

EPFL Innovation Park- Bldg B  
1015 Lausanne, Switzerland

December 20, 2019

**Re: AC Immune SA  
Form 20-F for the Fiscal Year Ended December 31, 2018  
Filed April 19, 2019  
Form 6-K for the Quarterly Period Ended June 30, 2019  
Filed August 14, 2019  
File No. 001 - 37891**

Ms. Ibolya Ignat  
Mr. Franklin Wyman  
U.S. Securities and Exchange Commission  
Division of Corporation Finance  
Office of Life Sciences  
100 F Street N.E.  
Washington, D.C. 20549-4628  
Dear Ms. Ignat and Mr. Wyman,

On behalf of AC Immune SA (the "Company" or "AC Immune"), I am responding to the comments from the Staff (the "Staff") of the Securities and Exchange Commission (the "Commission") relating to the Company's financial statements and disclosure in the Company's Form 6-K dated August 14, 2019.

Set forth below are the Company's responses to the Staff's comments. For convenience, the Staff's comments are repeated below in italics, followed by the Company's response to the comments.

Form 6-K dated August 14, 2019

Exhibit 99.1  
Interim Condensed Financial Statements (unaudited)  
Notes to Interim Condensed Financial Statements  
3.1 Licensing and collaboration agreements, page 13

*Please provide us the following information supporting your revenue recognition for the license granted under the collaboration agreement with Eli Lilly and Company ("Lilly").*

- Explain the factors that you considered in characterizing this license transferred to Lilly as a distinct performance obligation representing a "right-to-use" rather than a "right-to-access."*

**Company response:**

The Company considered both aspects in its analysis, looking first at whether the license is a distinct performance obligation, and then looking at the license as a "right-to-use", as follows.

The Company identified the following significant performance obligations under the contract: (i) a right-to-use license, and (ii) research and development activities outlined in the development plan.

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The Company granted Lilly an exclusive, non-transferrable worldwide license to develop and commercialize drug candidates from the Company's Tau therapeutic small molecule program. More specifically, this is an exclusive license with the right to grant sublicenses in accordance with Section 2.3.1, under the ACIU Patents, the ACIU Know-How, and ACIU's interests in the Joint Patents and the Joint Know-How to Exploit the Licensed Compounds and Licensed Products (Section 2.1.1). Additionally, AC Immune will be responsible and shall bear all Development Costs for performing the ACI pre-clinical and Phase 1 activities in accordance with Section 3.1.2(iii).

Currently, the lead compound, ACI-3024, is in a Phase 1 clinical trial which has a primary objective to assess the safety and tolerability of ACI-3024 in study participants, among other objectives. AC Immune, per Section 3.1.2(iii), is responsible for the pre-clinical and Phase 1 activities. Pre-clinical activities for which AC Immune was responsible included final manufacturing of materials for use in the Phase 1 and regulatory submission of the protocols. These were completed by May 2019. For the current Phase 1, AC Immune is responsible for leading the study design, obtaining relevant regulatory agency approvals, arranging necessary third party contracts, completing patient selection, ensuring patient treatment, following up with patients, drafting the clinical study report development and other relevant clinical activities to ensure that the primary objective of the study is completed.

The accounting guidance in International Financial Reporting Standards ("IFRS"), as adopted by the International Accounting Standards Boards ("IASB") provides the following:

- IFRS 15.22 states that at contract inception, an entity shall assess the goods or services promised in a contract with a customer and shall identify as a performance obligation each promise to transfer to the customer either (a) a good or service (or bundle of goods or services) that is distinct or (b) a series of distinct goods or services that are substantially the same and that have the same pattern of transfer.
- IFRS 15.26(i) further provides that the granting of licenses may constitute a promised good or service.
- IFRS 15.27 clarifies that a good or service that is promised is distinct if both of the following criteria are met:
  - o the customer can benefit from the good or service on its own or together with other resources that are readily available to the customer; and
  - o the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

The Company determined that the upfront license is distinct from Lilly's perspective. Lilly has received a license to use relevant intellectual property for development and commercialization at the commencement of the collaboration agreement. Lilly has the expertise and capability, without requiring know-how from AC Immune specifically, to complete pre-clinical and clinical development work on its own with only the rights granted under this license. AC Immune used third party clinical manufacturing organizations ("CMOs") for certain of its pre-clinical activities and is currently using third party clinical research organizations ("CRO") to complete certain Phase 1 activities.

