

Date: 4 Aug 2025

## **Invitation To Tender: CMC Service for IVD-Grade Monoclonal Antibody to Support Medical Device Development**

Dear Sir/Madam,

You are invited to submit a tender to support Tiberias Technology (HK) Limited and its affiliates (**the Company**) to manufacture monoclonal antibody (mAb) for its IVD pipeline.

By participating in this tender, you are indicating your acceptance to be bound by the guidelines set out in this letter and attachments. We provide below the key details of requirements, which you should consider in your response.

To simplify exchange of information regarding this Invitation to Tender (ITT) please nominate a Bid Manager (together with their deputy) and relevant contact telephone, facsimile numbers, and email addresses.

Please direct any questions regarding the ITT content or process to the Company's representatives named below. You should not contact other Tiberias Technology (HK) Limited personnel unless directed to do so by Tiberias Technology (HK) Limited representative. The Company reserves the right to disqualify and reject proposals from suppliers who do not comply with these guidelines. All questions should be submitted in writing either by post or to the email address below.

Only communications made by your Bid Manager (or their deputy) to our named representatives, Mandy Li, Executive Director of Personalized Healthcare, will be considered during the pre-contact tender period.

As part of this tender process Tiberias Technology (HK) Limited makes no obligations in any way to:

- i. pay any vendor for any ITT response; or
- ii. award the contract with the lowest or any bidder; or
- iii. accept any ITT information received from vendors; or
- iv. include vendors responding to this ITT, in any future invitation; or
- v. any other commitment to vendors whatsoever.

I look forward to receiving your response.

Yours sincerely,

Mandy LI  
Executive Director of Personalized Healthcare  
Tiberias Technology (HK) Ltd  
E: [mandy.li@arbelebio.com](mailto:mandy.li@arbelebio.com)  
T: (852) 36203011

## **Invitation To Tender**

### **Invitation To Tender for CMC Service for IVD-Grade Monoclonal Antibody**

#### **A. Background**

Tiberias Technology (HK) Limited, a sister company of Arbele Limited and a wholly owned subsidiary of Arbele Investment Limited, is currently developing its IVD pipeline for medical device registration in China and the United States. To fulfill clinical study and registration requirements, Tiberias Technology (HK) Limited must manufacture its proprietary monoclonal antibody (mAb) components for integration into the company's medical devices.

#### **B. Project Summary**

To initiate the clinical pilot study in Hong Kong, we are seeking a proposal for CMC services to support the manufacturing of IVD-grade monoclonal antibodies for Class III Medical Device registration. The services must comply with regulatory requirements, policies, and guidelines relevant to NMPA (China), FDA (U.S.), and EMA (EU) registrations.

The required scope of services includes the following:

- Project management
- Materials and technology transfer
- Stable cell pool development
- Clone screening
- RED"dcpn1pi
- RED"uvcdkik\{ 'tugctej
- Cell culture process development
- Purification process development
- IVD mAb buffer development
- Analytical method development and qualification
- Production for IVD mAb
- Stability study for IVD mAb
- Regulatory support for CMC of IVD mAb

#### **C." Respondent Instruction**

For further information or inquiries, interested parties and manufacturers may contact us during office hours. Tender submissions should be made as soon as possible, but no later than 18:00 Hong Kong Time on 30 September 2025. Submitted proposals will undergo immediate review. A bid defense meeting will be scheduled upon receipt of multiple qualified tenders. The award notice will be issued in early October 2025. Please submit an electronic copy of the written proposal, including pricing details, to:

Dr. Mandy LI, Executive Director of Personalized Healthcare  
E: [mandy.li@arbelebio.com](mailto:mandy.li@arbelebio.com)

Tiberias Technology (HK) Limited reserves the right to:

- disregard any submissions received after the deadline
- modify the terms of this Invitation to Tender (ITT) at any time prior to the submission deadline.
- introduce additional scope or requirements as needed, with timely notification provided to all vendors.

Additional scope and requirements can be added. Notification of such changes will be provided to all vendors. It is requested that all activities listed in Part B be addressed in your proposal (including services that you do not provide). Further items that also need to be addressed in the proposal are:

- Organization chart
- Gantt chart
- Detailed budget
- Team experience summary

#### **D. Evaluation criteria**

1. Fulfilment of the criteria below is compulsory. The service provider should:

- demonstrate regulatory capability for assisting pharmaceutical and biotechnology companies.
- have extensive experience in handling similar projects in terms of mAb production.

If the service providers pass criterion no.1, the responses will be assessed using the following criteria and weightings (% ratio):

2. The price should be competitive with reasonable payment terms (30%)
3. The service provider shows a good track record for the similar production project (30%)
4. The project deliverables timeline, milestones will also be considered (30%)
5. Experience of the project leads and functional team (10%)

The procurement contract will be awarded to the service provider with the highest assessment scores.