligations under international law and principles of international comity. The data importer shall, under the same conditions, pursue possibilities of appeal. When challenging a request, the data importer shall seek interim measures with a view to suspending the effects of the request until the competent judicial authority has decided on its merits. It shall not disclose the personal data requested until required to do so under the applicable procedural rules. These requirements are without prejudice to the obligations of the data importer under Clause 14(e).
- (b) The data importer agrees to document its legal assessment and any challenge to the request for disclosure and, to the extent permissible under the laws of the country of destination, make the documentation available to the data exporter. It shall also make it available to the competent supervisory authority on request.
- (c) The data importer agrees to provide the minimum amount of information permissible when responding to a request for disclosure, based on a reasonable interpretation of the request.

#### **SECTION IV** – FINAL PROVISIONS

## Clause 16

# Non-compliance with the Clauses and termination

- (a) The data importer shall promptly inform the data exporter if it is unable to comply with these Clauses, for whatever reason.
- (b) In the event that the data importer is in breach of these Clauses or unable to comply with these Clauses, the data exporter shall suspend the transfer of personal data to the data importer until compliance is again ensured or the contract is terminated. This is without prejudice to Clause 14(f).

The data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses, where:

(c)

- (i) the data exporter has suspended the transfer of personal data to the data importer pursuant to paragraph (b) and compliance with these Clauses is not restored within a reasonable time and in any event within one month of suspension;
- (ii) the data importer is in substantial or persistent breach of these Clauses; or
- (iii) the data importer fails to comply with a binding decision of a competent court or supervisory authority regarding its obligations under these Clauses.

In these cases, it shall inform the competent supervisory authority of such noncompliance. Where the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise.

- (d) Personal data that has been transferred prior to the termination of the contract pursuant to paragraph (c) shall at the choice of the data exporter immediately be returned to the data exporter or deleted in its entirety. The same shall apply to any copies of the data. The data importer shall certify the deletion of the data to the data exporter. Until the data is deleted or returned, the data importer shall continue to ensure compliance with these Clauses. In case of local laws applicable to the data importer that prohibit the return or deletion of the transferred personal data, the data importer warrants that it will continue to ensure compliance with these Clauses and will only process the data to the extent and for as long as required under that local law.
- (e) Either Party may revoke its agreement to be bound by these Clauses where (i) the European Commission adopts a decision pursuant to Article 45(3) of Regulation (EU) 2016/679 that covers the transfer of personal data to which these Clauses apply; or (ii) Regulation (EU) 2016/679 becomes part of the legal framework of the country to which the personal data is transferred. This is without prejudice to other obligations applying to the processing in question under Regulation (EU) 2016/679.

#### Clause 17

# Governing law

These Clauses shall be governed by the law of one of the EU Member States, provided such law allows for third-party beneficiary rights. The Parties agree that this shall be the law of Ireland.

#### Clause 18

Choice of forum and jurisdiction

(a)	Any dispute arising from these Clauses shall be resolved by the courts of an EU Member State.							
(b)	The Parties agree that those shall be the courts of Ireland.							

(a)

(d)	The Parties agree to submit themselves to the jurisdiction of such courts.								
	<u> </u>								

A data subject may also bring legal proceedings against the data exporter and/or data importer before the courts of the Member State in which he/she has his/

(c)

her habitual residence.

# **ANNEX III to Module I**

# UK Addendum to the EU Commission Standard Contractual Clauses

#### **EU Commission Standard Contractual Clauses**

This Addendum has been issued by the Information Commissioner for Parties making Restricted Transfers. The Information Commissioner considers that it provides Appropriate Safeguards for Restricted Transfers when it is entered into as a legally binding contract.

#### Part 1: Tables

# **Table 1: Parties**

Start Date	The date of this Agreement.

	The Parties						
Parties' details	The details of the data exporter and the data importer can be found in Annex 1.A. of the attached EU SCCs.						
Key Contact	Key Contact information of the data exporter and the data importer can be found in Annex 1.A. of the attached EU SCCs.						

# Table 2: Selected SCCs, Modules and Selected Clauses

The version of the Approved EU SCCs which this Addendum is appended to								d to		
including the Appendix Information.										
Addendum EU SCCS	×									
EUSCCS	OR									
		following	ne Approved EU SCCs, including the Appendix Information and with only the following modules, clauses or optional provisions of the Approved EU SCCs rought into effect for the purposes of this Addendum:							
		Module	Module	Clause 7	Clause	Clause 9a	Clause	Is		
			in	(Docking	11	(Prior	9a	personal		
			operation	Clause)	(Option)	Authorisation	(Time	data		
						or General	Period)	received		
						Authorisation)		from the		
								Importer		
								combined		
								with		
								personal		

				data collected by the Exporter?
	1			

2			
3			
4			

#### **Table 3: Appendix Information**

"Appendix Information" means the information which must be provided for the selected modules as set out in the Appendix of the Approved EU SCCs (other than the Parties), and which for this Addendum is set out in the Annexes to the Approved EU SCCs which this Addendum is appended to.

Table 4: Ending this Addendum when the Approved Addendum Changes

Ending this Addendum when the Approved Addendum changes	Which 19:	Parties may end this Addendum as set out in Section
	×	Importer
	×	Exporter
		neither Party

#### Part 2: Mandatory Clauses

#### **Entering into this Addendum**

- 1. Each Party agrees to be bound by the terms and conditions set out in this Addendum, in exchange for the other Party also agreeing to be bound by this Addendum.
- 2. Although Annex 1A and Clause 7 of the Approved EU SCCs require signature by the Parties, for the purpose of making Restricted Transfers, the Parties may enter into this Addendum in any way that makes them legally binding on the Parties and allows data subjects to enforce their rights as set out in this Addendum. Entering into this Addendum will have the same effect as signing the Approved EU SCCs and any part of the Approved EU SCCs.

# Interpretation of this Addendum

Where this Addendum uses terms that are defined in the Approved EU SCCs those terms shall have the same meaning as in the Approved EU SCCs. In addition, the following terms have the following meanings:

Term	Meaning
Addendum	This International Data Transfer Addendum which is made up of this Addendum incorporating the Addendum EU SCCs.

Addendum EU SCCs	The version(s) of the Approved EU SCCs which this Addendum
	is appended to, as set out in Table 2, including the Appendix
	Information.
Appendix Information	As set out in Table 3.
Appropriate Safeguards	The standard of protection over the personal data and of data subjects' rights, which is required by UK Data Protection Laws when you are making a Restricted Transfer relying on standard data protection clauses under Article 46(2)(d) UK GDPR.
Approved Addendum	The template Addendum issued by the ICO and laid before Parliament in accordance with s119A of the Data Protection Act 2018 on 2 February 2022, as it is revised under Section 18.
Approved EU SCCs	The Standard Contractual Clauses set out in the Annex of Commission Implementing Decision (EU) 2021/914 of 4 June 2021.
ICO	The Information Commissioner.
Restricted Transfer	A transfer which is covered by Chapter V of the UK GDPR.
UK	The United Kingdom of Great Britain and Northern Ireland.
UK Data	All laws relating to data protection, the processing of personal
Protection Laws	data, privacy and/or electronic communications in force from
	time to time in the UK, including the UK GDPR and the Data Protection Act 2018.
UK GDPR	As defined in section 3 of the Data Protection Act 2018.

- 4. This Addendum must always be interpreted in a manner that is consistent with UK Data Protection Laws and so that it fulfils the Parties' obligation to provide the Appropriate Safeguards.
- 5. If the provisions included in the Addendum EU SCCs amend the Approved SCCs in any way which is not permitted under the Approved EU SCCs or the Approved Addendum, such amendment(s) will not be incorporated in this Addendum and the equivalent provision of the Approved EU SCCs will take their place.
- 6. If there is any inconsistency or conflict between UK Data Protection Laws and this Addendum, UK Data Protection Laws applies.

- 7. If the meaning of this Addendum is unclear or there is more than one meaning, the meaning which most closely aligns with UK Data Protection Laws applies.
- 8. Any references to legislation (or specific provisions of legislation) means that legislation (or specific provision) as it may change over time. This includes where that legislation (or specific provision) has been consolidated, re- enacted and/or replaced after this Addendum has been entered into.

#### Hierarchy

- 9. Although Clause 5 of the Approved EU SCCs sets out that the Approved EU SCCs prevail over all related agreements between the parties, the parties agree that, for Restricted Transfers, the hierarchy in Section 10 will prevail.
- 10. Where there is any inconsistency or conflict between the Approved Addendum and the Addendum EU SCCs (as applicable), the Approved Addendum overrides the Addendum EU SCCs, except where (and in so far as) the inconsistent or conflicting terms of the Addendum EU SCCs provides greater protection for data subjects, in which case those terms will override the Approved Addendum.
- 11. Where this Addendum incorporates Addendum EU SCCs which have been entered into to protect transfers subject to the General Data Protection Regulation (EU) 2016/679 then the Parties acknowledge that nothing in this Addendum impacts those Addendum EU SCCs.

#### Incorporation of and changes to the EU SCCs

- 12. This Addendum incorporates the Addendum EU SCCs which are amended to the extent necessary so that:
  - a. together they operate for data transfers made by the data exporter to the data importer, to the extent that UK Data Protection Laws apply to the data exporter's processing when making that data transfer, and they provide Appropriate Safeguards for those data transfers;
  - b. Sections 9 to 11 override Clause 5 (Hierarchy) of the Addendum EU SCCs; and
  - c. this Addendum (including the Addendum EU SCCs incorporated into it) is (1) governed by the laws of England and Wales and (2) any dispute arising from it is resolved by the courts of England and Wales, in each case unless the laws and/or courts of Scotland or Northern Ireland have been expressly selected by the Parties.
- 13. Unless the Parties have agreed alternative amendments which meet the requirements of Section 12, the provisions of Section 15 will apply.
- 14. No amendments to the Approved EU SCCs other than to meet the requirements of Section 12 may be made.
- 15. The following amendments to the Addendum EU SCCs (for the purpose of Section 12) are made:

- a. References to the "Clauses" means this Addendum, incorporating the Addendum EU SCCs;
- b. In Clause 2, delete the words:
  - "and, with respect to data transfers from controllers to processors and/or processors to processors, standard contractual clauses pursuant to Article 28(7) of Regulation (EU) 2016/679";
- C. Clause 6 (Description of the transfer(s)) is replaced with:
  - "The details of the transfers(s) and in particular the categories of personal data that are transferred and

the purpose(s) for which they are transferred are those specified in Annex I.B where UK Data Protection Laws apply to the data exporter's processing when making that transfer.";

d. Clause 8.7(i) of Module 1 is replaced with:

"it is to a country benefitting from adequacy regulations pursuant to Section 17A of the UK GDPR that covers the onward transfer";

e. Clause 8.8(i) of Modules 2 and 3 is replaced with:

"the onward transfer is to a country benefitting from adequacy regulations pursuant to Section 17A of the UK GDPR that covers the onward transfer;"

- f. References to "Regulation (EU) 2016/679", "Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)"and "that Regulation" are all replaced by "UK Data Protection Laws". References to specific Article(s) of "Regulation (EU) 2016/679" are replaced with the equivalent Article or Section of UK Data Protection Laws;
- 9. References to Regulation (EU) 2018/1725 are removed;
- h. References to the "European Union", "Union", "EU", "EU Member State", "Member State" and "EU or Member State" are all replaced with the "UK";
- i. The reference to "Clause 12(c)(i)" at Clause 10(b)(i) of Module one, is replaced with "Clause 11(c)(i)";
- j. Clause 13(a) and Part C of Annex I are not used;
- k. The "competent supervisory authority" and "supervisory authority" are both replaced with the "Information Commissioner":
- In Clause 16(e), subsection (i) is replaced with:

"the Secretary of State makes regulations pursuant to Section 17A of the Data Protection Act 2018 that cover the transfer of personal data to which these clauses apply;";

m. Clause 17 is replaced with:

"These Clauses are governed by the laws of England and Wales.";

n. Clause 18 is replaced with:

"Any dispute arising from these Clauses shall be resolved by the courts of England and Wales. A data subject may also bring legal proceedings against the data exporter and/or

	data importer before the courts of any country in the UK. The Parties agree to submit themselves to the jurisdiction of such courts."; and	
0.	The footnotes to the Approved EU SCCs do not form part of the Addendum, except for footnotes 8, 9, 10 and 11.	

#### Amendments to this Addendum

- 16. The Parties may agree to change Clauses 17 and/or 18 of the Addendum EU SCCs to refer to the laws and/or courts of Scotland or Northern Ireland.
- 17. If the Parties wish to change the format of the information included in Part 1: Tables of the Approved Addendum, they may do so by agreeing to the change in writing, provided that the change does not reduce the Appropriate Safeguards.
- 18. From time to time, the ICO may issue a revised Approved Addendum which:
  - a. makes reasonable and proportionate changes to the Approved Addendum, including correcting errors in the Approved Addendum; and/or
  - b. reflects changes to UK Data Protection Laws;

The revised Approved Addendum will specify the start date from which the changes to the Approved Addendum are effective and whether the Parties need to review this Addendum including the Appendix Information. This Addendum is automatically amended as set out in the revised Approved Addendum from the start date specified.

- 19. If the ICO issues a revised Approved Addendum under Section 18, if any Party selected in Table 4 "Ending the Addendum when the Approved Addendum changes", will as a direct result of the changes in the Approved Addendum have a substantial, disproportionate and demonstrable increase in:
  - a. its direct costs of performing its obligations under the Addendum; and/or
  - b. its risk under the Addendum.

and in either case it has first taken reasonable steps to reduce those costs or risks so that it is not substantial and disproportionate, then that Party may end this Addendum at the end of a reasonable notice period, by providing written notice for that period to the other Party before the start date of the revised Approved Addendum.

20. The Parties do not need the consent of any third party to make changes to this Addendum, but any changes must be made in accordance with its terms.

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

		As	of
		June 30,	December 31,
	Note	2024	2023
Assets			
Non-current assets			
Property, plant and equipment	5	2,926	3,376
Right-of-use assets	6	3,235	3,508
Intangible asset	8	50,416	50,416
Long-term financial assets	6	415	361
Total non-current assets		56,992	57,661
Current assets			
Prepaid expenses	9	3,864	6,437
Accrued income		402	246
Other current receivables		1,153	622
Accounts receivable	11		14,800
Short-term financial assets	10	123,560	24,554
Cash and cash equivalents	10	51,564	78,494
Total current assets	10	180,543	125,153
Total assets		237,535	182,814
Shareholders' equity and liabilities			
Shareholders' equity			
Share capital	12	2,212	2,089
Share premium		476,074	474,907
Treasury shares	12	(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	3	5,170	
Long-term lease liabilities	6	2,542	2,825
Net employee defined benefit liabilities	O .	5,868	5,770
Total non-current liabilities		13,580	8,595
Current liabilities			
Trade and other payables		1,435	1,679
Accrued expenses	7	11,895	11,087
Short-term deferred income		45	138
Short-term deferred contract revenue	3	86,468	_
Short-term lease liabilities	6	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,	
	Note	2024	2023	2024	2023
Revenue					
Contract revenue	3	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		$\overline{(20,961)}$	$\overline{(17,046)}$	$\overline{(41,029)}$	$\overline{(34,617)}$
Financial income	13	739	259	1,368	468
Financial expense	13	(34)	(27)	(70)	(124)
Exchange differences, net	13	(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:	4				
Basic and diluted loss per share for the period					
attributable to equity holders		(0.23)	(0.20)	(0.41)	(0.41)

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

		For the Th	ree Months	For the S	ix Months
		Ended J	June 30,	Ended J	une 30,
	Note	2024	2023	2024	2023
Loss for the period		(22,760)	$\overline{(16,833)}$	$\overline{(40,622)}$	(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)