Consistent with this conclusion, Lilly is in fact conducting its own pre-clinical activities as contemplated by the collaboration agreement. Lilly has also begun certain manufacturing activities in preparation for a Phase 2 without our assistance and could use other CROs to provide Phase 1 services that we perform. As AC Immune is performing Phase 1 activities that are not proprietary to AC Immune and Lilly can benefit from the license itself without specifically our know-how, the Company concluded that the license to Lilly is capable of being distinct.

The Company has also determined that this license is distinct within the context of the collaboration agreement. IFRS 15.29 includes various factors that are intended to clarify as to when goods or services are not separately identifiable within the context of a contract and therefore should be combined as one performance obligation per the considerations in IFRS 15.27(b). In relation to the above, these include, but are not limited, the following:

- the entity provides a significant service of integrating the goods or services with other goods or services promised in the contract into a bundle of goods or services that represent the combined output or outputs for which the customer has contracted. In other words, the entity is using the goods or services as inputs to produce or deliver the combined output or outputs specified by the customer. A combined output or outputs might include more than one phase, element or unit.
- one or more of the goods or services significantly modifies or customizes, or are significantly modified or customized by, one or more of the other goods or services promised in the contract.
- the goods or services are highly interdependent or highly interrelated. In other words, each of the goods or services is significantly affected by one or more of the other goods or services in the contract. For example, in some cases, two or more goods or services are significantly affected by each other because the entity would not be able to fulfil its promise by transferring each of the goods or services independently.

In assessing drug compounds and in view of the guidance at IFRS 15.29, the key element for being distinct within the context of the contract relates to whether there is significant functionality of the licensed IP.

Regarding point (i), AC Immune's pre-clinical and Phase 1 activities do not represent integrated services with the licensed IP for which the customer has contracted. Lilly has purchased a license to the Company's Tau therapeutic small molecule program, which was delivered at commencement of the agreement and AC Immune's pre-clinical and Phase 1 activities do not affect this license.

Regarding point (ii), the objective of the current Phase 1 activity is to assess safety and tolerability and does not modify or customize the lead compound. The Company is no longer completing activities associated with adjusting the compound that would further alter the functionality of the IP. Rather, we are leading a Phase 1 and are currently using a CRO. Lilly has the ability to obtain substantial benefit from the functionality of the intellectual property that has been granted

Finally, regarding point (iii), the completion of this work will not affect the licensed IP.

Once the Company determined that the license is a distinct performance obligation separate from other performance obligations, IFRS 15.B56 states that an entity shall determine whether the license transfers to a customer either at a point in time or over time. In this regard, the Company must consider whether the license provides Lilly with (i) a right to access the Company's intellectual property as it exists throughout the license period; or (ii) a right to use the Company's intellectual property as it exists at the point in time at which the license is granted. IFRS 15.B58 clarifies that in making this determination, a license is a right to access if all of the following criteria are met:

- The contract requires, or the customer reasonably expects, that the entity will undertake activities that significantly affect the intellectual property to which the customer has rights;
- The rights granted by the license directly expose the customer to any positive or negative effects of the entity's activities; and
- Those activities do not result in the transfer of a good or service to the customer as those activities occur

The Company delivered the license on the effective date of the collaboration agreement.

For the first criterion listed above, IFRS 15.B59A further clarifies that an entity significantly affects the intellectual property if those activities are expected to significantly change the form or the functionality of the intellectual property. IFRS 15.B59A states as an example that an entity's ongoing activities do not significantly affect the IP when that IP has significant stand-alone functionality such as biological compounds and drug formulas.

