Jingsong Wang – Chairman & CEO, Harbour BioMed, China

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15.04.2020

Tags: China, Harbour BioMed, Biotech, IPO, Strategy

PharmaBoardroom caught up with Dr Jingsong Wang, chairman & CEO of Harbour BioMed to discuss the exciting clinical and commercial milestones of the prolific biotech in the last year since we last met them in January 2019, including their March USD 75 million Series B+ fundraising round and their preparations for several Phase II/III pivotal to come later this year.

Dr Wang, what have been the key milestones and achievements since our last interview with you in January 2019?

Harbour BioMed has made significant progress across three different fronts: a robust portfolio; the evolution of our platform technology; and an innovative business model. over the past 18 months.

From the time of Harbour BioMed's inception in 2016, we have always set out to be a patient-centric global biotech company with multiple forms of value generation for our shareholders. Over the last year alone, we created opportunities to make an impact on our patients, the industry and the shareholders in various ways.

Starting with our portfolio, we made several significant advancements. First and foremost, we brought a *de novo* internal discovery program (HBM4003) all the way from discovery to pre-clinical to clinical trials. This is the first compound from our internal pipeline that we have advanced from

pre-clinical to clinical, thereby fully validating our capabilities to innovate on our own. HBM4003 is a next-generation, fully-human anti-CTLA-4 antibody that has demonstrated superior clinical efficacy and a better safety profile compared to first-generation anti-CTLA-4 antibodies such as ipilimumab in preclinical settings. This is driven by the unique pharmacokinetic profile and enhanced antibody-dependent cell toxicity (ADCC) mediated Treg depletion. We started Phase I clinical trials in Australia at the end of 2019 and have also obtained US FDA IND, with additional INDs pending in other regions. We are very excited about this compound.

In addition to this, we also have a portfolio of our in-licensed programs for the China market where we have generated our own data and achieved multiple IND approvals for our HBM9161 compound. This anti-FcRn antibody is aimed at the treatment of multiple severe autoimmune diseases including myasthenia gravis, adult immune thrombocytopenia and Graves' ophthalmology. We plan to initiate Phase II/III pivotal trials in the first half of 2020. For our second compound, HBM9036, we have completed a Phase II study in China for dry eye disease. Based on this data, we have communicated with the Chinese National Medical Products Administration (NMPA) and Center for Drug Evaluation (CDE) and will proceed with our Phase III registrational trial likely in the first half of 2020 as well.

In addition to these more advanced programs, we have built a strong pipeline with multiple discovery programs based on our Harbour Mice® antibody discovery platform. A significant proportion of these are based on the highly differentiated heavy chain only bispecific antibodies, we hope to move to the clinic soon.

Secondly, we are continuing to expand and enhance our capabilities to innovate by building discovery capabilities beyond our original Harbour transgenic mice technology. We have integrated another cutting-edge technology, a single-cell antibody screening and analysis technology, into our Harbour mice platform, which further empowers us to compete at the global level.

Finally, we have also transformed our business model from the previous legacy model of technology licensing to what we call the 'Platform Plus' model, which leverages the above-mentioned discovery and platform technology capabilities to work with the best institutions and researchers around the world on co-discovery programs. We have done this with leading Chinese pharmacos like Chiatai Tianqing. Technology is of course still a component of these partnerships, but the collaboration model is switched to co-discovery and co-development thereby creating higher value and returns for all parties involved. We have also started in 2020 to out-license our discovery programs to external partners, demonstrating our capabilities to build innovative discovery programs valued by our partners.

In March, Harbour BioMed successfully completed a USD 75 million Series B+ fundraising round. How did you find the fundraising experience in light of the COVID-19 situation?

It indeed was a unique situation, but to our benefit, much of the discussion and negotiations about Harbour BioMed's capabilities to create value for the patients, and investors occurred before the COVID-19 pandemic outbreak. In general, the overall private investment climate for biotech companies in China has matured over the past two to three years, aligning more with other mature markets like the US and Europe.

We built our portfolio with the goal of value generation and we have reached out to a broad network of partners around the world in order to capture the best of global science and innovation. As a result, we are confident that we offer a unique proposition, no matter where and how the funding comes. The milestones I outlined above over the past few years and particularly in 2019 gave our investors – existing and new – the confidence to (continue to) support us.