# **Condensed Consolidated Statements of Changes in Equity (Unaudited)** (In CHF thousands)

		Share	Share	Treasury	Accumulated	Currency translation	
	Note	capital	premium	shares	losses	differences	Total
Balance as of January 1, 2023	11010	1,797	431,323	(124)	(264,015)	10	168,991
Net loss for the period				(12.)	(34,346)		(34,346)
Other comprehensive loss		_	_	_	(3 1,3 10)	(16)	(16)
Total comprehensive loss					(34,346)	(16)	(34,362)
10 <b></b> 00					(6 1,6 10)		(= 1,5 ==)
Share-based payments		_		_	2,701	_	2,701
Proceeds from sale of treasury shares					_,,,,		_,, , , _
in public offerings, net of							
underwriting fees and transaction							
costs		_	1,997	14	_	_	2,011
Issuance of shares, net of transaction							
costs:							
restricted share awards		3	388	_	(395)	_	(4)
exercise of options			(9)				(9)
Balance as of June 30, 2023		1,800	433,699	(110)	(296,055)	(6)	139,328
	Note	Share capital	Share premium	Treasury shares	Accumulated losses	Currency translation differences	Total
Balance as of January 1, 2024	Note			•		translation	Total 160,643
Balance as of January 1, 2024 Net loss for the period	Note	capital	premium	shares	losses	translation differences	
	Note	capital	premium	shares	losses (316,197)	translation differences	160,643
Net loss for the period	Note	capital	premium	shares	losses (316,197)	translation differences (51)	160,643 (40,622)
Net loss for the period Other comprehensive income Total comprehensive income/(loss)	Note	capital	premium	shares	losses   (316,197)   (40,622)	translation differences (51) — 16	160,643 (40,622) 16 (40,606)
Net loss for the period Other comprehensive income Total comprehensive income/(loss) Share-based payments	Note	capital	premium	shares	losses   (316,197)   (40,622)   —	translation differences (51) — 16	160,643 (40,622) 16
Net loss for the period Other comprehensive income Total comprehensive income/(loss)	<u>Note</u>	capital	premium	shares	losses   (316,197)   (40,622)	translation differences (51) — 16	160,643 (40,622) 16 (40,606)
Net loss for the period Other comprehensive income Total comprehensive income/(loss)  Share-based payments Proceeds from sale of treasury shares in public offerings, net of underwriting fees and transaction costs Issuance of shares to be held as		capital	premium 474,907 ————————————————————————————————————	shares (105) ————————————————————————————————————	losses   (316,197)   (40,622)	translation differences (51) — 16	160,643 (40,622) 16 (40,606) 3,277
Net loss for the period Other comprehensive income Total comprehensive income/(loss)  Share-based payments Proceeds from sale of treasury shares in public offerings, net of underwriting fees and transaction costs	12	<u>capital</u> 2,089	premium 474,907 ————————————————————————————————————	shares	losses   (316,197)   (40,622)	translation differences (51) — 16	160,643 (40,622) 16 (40,606) 3,277
Other comprehensive income Total comprehensive income/(loss)  Share-based payments Proceeds from sale of treasury shares in public offerings, net of underwriting fees and transaction costs Issuance of shares to be held as treasury shares Issuance of shares, net of transaction	12	<u>capital</u> 2,089	premium 474,907 ————————————————————————————————————	shares	losses   (316,197)   (40,622)	translation differences (51) — 16	160,643 (40,622) 16 (40,606) 3,277
Other comprehensive income Total comprehensive income/(loss)  Share-based payments Proceeds from sale of treasury shares in public offerings, net of underwriting fees and transaction costs Issuance of shares to be held as treasury shares Issuance of shares, net of transaction costs:	12	capital   2,089	premium 474,907 — — — — — — — — — — — — — — — — — — —	shares (105) ————————————————————————————————————	losses   (316,197)   (40,622)	translation differences (51) — 16	160,643 (40,622) 16 (40,606) 3,277

# **Condensed Consolidated Statements of Cash Flows (Unaudited)** (In CHF thousands)

		For the Si Ended J	
	Note	2024	2023
Operating activities			
Loss for the period		(40,622)	(34,346
Adjustments to reconcile net loss for the period to net cash flows:			
Depreciation of property, plant and equipment	5	767	842
Depreciation of right-of-use assets	6	337	269
Finance (income), net		110	(132
Share-based compensation expense		3,277	2,701
Change in net employee defined benefit liability		98	558
Interest expense		68	125
Changes in working capital:			
(Increase)/decrease in prepaid expenses	9	2,574	(471
(Increase)/decrease in accrued income		(156)	(267
(Increase)/decrease in accounts receivable	11	14,800	
(Increase)/decrease in other current receivables		(510)	89
(Decrease)/increase in accrued expenses	7	1,328	(633
(Decrease)/increase in deferred contract revenue, short-term	3	86,468	_
(Decrease)/increase in deferred income		(93)	(157
(Decrease)/increase in trade and other payables		(246)	433
(Decrease)/increase in deferred contract revenue, long-term	3	5,170	_
Cash from/(used in) operating activities		73,370	(30,989
Interest received		749	197
Interest paid		(60)	(120
Finance expenses paid		(8)	(5
Net cash flows from/(used in) operating activities		74,051	(30,917)
rect cash nows from/(used iii) operating activities		71,031	(30,717)
Investing activities			
Short-term financial assets, net	10	(99,006)	38,000
Purchases of property, plant and equipment	5	(317)	(355)
Rental deposits	6	(54)	_
Net cash flows (used in)/provided by investing activities		(99,377)	37,645
Financing activities	10	101	2.055
Proceeds from sale of treasury shares in public offerings, net of underwriting fees and transaction costs	12	131	2,057
Proceeds from issuance of common shares – equity plan, net of transaction costs		6	(13)
Transaction costs and stamp duty associated with the public offerings of common shares previously recorded in		(501)	
Accrued expenses		(521)	_
Transaction costs associated with the sale of treasury shares in public offering previously recorded in Accrued expenses		(26)	
Principal payments of lease obligations	6	(340)	(270)
Net cash flows provided by/(used in) financing activities		(750)	1,774
Net increase/(decrease) in cash and cash equivalents		(26,076)	8,502
Cash and cash equivalents at January 1		78,494	31,586
Exchange (loss)/gain on cash and cash equivalents		(854)	(81
Cash and cash equivalents at June 30		51,564	40,007
		(26,076)	8,502
Net increase/(decrease) in cash and cash equivalents		(20,070)	0,502
Supplemental non-cash activity			
Transaction costs associated with the sale of treasury shares in public offering recorded in Accrued expenses	12	26	46

## Notes to the Interim Condensed Consolidated Financial Statements (Unaudited) (in CHF thousands, except share and per share amounts)

## 1. Corporate information

AC Immune SA was founded in 2003. The Company controls a fully-owned subsidiary, AC Immune USA, Inc. ("AC Immune USA" or "Subsidiary" and, together with AC Immune SA, "AC Immune," "ACIU," "Company," "we," "our," "ours," "us"), which was organized under the laws of Delaware, USA in June 2021. The Company and its Subsidiary form the Group.

AC Immune SA is a clinical-stage biopharmaceutical company leveraging our two proprietary technology platforms to discover, design and develop novel proprietary medicines and diagnostics for prevention and treatment of neurodegenerative diseases (NDD) associated with protein misfolding. Misfolded proteins are generally recognized as the leading cause of NDD, such as Alzheimer's disease (AD) and Parkinson's disease (PD), with common mechanisms and drug targets, such as amyloid beta (Abeta), Tau, alpha-synuclein (a-syn) and TDP-43. Our corporate strategy is founded upon a three-pillar approach that targets (i) AD, (ii) focused non-AD NDD including Parkinson's disease, ALS and NeuroOrphan indications and (iii) diagnostics. We use our two unique proprietary platform technologies, SupraAntigen (conformation-specific biologics) and Morphomer (conformation-specific small molecules), to discover, design and develop novel medicines and diagnostics to target misfolded proteins.

The Interim Condensed Consolidated Financial Statements of AC Immune SA as of and for the three and six months ended June 30, 2024 were authorized for issuance by the Company's Audit and Finance Committee on August 5, 2024.

## 2. Basis of preparation and changes to the Company's accounting policies

#### **Statement of compliance**

These Interim Condensed Consolidated Financial Statements as of June 30, 2024 and for the three and six months ended June 30, 2024 and 2023, have been prepared in accordance with International Accounting Standard 34 (IAS 34), *Interim Financial Reporting*, as issued by the International Accounting Standards Board (IASB), and such financial information should be read in conjunction with the audited consolidated financial statements in AC Immune's Annual Report on Form 20-F for the year ended December 31, 2023.

## **Basis of measurement**

These Interim Condensed Consolidated Financial Statements have been prepared under the historical cost convention.

## Functional and reporting currency

These Interim Condensed Consolidated Financial Statements and accompanying notes are presented in Swiss Francs (CHF), which is AC Immune SA's functional currency and the Group's reporting currency. The Company's subsidiary has a functional currency of the US Dollar (USD). The following exchange rates have been used for the translation of the financial statements of AC Immune USA:

			For th	e	
	Three Months		Six Months Ended		Year Ended
	Ended June 30,		June 30,		December 31,
	2024	2023	2024	2023	2023
CHF/USD					
Closing rate, USD 1	0.909	0.908	0.909	0.908	0.851
Weighted average exchange rate, USD 1	0.914	0.908	0.898	0.921	0.908

#### Critical judgments and accounting estimates

The preparation of the Company's Interim Condensed Consolidated Financial Statements in conformity with IAS 34 requires management to make judgments, estimates and assumptions that affect the amounts reported in the Interim Condensed Consolidated Financial Statements and accompanying notes, and the related application of accounting policies as it relates to the reported amounts of assets, liabilities, income and expenses.

The areas where AC Immune has had to make judgments, estimates and assumptions relate to (i) revenue recognition on Licensing and Collaboration Agreements (LCAs), (ii) clinical development accruals, (iii) net employee defined benefit liability, (iv) share-based compensation, (v) right-of-use assets and lease liabilities and (vi) our IPR&D asset (intangible asset). Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

#### Fair value of financial assets and liabilities

The Company's financial assets and liabilities are composed of receivables, short-term financial assets, cash and cash equivalents, trade payables, deferred contract revenue and lease liabilities. The fair value of these financial instruments approximates their respective carrying values due to the short-term maturity of these instruments, and are held at their amortized cost in accordance with IFRS 9, unless otherwise explicitly noted.

#### Accounting policies, new standards, interpretations and amendments adopted by the Company

The accounting policies adopted in the preparation of the Interim Condensed Consolidated Financial Statements are consistent with those followed in the preparation of the Company's annual consolidated financial statements for the year ended December 31, 2023.

As of January 1, 2024 the amendments to paragraphs 69 to 76 of IAS 1, Presentation of Financial Statements (IAS 1), as issued by the IASB became effective. The Company assessed the changes to the accounting standard and determined the amendments had an immaterial impact on the Company's financial statements. There are no other new IFRS standards, amendments or interpretations that are mandatory as of January 1, 2024 that are relevant to the Company. Additionally, in April 2024, the IASB issued IFRS 18 Presentation and Disclosure in Financial Statements (IFRS 18). The new standard on presentation and disclosure in the financial statements will change the structure of the statement of profit or loss, require disclosures for certain profit or loss performance measure that are reported outside of the financial statements, and will enhance principles on aggregation and disaggregation within the notes to the financial statements. This new standard will be effective for annual reporting periods beginning on January 1, 2027 and will require retroactive adoption. The Company is currently evaluating the new standard to determine how it will impact the presentation and disclosure in its financial statements.

## Going concern

The Company believes that it will be able to meet all of its obligations as they fall due for at least 12 months from the filing date of this Form 6-K, after considering the Company's cash position of CHF 51.6 million and short-term financial assets of CHF 123.6 million as of June 30, 2024. Hence, these unaudited Interim Condensed Consolidated Financial Statements have been prepared on a going-concern basis.

To date, the Company has financed its cash requirements primarily from its public offerings, share issuances, contract revenues from its LCAs and grants. The Company is a clinical stage company and is exposed to all the risks inherent to establishing a business. Inherent to the Company's business are various risks and uncertainties, including the substantial uncertainty as to whether current projects will succeed and our ability to raise additional capital as needed. These risks may require us to take certain measures such as delaying, reducing or eliminating certain programs. The Company's success may depend in part upon its ability to (i) establish and maintain a strong patent position and protection, (ii) enter into collaborations with partners in the pharmaceutical and biopharmaceutical industries, (iii)

successfully move its product candidates through clinical development, (iv) attract and retain key personnel and (v) acquire capital to support its operations.

## 3. Contract revenues and other operating income

For the three and six months ended June 30, 2024, AC Immune generated CHF 0.7 million in contract revenue compared with no contract revenue in the prior comparable periods, respectively.

	For the Thr	ee Months
	Ended J	une 30,
In CHF thousands, unaudited	2024	2023
Takeda	687	
Total contract revenue	687	_
	For the Si	
	Ended J	une 30,
In CHF thousands, unaudited	2024	2023
Takeda	687	
Total contract revenue	687	

## 3.1 Licensing and collaboration agreements

For a discussion of our licensing and collaboration agreements for the fiscal year ended December 31, 2023, please refer to Note 14.1 "Licensing and Collaboration agreements" of our Annual Report on Form 20-F for the year ended December 31, 2023 filed on March 14, 2024.

On January 22, 2024, the Company announced that the development of semorinemab and crenezumab in the collaboration agreements with Genentech, a member of the Roche Group, was terminated. These terminations became effective in April 2024.

Anti-Abeta Active Immunotherapy in AD – 2024 agreement Takeda Pharmaceuticals, USA, Inc.

In May 2024, the Company entered into a worldwide option and license agreement with Takeda Pharmaceuticals, USA, Inc. (Takeda) for our active immunotherapies targeting Abeta, including ACI-24.060 for the treatment of AD. AC Immune will be responsible for completing the ABATE trial. Following option exercise, Takeda would conduct and fund all further clinical development and be responsible for all global regulatory activities as well as worldwide commercialization. Under the terms of the agreement, AC Immune received an upfront payment of USD 100.0 (CHF 92.3) million in May 2024 and is eligible to receive an option exercise fee in the low-to-mid nine-figure USD range and additional potential development, commercial and sales-based milestones of up to approximately USD 2.1 (CHF 1.9) billion if all related milestones are achieved over the course of the agreement. Upon commercialization, AC Immune will be entitled to receive tiered mid-to-high teens percentages royalties on worldwide net sales.

Under the terms of the agreement, Takeda may terminate the agreement at any time by providing 90 days' notice to the Company. If not otherwise terminated, the agreement shall continue until Takeda decides not to exercise its license option or until the expiration of all royalty obligations as outlined in the contract.

AC Immune assessed this arrangement in accordance with IFRS 15 and concluded that Takeda is a customer. The Company identified the following performance obligations under the contract: (i) a license option and (ii) development, chemistry, manufacturing, and controls ("CMC") and regulatory activities as outlined in the development and CMC plans, which are necessary to deliver the data package to Takeda. AC Immune concluded that the license option is considered a material right, as the value of the license exceeds the option exercise fee, thereby considering it a distinct

performance obligation. The development, CMC, and regulatory activities are treated as one distinct performance obligation because the underlying activities are not distinguishable in the context of the contract and are inputs to an integrated development program that will generate valuable data and information for Takeda in determining whether to exercise the option.

At the agreement's execution, the transaction price included only the upfront and non-refundable consideration of USD 100.0 (CHF 92.3) million. At inception, none of the development milestones, which may occur prior to the Takeda option exercise, were included in the transaction price, as all milestone amounts were fully constrained. The Takeda option exercise payment and any future development and commercial milestone payments, and royalties following the Takeda option exercise were excluded from the initial transaction price at contract inception. The option exercise fee is considered variable consideration as it depends on Takeda's decision to exercise. In assessing that future development or commercial milestones are fully constrained, the Company considered numerous factors, including that the receipt of these milestones is contingent upon success in future clinical trials and the licensee's efforts, and thus not highly probable to obtain. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur, as they predominantly relate to the license that will be granted to Takeda upon exercise and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period as uncertain events are resolved or other changes in circumstances occur.

The valuation of each performance obligation involves estimates and assumptions, with the timing of revenue recognition determined by either delivery or the provision of services. In line with the allocation objective under IFRS 15, the Company allocated the USD 100.0 (CHF 92.3) million upfront payment within the transaction price to the license option and development, CMC, and regulatory activities, using the relative stand-alone selling price method. For the standalone selling price of the license option, the Company utilized an income-based approach, which included key assumptions such as the post-option development timeline and costs, revenue forecasts, discount rates, and probabilities of development and regulatory success. The standalone selling price for the development, CMC and regulatory activities was calculated using a cost-plus margin approach based on the estimated development timeline. The Company allocated the transaction price based on the relative standalone selling prices, assigning USD 87.4 (CHF 80.7) million to the license option and USD 12.6 (CHF 11.6) million to development, CMC, and regulatory activities.

The Company has deferred revenue recognition for the license option and will recognize the entirety of the revenue either when the option is exercised and Takeda obtains the exclusive license, or when the option expires. The Company will recognize revenue related to the development, CMC and regulatory performance obligation over the estimated period of completion of these obligations, using an input method reflecting the costs incurred relative to the total costs expected to be incurred.

During the three and six months ended June 30, 2024, the Company recorded contract revenue of CHF 0.7 million, reflecting its efforts under this agreement. As of June 30, 2024, the Company recorded CHF 91.6 million in deferred contract revenue related to the unsatisfied performance obligations under this agreement. The deferred contract revenue allocated to the license option is classified as short-term on the condensed consolidated balance sheets because, in accordance with IAS 1, the Company does not have the right to defer the settlement of that portion for at least twelve months after the reporting period. The deferred contract revenue allocated to development, CMC, and regulatory activities will be recognized over the remaining performance period and classified as either current or non-current on the condensed consolidated balance sheets, based on the expected timing of satisfaction of the performance obligations.

#### 3.2 Grant income

Grants from the Michael J. Fox Foundation

For a discussion of our Grants from the Michael J. Fox Foundation (MJFF) for the fiscal year ended December 31, 2023, please refer to Note 14.2 "Grant Income" of our Annual Report on Form 20-F for the year ended December 31, 2023 filed on March 14, 2024.