In the Company's case, it has licensed a compound to Lilly as of the effective date of the contract. Lilly benefits from the intellectual property directly on its own. They may complete the work proprietarily or together with other contractors other than AC Immune to complete the development activities contemplated by the collaboration. Additionally, there is no explicit or implied obligation associated or bundled with the license to undertake activities during the period to (a) significantly affect the intellectual property or (b) support or maintain the value of the intellectual property during the license period (other than costs to protect the patent which are not considered per IFRS 15.B62). The purpose of the pre-clinical and Phase 1 activities is instead to assess the safety of the compound. As noted above, the Company has determined that these activities are capable of being conducted by Lilly or another party. These factors combined with the distinct nature of the license indicate that it is a right to use license and revenue is recognized at a point in time (i.e., upon the transfer of the license at the effective date of the collaboration agreement). The Company has no other contractual obligation to benefit the licensee after the effective date – aside from the separately outlined development activities. Therefore, the Company concluded that Lilly has obtained the right to use the license and the license is considered a distinct performance obligation in accordance with IFRS 15.

- *Explain how Lilly has used and is expected to use this license during Phase 1 clinical trials and whether it has benefited from this license since the effective date.*

**Company response:**

Lilly licensed rights to ACI-3024, a unique compound that has demonstrated the ability to prevent aggregation of pathological tau and promote disaggregation. Additionally, this compound reduces neuroinflammatory processes that eventually lead to neurodegeneration.

Lilly has engaged in its own pre-clinical activities as detailed in the agreement, and Lilly is completing these activities in its sole discretion. The nature of these pre-clinical activities is for its own data collection and does not impact the form or functionality of the underlying intellectual property.

Additionally, although the Company is leading the pre-clinical and Phase 1 activities, Lilly is actively collaborating and consulting on these activities via the joint steering committee established under the collaboration agreement, and Lilly benefits from additional data derived from the project. Lilly has gained safety and tolerability data to use into potentially moving into a Phase 2.

Finally, Lilly will be responsible for development after Phase 1 and Lilly has commenced multiple activities leading for the preparation of a phase 2 clinical study. These activities include preparation for the clinical manufacturing for a potential phase 2 study.

AC Immune and Lilly negotiated for AC Immune to lead the Phase 1 so that the Company had the opportunity to demonstrate that it could perform such Phase 1 activities. AC Immune has historically performed activities up to Phase 1 and wanted to further enhance its competitive position. AC Immune is leading the Phase 1, but uses a CRO to perform certain activities to complete the primary objective. AC Immune does not have proprietary information nor employees performing the Phase 1 that are not available via other contractors. Therefore, Lilly does not rely solely on AC Immune for the Phase 1.

- *Explain your consideration of factors discussed in IFRS 15.B58 and B59, particularly the extent to which Lilly has been or will be exposed to the positive or negative results of your Phase 1 clinical trials.*

**Company response:**

As noted above, although the results of the Phase 1 clinical trial will dictate the extent to which the compound is pursued further in the clinical development process, the Company's activities in conducting a Phase 1 clinical trial do not affect either the form or the functionality of the lead compound that is the subject to the collaboration agreement. The composition of a lead compound is completed prior to pre-clinical work, with subsequent development work intended to assess safety and then potentially efficacy of the compound. AC Immune recognizes that the standard foresaw the benefits of biological compounds or drug formulas independent of subsequent development. Clinical development is an inherently risk-laden endeavor, but it does not alter the form or functionality of the underlying IP. Ultimately, IFRS 15.B59A specifically notes that form and functionality are the key elements to consider, stating the following:

Consequently, the ability of the customer to obtain benefit from that intellectual property would not be significantly affected by the entity's activities unless those activities significantly change its form or functionality. Type of intellectual property that often have significant stand-alone functionality include software, **biological compounds or drug formulas** [emphasis added].

