Vishal Doshi – Chairman and CEO, AUM Biosciences, Singapore

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Vishal Doshi, founder and CEO of AUM Biosciences, shares his motivation behind establishing the company and his mission to build an ecosystem within AUM for a decentralized biotech innovation model; their focus on oncology and specifically small molecule cancer therapies; and the critical importance of the China market within their Asia-Pacific-focused development.

Vishal, could you start by introducing AUM Biosciences and your motivation for establishing the company?

AUM Biosciences is on a mission to unlock the value of innovation by focusing on smart drug development to address unmet medical needs globally.

Over the past decade, the conventional centralized innovation model has resulted in >100% increase in cost of developing new drugs, 10X reduction in IRR and >20% reduction in commercial ROI. This emphasizes on the intrinsic need to drive a decentralized innovation model.

AUM is an ecosystem for decentralized innovation model. We focus on oncology for one simple reason. The major challenge within oncology drug development is the low likelihood of approvals of 9 percent from Phase I to II completion. One in ten drugs does not even make it to Phase III. We

believe that this has a domino effect on the cost of the treatment options for our most important stakeholder, i.e. patients.

AUM Biosciences is disrupting the industry. Looking at the situation, I wanted to set up a biotech company that could do more with less. Specifically, we want to optimize and accelerate drug development from that critical Phase I to Phase II period, and within our target therapeutic area of oncology, increase the probability of success from 9 percent to a minimum target of 30 percent. That was our starting point. We therefore created our unique and innovative holistic strategy, which is founded on a singular purpose: maximum value creation for both patients and drug development companies.

Could you elaborate more on the different elements of your holistic drug development strategy?

We acquire global rights of early-stage compounds through win-win risk-sharing arrangements, and then invest our own intellectual and financial resources to develop them in the most efficient way. Upon achieving maximum value inflection at clinical POC, we partner with industry partners to advance it towards commercialization.

Our first mandate is to focus on small molecules. We believe they still have great promise and potential. Secondly, with small molecules, having a targeted approach is crucial, which is why we have implemented our ‘no biomarker, no drug’ rule. We need to develop precise and targeted medicines in order to improve the likelihood of approvals. If we can point to a specific biomarker that would respond to our drug, that would certainly help during the regulatory approval process.

The third aspect is integration and normalization of tech enabled data through proprietary approaches to significantly improve our decision making. This will drive our ambition of becoming a globally innovative biotech company.

Another critical aspect of our drug development strategy is clinical trial design. We believe that this would significantly de-risk later phases of clinical development, where failure would become much more costly. Here we also leverage the use of artificial intelligence (AI) to make better-informed decisions.

All these factors create a virtuous ecosystem within which AUM can operate far more effectively and efficiently. It also means that our model is highly scalable since we operate in a decentralized manner.

At its core, the model is all about value creation. We want to help our partners maximize the value of their early-stage asset in the most efficient way possible and allow patients to access cancer medicines at an affordable price. Inefficiency and high risk of failure is a major challenge in drug development today, and we believe if we can fail earlier rather than later, we avoid wasting some crucial financial and intellectual resources.

Your extensive clinical development experience actually comes from your background with a number of leading global and regional CROs like IQVIA, ICON and EPS Group. What made you decide to establish a biotech company rather than a new CRO?

The experience with the drug development is our biggest strength towards executing on process innovation. AUM's team has extensive experience on running highly successful virtual pharma model. The average experience tenure of our management team is three decades. Our track record of working with pharma and biotech companies makes us an ideal partner to achieve the larger purpose of developing affordable and accessible small-molecule cancer drugs for global markets.

AUM currently has a couple of assets in-licensed from your partners. Could you tell us more about their potential?

Our small molecule inhibitors have been chosen to target 'choke points' in cell signaling and survival pathways and are chosen for both potential efficacy as well as lower toxicity to facilitate intra-pipeline combinatorial strategies.