For the three months ended June 30, 2024 and 2023, the Company has recognized less than CHF 0.1 million and CHF 0.3 million in grant income, respectively. For the six months ended June 30, 2024 and 2023, the Company has recognized less than CHF 0.1 million and CHF 0.7 million in grant income, respectively.

## 4. Loss per share

	For the Th Ended J	
In CHF thousands except for share and per share data	2024	2023
Loss per share (EPS)		
Numerator		
Net loss attributable to equity holders of the Company	(22,760)	(16,833)
Denominator		
Weighted-average number of shares outstanding used to compute EPS basic and		
diluted attributable to equity holders	99,549,910	84,612,997
Basic and diluted loss per share for the period attributable to equity holders	(0.23)	(0.20)
	For the Si	x Months
	For the Si Ended J	
In CHF thousands except for share and per share data	- 0- 0-0	
In CHF thousands except for share and per share data  Loss per share (EPS)	Ended J	une 30,
	Ended J	une 30,
Loss per share (EPS)	Ended J	une 30,
Loss per share (EPS) Numerator	Ended J 2024	une 30, 2023
Numerator Net loss attributable to equity holders of the Company	Ended J 2024	une 30, 2023
Numerator Net loss attributable to equity holders of the Company Denominator	Ended J 2024	une 30, 2023

The weighted-average number of potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	For the Th Ended 3	ree Months June 30,
	2024	2023
Share options issued and outstanding	1,578,645	97,875
Restricted share awards subject to future vesting	1,631,911	1,213,703
	For the S Ended J	ix Months
	2024	2023
Share options issued and outstanding	1,659,854	97,875
Restricted share awards subject to future vesting		

## 5. Property, plant and equipment

The following table shows the movement in the net book values of property, plant and equipment for the six months ended June 30, 2024:

			As of J	une 30, 2024		
In CHF thousands	Furniture	IT equipment	Lab equipment	Leasehold improvements	Assets under construction	Total
Acquisition cost:						
Balance at December 31, 2023	309	2,168	10,233	1,662	_	14,372
Additions	15	45	214	43	_	317
Balance at June 30, 2024	324	2,213	10,447	1,705	_	14,689
Accumulated depreciation:						
Balance at December 31, 2023	(212)	(1,851)	(8,101)	(832)	_	(10,996)
Depreciation expense	(25)	(103)	(504)	(135)	_	(767)
Balance at June 30, 2024	(237)	(1,954)	(8,605)	(967)		(11,763)
Carrying amount:						
December 31, 2023	97	317	2,132	830		3,376
June 30, 2024	87	259	1,842	738	_	2,926

## 6. Right-of-use assets, long-term financial assets and lease liabilities

AC Immune recognized additions of less than CHF 0.1 million for its right-of-use of leased assets for the six months ended June 30, 2024.

Regarding lease liabilities, the amortization depends on the rate implicit in the contract or the incremental borrowing rate for the respective lease component. The weighted averages of the incremental borrowing rates are 3.5% for buildings, 3.3% for office equipment and 2.6% for IT equipment, respectively.

The following table shows the movements in the net book values of right-of-use of leased assets for the six months ended June 30, 2024:

		Office	IT	
In CHF thousands	Buildings	equipment	equipment	Total
Balance as of December 31, 2023	3,446	50	12	3,508
Additions and remeasurements	_	64	_	64
Depreciation	(318)	(12)	(7)	(337)
Balance as of June 30, 2024	3,128	102	5	3,235

There are no variable lease payments that are not included in the measurement of lease obligations. All extension options have been included in the measurement of lease obligations.

For the three and six months ended June 30, 2024, and 2023, the impact on the Company's condensed consolidated statements of income/(loss) and the condensed consolidated statements of cash flows is as follows:

	For the Thre	ee Months
	Ended Ju	ine 30,
In CHF thousands	2024	2023
Statements of income/(loss)		
Depreciation of right-of-use assets	169	134
Interest expense on lease liabilities	29	24
Expense for short-term leases and leases of low value	170	189
Total	368	347
Statements of cash flows		
Total cash outflow for leases	372	349
	For the Six	Months
	For the Six Ended Ju	
In CHF thousands		
In CHF thousands  Statements of income/(loss)	Ended Ju	ine 30,
	Ended Ju	ine 30,
Statements of income/(loss)	Ended Ju 2024	2023
Statements of income/(loss) Depreciation of right-of-use assets	Ended Ju 2024	2023 269
Statements of income/(loss) Depreciation of right-of-use assets Interest expense on lease liabilities	2024 337 59	2023 269 47
Statements of income/(loss)  Depreciation of right-of-use assets Interest expense on lease liabilities  Expense for short-term leases and leases of low value	337 59 363	269 47 488
Statements of income/(loss)  Depreciation of right-of-use assets Interest expense on lease liabilities  Expense for short-term leases and leases of low value	337 59 363	269 47 488

The following table presents the contractual undiscounted cash flows for lease obligations as of June 30, 2024:

	As of
In CHF thousands	June 30, 2024
Less than one year	789
1-3 years	1,550
3-5 years	1,155
Total	3,494

The Company also has deposits in escrow accounts totaling CHF 0.4 million for leases of the Company's premises as of both June 30, 2024 and December 31, 2023, respectively. These deposits are presented in Long-term financial assets on the Company's condensed consolidated balance sheets.

## 7. Accrued expenses

	As of		
In CHF thousands	June 30, 2024	December 31, 2023	
Accrued expenses	11,895	11,087	
Total accrued expenses	11,895	11,087	

Accrued expenses consists of accrued R&D costs, accrued payroll expenses and other accrued expenses totaling CHF 11.9 million and CHF 11.1 million as of June 30, 2024 and December 31, 2023, respectively.

## 8. Intangible assets

AC Immune's acquired IPR&D asset is a clinically-validated active vaccine candidate for the treatment of Parkinson's disease. The asset is not yet ready for use until the asset obtains market approval and is therefore not currently being amortized. The carrying amount and net book value are detailed below:

	As of June 30, 2024		2024 As of December 31, 202		2023	
	Gross			Gross		
	Carrying	Accumulated	Net Book	Carrying	Accumulated	Net Book
In CHF thousands	Amount	<b>Amortization</b>	Value	Amount	Amortization	Value
Acquired IPR&D asset	50,416		50,416	50,416		50,416
Total intangible assets	50,416		50,416	50,416		50,416

In accordance with IAS 36 *Impairment of Assets*, the IPR&D asset is reviewed at least annually for impairment by assessing the fair value less costs to sell (recoverable amount) and comparing this to the carrying value of the asset. The valuation is considered to be Level 3 in the fair value hierarchy in accordance with IFRS 13 *Fair Value Measurement* due to unobservable inputs used in the valuation. The Company has determined the IPR&D asset not to be impaired as of December 31, 2023. As of June 30, 2024, the Company did not identify any triggering events that could result in an impairment of the IPR&D asset.

## 9. Prepaid expenses

Prepaid expenses include prepaid R&D costs, administrative costs and employee social obligations totaling CHF 3.9 million and CHF 6.4 million as of June 30, 2024 and December 31, 2023, respectively.

#### 10. Cash and cash equivalents and short-term financial assets

The following table summarizes AC Immune's cash and cash equivalents and short-term financial assets as of June 30, 2024 and December 31, 2023:

	As of		
In CHF thousands	June 30, 2024	<b>December 31, 2023</b>	
Cash and cash equivalents	51,564	78,494	
Total cash and cash equivalents	51,564	78,494	
		As of	
In CHF thousands	June 30, 2024	As of December 31, 2023	
In CHF thousands Short-term financial assets due in one year or less			

For the six months ended June 30, 2024, the net investments associated with the short-term financial assets amounted to CHF 99.0 million, compared to net proceeds associated with the maturity of investments of CHF 38.0 million in the prior comparable period.

#### 11. Accounts receivable

As of June 30, 2024, the balance of accounts receivable is nil following the receipt of the CHF 14.8 million milestone payment from Janssen, which was due as of December 31, 2023.

#### 12. Share capital and Treasury shares

For a discussion of our at the market offering program with Jefferies LLC for the fiscal year ended December 31, 2023, please refer to Note 12 "Share capital" of our Annual Report on Form 20-F for the year ended December 31, 2023 filed on March 14, 2024.

In Q2 2024, the Company issued 5,700,000 registered shares to AC Immune USA, Inc. pursuant to a share agreement, which were subsequently repurchased to be held as treasury shares.

In Q2 2024, the Company sold 30,232 common shares previously held as treasury shares pursuant to the Sales Agreement, raising USD 0.1 (CHF 0.1) million, net of underwriting fees.

As of June 30, 2024 and December 31, 2023, the Company had 10,902,617 and 5,243,958 treasury shares remaining, respectively.

## 13. Finance result, net

For the three months ended June 30, 2024 and 2023, the net finance result amounted to a loss of CHF 1.8 million and a gain of CHF 0.2 million, respectively. The loss in 2024 is primarily due to unfavorable foreign currency exchange differences related to movement in the CHF versus foreign currencies, predominantly the US Dollar. It is partially offset by an increase in financial income due to higher interest received on net investments in short-term financial assets, attributed to more deposits in 2024 compared to the prior period.

For the six months ended June 30, 2024 and 2023, AC Immune recorded CHF 0.4 million and CHF 0.3 million in net financial gains, respectively. The increase in 2024 is primarily related to an increase in financial income due to higher interest received on net investments in short-term financial assets, attributed to more deposits in 2024 compared to the prior period. This is partially offset by unfavorable foreign currency exchange differences related to movement in the CHF versus foreign currencies, predominantly the US Dollar.

## 14. Subsequent events

Management has evaluated subsequent events after the balance sheet date, through the issuance of these Interim Condensed Consolidated Financial Statements, for appropriate accounting and disclosures. The Company has determined that there were no other such events that warrant disclosure or recognition in these Interim Condensed Consolidated Financial Statements.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This management's discussion and analysis is designed to provide you with a narrative explanation of our financial condition and results of operations. We recommend that you read this in conjunction with our unaudited interim condensed consolidated financial information as of and for the three and six months ended June 30, 2024, included as Exhibit 99.1 to this Report on Form 6-K. We also recommend that you read our management's discussion and analysis and our audited consolidated financial statements and the notes thereto, which appear in our Annual Report on Form 20-F for the year ended December 31, 2023 on file with the U.S. Securities and Exchange Commission (the "SEC").

Unless otherwise indicated or the context otherwise requires, the terms "Company," "AC Immune," "ACIU," "we," "our," "ours," or "us" refer to AC Immune SA together with its fully-owned subsidiary, AC Immune USA, Inc.

We prepare and report our consolidated financial statements and financial information in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). None of our consolidated financial statements were prepared in accordance with generally accepted accounting principles in the United States. We maintain our books and records in Swiss Francs (CHF). We have made rounding adjustments to some of the figures included in this management's discussion and analysis. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that precede them. Unless otherwise indicated, all references to currency amounts in this discussion and analysis are in Swiss Francs.

This discussion and analysis is dated as of August 6, 2024.

#### **Business Overview**

Our goal is to continue leveraging our proprietary discovery platforms, SupraAntigen and Morphomer, to shift the treatment paradigm for neurodegenerative diseases towards Precision Medicine and disease prevention. We are executing a clear business strategy built on three pillars: (i) accelerate development of novel therapeutics in Alzheimer's disease (AD) with our partners; (ii) expand our strategic focus on Parkinson' disease (PD) and non-AD neurodegenerative diseases, including NeuroOrphan indications; and (iii) a continued focus on diagnostics enabling Precision Medicine to be an ultimate differentiator for the Company.

Our three-pillar execution strategy reflects our unique Precision Medicine approach, which ultimately creates differentiation due to our ability to address the high levels of co-pathologies present in AD and other neurodegenerative diseases. Much like cancer, neurodegenerative diseases are heterogeneous and may require multiple therapeutic interventions tailored to patients' specific disease drivers, to be used in combination in order to slow or stop the disease course. Ultimately, it is our belief that Precision Medicine will increase the chance of treatment success by enabling clinical trial participants to be better defined by their various proteinopathies, allowing for treatment with the right therapies at the right time.

Leveraging our dual proprietary technology platforms, SupraAntigen and Morphomer, we have built a comprehensive pipeline of first-in-class or best-in-class candidates spanning multiple treatment modalities and targeting both established and emerging neurodegenerative pathologies. We are currently advancing numerous therapeutic and diagnostic programs, including one in a Phase 3 clinical trial and three in Phase 2 clinical trials, targeting five different types of misfolded pathological proteins related to AD, PD and other neurodegenerative disorders. Our pipeline assets are further validated by the multiple partnerships we have established with leading global pharmaceutical companies. We believe our clinically validated technology platforms and multi-target, multimodal approach position AC Immune to revolutionize the treatment of neurodegenerative diseases by shifting the paradigm towards Precision Medicine and disease prevention.

Our clinical-stage product candidates include:

• ACI-24.060 for AD and for AD in DS. ACI-24.060 is an enhanced formulation of an earlier version of ACI-24 which incorporates Abeta-unrelated T-helper cell epitopes to increase the magnitude and the boostability of the antibody response against pathologic Abeta. ACI-24.060 is currently being tested at 3 different incremental doses in the ABATE Phase 1b/2 trial (NCT05462106) and amyloid plaque reduction is being assessed using Abeta-PET imaging.

ABATE is a multicenter, adaptive, double-blind, randomized, placebo-controlled study designed to assess the safety, tolerability, immunogenicity, and pharmacodynamic effects of ACI-24.060 in subjects with prodromal AD and in adults with Down Syndrome (DS). The Clinical Trial Application (CTA) was approved by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and Spanish Agency for Medicines and Health Products (AEMPS) with the first AD patient dosed in June 2022. In June 2023, AC Immune received Fast Track designation from the FDA for ACI-24.060, for the treatment of AD. This followed FDA clearance of the Investigational New Drug (IND) application in May 2023 enabling the ABATE study to include clinical trial sites to enroll participants with DS in the U.S. Based on the safety profile and induction of an anti-Abeta antibody response post-dosing of ACI-24.060 in patients with AD, dosing of the first individual with DS occurred in June 2023.

As announced on May 13, 2024, this program is the subject of an exclusive option and license agreement with Takeda Pharmaceuticals USA, Inc. (Takeda). Under the terms of the agreement, AC Immune received an upfront payment of USD 100.0 (CHF 92.3) million from Takeda and is eligible to receive payments of up to approximately USD 2.1 (CHF 1.9) billion including an option exercise fee in the low-to-mid nine-figure USD range and potential development, commercial and sales-based milestone payments. Upon commercialization, AC Immune will be entitled to receive tiered mid-to-high teens percentages royalties on worldwide net sales. Further details related to the agreement are available on the Current Report on Form 6-K furnished by the Company on May 13, 2024 with the SEC.

- ACI-7104.056. ACI-7104.056, the optimized formulation of the clinically-validated PD anti-a-syn active immunotherapy PD01A, is currently being tested in a placebo-controlled, double-blind, adaptive, biomarker-based Phase 2 study (VacSYn; NCT06015841) in the EU and in the UK. This trial is evaluating the safety and immunogenicity of ACI-7104.056 against a-syn and pathological a-syn species in early PD. Additionally, disease-specific imaging and fluid biomarkers and progression of motor and non-motor symptoms of PD will be monitored. The VacSYn trial commenced in July 2023 with the dosing of the first patient, and enrollment of cohort 1 was completed in December 2023, with 16 patients randomized. No safety concerns have been reported to date.
- ACI-35.030 (JNJ-64042056). AC Immune and Janssen Pharmaceuticals, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson, evaluated the anti-phosphorylated-Tau (anti-pTau) active immunotherapy ACI-35.030 in a Phase 1b/2a study in subjects with early AD (NCT04445831). Results showed that ACI-35.030 immunization generated a rapid antibody response (anti-pTau, anti-ePHF and anti-Tau IgG) after the first injection (at week 2) at the 3 tested doses. An apparent dose-effect was observed between low- and mid-doses but not between the mid- and high-doses. A boosting effect was observed after each injection especially against pathological Tau species (pTau and ePHF). The antibody response was strongly directed against pathological Tau species but not against non-phosphorylated Tau. Long-term maintenance of the anti-ePHF IgG titers against endogenous pathological Tau was observed at the mid- and high-dose.

In addition to ACI-35.030, an exploratory alternative anti-pTau active immunotherapy candidate, JACI-35.054, was also evaluated in the same Phase 1b/2a trial. It generated a more varied antibody response (anti-pTau, anti-ePHF and anti-Tau IgG) after the second injection (at week 10) at the 2 tested doses. While there was no apparent dose-effect between the 2 tested doses, a higher variability of titers was observed at the low dose. A boosting effect was seen against both pathological Tau and non-phosphorylated Tau species from the 2nd injection. For JACI-35.054, there was a lower extent of specific antibody response against pathological Tau species compared to non-phosphorylated Tau as observed with ACI-35.030. Both ACI-35.030 and JACI-35.054

showed good safety and tolerability profiles. The majority of adverse events (AEs) were of mild intensity. No deaths were reported. No AE led to study discontinuation or to study treatment discontinuation. Injection site

reactions were the most frequently reported AEs in actively treated subjects. Serious adverse events (SAEs) observed in subjects treated with ACI-35.030 did not appear to have any particular relationship to the dose.