This is reflected in our geographic positioning, which aims to capture the best of innovations globally while mitigating the risks associated with biotech innovation. We have key locations in Rotterdam, Boston and Shanghai, with each site occupying a unique positioning and role. Our Rotterdam site is focusing on technology optimization and external partnerships. Our Boston site aims to fully leverages the innovation ecosystem in the region through collaboration with the best scientists and biotech centers, with the goal of capturing the sources of first-in-class innovation. Once these programs receive preliminary validation and we decide to invest further, we bring them to our China site, where we can advance programs on a larger scale at a faster pace in a bigger space.

Despite previously focusing on immunology and immuno-oncology, last month Harbour BioMed announced a collaboration with the Mount Sinai Health System in the US to develop antibodies for SARS-Cov-19. What was the reason for this?

This fits in our overall corporate strategy. Despite having a laser-sharp focus on immunology-based therapeutic areas for our internal portfolio, our antibody-generation technology has broader applications across all therapeutic areas. This is why we are working with partners around the globe to fully leverage their knowledge in particular disease areas and biological pathways to help

them develop different therapeutics in different areas.

With the immediate global needs in fighting COVID-19 pandemic, we are not shy away from the chance to be part of it. Mount Sinai has a globally leading virology department, so we believe that their expertise combined with our efficient antibody-generating and screening technology constitute a win-win partnership to develop potential therapeutics for patients and populations potentially at risk of contracting COVID-19. From our company standpoint, this is another way for us to deliver value to patients.

The COVID-19 situation has focused even more attention on the healthcare and pharmaceutical landscape in China. How do you think the industry – particularly companies with a significant footprint in China – will be affected?

Given the spread of the pandemic and the impact on all of our everyday life, I believe there will be a negative impact on pharma companies big and small across the world. Recently I hosted a Drug Information Association (DIA) global webinar about the experience of Chinese pharmaceutical industry on running clinical trials during the COVID-19 outbreak, which attracted more than five thousands colleagues around the world who registered for the event. Such high interest in the sharing of our experience in China reflects the fact that other regions will eventually experience the same disruption. In addition, the disruption of clinical trials in China also has global impact because looking across the world, one in five global clinical trials today have China sites and China involvement.

On the positive side, this ordeal has emphasized the importance of delivering therapeutic solutions to patients during moments of crisis. We have seen the flexibility of regulatory systems globally to open the window for such innovations where necessary, for instance, in terms of the rapid approvals of COVID-19 diagnostic tests and clinical trials. From that perspective, what has been positive is the ability and flexibility of healthcare systems to welcome and incorporate such innovations in order to truly bring value to patients in global societies as quickly as possible. The value of biotech innovation is clear.

Looking forward, what do you hope to accomplish in 2020?

After over three years of operations, our strategy, business model and approach have now been validated and I believe we are in the position to achieve even more in the coming years

In 2020, specifically, I hope to see significant advancement in our late-stage clinical programs. By this year, Harbour BioMed would have initiated at least eight clinical programs, of which three will be registration trials, which sets the stage for us to become a commercial-stage company soon. This is highly momentous for a biotech start-up and we are now lining up the resources to push and drive those programs. Additionally, you will see more of our internal portfolio transitioning from pre-clinical to clinical trials.

In 2019, we signed a major partnership with a global top five pharma company for our HCAb antibody discovery technology platform, and we anticipate more of such partnerships with other global pharma giants, not just for our technology but on specific clinical programs.

A final message to our international community?

Considering the current situation, we are all encountering unprecedented challenges in terms of business operations and even our personal lives. Despite the challenges, we must continue to forge ahead in developing unique and differentiated solutions to fulfil the needs of patients that saves and improves their quality of lives. At the same time, we need to protect ourselves and our colleagues. Currently, while our Rotterdam and Boston sites are affected, our China site is almost back to full operations and we are working tirelessly to drive our discovery and clinical programs forward. We are a global biotech company with the vision to leverage whatever resources and opportunities exist out there to address patients' needs; work with partners around the world; drive the company business; and generate value for our stakeholders.

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