- *Provide support for your use of the residual approach to estimate the standalone selling price for this license, given that this approach is only permissible in limited circumstances.*

**Company response:**

The extent of the revenue recognized depends on the allocation of the fair value of the transaction price allocated between the exclusive license and the research and development activities (which represent the two distinct performance obligations).

The agreement states at Article 7.1 that the CHF 80 million upfront payment is for the "partial consideration of the rights granted by ACI to Lilly hereunder and subject to the terms and conditions of the Agreement." Although this does not make reference to the Company's pre-clinical and Phase 1 activities, AC Immune identified these activities as a separate performance obligation to allocate a portion of this CHF 80 million upfront payment.

IFRS 15.73 states that the objective when allocating the transaction price is for an entity to allocate the transaction price to each performance obligation in an amount that depicts the amount of consideration to which the entity expects to be entitled in exchange for transferring the promised goods or services to the customer.

The guidance clarifies that to meet the allocation objective, an entity shall allocate the transaction price to each performance obligation identified in the contract on a relative standalone selling price basis in accordance with paragraphs 76–80. These paragraphs provide the considerations that a Company must make to ensure fair value is applied.

IFRS 15.76 states that an entity shall determine the stand-alone selling price at contract inception of the distinct good or service underlying each performance obligation in the contract and allocate the transaction price in proportion to those stand-alone selling prices. IFRS 15.77 expands that the selling price is the price at which an entity would sell a promised good or service separately to a customer. The best evidence of a stand-alone selling price is the observable price of a good or service when the entity sells that good or service separately in similar circumstances and to similar customers. It also notes that

the contractually stated shall not be presumed to be the stand-alone selling price. This could require further assessments.

As stated above, AC Immune has not historically sold pre-clinical or Phase 1 services. Rather we have negotiated to perform these services specifically in this context. Additionally, the Company's license to intellectual property does not have an observable price in the marketplace. In fact, in negotiating specific terms and conditions with Lilly and other partners, the transaction prices differed materially and did not provide a reasonable range from which to determine the selling price.

Therefore, the Company considered when estimating the value of the performance obligations (i.e., the pre-clinical and Phase 1 activities and the license) IFRS 15.78. There, the guidance explicitly states that if a stand-alone selling price is not directly observable, an entity shall estimate the stand-alone selling price at an amount that would result in the allocation of the transaction price meeting the allocation objective in paragraph 73. When estimating a stand-alone selling price, an entity shall consider all information (including market conditions, entity-specific factors and information about the customer or class of customer) that is reasonably available to the entity.

The Company is required to consider all information – including entity-specific factors and information about the customer – that is reasonably available to the entity. In doing so, the Company is required to maximize the use of observable inputs and apply estimation methods consistently. Stand-alone selling prices are determined at contract inception and not updated to reflect changes between contract inception and when the obligation is complete, according to IFRS 15.88.

IFRS 15.79 prescribes three methods for calculating the stand-alone selling price:

- The adjusted market assessment approach – an entity could evaluate the market in which it sells goods or services and estimate the price that a customer in that market would be willing to pay for those goods or services
- The expected cost plus a margin approach – an entity could forecast its expected costs of satisfying a performance obligation and then add an appropriate margin for that good or service
- A residual approach – an entity may estimate the stand-alone selling price by reference to the total transaction price less the sum of the observable stand-alone selling prices of other goods or services promised in the contract.

The Company began its assessment for determining the stand-alone selling price by considering the three methods. In using the adjusted market assessment approach, the Company considered the value of the license based on various deal terms discussed with other potential partners in the process prior to ultimately agreeing to terms with Lilly. The Company completed various risk adjusted discounted cash flow analysis. These various assessments provided a wide range of values (for which our calculated residual value, discussed below, is in between) . In performing these assessments, the Company considered potential limits on the selling price, market factors such as the targeted disease(s), modality of the product, market potential, potential effects of various regions on pricing, and patent protection timelines among other factors.