Consequently, ACI-35.030, targeting pathological phosphorylated Tau (pTau), is being advanced and will be assessed in subjects with preclinical (i.e., pre-symptomatic) AD in a Phase 2b study in which the first patient will be dosed imminently. The trial will randomize approximately 500 participants with confirmed early-stage Tau pathology, who will be treated over a four-year period. The trial will include interim analyses potentially allowing for acceleration towards a regulatory filing. AC Immune's ACI-35.030 was granted Fast Track designation from the FDA, for the treatment of AD in July 2024.

- PI-2620. PI-2620 is the Tau-PET imaging agent discovered during the collaboration of AC Immune and Life Molecular Imaging (LMI). We are working with our partner, LMI, to advance PI-2620 as a highly differentiated, best-in-class Tau diagnostic for AD as well as non-AD Tauopathies such as progressive supranuclear palsy (PSP) and corticobasal degeneration (CBD). Results have demonstrated PI-2620's differentiated characteristics as a diagnostic tool for studying Tau-related diseases. Results on the use of PI-2620 in AD patients from an investigator sponsored Phase 2 trial at the Asan Medical Center (NCT03903211) were presented at the 2022 AAIC. Following these results, LMI moved PI-2620 into late-stage clinical development in AD and made a milestone payment. The first Alzheimer's patient in ADvance, the pivotal Phase 3 histopathology study in AD (NCT05641688), was imaged in January 2023.
- ACI-12589. Our Morphomer platform has delivered the first clinically validated a-syn-PET tracer which now can support the differential diagnosis of multiple system atrophy (MSA) from other neurodegenerative disease and allow precision medicine approaches and biomarker-based clinical development in this indication. ACI-12589 preclinical and clinical data were published in October 2023 in Nature Communications. In addition, medicinal chemistry optimization strategies have allowed the identification of our next-generation clinical candidate, ACI-15916. Compared to ACI-12589, ACI-15916 shows significantly higher target occupancy in brain slices from idiopathic forms of PD and has therefore the potential to enable imaging of a-syn pathology in patients with PD. IND/CTA-enabling studies for ACI-15196 were initiated in Q1 2024 with the regulatory submission planned in Q4 2024.
- Morphomer Tau aggregation inhibitors. In collaboration with our partner, Lilly, we are
  researching and developing small molecule Tau aggregation inhibitors with plans to evaluate
  candidates in AD and NeuroOrphan 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.
- Semorinemab. Semorinemab is an investigational monoclonal anti-Tau antibody that targets the Nterminal portion of the Tau protein and is designed to bind to Tau and slow its spread between neurons for the treatment of AD. As announced on January 22, 2024, the development of semorinemab in the collaboration agreement with Genentech, a member of the Roche Group, was terminated. This termination became effective in April 2024. Semorinemab has been studied in two Phase 2 studies: Tauriel in early (prodromal-to-mild) AD, where the primary efficacy endpoint was not met; and Lauriet in mild-to-moderate AD. In Lauriet, a strongly positive and highly statistically significant effect was seen on ADAS-Cog11 (one of two co-primary endpoints) plus statistically significant effects on several key biomarkers, including total Tau and pTau217 in CSF and plasma. The second co-primary endpoint, ADCS-ADL, and the secondary efficacy endpoints did not reach significance. Final open label extension results from the Lauriet trial will be reviewed when they become available and are received in full by AC Immune. The Company will then carefully review and evaluate available data sets, before decisions are made on potential further development and other opportunities.
- Crenezumab. Crenezumab is a humanized monoclonal antibody, an investigational treatment
  designed to slow AD progression by neutralizing neurotoxic Abeta oligomers. It was designed by
  AC Immune to be a conformation-specific monoclonal antibody targeting multiple forms of
  misfolded Abeta. As announced on January 22, 2024, the development of crenezumab in the

collaboration agreement with Genentech, a member of the Roche Group, was terminated. This termination became effective in April 2024. Crenezumab has an antibody backbone (IgG4) designed to minimize the inflammatory response in the brain, which may result in a lower incidence of side effects known as ARIA (Amyloid-Related Imaging Abnormalities). The investigational

medicine has demonstrated excellent safety (e.g. less than 1% of ARIA-E cases in the Phase 3 studies; Ostrowitzki et al., JAMA Neurology, 2022) and encouraging efficacy signals while undergoing extensive Phase 2 clinical testing. While the Colombian autosomal-dominant AD prevention trial was not sufficiently powered to show significant cognitive benefits, crenezumab was proven to be safe with numeric trends on the primary and vast majority of secondary and exploratory endpoints in its favor. The lessons from this study provided useful insights regarding the desired anti-amyloid immunotherapy profile and designs for prevention trials. AC Immune will carefully review and evaluate available data sets, before decisions are made on potential further development and other opportunities.

## **Interim 2024 Company 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 USD 100.0 (CHF 92.3) 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 USD 2.1 (CHF 1.9) 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<sup>TM</sup> 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 [<sup>18</sup>F]ACI-19626, a first-in-class TDP-43 PET tracer, presented by Tamara Seredenina (AC Immune), described the selection of [<sup>18</sup>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.

## **Results of Operations**

## Comparison of the three and six months ended June 30, 2024 and 2023

Contract revenues

The Company generated CHF 0.7 million in contract revenues for the three months ended June 30, 2024, compared to nil in the comparable prior period. This represents an increase of CHF 0.7 million. The following table summarizes our contact revenues during the three months ended June 30, 2024 and 2023:

	For the Thr	ee Months
	Ended June 30,	
In CHF thousands, unaudited	2024	2023
Takeda	687	_
Total contract revenue	687	

For the three months ended June 30, 2024, the increase of CHF 0.7 million compared with the prior period is due to the efforts made under the agreement with Takeda.

For the six months ended June 30, 2024, the Company generated CHF 0.7 million in contract revenues compared to nil in the comparable period. This represents an increase of CHF 0.7 million. The following table summarizes our contact revenues during the six months ended June 30, 2024 and 2023:

	For the Six Months	
	Ended June 30,	
In CHF thousands, unaudited	2024	2023
Takeda	687	_
Total contract revenue	687	

For the six months ended June 30, 2024, the increase of CHF 0.7 million compared with the prior period is due to the efforts made under the agreement with Takeda.

## Research and development expenses

Research and development (R&D) activities are essential to our business and represent the majority of our costs incurred. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using information from the clinical sites and our vendors. Our collaboration agreements have different arrangements to share costs for the development of our product candidates.

We have completed our co-development costs with Janssen for the Phase 1b/2a studies for our active immunotherapy, ACI-35.030 and JACI-35.054. AC Immune and Janssen will jointly share research and development costs for the first Phase 2b, however, AC Immune's contribution to the first Phase 2b trial is capped (and remaining costs for AC Immune are non-material). From Phase 2b and onwards, Janssen will assume responsibility for clinical development, manufacturing and commercialization.

We intend to increase our R&D costs associated with the advancement of our active immunotherapies, ACI-24.060 targeting Abeta in AD and AD in DS and ACI-7104.056 targeting a-syn in PD, through midand late-stage clinical development, as well as through investments in our diagnostic programs.

Finally, we intend to further advance the characterization of our other clinical and preclinical candidates, such as our Morphomer Tau program. In addition to the collaborative arrangements and proprietarily held assets, we expect that our total future R&D costs will increase over current levels, in line with our three-pillar strategy that focuses on (i) AD, (ii) expansion in PD and non-AD neurodegenerative diseases, including NeuroOrphan indications and (iii) diagnostics.

The table below provides a breakdown of our R&D costs, including direct R&D costs, manufacturing costs related to R&D and other R&D costs not allocated directly to programs for the periods covered by

these Interim Condensed Consolidated Financial Statements. The R&D costs not allocated to specific programs include employment costs,
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regulatory, quality assurance and intellectual property costs. We do not assign our internal costs, such as salary and benefits, share-based compensation expenses, laboratory supplies, and other direct expenses and infrastructure costs to individual R&D projects, because the employees within our R&D groups are typically deployed across multiple R&D programs.

For the three months ended June 30, 2024, R&D expenses totaled CHF 17.1 million compared with CHF 13.7 million for the comparable period in 2023. This represents an increase of CHF 3.4 million. The following table presents the R&D expenses during the three months ended June 30, 2024 and 2023:

	For the Thi		
	Ended June 30,		
In CHF thousands, unaudited	2024	2023	Change
Discovery and preclinical expenses	2,743	2,283	460
Clinical expenses	5,884	3,159	2,725
Group function expenses	586	317	269
Total direct R&D expenses	9,213	5,759	3,454
Payroll expenses	5,035	5,077	(42)
Share-based compensation	608	559	49
Other non-allocated	2,282	2,287	(5)
Total R&D expenses	17,138	13,682	3,456
	For the Three Months		
	Ended J	une 30,	
In CHF thousands, unaudited	2024	2023	Change
Operating expenses <sup>1</sup>	11,495	8,046	3,449
Salaries and related costs <sup>2</sup>	5,643	5,636	7

<sup>&</sup>lt;sup>1</sup> Includes depreciation expense

**Total R&D expenses** 

For the three months ended June 30, 2024:

Discovery and preclinical expenses increased by CHF 0.5 million, primarily due to:

• an increase in ACI-24.060 of CHF 0.3 million due to ongoing preclinical activities, which had not started in the prior comparative period.

17,138

13,682

3,456

Clinical expenses increased by CHF 2.7 million, primarily due to:

 an increase of CHF 1.4 million attributed to the ramp-up of activities for our Phase 2 VacSYn study evaluating ACI-7104.056 in early PD and CHF 1.3 million in our ACI-24.060 active immunotherapy for expansion of the ABATE study.

The variances in Group function expenses are related to regulatory and quality assurance, and intellectual property costs.

Other non-allocated expenses are related to infrastructure and functional expenses not allocated to direct R&D expenses.

<sup>&</sup>lt;sup>2</sup> Includes share-based compensation expense

For the six months ended June 30, 2024, R&D expenses totaled CHF 32.3 million compared with CHF 27.6 million for the comparable period in 2023. This represents an increase of CHF 4.7 million. The following table presents the R&D expenses during the six months ended June 30, 2024 and 2023:

	For the Six Months Ended June 30,			
In CHF thousands, unaudited	2024	2023	Change	
Discovery and preclinical expenses	4,980	4,756	224	
Clinical expenses	10,583	5,898	4,685	
Group function expenses	948	785	163	
Total direct R&D expenses	16,511	11,439	5,072	
Payroll expenses	10,163	9,973	190	
Share-based compensation	1,247	1,217	30	
Other non-allocated	4,382	4,926	(544)	
Total R&D expenses	32,303	27,555	4,748	
	For the Si	x Months		
	Ended J	une 30,		
In CHF thousands, unaudited	2024	2023	Change	
Operating expenses <sup>1</sup>	20,893	16,365	4,528	
Salaries and related costs <sup>2</sup>	11,410	11,190	220	
Total R&D expenses	32,303	27,555	4,748	

Includes depreciation expense

For the six months ended June 30, 2024:

Clinical expenses increased by CHF 4.7 million, primarily due to:

• an increase of CHF 3.0 million in our ACI-24.060 active immunotherapy for expansion of the ABATE study and CHF 1.7 million attributed to the ramp-up of activities for our Phase 2 VacSYn study evaluating ACI-7104.056 in early PD.

The variances in Group function expenses are related to regulatory and quality assurance, and intellectual property costs.

Other non-allocated expenses are related to infrastructure and functional expenses not allocated to direct R&D expenses.

General and administrative expenses

General and administrative expenses consist of salaries and related costs, including share-based compensation, professional fees such as legal and accounting related services, infrastructure expenses, and other operating expenses.

For the three months ended June 30, 2024, general and administrative expenses totaled CHF 4.6 million compared with CHF 3.7 million for the comparable period in 2023. This represents an increase of CHF 0.9 million. The following table presents the general and administrative expenses during the three months ended June 30, 2024 and 2023:

	For the Three Months		
	Ended June 30,		
In CHF thousands, unaudited	2024	2023	Change
Operating expenses <sup>1</sup>	1,462	993	469
Salaries and related costs <sup>2</sup>	3,089	2,688	401
Total general and administrative expenses	4,551	3,681	870

<sup>&</sup>lt;sup>2</sup> Includes share-based compensation expense

Includes depreciation expe
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<sup>2</sup> Includes share-based compensation expense

For the three months ended June 30, 2024, this increase is primarily due to:

- an increase of CHF 0.5 million in operating expenses, predominantly due to a rise of CHF 0.4 million in legal fees related to business development and licensing activities.
- an increase of CHF 0.4 million in salaries and related costs, largely attributable to the higher expenses from equity awards granted in 2024, which have a higher fair value.

For the six months ended June 30, 2024, general and administrative expenses totaled CHF 9.5 million compared with CHF 7.8 million for the comparable period in 2023. This represents an increase of CHF 1.7 million. The following table presents the general and administrative expenses during the six months ended June 30, 2024 and 2023:

	For the Six Months			
	Ended June 30,			
In CHF thousands, unaudited	2024	2023	Change	
Operating expenses <sup>1</sup>	3,377	2,271	1,106	
Salaries and related costs <sup>2</sup>	6,145	5,516	629	
Total general and administrative expenses	9,522	7,787	1,735	

Includes depreciation expense

For the six months ended June 30, 2024, this increase is primarily due to:

- an increase of CHF 1.1 million in operating expenses, predominantly due to a rise of CHF 0.9 million in legal fees related to business development and licensing activities.
- an increase of CHF 0.6 million in salaries and related costs, largely attributable to the higher expenses from equity awards granted in 2024, which have a higher fair value.

Other operating income/(expense), net

Other operating income/(expense), net consists primarily of income associated with foundation grants such as those from the MJFF or Target ALS.

For the three months ended June 30, 2024, other operating income/(expense), net totaled less than CHF 0.1 million compared with CHF 0.3 million for the comparable period in 2023. This represents a decrease of CHF 0.3 million. The following table presents the other operating income/(expense), net during the three months ended June 30, 2024 and 2023:

	For the Three Months		
	Ended June 30,		
In CHF thousands, unaudited	2024	2023	Change
Other operating income/(expense), net	41	317	(276)
Total other operating income/(expense), net	41	317	(276)

For the three months ended June 30, 2024, the decrease of CHF 0.3 million in grant income primarily resulted from activities related to our MJFF awards that were completed prior to the start of the current period.

Includes share-based compensation expense

For the six months ended June 30, 2024, other operating income/(expense), net totaled CHF 0.1 million compared with CHF 0.7 million for the comparable period in 2023. This represents a decrease of CHF 0.6 million. The following table presents the other operating income/(expense), net during the six months ended June 30, 2024 and 2023:

	For the Six Months		
	Ended June 30,		
In CHF thousands, unaudited	2024	2023	Change
Other operating income/(expense), net	109	725	(616)
Total other operating income/(expense), net	109	725	(616)

For the six months ended June 30, 2024, the decrease of CHF 0.6 million in grant income primarily resulted from activities related to our MJFF awards that were completed prior to the start of the current period.

Finance result, net

For the three months ended June 30, 2024, net finance result was a CHF 1.8 million loss compared with a CHF 0.2 million gain for the comparable period in 2023. This represents a decrease of CHF 2.0 million. The following table presents the net finance result during the three months ended June 30, 2024 and 2023:

	For the Three Months		
	Ended June 30,		
In CHF thousands, unaudited	2024	2023	Change
Financial income	739	259	480
Financial expense	(34)	(27)	(7)
Exchange differences, net	(2,504)	(16)	(2,488)
Finance result, net	(1,799)	216	(2,015)

For the three months ended June 30, 2024, the change in net finance result of CHF 2.0 million primarily related to:

• a loss of CHF 2.5 million explained by unfavorable foreign currency exchange differences related to movement in the CHF versus foreign currencies, predominantly the US Dollar.

This was partially offset by:

 an increase of CHF 0.5 million in financial income due to higher interest received on net investments in short-term financial assets, attributed to more deposits in 2024 compared to the prior period.

For the six months ended June 30, 2024, net finance result was a CHF 0.4 million gain compared with a CHF 0.3 million gain for the comparable period in 2023. This represents an increase of CHF 0.1 million. The following table presents the net finance result during the six months ended June 30, 2024 and 2023:

	For the Six Months		
	Ended June 30,		
In CHF thousands, unaudited	2024	2023	Change
Financial income	1,368	468	900
Financial expense	(70)	(124)	54
Exchange differences, net	(891)	(67)	(824)
Finance result, net	407	277	130

For the six months ended June 30, 2024, the increase of CHF 0.1 million in finance result, net primarily related to:

• an increase of CHF 0.9 million in financial income due to higher interest received on net investments in short-term financial assets, attributed to more deposits in 2024 compared to the prior period.

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• a loss of CHF 0.9 million explained by unfavorable foreign currency exchange differences related to movement in the CHF versus foreign currencies, predominantly the US Dollar.

#### Liquidity and Capital Resources

To date, the Company has financed its cash requirements primarily from its public offerings, share issuances, contract revenues from license and collaboration agreements (LCAs) and grants. The Company is a clinical stage company and is exposed to all the risks inherent to establishing a business. Inherent to the Company's business are various risks and uncertainties, including the substantial uncertainty as to whether current projects will succeed and our ability to raise additional capital as needed. These risks may require us to take certain measures such as delaying, reducing or eliminating certain programs. The Company's success may depend in part upon its ability to (i) establish and maintain a strong patent position and protection, (ii) enter into collaborations with partners in the pharmaceutical and biopharmaceutical industries, (iii) successfully move its product candidates through clinical development, (iv) attract and retain key personnel and (v) acquire capital to support its operations. As of June 30, 2024, we had cash and cash equivalents of CHF 51.6 million and short-term financial assets of CHF 123.6 million for a total liquidity balance of CHF 175.2 million.

Our primary uses of capital are, and we expect will continue to be, R&D expenses, compensation and related expenses and other operating expenses including rent. Cash and cash equivalents used to fund operating expenses are impacted by the timing of when we pay expenses, as reflected in the change in our outstanding trade and other payables and accrued expenses. We expect to incur substantial expenses in connection with our product candidates in various stages of clinical development. We and Janssen have completed the co-development of the second-generation lead active immunotherapies, ACI-35.030 and JACI-35.054, through Phase 1b/2a. In November 2022, it was announced that ACI-35.030 was selected to advance into further development based on interim data from the ongoing Phase 1b/2a trial. In December 2023, it was announced that Janssen has programmed the launch of a Phase 2b clinical study to evaluate ACI-35.030 (JNJ-64042056) in patients with preclinical AD, those individuals not yet showing symptoms. AC Immune and Janssen will jointly share research and development costs until the completion of the first Phase 2b, however AC Immune's contribution to the first Phase 2b trial is capped (and remaining costs for AC Immune are non-material). From Phase 2b and onwards, Janssen will assume responsibility for the clinical development, manufacturing and commercialization of ACI-35.030. We intend to increase our R&D costs associated with the advancement of the active immunotherapies, ACI-24.060 targeting Abeta in AD and AD in DS and ACI-7104.056 targeting a-syn in PD, through clinical development, as well as through investments in our diagnostic programs.

We plan to continue to fund our operating and capital funding needs through proceeds received from licensing and collaboration agreements (LCAs) and through equity or other forms of financing. For example, in Q3 2020 we entered into the Open Market Sale Agreement (Sale Agreement) with Jefferies LLC (Jefferies), which provides that, upon the terms and subject to the conditions and limitations set forth in the Sale Agreement, we may elect to issue and sell, from time to time, shares of our common shares having an aggregate offering price of up to USD 80.0 (CHF 72.7) million through Jefferies acting as our sales agent. We first replaced this Sale Agreement in Q2 2021 to continue the ATM program and have subsequently replaced this Sale Agreement on August 6, 2024 to continue the ATM program under a new Registration Statement on Form F-3. Under each new Sale Agreement, Jefferies may sell the shares of common shares by any method permitted by law deemed to be an "at the market offering" as defined under the Securities Act of 1933, as amended, in privately negotiated transactions with our consent or in block transactions. Jefferies will use commercially reasonable efforts to sell the shares of common shares subject to the new Sales Agreement from time to time, consistent with its normal sales and trading practices, on mutually agreed terms. We will pay Jefferies a commission of up to 3.0% of the gross sales proceeds of any common shares sold through Jefferies under the new Sales Agreement. We are not obligated to make any sales of common shares under the new Sales Agreement.

We may also consider entering into additional LCAs and selectively partnering for clinical development and commercialization.

#### **Cash Flows**

The following table summarizes AC Immune's cash flows for the periods indicated:

	For the Six Months		
	Ended June 30,		
In CHF thousands, unaudited	2024	2023	Change
Net cash provided by/(used in):			
Operating activities	74,051	(30.917)	104,968
Investing activities	(99,377)	37,645	(137,022)
Financing activities	(750)	1,774	(2,524)
	<u> </u>		
Net increase/(decrease) in cash and cash equivalents	(26,076)	8,502	(34,578)

#### Operating activities

Net cash provided by operating activities was CHF 74.1 million for the six months ended June 30, 2024, compared with net cash used in operating activities of CHF 30.9 million for the six months ended June 30, 2023. The change in cash provided by operating activities for the six months ended June 30, 2024 was due to (i) the Company's reporting a net loss of CHF 40.6 million for the period, compared with a net loss of CHF 34.3 million for the same period in 2023, (ii) an increase of CHF 91.6 million in deferred contract revenue, resulting from the receipt of the upfront payment from our agreement with Takeda and (iii) the receipt of the CHF 14.8 million milestone payment from Janssen for the commencement of first Phase 2b clinical study.

#### *Investing activities*

Net cash used in investing activities was CHF 99.4 million for the six months ended June 30, 2024, compared with net cash provided by investing activities of CHF 37.6 million for the six months ended June 30, 2023. A net amount of CHF 99.0 million in short-term financial assets was invested in the current period compared to a net maturation of CHF 38.0 million in the comparable prior period.

#### Financing activities

Net cash used in financing activities was CHF 0.8 million for the six months ended June 30, 2024, compared with net cash provided by financing activities of CHF 1.8 million for the six months ended June 30, 2023. The change of CHF 2.6 million is primarily related to CHF 2.1 million received from proceeds from the sale of treasury shares in public offerings, net of underwriting fees and transaction costs in the prior period compared to CHF 0.1 million in the current period. Additionally, in 2024, the Company paid CHF 0.5 million in transaction costs and stamp duty associated with the public offerings of common shares that had been previously accrued.

#### Operating Capital Requirements and Plan of Operations

We do not expect to generate revenues from royalties based on product sales unless and until our partners or we obtain regulatory approval of, and successfully commercialize, our current or any future product candidates. As of June 30, 2024, we had cash and cash equivalents of CHF 51.6 million and short-term financial assets of CHF 123.6 million, resulting in CHF 175.2 million of liquidity. The increase of CHF 72.1 million relative to December 31, 2023 was predominantly related to the receipt of the upfront payment of USD 100.0 (CHF 92.3) million from Takeda as part of the option and license agreement for ACI-24.060 and the CHF 14.8 million milestone payment from Janssen for the commencement of first Phase 2b clinical study of ACI-35.030. This was partially offset by R&D spending on our major discovery and R&D programs, the strengthening of the Company's infrastructure, systems and organization and other operating expenditures. We believe that our existing capital resources, along with the assumed potential milestone payment of CHF 24.6 million related to achieving a non-disclosed enrollment target for our ACI-35.030, and no other milestones, will be sufficient to meet our projected operating requirements for three years. There can be no certainty as to the exact timing of future milestone payments (including option

exercise fees), or in fact, whether any of these will ever be made, given that they are contingent on clear milestones being reached or the option being exercised.

We expect to generate losses for the foreseeable future, and these losses could increase as we continue product development until we successfully achieve regulatory approvals for our product candidates and begin to commercialize

any approved products. We are subject to all the risks pertinent to the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. We anticipate that we will need substantial additional funding in connection with our continuing operations. If we need to raise additional capital to fund our operations and complete our ongoing and planned clinical studies, funding may not be available to us on acceptable terms, or at all.

Our future funding requirements will depend on many factors, including but not limited to the following:

- The scope, rate of progress, results and cost of our preclinical and clinical studies and other related activities, according to our long-term strategic plan;
- The cost of manufacturing clinical supplies and establishing commercial supplies of our product candidates and any other products we may develop;
- The cost, timing and outcomes of regulatory approvals;
- The costs and timing of establishing sales, marketing and distribution capabilities;
- The terms and timing of any collaborative, licensing and other arrangements that we may establish, including any required milestone and royalty payments thereunder;
- The emergence of competing technologies or other adverse market developments; and
- The potential cost and timing of managing, protecting, defending, and enforcing our portfolio of intellectual property.

Quantitative and Qualitative Disclosures about Market Risk

During the three and six months ended June 30, 2024, there were no significant changes to our quantitative and qualitative disclosures about market risk described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations – Quantitative and Qualitative Disclosures About Market Risk" in the Annual Report on Form 20-F.

Critical Judgments and Accounting Estimates

There have been no material changes to the significant accounting policies and estimates described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Judgments and Accounting Estimates" in the Annual Report on Form 20-F.

#### Cautionary Statement Regarding Forward Looking Statements

This discussion and analysis contains statements that constitute forward-looking statements. All statements other than statements of historical facts contained in this discussion and analysis, including statements regarding our future results of operations and financial position, business strategy, product candidates, product pipeline, ongoing and planned clinical studies, including those of our collaboration partners, regulatory approvals, R&D costs, timing and likelihood of success, as well as plans and objectives of management for future operations are forward-looking statements. Many of the forward-looking statements contained in this prospectus can be identified by the use of forward-looking words such as "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "will" and "potential," among others. Forward-looking statements appear in a number of places in this discussion and analysis and include, but are not limited to, statements regarding our intent, belief or current expectations. Forwardlooking statements are based on our management's beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified under the section entitled "Risk Factors" in our Annual Report on Form 20-F. These forward-looking statements speak only as of the date of this discussion and analysis, and are subject to a number of risks, uncertainties and assumptions as described under the sections in our Annual Report on Form 20-F entitled "Risk Factors" and in this discussion and analysis. Because forwardlooking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.



#### PRESS RELEASE

## 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 <sup>TM</sup> 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 [<sup>18</sup>F]ACI-19626, a first-in-class TDP-43 PET tracer, presented by Tamara Seredenina (AC Immune), described the selection of [<sup>18</sup>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	<ul> <li>Interim safety and immunogenicity update from the Phase 2 VacSYn study in Parkinson's disease expected in H2 2024</li> </ul>
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	<ul> <li>Phase 1 initiation expected in H2 2024</li> </ul>
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:

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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. Forwardlooking 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
Total non-current numbers		
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
	237,535	182,814
Total shareholders' equity and liabilities	251,333	102,014

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

	For the Th	For the Three Months Ended June 30,		For the Six Months	
	Ended J			une 30,	
	2024	2024 2023		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
Logg for the named	(22.760)	(16 922)	(40,622)	(24 246)
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)

#### 6 Months Ended **Document and Entity** Jun. 30, 2024 **Information Cover [Abstract]**

**Document Type** 

6-K **Entity Registrant Name** 

AC IMMUNE SA **Entity Central Index Key** 0001651625

**Document Period End Date** Jun. 30, 2024

Document Fiscal Period Focus Q2 **Document Fiscal Year Focus** 2024 **Amendment Flag** false Current Fiscal Year End Date --12-31

Consolidated Balance Sheets - CHF (SFr) SFr in Thousands	Jun. 30, 2024	4 Dec. 31, 2023
Non-current assets	GE 2.026	GE 2.256
Property, plant and equipment	SFr 2,926	SFr 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	- 0 - 1	
<u>Prepaid expenses</u>	3,864	6,437
Accrued income	402	246
Other current receivables	1,153	622
Accounts receivable	0	14,800
Short-term financial assets	123,560	24,554
Cash and cash equivalents	51,564	78,494
<u>Total current assets</u>	180,543	125,153
<u>Total assets</u>	237,535	182,814
<b>Shareholders' equity</b>		
Share capital	2,212	2,089
Share premium	476,074	474,907
<u>Treasury shares</u>	(218)	(105)
<u>Currency translation differences</u>	(35)	(51)
Accumulated losses	(354,608)	(316,197)
Total shareholders' equity	123,425	160,643
<b>Non-current liabilities</b>		
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
<b>Current liabilities</b>		
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	SFr 237,535	SFr 182,814

<b>Consolidated Statements of</b>	3 Months Ended		6 Mont	hs Ended
Income/(Loss) - CHF (SFr) SFr in Thousands	Jun. 30, 2024	Jun. 30, 2023	Jun. 30, 2024	Jun. 30, 2023
<b>Contract revenues and other operating income</b>				
Contract revenue	SFr 687		SFr 687	SFr 0
<u>Total revenue</u>	687		687	
Operating expenses				
Research & development expenses	(17,138)	SFr (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
<u>Total operating expenses</u>	(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, net	(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	SFr (22,760	) SFr (16,833)	SFr (40,622	) SFr (34,346)
Loss per share:				
Basic loss per share for the period attributable to equity holders	SFr (0.23)	SFr (0.20)	SFr (0.41)	SFr (0.41)
Diluted loss per share for the period attributable to equity holders	SFr (0.23)	SFr (0.20)	SFr (0.41)	SFr (0.41)

Consolidated Statements of Comprehensive Income/	3 Months Ended	6 Months Ended	
(Loss) - CHF (SFr) SFr in Thousands	Jun. 30, 2023	Jun. 30, 2024	Jun. 30, 2023
<b>Consolidated Statements of Comprehensive Income/(Loss)</b>			
Loss for the period	SFr (16,833)	SFr (40,622)	SFr (34,346)
Items that may be reclassified to income or loss in subsequent			
periods (net of tax):			
Currency translation differences	(8)	16	(16)
Total comprehensive loss (net of tax)	SFr (16,841)	SFr (40,606)	SFr (34,362)

Consolidated Statements of Changes in Equity - CHF (SFr) SFr in Thousands	Share capital	Share I premium	-	Accumulated losses	Currency translation differences	Total
Balance, beginning of period at Dec. 31, 2022		SFr	SFr	SFr (264,015)	SFr 10	SFr
N. 1. 0. 1 1	1,797	431,323	(124)	,		168,991
Net loss for the period				(34,346)	(4.6)	(34,346)
Other comprehensive income/(loss)					(16)	(16)
Total comprehensive loss (net of tax)				, ,	(16)	(34,362)
Share-based payments				2,701		2,701
Proceeds from sale of treasury shares in public offerings, net of underwriting fees and		1,997	14			2,011
transaction costs						
<b>Issuance of shares, net of transaction costs:</b>						
Restricted share awards	3	388		(395)		(4)
Exercise of options		(9)				(9)
Balance, end of period at Jun. 30, 2023	1,800	433,699	(110)	(296,055)	(6)	139,328
Balance, beginning of period at Dec. 31, 2023	2,089	474,907	(105)	(316,197)	(51)	160,643
Net loss for the period				(40,622)		(40,622)
Other comprehensive income/(loss)					16	16
Total comprehensive loss (net of tax)				(40,622)	16	(40,606)
Share-based payments				3,277		3,277
Proceeds from sale of treasury shares in						
public offerings, net of underwriting fees and		104	1			105
transaction costs						
<u>Issuance of shares to be held as treasury shares</u>	114		(114)			
Issuance of shares, net of transaction costs:						
Restricted share awards	9	1,057	0	(1,066)		0
Exercise of options	0	6				6
Balance, end of period at Jun. 30, 2024	SFr 2,212	SFr 476,074	SFr (218)	SFr (354,608)	SFr (35)	SFr 123,425

Consolidated Statements of Cash Flows - CHF (SFr) SFr in Thousands Operating activities		6 Months Ended Jun. 30, Jun. 30, 2024 2023		
Loss for the period	SFr	SFr		
Loss for the period	(40,622)			
Adjustments to reconcile net loss for the period to net cash flows:	(10,000)	(= 1,0 10)		
Depreciation of property, plant and equipment	767	842		
Depreciation of right-of-use assets	337	269		
Finance (income), net	110	(132)		
Share-based compensation expense	3,277	2,701		
Change in net employee defined benefit liability	98	558		
Interest expense	68	125		
Changes in working capital:				
(Increase)/decrease in prepaid expenses	2,574	(471)		
(Increase)/decrease in accrued income	(156)	(267)		
(Increase)/decrease in accounts receivable	14,800	,		
(Increase)/decrease in other current receivables	(510)	89		
(Decrease)/increase in accrued expenses	1,328	(633)		
(Decrease)/increase in deferred contract revenue, short-term	86,468			
(Decrease)/increase in deferred income	(93)	(157)		
(Decrease)/increase in trade and other payables	(246)	433		
(Decrease)/increase in deferred contract revenue, long-term	5,170			
Cash from/(used in) operating activities	73,370	(30,989)		
Interest received	749	197		
Interest paid	(60)	(120)		
Finance expenses paid	(8)	(5)		
Net cash flows from/(used in) operating activities	74,051	(30,917)		
Investing activities	•	, , ,		
Short-term financial assets, net	(99,006)	38,000		
Purchases of property, plant and equipment	(317)	(355)		
Rental deposits	(54)	, ,		
Net cash flows (used in)/provided by investing activities	(99,377)	37,645		
Financing activities				
Proceeds from sale of treasury shares in public offerings, net of underwriting fees and	121	2.057		
transaction costs	131	2,057		
Proceeds from issuance of common shares - equity plan, net of transaction costs	6	(13)		
Transaction costs and stamp duty associated with the public offerings of common shares	(521)			
previously recorded in Accrued expenses	(321)			
Transaction costs associated with the sale of treasury shares in public offering previously	(26)			
recorded in Accrued expenses	. ,			
Principal payments of lease obligations	(340)	(270)		
Net cash flows provided by/(used in) financing activities	(750)	1,774		
Net increase/(decrease) in cash and cash equivalents	(26,076)	8,502		

Cash and cash equivalents at beginning of period	78,494	31,586
Exchange (loss)/gain on cash and cash equivalents	(854)	(81)
Cash and cash equivalents at end of the period	51,564	40,007
Supplemental non-cash activity		
Transaction costs associated with the sale of treasury shares in public offering recorded in	SFr 26	SFr 46
Accrued expenses	51120	511 70

#### **Corporate information**

6 Months Ended Jun. 30, 2024

Corporate information
Corporate information

Notes to the Interim Condensed Consolidated Financial Statements (Unaudited) (in CHF thousands, except share and per share amounts)

#### 1. Corporate information

AC Immune SA was founded in 2003. The Company controls a fully-owned subsidiary, AC Immune USA, Inc. ("AC Immune USA" or "Sul AC Immune SA, "AC Immune," "ACIU," "Company," "we," "our," "ours," "us"), which was organized under the laws of Delaware, USA in Jun its Subsidiary form the Group.