The wide range was expected as licensing deals are complex arrangements with many variable factors that impact the overall transaction price (e.g. milestone and royalty terms). Additional to the above factors, forecasting and valuations for pre-clinical assets are nuanced and rely on a variety of assumptions. For example, estimating the likely probability of success at each stage of clinical development stage 10-20 years into the future is material to any calculation but varies widely. Although some key inputs are observable, many are not or are not within a close range that could reasonably determine a stand-alone selling price.

The standard also indicates to look to competitor's prices for similar goods and services. However, the variety of key factors that competitors use to determine fair value are not knowable or observable as these are proprietary and confidential. These may be also irrelevant in any case to our situation. Therefore, the adjusted market assessment approach did not provide a meaningful fair value as it is intended in the standard to elucidate the issue for stand-alone selling price.

The Company therefore reviewed IFRS 15.79(c)(i) which states that the residual approach may be used if the entity sells the same good or service to different customers for a broad range of amounts – i.e., the selling price is highly variable because a representative stand-alone selling price is not discernable from past transactions or other observable evidence. AC Immune concludes this to be the case here.

In determining the amount to allocate, the Company reviewed IFRS 15.80. This guidance allows a combination of methods to be used to estimate the stand-alone selling prices of the goods or services promised in the contract if two or more of those goods have highly variable or uncertain stand-alone selling prices. IFRS 15.80 explicitly states:

*For example, an entity may use a residual approach to estimate the aggregate stand-alone selling price for those promised goods or services with highly variable or uncertain stand-alone selling prices and then use another method to estimate the stand-alone selling prices of the individual goods or services relative to that estimated aggregate stand-alone selling price determined by the residual approach.*

This is acceptable as long as it is within the requirements of IFRS 15.73 and 15.78. Given the variability above, the Company determined that using this approach followed the intent of the standard.

The Company determined the amount to allocate to its pre-clinical and Phase 1 activities using the expected cost plus a margin approach. The Company used this approach by projecting the costs it expected to incur to complete the overall pre-clinical and Phase 1 activities contracted for in the collaboration agreement. The Company reviewed a combination of budgeted activities and committed costs to determine the overall projected costs as a basis. The margin was based on internal assessments for such services.. The amount remaining from the total CHF 80 million (namely, CHF 73.1 million) was allocated to the license in accordance with the residual method and general principle outlines in IFRS 15.73.

*Explain how the apparent premium implicit in the contemporaneously-negotiated convertible note, which converted to common shares on April 23, 2019, impacted your determination of transaction price and revenue recognized in 2019.*

#### **Company response:**

Under the Company's constitutive documents and relevant laws, the ability to issue equity to Lilly was limited under the Company's articles of association due to the absence of authorized capital, which would have a lengthy shareholder approval process to obtain. To ensure the Company could issue Lilly an equity stake, the Company relied on a provision of its articles of association that allowed it to issue a convertible note that would convert into common stock upon appropriate approvals as a corporate law matter.

The Company negotiated the terms of the convertible note independently of the collaboration agreement and determined the fair value of the convertible based on a review of market factors in accordance with financial instrument guidance in IFRS 9. Given the low interest rates in Switzerland, the short duration of the Company's convertible note (i.e. less than one year) and the equity feature, the Company and Lilly negotiated an interest rate that best reflected these conditions. The premium to the Company' share price was based on analysis of the 20 comparable deals and was priced based on the median ranges. The premium for our shares was also viewed in tandem with providing for an equity stake around 5% of the Company's outstanding shares. The convertible debt was at fair value as discussed above and accounted

for under IFRS 9, which outlines the method to measure convertible debt. There is no premium that would need to be allocated to the collaboration agreement and that has been assessed separately under IFRS 15.

- *Refer us to the technical guidance upon which you relied.*

**Company response:**

Please see the technical guidance cited in the foregoing responses.





To the extent you have any questions regarding the response contained in this letter, please do not hesitate to contact me at +41 21 345 91 37 or [joerg.hornstein@acimmune.com](mailto:joerg.hornstein@acimmune.com). Thank you for your time and attention.

Very truly yours,

/s/ Joerg Hornstein  
Joerg Hornstein  
Chief Financial Officer

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