AC Immune SA is a clinical-stage biopharmaceutical company leveraging our two proprietary technology platforms to discover, design and of medicines and diagnostics for prevention and treatment of neurodegenerative diseases (NDD) associated with protein misfolding. Misfolded protein recognized as the leading cause of NDD, such as Alzheimer's disease (AD) and Parkinson's disease (PD), with common mechanisms and drug tat (Abeta), Tau, alpha-synuclein (a-syn) and TDP-43. Our corporate strategy is founded upon a three-pillar approach that targets (i) AD, (ii) focused Parkinson's disease, ALS and NeuroOrphan indications and (iii) diagnostics. We use our two unique proprietary platform technologies, SupraAnt specific biologics) and Morphomer (conformation-specific small molecules), to discover, design and develop novel medicines and diagnostics to

The Interim Condensed Consolidated Financial Statements of AC Immune SA as of and for the three and six months ended June 30, 2024 we by the Company's Audit and Finance Committee on August 5, 2024.

Basis of preparation and changes to the Company's accounting policies

Basis of preparation and changes to the Company's accounting policies

Basis of preparation and changes to the Company's

accounting policies

6 Months Ended Jun. 30, 2024

#### 2. Basis of preparation and changes to the Company's accounting policies

#### Statement of compliance

These Interim Condensed Consolidated Financial Statements as of June 30, 2024 and for the three and six months ended June 30, 2024 and 2 accordance with International Accounting Standard 34 (IAS 34), *Interim Financial Reporting*, as issued by the International Accounting Standard financial information should be read in conjunction with the audited consolidated financial statements in AC Immune's Annual Report on Form 2 December 31, 2023.

#### **Basis of measurement**

These Interim Condensed Consolidated Financial Statements have been prepared under the historical cost convention.

#### Functional and reporting currency

These Interim Condensed Consolidated Financial Statements and accompanying notes are presented in Swiss Francs (CHF), which is AC Imcurrency and the Group's reporting currency. The Company's subsidiary has a functional currency of the US Dollar (USD). The following exchant the translation of the financial statements of AC Immune USA:

		For the	
		Three Months Ended June 30,	
	2024	2023	2024
CHF/USD		_	
Closing rate, USD 1	0.909	0.908	0.909
Weighted average exchange rate, USD 1	0.914	0.908	0.898

#### Critical judgments and accounting estimates

The preparation of the Company's Interim Condensed Consolidated Financial Statements in conformity with IAS 34 requires management to estimates and assumptions that affect the amounts reported in the Interim Condensed Consolidated Financial Statements and accompanying notes application of accounting policies as it relates to the reported amounts of assets, liabilities, income and expenses.

The areas where AC Immune has had to make judgments, estimates and assumptions relate to (i) revenue recognition on Licensing and Colla (LCAs), (ii) clinical development accruals, (iii) net employee defined benefit liability, (iv) share-based compensation, (v) right-of-use assets and IPR&D asset (intangible asset). Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

#### Fair value of financial assets and liabilities

The Company's financial assets and liabilities are composed of receivables, short-term financial assets, cash and cash equivalents, trade paya revenue and lease liabilities. The fair value of these financial instruments approximates their respective carrying values due to the short-term mattand are held at their amortized cost in accordance with IFRS 9, unless otherwise explicitly noted.

### Accounting policies, new standards, interpretations and amendments adopted by the Company

The accounting policies adopted in the preparation of the Interim Condensed Consolidated Financial Statements are consistent with those fol the Company's annual consolidated financial statements for the year ended December 31, 2023.

As of January 1, 2024 the amendments to paragraphs 69 to 76 of IAS 1, Presentation of Financial Statements (IAS 1), as issued by the IASB Company assessed the changes to the accounting standard and determined the amendments had an immaterial impact on the Company's financial other new IFRS standards, amendments or interpretations that are mandatory as of January 1, 2024 that are relevant to the Company. Additionally issued IFRS 18 Presentation and Disclosure in Financial Statements (IFRS 18). The new standard on presentation and disclosure in the financial structure of the statement of profit or loss, require disclosures for certain profit or loss performance measure that are reported outside of the finance enhance principles on aggregation and disaggregation within the notes to the financial statements. This new standard will be effective for annual ron January 1, 2027 and will require retroactive adoption. The Company is currently evaluating the new standard to determine how it will impact to disclosure in its financial statements.

#### Going concern

The Company believes that it will be able to meet all of its obligations as they fall due for at least 12 months from the filing date of this Form Company's cash position of CHF 51.6 million and short-term financial assets of CHF 123.6 million as of June 30, 2024. Hence, these unaudited I Consolidated Financial Statements have been prepared on a going-concern basis.

To date, the Company has financed its cash requirements primarily from its public offerings, share issuances, contract revenues from its LCA Company is a clinical stage company and is exposed to all the risks inherent to establishing a business. Inherent to the Company's business are vauncertainties, including the substantial uncertainty as to whether current projects will succeed and our ability to raise additional capital as needed. to take certain measures such as delaying, reducing or eliminating certain programs. The Company's success may depend in part upon its ability to a strong patent position and protection, (ii) enter into collaborations with partners in the pharmaceutical and biopharmaceutical industries, (iii) successfully move its product candidates through clinical development, (iv) attract and retain key personnel and (v) acquire capital to support its of the company's successfully move its product candidates through clinical development, (iv) attract and retain key personnel and (v) acquire capital to support its of the company's success that the company is a contract revenues from its LCA.

## Contract revenues and other operating income

Contract revenues and other operating income

Contract revenues and other operating income

### 6 Months Ended Jun. 30, 2024

#### 3. Contract revenues and other operating income

For the three and six months ended June 30, 2024, AC Immune generated CHF 0.7 million in contract revenue compared with no contract revenue in the prior comparable periods, respectively.

For the Three Months Ended June 30,

In CHF thousands, unaudited	2024	2023
Takeda	687	
Total contract revenue	687	_
	For the Six	Months
	Ended J	une 30,
In CHF thousands, unaudited	2024	2023
Takeda	687	

#### 3.1 Licensing and collaboration agreements

For a discussion of our licensing and collaboration agreements for the fiscal year ended December 31, 2023, please refer to Note 14.1 "Licensing and Collaboration agreements" of our Annual Report on Form 20-F for the year ended December 31, 2023 filed on March 14, 2024.

On January 22, 2024, the Company announced that the development of semorinemab and crenezumab in the collaboration agreements with Genentech, a member of the Roche Group, was terminated. These terminations became effective in April 2024.

Anti-Abeta Active Immunotherapy in AD – 2024 agreement Takeda Pharmaceuticals, USA, Inc.

In May 2024, the Company entered into a worldwide option and license agreement with Takeda Pharmaceuticals, USA, Inc. (Takeda) for our active immunotherapies targeting Abeta, including ACI-24.060 for the treatment of AD. AC Immune will be responsible for completing the ABATE trial. Following option exercise, Takeda would conduct and fund all further clinical development and be responsible for all global regulatory activities as well as worldwide commercialization. Under the terms of the agreement, AC Immune received an upfront payment of USD 100.0 (CHF 92.3) million in May 2024 and is eligible to receive an option exercise fee in the low-to-mid nine-figure USD range and additional potential development, commercial and sales-based milestones of up to approximately USD 2.1 (CHF 1.9) billion if all related milestones are achieved over the course of the agreement. Upon commercialization, AC Immune will be entitled to receive tiered mid-to-high teens percentages royalties on worldwide net sales.

Under the terms of the agreement, Takeda may terminate the agreement at any time by providing 90 days' notice to the Company. If not otherwise terminated, the agreement shall continue until Takeda decides not to exercise its license option or until the expiration of all royalty obligations as outlined in the contract.

AC Immune assessed this arrangement in accordance with IFRS 15 and concluded that Takeda is a customer. The Company identified the following performance obligations under the

contract: (i) a license option and (ii) development, chemistry, manufacturing, and controls ("CMC") and regulatory activities as outlined in the development and CMC plans, which are necessary to deliver the data package to Takeda. AC Immune concluded that the license option is considered a material right, as the value of the license exceeds the option exercise fee, thereby considering it a distinct

performance obligation. The development, CMC, and regulatory activities are treated as one distinct performance obligation because the underlying activities are not distinguishable in the context of the contract and are inputs to an integrated development program that will generate valuable data and information for Takeda in determining whether to exercise the option.

At the agreement's execution, the transaction price included only the upfront and non-refundable consideration of USD 100.0 (CHF 92.3) million. At inception, none of the development milestones, which may occur prior to the Takeda option exercise, were included in the transaction price, as all milestone amounts were fully constrained. The Takeda option exercise payment and any future development and commercial milestone payments, and royalties following the Takeda option exercise were excluded from the initial transaction price at contract inception. The option exercise fee is considered variable consideration as it depends on Takeda's decision to exercise. In assessing that future development or commercial milestones are fully constrained, the Company considered numerous factors, including that the receipt of these milestones is contingent upon success in future clinical trials and the licensee's efforts, and thus not highly probable to obtain. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur, as they predominantly relate to the license that will be granted to Takeda upon exercise and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period as uncertain events are resolved or other changes in circumstances occur.

The valuation of each performance obligation involves estimates and assumptions, with the timing of revenue recognition determined by either delivery or the provision of services. In line with the allocation objective under IFRS 15, the Company allocated the USD 100.0 (CHF 92.3) million upfront payment within the transaction price to the license option and development, CMC, and regulatory activities, using the relative stand-alone selling price method. For the standalone selling price of the license option, the Company utilized an income-based approach, which included key assumptions such as the post-option development timeline and costs, revenue forecasts, discount rates, and probabilities of development and regulatory success. The standalone selling price for the development, CMC and regulatory activities was calculated using a cost-plus margin approach based on the estimated development timeline. The Company allocated the transaction price based on the relative standalone selling prices, assigning USD 87.4 (CHF 80.7) million to the license option and USD 12.6 (CHF 11.6) million to development, CMC, and regulatory activities.

The Company has deferred revenue recognition for the license option and will recognize the entirety of the revenue either when the option is exercised and Takeda obtains the exclusive license, or when the option expires. The Company will recognize revenue related to the development, CMC and regulatory performance obligation over the estimated period of completion of these obligations, using an input method reflecting the costs incurred relative to the total costs expected to be incurred.

During the three and six months ended June 30, 2024, the Company recorded contract revenue of CHF 0.7 million, reflecting its efforts under this agreement. As of June 30, 2024, the Company recorded CHF 91.6 million in deferred contract revenue related to the unsatisfied performance obligations under this agreement. The deferred contract revenue allocated to the license option is classified as short-term on the condensed consolidated balance sheets because, in accordance with IAS 1, the Company does not have the right to defer the settlement of that portion for at least twelve months after the reporting period. The deferred contract revenue allocated to development, CMC, and regulatory activities will be recognized over the remaining performance period and classified as either current or non-current on the condensed consolidated balance sheets, based on the expected timing of satisfaction of the performance obligations.

#### 3.2 Grant income

Grants from the Michael J. Fox Foundation

For a discussion of our Grants from the Michael J. Fox Foundation (MJFF) for the fiscal year ended December 31, 2023, please refer to Note 14.2 "Grant Income" of our Annual Report on Form 20-F for the year ended December 31, 2023 filed on March 14, 2024.

For the three months ended June 30, 2024 and 2023, the Company has recognized less than CHF 0.1 million and CHF 0.3 million in grant income, respectively. For the six months ended June 30, 2024 and 2023, the Company has recognized less than CHF 0.1 million and CHF 0.7 million in grant income, respectively.

### Loss per share

## 6 Months Ended Jun. 30, 2024

# Loss per share Loss per share

### 4. Loss per share

	For the Three Months		
	Ended J	une 30,	
In CHF thousands except for share and per share data	2024	2023	
Loss per share (EPS)			
Numerator			
Net loss attributable to equity holders of the Company	(22,760)	(16,833)	
Denominator			
Weighted-average number of shares outstanding used to compute			
EPS basic and diluted attributable to equity holders	99,549,910	84,612,997	
Basic and diluted loss per share for the period attributable to equity			
holders	(0.23)	(0.20)	
	For the Si	x Months	
	For the Si Ended J		
In CHF thousands except for share and per share data			
In CHF thousands except for share and per share data  Loss per share (EPS)	Ended J	une 30,	
	Ended J	une 30,	
Loss per share (EPS)	Ended J	une 30,	
Loss per share (EPS) Numerator	Ended J 2024	une 30, 2023	
Loss per share (EPS) Numerator Net loss attributable to equity holders of the Company	Ended J 2024	une 30, 2023	
Loss per share (EPS) Numerator Net loss attributable to equity holders of the Company Denominator	Ended J 2024	une 30, 2023	
Loss per share (EPS)  Numerator  Net loss attributable to equity holders of the Company  Denominator  Weighted-average number of shares outstanding used to compute	Ended J 2024 (40,622)	2023 (34,346)	
Loss per share (EPS)  Numerator  Net loss attributable to equity holders of the Company  Denominator  Weighted-average number of shares outstanding used to compute EPS basic and diluted attributable to equity holders	Ended J 2024 (40,622)	2023 (34,346)	

The weighted-average number of potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	For the Thi	ree Months
	Ended J	une 30,
	2024	2023
Share options issued and outstanding	1,578,645	97,875
Restricted share awards subject to future vesting	1,631,911	1,213,703
	For the Si	x Months
	Ended J	une 30,
	2024	2023
Share options issued and outstanding	1,659,854	97,875
Restricted share awards subject to future vesting	1,684,826	1,225,175

### Property, plant and equipment

Property, plant and equipment.

Property, plant and equipment 5. Property, plant and equipment

## 6 Months Ended Jun. 30, 2024

The following table shows the movement in the net book values of property, plant and equipment for the six months ended June 30, 2024:

			As of J	fune 30, 2024		
		IT	Lab	Leasehold	Assets under	
In CHF thousands	<u>Furniture</u>	equipment	equipment	improvements	construction	Total
Acquisition cost:						
Balance at						
<b>December 31, 2023</b>	309	2,168	10,233	1,662	_	14,372
Additions	15	45	214	43	_	317
Balance at June 30, 2024	324	2,213	10,447	1,705		14,689
Accumulated						
depreciation:						
Balance at						
<b>December 31, 2023</b>	(212)	(1,851)	(8,101)	(832)	_	(10,996)
Depreciation expense	(25)	(103)	(504)	(135)	_	(767)
Balance at June 30, 2024	(237)	(1,954)	(8,605)	(967)		(11,763)
					-	
Carrying amount:						
December 31, 2023	97	317	2,132	830	_	3,376
June 30, 2024	87	259	1,842	738	_	2,926

### Right-of-use assets, longterm financial assets and lease liabilities

Right-of-use assets, longterm financial assets and lease liabilities

Right-of-use assets, long-term 6. financial assets and lease liabilities

## 6 Months Ended Jun. 30, 2024

#### 6. Right-of-use assets, long-term financial assets and lease liabilities

AC Immune recognized additions of less than CHF 0.1 million for its right-of-use of leased assets for the six months ended June 30, 2024.

Regarding lease liabilities, the amortization depends on the rate implicit in the contract or the incremental borrowing rate for the respective lease component. The weighted averages of the incremental borrowing rates are 3.5% for buildings, 3.3% for office equipment and 2.6% for IT equipment, respectively.

The following table shows the movements in the net book values of right-of-use of leased assets for the six months ended June 30, 2024:

		Office	IT	
In CHF thousands	Buildings	equipment	equipment	Total
Balance as of December 31, 2023	3,446	50	12	3,508
Additions and remeasurements	_	64	_	64
Depreciation	(318)	(12)	(7)	(337)
Balance as of June 30, 2024	3,128	102	5	3,235

There are no variable lease payments that are not included in the measurement of lease obligations. All extension options have been included in the measurement of lease obligations.

For the three and six months ended June 30, 2024, and 2023, the impact on the Company's condensed consolidated statements of income/(loss) and the condensed consolidated statements of cash flows is as follows:

	For the Thre	ee Months
	Ended Ju	ıne 30,
In CHF thousands	2024	2023
Statements of income/(loss)		
Depreciation of right-of-use assets	169	134
Interest expense on lease liabilities	29	24
Expense for short-term leases and leases of low value	170	189
Total	368	347
Statements of cash flows		
Total cash outflow for leases	<u>372</u>	349
	TD 41 C*	3.5

	For the Six Months	
	Ended June 30,	
In CHF thousands	2024	2023
Statements of income/(loss)		
Depreciation of right-of-use assets	337	269
Interest expense on lease liabilities	59	47
Expense for short-term leases and leases of low value	363	488
Total	759	804

Statements of cash flows		
Total cash outflow for leases	762	805

The following table presents the contractual undiscounted cash flows for lease obligations as of June 30, 2024:

	As of
In CHF thousands	June 30, 2024
Less than one year	789
1-3 years	1,550
3-5 years	1,155
Total	3,494

The Company also has deposits in escrow accounts totaling CHF 0.4 million for leases of the Company's premises as of both June 30, 2024 and December 31, 2023, respectively. These deposits are presented in Long-term financial assets on the Company's condensed consolidated balance sheets.

### **Accrued expenses**

6 Months Ended Jun. 30, 2024

Trade and other payables and accrued expenses

Accrued expenses

### 7. Accrued expenses

	As of	
In CHF thousands	June 30, 2024	<b>December 31, 2023</b>
Accrued expenses	11,895	11,087
Total accrued expenses	11,895	11,087

Accrued expenses consists of accrued R&D costs, accrued payroll expenses and other accrued expenses totaling CHF 11.9 million and CHF 11.1 million as of June 30, 2024 and December 31, 2023, respectively.

### **Intangible assets**

Intangible assets
Intangible assets

### 6 Months Ended Jun. 30, 2024

#### 8. Intangible assets

AC Immune's acquired IPR&D asset is a clinically-validated active vaccine candidate for the treatment of Parkinson's disease. The asset is not yet ready for use until the asset obtains market approval and is therefore not currently being amortized. The carrying amount and net book value are detailed below:

	A	s of June 30, 202	24	As o	f December 31,	2023
	Gross			Gross		
	Carrying	Accumulated	Net Book	Carrying	Accumulated	Net Book
In CHF thousands	Amount	Amortization	Value	Amount	Amortization	Value
Acquired IPR&D asset	50,416	_	50,416	50,416		50,416
Total intangible assets	50,416		50,416	50,416		50,416

In accordance with IAS 36 *Impairment of Assets*, the IPR&D asset is reviewed at least annually for impairment by assessing the fair value less costs to sell (recoverable amount) and comparing this to the carrying value of the asset. The valuation is considered to be Level 3 in the fair value hierarchy in accordance with IFRS 13 *Fair Value Measurement* due to unobservable inputs used in the valuation. The Company has determined the IPR&D asset not to be impaired as of December 31, 2023. As of June 30, 2024, the Company did not identify any triggering events that could result in an impairment of the IPR&D asset.

### **Prepaid expenses**

6 Months Ended Jun. 30, 2024

Prepaid expenses and accrued income
Prepaid expenses

### 9. Prepaid expenses

Prepaid expenses include prepaid R&D costs, administrative costs and employee social obligations totaling CHF 3.9 million and CHF 6.4 million as of June 30, 2024 and December 31, 2023, respectively.

### Cash and cash equivalents and short-term financial assets

Cash and cash equivalents and financial assets

Cash and cash equivalents and short-term financial assets

## 6 Months Ended Jun. 30, 2024

### Cash and cash equivalents and 10. Cash and cash equivalents and short-term financial assets

The following table summarizes AC Immune's cash and cash equivalents and short-term financial assets as of June 30, 2024 and December 31, 2023:

	As of		
In CHF thousands	June 30, 2024	<b>December 31, 2023</b>	
Cash and cash equivalents	51,564	78,494	
Total cash and cash equivalents	51,564	78,494	
		As of	
In CHF thousands	June 30, 2024	<b>December 31, 2023</b>	
Chart tame financial agests due in one year on logs	122 560	24 554	
Short-term financial assets due in one year or less	123,560	24,554	

For the six months ended June 30, 2024, the net investments associated with the short-term financial assets amounted to CHF 99.0 million, compared to net proceeds associated with the maturity of investments of CHF 38.0 million in the prior comparable period.

### Accounts receivable

## 6 Months Ended Jun. 30, 2024

Accounts receivable

Accounts receivable

#### 11. Accounts receivable

As of June 30, 2024, the balance of accounts receivable is nil following the receipt of the CHF 14.8 million milestone payment from Janssen, which was due as of December 31, 2023.

# Share capital and Treasury shares

**Share capital and Treasury shares** 

Share capital and Treasury shares

### 6 Months Ended Jun. 30, 2024

#### 12. Share capital and Treasury shares

For a discussion of our at the market offering program with Jefferies LLC for the fiscal year ended December 31, 2023, please refer to Note 12 "Share capital" of our Annual Report on Form 20-F for the year ended December 31, 2023 filed on March 14, 2024.

In Q2 2024, the Company issued 5,700,000 registered shares to AC Immune USA, Inc. pursuant to a share agreement, which were subsequently repurchased to be held as treasury shares.

In Q2 2024, the Company sold 30,232 common shares previously held as treasury shares pursuant to the Sales Agreement, raising USD 0.1 (CHF 0.1) million, net of underwriting fees.

As of June 30, 2024 and December 31, 2023, the Company had 10,902,617 and 5,243,958 treasury shares remaining, respectively.

### Finance result, net

### 6 Months Ended Jun. 30, 2024

Finance result, net Finance result, net

#### 13. Finance result, net

For the three months ended June 30, 2024 and 2023, the net finance result amounted to a loss of CHF 1.8 million and a gain of CHF 0.2 million, respectively. The loss in 2024 is primarily due to unfavorable foreign currency exchange differences related to movement in the CHF versus foreign currencies, predominantly the US Dollar. It is partially offset by an increase in financial income due to higher interest received on net investments in short-term financial assets, attributed to more deposits in 2024 compared to the prior period.

For the six months ended June 30, 2024 and 2023, AC Immune recorded CHF 0.4 million and CHF 0.3 million in net financial gains, respectively. The increase in 2024 is primarily related to an increase in financial income due to higher interest received on net investments in short-term financial assets, attributed to more deposits in 2024 compared to the prior period. This is partially offset by unfavorable foreign currency exchange differences related to movement in the CHF versus foreign currencies, predominantly the US Dollar.

### **Subsequent events**

6 Months Ended Jun. 30, 2024

Subsequent events
Subsequent events

#### 14. Subsequent events

Management has evaluated subsequent events after the balance sheet date, through the issuance of these Interim Condensed Consolidated Financial Statements, for appropriate accounting and disclosures. The Company has determined that there were no other such events that warrant disclosure or recognition in these Interim Condensed Consolidated Financial Statements.

Basis of preparation and changes to the Company's accounting policies (Policies)

Summary of material accounting policies

Functional and reporting currency

6 Months Ended Jun. 30, 2024

#### Functional and reporting currency

These Interim Condensed Consolidated Financial Statements and accompanying notes are presented in Swiss Francs (CHF), which is AC Immune SA's functional currency and the Group's reporting currency. The Company's subsidiary has a functional currency of the US Dollar (USD). The following exchange rates have been used for the translation of the financial statements of AC Immune USA:

	For the				
	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
	2024	2023	2024	2023	2023
CHF/USD					
Closing rate, USD 1	0.909	0.908	0.909	0.908	0.851
Weighted average exchange rate, USD 1	0.914	0.908	0.898	0.921	0.908

# Critical judgments and accounting estimates

#### Critical judgments and accounting estimates

The preparation of the Company's Interim Condensed Consolidated Financial Statements in conformity with IAS 34 requires management to make judgments, estimates and assumptions that affect the amounts reported in the Interim Condensed Consolidated Financial Statements and accompanying notes, and the related application of accounting policies as it relates to the reported amounts of assets, liabilities, income and expenses.

The areas where AC Immune has had to make judgments, estimates and assumptions relate to (i) revenue recognition on Licensing and Collaboration Agreements (LCAs), (ii) clinical development accruals, (iii) net employee defined benefit liability, (iv) share-based compensation, (v) right-of-use assets and lease liabilities and (vi) our IPR&D asset (intangible asset). Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

# Fair value of financial assets and liabilities

#### Fair value of financial assets and liabilities

The Company's financial assets and liabilities are composed of receivables, short-term financial assets, cash and cash equivalents, trade payables, deferred contract revenue and lease liabilities. The fair value of these financial instruments approximates their respective carrying values due to the short-term maturity of these instruments, and are held at their amortized cost in accordance with IFRS 9, unless otherwise explicitly noted.

# Accounting policies, new standards, interpretations and amendments adopted by the Company

# Accounting policies, new standards, interpretations and amendments adopted by the Company

The accounting policies adopted in the preparation of the Interim Condensed Consolidated Financial Statements are consistent with those followed in the preparation of the Company's annual consolidated financial statements for the year ended December 31, 2023.

As of January 1, 2024 the amendments to paragraphs 69 to 76 of IAS 1, Presentation of Financial Statements (IAS 1), as issued by the IASB became effective. The Company assessed the changes to the accounting standard and determined the amendments had an immaterial impact

on the Company's financial statements. There are no other new IFRS standards, amendments or interpretations that are mandatory as of January 1, 2024 that are relevant to the Company. Additionally, in April 2024, the IASB issued IFRS 18 Presentation and Disclosure in Financial Statements (IFRS 18). The new standard on presentation and disclosure in the financial statements will change the structure of the statement of profit or loss, require disclosures for certain profit or loss performance measure that are reported outside of the financial statements, and will enhance principles on aggregation and disaggregation within the notes to the financial statements. This new standard will be effective for annual reporting periods beginning on January 1, 2027 and will require retroactive adoption. The Company is currently evaluating the new standard to determine how it will impact the presentation and disclosure in its financial statements.

# Basis of preparation and changes to the Company's accounting policies (Tables)

**Summary of material accounting policies** 

Schedule of exchange rates used for translation of financial statements

# 6 Months Ended Jun. 30, 2024

	For the														
	Three Months Ended June 30,		Six Months Ended June 30,												Year Ended December 31,
	2024	2023	2024	2023	2023										
CHF/USD															
Closing rate, USD 1	0.909	0.908	0.909	0.908	0.851										
Weighted average exchange rate,															
USD 1	0.914	0.908	0.898	0.921	0.908										

# Contract revenues and other operating income (Tables)

### 6 Months Ended Jun. 30, 2024

 $\underline{\textbf{Contract revenues and other operating income}}$ 

Schedule of contract revenues

For the Three Months			
Ended June 30,			
2024	2023		
687	_		
687			
	Ended J 2024 687		

	For the Six Months		
	Ended June 30,		
In CHF thousands, unaudited	2024	2023	
Takeda	687		
<b>Total contract revenue</b>	687		

### Loss per share (Tables)

### 6 Months Ended Jun. 30, 2024

### Loss per share

Schedule of earnings per share

	For the Three Months Ended June 30,	
In CHF thousands except for share and per share data	2024	2023
Loss per share (EPS)		
Numerator		
Net loss attributable to equity holders of the Company	(22,760)	(16,833)
Denominator		
Weighted-average number of shares outstanding used to compute		
EPS basic and diluted attributable to equity holders	99,549,910	84,612,997
Basic and diluted loss per share for the period attributable to equity		
holders	(0.23)	(0.20)
	For the Si	ix Months
	Ended J	
In CHF thousands except for share and per share data	2024	2023
Loss per share (EPS)		
Numerator		
Net loss attributable to equity holders of the Company	(40,622)	(34,346)
Denominator	( ) )	( , ,
Weighted-average number of shares outstanding used to compute		
EPS basic and diluted attributable to equity holders	99,467,690	83,654,663
Basic and diluted loss per share for the period attributable to equity		
holders	(0.41)	(0.41)
	For the T	hree Months
		June 30,
	2024	2023
Share options issued and outstanding	1,578,645	
Restricted share awards subject to future vesting	1,631,911	1,213,703
	For the	Six Months
	Ended June 30,	
	2024	2023

1,659,854

1,684,826

97,875

1,225,175

# Schedule of antidilutive securities

Share options issued and outstanding

Restricted share awards subject to future vesting

# Property, plant and equipment (Tables)

Property, plant and equipment.
Schedule of movement in the net
book values of property, plant and
equipment

### 6 Months Ended Jun. 30, 2024

	As of June 30, 2024					
		IT	Lab	Leasehold	Assets under	
In CHF thousands	<u>Furniture</u>	equipment	equipment	improvements	construction	Total
Acquisition cost:						
Balance at						
<b>December 31, 2023</b>	309	2,168	10,233	1,662		14,372
Additions	15	45	214	43	_	317
Balance at						
June 30, 2024	324	2,213	10,447	1,705	_	14,689
Accumulated						
depreciation:						
Balance at						
<b>December 31, 2023</b>	(212)	(1,851)	(8,101)	(832)	_	(10,996)
Depreciation						
expense	(25)	(103)	(504)	(135)	_	(767)
Balance at						
June 30, 2024	(237)	(1,954)	(8,605)	(967)		(11,763)
Carrying amount:						
December 31, 2023	97	317	2,132	830		3,376
June 30, 2024	87	259	1,842	738	_	2,926

### Right-of-use assets, longterm financial assets and lease liabilities (Tables)

# Right-of-use assets, long-term financial assets and lease liabilities

Schedule of the movements in the net value book value of right-of-use assets

<u>Schedule of impact on condensed consolidated statements of income/(loss) and cash flows</u>

<u>Schedule of contractual undiscounted cash flows for lease obligations</u>

# 6 Months Ended Jun. 30, 2024

In CHF thousands	Buildings	Office equipment	IT equipment	Total
Balance as of				
<b>December 31, 2023</b>	3,446	50	12	3,508
Additions and				
remeasurements	_	64	_	64
Depreciation	(318)	(12)	(7)	(337)
Balance as of				
June 30, 2024	3,128	102	5	3,235

	For the Thr	ee Months
	Ended Ju	ıne 30,
In CHF thousands	2024	2023
Statements of income/(loss)		
Depreciation of right-of-use assets	169	134
Interest expense on lease liabilities	29	24
Expense for short-term leases and		
leases of low value	170	189
Total	368	347
Statements of cash flows		
Total cash outflow for leases	372	349

	For the Six Month Ended June 30,	
In CHF thousands	2024	2023
Statements of income/(loss)		
Depreciation of right-of-use assets	337	269
Interest expense on lease liabilities	59	47
Expense for short-term leases and leases		
of low value	363	488
Total	759	804
Statements of cash flows		
Total cash outflow for leases	762	805

In CHF thousands	As of June 30, 2024
Less than one year	789
1-3 years	1,550
3-5 years	1,155
Total	3,494

### **Accrued expenses (Tables)**

### 6 Months Ended Jun. 30, 2024

<u>Trade and other payables and accrued expenses</u> <u>Schedule of accrued expenses</u>

		As of
In CHF thousands	June 30, 2024	December 31, 2023
Accrued expenses	11,895	11,087
Total accrued		
expenses	11,895	11,087

### **Intangible assets (Tables)**

### 6 Months Ended Jun. 30, 2024

### **Intangible assets**

<u>Schedule of net book value of intangible assets</u>

	A	s of June 30, 202	24	As of December 31, 2023		
	Gross			Gross		
In CHF thousands		Accumulated Amortization	Net Book Value		Accumulated Amortization	Net Book Value
Acquired						
IPR&D asset	50,416	_	50,416	50,416	_	50,416
Total intangible						
assets	50,416		50,416	50,416		50,416

### Cash and cash equivalents and short-term financial assets (Tables)

<u>Cash and cash equivalents and financial assets</u>
<u>Schedule of cash and cash equivalents and short-term</u>
financial assets

# 6 Months Ended Jun. 30, 2024

		As of
In CHF thousands	June 30, 2024	December 31, 2023
Cash and cash equivalents	51,564	78,494
Total cash and cash equivalents	51,564	78,494
In CHF thousands		As of December 31, 2023
In CHF thousands Short-term financial assets due in	June 30, 2024	As of December 31, 2023
Short-term financial assets due in	June 30, 2024	<b>December 31, 2023</b>

Corporate information (Details) Jun. 30, 2024

<u>Corporate information</u> <u>Number of technology platforms 2</u>

Basis of preparation and changes to the Company's	3 Months Ended		<b>5 Ended</b> 6 Months Ended		3 Months Ended 6 Months Ended		12 Months Ended
accounting policies - Functional and reporting currency (Details) - SFr / \$	Jun. 30, 2024	Jun. 30, 2023	Jun. 30, 2024	Jun. 30, 2023	Dec. 31, 2023		
<b>Functional and reporting currency</b>							
Closing rate, USD 1	0.909	0.908	0.909	0.908	0.851		
Weighted average exchange rate, USD 1	0.914	0.908	0.898	0.921	0.908		

Basis of preparation and changes to the Company's accounting policies - Going concern (Details) - CHF (SFr)

Jun. 30, 2024 Dec. 31, 2023 Jun. 30, 2023 Dec. 31, 2022

SFr in Thousands

**Going concern** 

Company's cash position SFr 51,564 SFr 78,494 SFr 40,007 SFr 31,586

Short-term financial assets SFr 123,560 SFr 24,554

Contract revenues and other operating income (Details) -	3 Months Ended	6 Months Ended		
CHF (SFr) SFr in Thousands	Jun. 30, 2024	Jun. 30, 2024	Jun. 30, 2023	
Disclosure of disaggregation of revenue from contracts with				
customers [line items]				
Contract revenue	SFr 687	SFr 687	SFr 0	
<u>Takeda</u>				
Disclosure of disaggregation of revenue from contracts with				
customers [line items]				
Contract revenue	SFr 687	SFr 687		

Contract revenues and other operating income - Anti- Abeta Active	1 Mon Ende		3 Months Ended	6 Mo Enc		
Immunotherapy in AD - 2024 agreement Takeda Pharmaceuticals, USA Inc. (Details) SFr in Thousands, \$ in Millions	May 31, 2024 CHF (SFr)	May 31, 2024 USD (\$)	30, 2024	Jun. 30, 2024 CHF (SFr)	CHF	May 31, 2024 USD (\$)
Disclosure of disaggregation of revenue from contracts with						
<u>customers [line items]</u> Period to provide notice of termination of agreement	90 days	90 days				
Contract revenue			SFr 687	SFr 687	SFr 0	
Anti-Abeta Active Immunotherapy in AD – 2024 agreement Takeda Pharmaceuticals, USA, Inc.				007		
Disclosure of disaggregation of revenue from contracts with customers [line items]						
Collaborative agreement, upfront payments received	SFr 92,300	\$ 100.0	)			
Transaction price	SFr 92,300					\$ 100.0
Number of development milestones that may occur prior to option	-					0
exercise included in transaction price Contract revenue			687	687		
Deferred revenue			SFr	SFr 91,600	)	
Anti-Abeta Active Immunotherapy in AD – 2024 agreement Takeda Pharmaceuticals, USA, Inc.   License option and development, CMC and regulatory activities	<u>d</u>					
Disclosure of disaggregation of revenue from contracts with						
<u>customers [line items]</u> <u>Transaction price</u>	SFr 92,300					\$ 100.0
Anti-Abeta Active Immunotherapy in AD – 2024	<i>5</i> <b>=</b> , <i>E</i>					
agreement Takeda Pharmaceuticals, USA, Inc.   License option						
<u>Disclosure of disaggregation of revenue from contracts with</u> customers [line items]						
Transaction price	SFr 80,700					87.4
Anti-Abeta Active Immunotherapy in AD – 2024 agreement Takeda Pharmaceuticals, USA, Inc.   Development, CMC and regulatory activities						
Disclosure of disaggregation of revenue from contracts with customers [line items]						

Transaction price  SFr 11,600  Anti-Abeta Active Immunotherapy in AD – 2024 agreement Takeda Pharmaceuticals, USA, Inc.   Maximum  Disclosure of disaggregation of revenue from contracts with customers [line items]  Collaborative agreement, potential receivables for option exercise fee and potential development, commercial and sales-based milestones  SFr 1,900,000  2,100	Number of performance obligations identified	1	1	
Anti-Abeta Active Immunotherapy in AD – 2024 agreement Takeda Pharmaceuticals, USA, Inc.   Maximum  Disclosure of disaggregation of revenue from contracts with customers [line items]  Collaborative agreement, potential receivables for option exercise fee and potential development, commercial and sales-based  SFr 1 900 000 2 100	Transaction price	SFr		12.6
agreement Takeda Pharmaceuticals, USA, Inc.   Maximum  Disclosure of disaggregation of revenue from contracts with  customers [line items]  Collaborative agreement, potential receivables for option exercise fee and potential development, commercial and sales-based  SFr 1 900 000 2 100		11,600		12.0
Disclosure of disaggregation of revenue from contracts with  customers [line items]  Collaborative agreement, potential receivables for option exercise fee and potential development, commercial and sales-based  SFr 1 900 000 2 100	Anti-Abeta Active Immunotherapy in AD – 2024			
<u>Collaborative agreement, potential receivables for option exercise</u> <u>fee and potential development, commercial and sales-based</u> SFr  1 900 000  2 100	agreement Takeda Pharmaceuticals, USA, Inc.   Maximum			
Collaborative agreement, potential receivables for option exercise fee and potential development, commercial and sales-based  SFr 1 900 000 2 100	Disclosure of disaggregation of revenue from contracts with			
fee and potential development, commercial and sales-based  1 900 000  2 100	customers [line items]			
tee and potential development, commercial and sales-based 1,900,000 2,100	Collaborative agreement, potential receivables for option exercise	CE <sub>r</sub>		¢
<u>milestones</u> 1,700,000 2,100	fee and potential development, commercial and sales-based		0	*
	milestones	1,700,00	O	2,100.0

Contract revenues and other operating income - Grants from the Michael J. Fox	3 Mon	ths Ended	6 Mon	ths Ended	
Foundation (Details) - CHF (SFr)	Jun. 30, 202	4 Jun. 30, 202	3 Jun. 30, 202	4 Jun. 30, 202	23 Dec. 31, 2023
SFr in Thousands					
<b>Contract revenues</b>					
Revenue from contracts with custome	<u>rs</u> SFr 687		SFr 687	SFr 0	
Income from grants	41	SFr 317	109	725	
Accrued income	402		402		SFr 246
Grant revenue					
<b>Contract revenues</b>					
Income from grants	SFr 100	SFr 300	SFr 100	SFr 700	

Loss per share (Details) -	3 Mont	hs Ended	6 Months Ended	
CHF (SFr) SFr / shares in Units, SFr in Thousands	Jun. 30, 2024	Jun. 30, 2023	Jun. 30, 2024	Jun. 30, 2023
Numerator				
Net loss attributable to equity holders of the Company	SFr (22,760)	SFr (16,833)	SFr (40,622)	SFr (34,346)
<b>Denominator</b>				
Weighted-average number of shares outstanding used to compute EPS basic attributable to equity holders	99,549,910	084,612,997	7 99,467,690	083,654,663
Weighted-average number of shares outstanding used to compute EPS diluted attributable to equity holders	99,549,910	084,612,997	7 99,467,690	083,654,663
Basic loss per share for the period attributable to equity holders	SFr (0.23)	SFr (0.20)	SFr (0.41)	SFr (0.41)
Diluted loss per share for the period attributable to equity holders	SFr (0.23)	SFr (0.20)	SFr (0.41)	SFr (0.41)

Loss per share - Antidilutive securities (Details) - shares			6 Month Jun. 30, 2024	
Share options issued and outstanding (in-the-money)				
Disclosure of instruments with potential future dilutive effect not				
included in calculation of diluted earnings per share [line items]				
Number of instruments that are antidilutive in period presented	1,578,645	97,875	1,659,854	97,875
Restricted share awards subject to future vesting				
Disclosure of instruments with potential future dilutive effect not				
included in calculation of diluted earnings per share [line items]				
Number of instruments that are antidilutive in period presented	1,631,911	1,213,703	3 1,684,826	1,225,175

Property, plant and equipment (Details) SFr in Thousands	6 Months Ended Jun. 30, 2024 CHF (SFr)
Property, plant and equipment:	OF 2.276
Property, plant and equipment, beginning of period	SFr 3,376
Property, plant and equipment, end of period	2,926
Acquisition Cost	
Property, plant and equipment:	
Property, plant and equipment, beginning of period	14,372
Additions	317
Property, plant and equipment, end of period	14,689
Accumulated depreciation	
Property, plant and equipment:	
Property, plant and equipment, beginning of period	(10,996)
<u>Depreciation expense</u>	(767)
Property, plant and equipment, end of period	(11,763)
<u>Furniture</u>	
<b>Property, plant and equipment:</b>	
Property, plant and equipment, beginning of period	97
Property, plant and equipment, end of period	87
Furniture   Acquisition Cost	
<b>Property, plant and equipment:</b>	
Property, plant and equipment, beginning of period	309
Additions	15
Property, plant and equipment, end of period	324
Furniture   Accumulated depreciation	
<b>Property, plant and equipment:</b>	
Property, plant and equipment, beginning of period	(212)
<u>Depreciation expense</u>	(25)
Property, plant and equipment, end of period	(237)
IT Equipment	
<b>Property, plant and equipment:</b>	
Property, plant and equipment, beginning of period	317
Property, plant and equipment, end of period	259
IT Equipment   Acquisition Cost	
Property, plant and equipment:	
Property, plant and equipment, beginning of period	2,168
Additions	45
Property, plant and equipment, end of period	2,213
IT Equipment   Accumulated depreciation	
<b>Property, plant and equipment:</b>	
Property, plant and equipment, beginning of period	(1,851)
<u>Depreciation expense</u>	(103)

Property, plant and equipment, end of period	(1,954)
Lab Equipment	
Property, plant and equipment:	
Property, plant and equipment, beginning of period	2,132
Property, plant and equipment, end of period	1,842
Lab Equipment   Acquisition Cost	
Property, plant and equipment:	
Property, plant and equipment, beginning of period	10,233
Additions	214
Property, plant and equipment, end of period	10,447
Lab Equipment   Accumulated depreciation	
Property, plant and equipment:	
Property, plant and equipment, beginning of period	(8,101)
<u>Depreciation expense</u>	(504)
Property, plant and equipment, end of period	(8,605)
<u>Leasehold Improvements</u>	
Property, plant and equipment:	
Property, plant and equipment, beginning of period	830
Property, plant and equipment, end of period	738
Leasehold Improvements   Acquisition Cost	
Property, plant and equipment:	
Property, plant and equipment, beginning of period	1,662
Additions	43
Property, plant and equipment, end of period	1,705
Leasehold Improvements   Accumulated depreciation	<u>1</u>
Property, plant and equipment:	
Property, plant and equipment, beginning of period	(832)
Depreciation expense	(135)
Property, plant and equipment, end of period	SFr (967)

Right-of-use assets, long- term financial assets and	3 Months Ended		6 Months Ended	
lease liabilities (Details) - CHF (SFr) SFr in Thousands	Jun. 30, 2024	Jun. 30, 2023	Jun. 30, 2024	Jun. 30, 2023
Right-of-use of leased assets:				
Balance, beginning of period			SFr 3,508	
Additions and remeasurements			64	
<u>Depreciation</u>	SFr (169)	SFr (134)	(337)	SFr (269)
Balance, end of period	SFr 3,235		3,235	
Variable lease payments that are not included in the measurement			0	
of lease obligations			U	
<u>Maximum</u>				
Right-of-use of leased assets:				
Additions and remeasurements			SFr 100	
Buildings				
Right-of-use assets and lease liabilities:				
Weighted average incremental borrowing rate	3.50%		3.50%	
Right-of-use of leased assets:				
Balance, beginning of period			SFr 3,446	
<u>Depreciation</u>			(318)	
Balance, end of period	SFr 3,128		SFr 3,128	
Office Equipment				
Right-of-use assets and lease liabilities:				
Weighted average incremental borrowing rate	3.30%		3.30%	
Right-of-use of leased assets:				
Balance, beginning of period			SFr 50	
Additions and remeasurements			64	
<u>Depreciation</u>			(12)	
Balance, end of period	SFr 102		SFr 102	
IT Equipment				
Right-of-use assets and lease liabilities:				
Weighted average incremental borrowing rate	2.60%		2.60%	
Right-of-use of leased assets:				
Balance, beginning of period			SFr 12	
<u>Depreciation</u>			(7)	
Balance, end of period	SFr 5		SFr 5	

Right-of-use assets, long- term financial assets and	3 Mont	3 Months Ended		6 Months Ended	
lease liabilities - Statement of income/(loss) and cash flow (Details) - CHF (SFr) SFr in Thousands	nt of low Jun. 30, 2024 Jun. 30, 2023 Jun. 30, 2024 Jun. 30, 202				
Statements of income/(loss) and cash flows					
Depreciation of right-of-use assets	SFr 169	SFr 134	SFr 337	SFr 269	
Interest expense on lease liabilities	29	24	59	47	
Expense for short-term leases and leases of low value	<u>2</u> 170	189	363	488	
<u>Total</u>	368	347	759	804	
Total cash outflow for leases	SFr 372	SFr 349	SFr 762	SFr 805	

Right-of-use assets, longterm financial assets and lease liabilities - Contractual undiscounted cash flows for lease obligations (Details) -CHF (SFr) SFr in Thousands

Jun. 30, 2024 Dec. 31, 2023

#### Contractual undiscounted cash flows for lease liabilities:

Contractual undiscounted cash flows for lease obligations SFr 3,494

Escrow deposits 400 SFr 400

Less than one year

Contractual undiscounted cash flows for lease liabilities:

Contractual undiscounted cash flows for lease obligations 789

1-3 years

**Contractual undiscounted cash flows for lease liabilities:** 

Contractual undiscounted cash flows for lease obligations 1,550

3-5 years

**Contractual undiscounted cash flows for lease liabilities:** 

Contractual undiscounted cash flows for lease obligations SFr 1,155

# Accrued expenses (Details) - CHF (SFr)

Jun. 30, 2024 Dec. 31, 2023 Jun. 30, 2023

### **SFr in Thousands**

### Trade and other payables and accrued expenses

Trade and other payablesSFr 1,435SFr 1,679Accrued Expenses11,89511,087

<u>Total</u> SFr 11,895 SFr 11,087 SFr 11,100

# Intangible assets (Details) - CHF (SFr)

Jun. 30, 2024 Dec. 31, 2023

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Disclosure of intangible assets material to entity [abstract	1				
Intangible Assets	SFr 50,416	SFr 50,416			
Gross Carrying Amount					
Disclosure of intangible assets material to entity [abstract	l				
Intangible Assets	50,416	50,416			
Acquired IPR&D Asset					
Disclosure of intangible assets material to entity [abstract	1				
Intangible Assets	50,416	50,416			
Acquired IPR&D Asset   Gross Carrying Amount					
Disclosure of intangible assets material to entity [abstract]					
Intangible Assets	SFr 50,416	SFr 50,416			

### Prepaid expenses (Details) -CHF (SFr) SFr in Thousands

Jun. 30, 2024 Dec. 31, 2023

Prepaid expenses and accrued income

Prepaid expenses SFr 3,864 SFr 6,437

Cash and cash equivalents and financial assets - Cash and cash equivalents (Details) SFr in Thousands

Jun. 30, 2024 Dec. 31, 2023 Jun. 30, 2023 CHF (SFr) CHF (SFr) CHF (SFr) SFr / \$ SFr / \$ SFr / \$ CHF (SFr)

**Cash and cash equivalents [Abstract]** 

Cash and cash equivalents | SFr S1,564 SFr 78,494 SFr 40,007 SFr 31,586

Translation rate into CHF | SFr / \$ 0.909 0.851 0.908

Cash and cash equivalents and short-term financial assets - Short-term financial assets (Details) - CHF (SFr) SFr in Thousands

6 Months Ended

Jun. 30, 2024 Jun. 30, 2023 Dec. 31, 2023

Miscellaneous current assets [abstract]

Short-term financial assets due in one year or less SFr 123,560

SFr 24,554

Proceeds from maturity of short-term financial assets SFr 99,000 SFr 38,000

**Accounts receivable (Details)** 

- CHF (SFr) Jun. 30, 2024 Dec. 31, 2023

**SFr in Thousands** 

**Accounts receivable** 

Accounts receivable SFr 0 SFr 14,800

Share capital and Treasury shares (Details) SFr in Millions, \$ in Millions	3 Mont	Dog 21 2022	
	Jun. 30, 2024 Jun. 30, 2024		
	USD (\$) shares	CHF (SFr) shares	Dec. 31, 2023 shares
Disclosure of classes of share capital [line items	1		
Number of treasury shares sold during period	30,232	30,232	
Proceeds from sale or issue of treasury shares	\$ 0.1	SFr 0.1	
Number of treasury shares outstanding	10,902,617	10,902,617	5,243,958
AC Immune USA			
Disclosure of classes of share capital [line items	1		
Number of shares issued during the period	5,700,000	5,700,000	

Finance results, net (Details)		3 Months Ended		6 Months Ended	
- CHF (SFr) SFr in Thousands	Jun. 30, 2024	Jun. 30, 2023	Jun. 30, 2024	Jun. 30, 2023	
Finance result, net					
Net financial gains (losses)	SFr (1,799)	SFr 216	SFr 407	SFr 277	
Finance income associated with change in fair value of derivative financial assets	SFr 739	SFr 259	SFr 1,368	SFr 468	

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