Through our recent partnership with Singapore's Agency for Science Technology and Research (A*STAR) and Inflection Biosciences, a highly innovative Irish biotech, we have two first-in-class candidates, AUM001 and AUM302.

AUM001 is a clinical stage orally available highly selective small-molecule MNK 1/2 inhibitor which belongs to the selective translation regulator (SRS) class of drugs. It has a well-defined mode of action, a strong safety profile and well-established pharmacokinetics (PK). AUM001 has shown potential in colorectal cancer (significant unmet medical need in china) – over USD 10 billion market globally and that is excluding China – as well as chronic myeloid leukemia (CML). Additional data suggests potential in major solid tumor indications which addresses a significant unmet medical need for Asian patients.

AUM302 is a first-in-class oral kinase inhibitor rationally designed to uniquely combine pan-PIM kinase, pan-PI3K and mTOR inhibition in a single agent. It has strong efficacy, good tolerability and favorable drug properties. AUM302 has potential to be developed in Breast cancer, Lung cancer along with orphan drug indications.

As a company, our goal is to be a multi-molecule company by end-2020. This would allow us to balance the risks of our portfolio, making us an excellent proposition for investors. The true value of AUM lies not in the individual molecules within our portfolio but in our intrinsic ecosystem of proprietary technologies.

AUM Biosciences is currently headquartered in Singapore. What is the strategic significance of the China market to you?

China is integral to our vision. Fundamentally, I believe that China is on the cusp of a unique opportunity when it comes to drug R&D. Firstly, the country has made pharma R&D a priority with a 5 to 10-year vision. There is the ambition to move up the innovation value chain. Secondly, the Chinese innovative pharma industry is still in its infancy, which leaves room for much opportunity and growth. In 2018, 51 percent of the entire Chinese innovation pipeline was pre-clinical. Nearly 20 percent was in Phase III, leaving around 30 percent in Phase I and II – which, if you recall, is where 90 percent of drugs fail. Plugging that figure in, it means that less than 3 percent of those Phase I/II assets will make it to Phase III. Even fewer drugs move from preclinical to clinical.

AUM welcomes partnership with Chinese companies with the ambition of developing first in class therapeutics. The biggest challenge – and therefore opportunity – lies in Phase I and II. AUM's holistic development model coupled with Chinese biotechs' vast and extensive localized knowledge of the oncology and regulatory trends, will allow us to conduct drug R&D more efficiently, maximizing the value of their early-stage assets.

As an Asian biotech, we are looking to reverse the model where innovative drugs are approved first in the West and then brought to the East. We want to minimize the regulatory lag between Western and Asian markets, in order to manage the heterogeneity of the Asian regulatory environments.

We welcome opportunities with our prospective partners investors to support us in our vision of developing affordable and accessible cancer drugs globally, including China, where many patients cannot afford major cancer therapies.

How do you see the current Chinese biotech ecosystem?

I believe that the Chinese biotech industry is a tremendously exciting and vibrant one, and China is an interesting market. The industry is still young, but poised for growth. I would highlight two points.

Firstly, is to clearly define the understanding of innovation. There are many ways to do innovation. It is not just about moving from ‘me too’ to ‘me better’ drugs or about following the new trends like immuno-oncology and CAR-T. Secondly, there will eventually be a need to balance between speed and quality – not only in terms of the product innovation itself but also innovation in business models.

From observation, China’s focus has been on research innovation – the ‘R’ part of R&D. But they also have the opportunity to become champions of development or process innovation – the ‘D’ part of R&D, which will catapult China up the innovation curve.

On a more personal note, what have been the most rewarding and challenging moments for you since the AUM journey started?

Every challenge is an opportunity for me, and I see a great opportunity in taking people along the disruptive and innovative journey of AUM. With our unique research & development model, we are confident that we can articulate the added value that AUM Biosciences brings to the table in the biotechnology industry. Our value lies not only in our molecules, but in our process innovation platform, model and vision. Ultimately, together with our partners, we aspire to create an ecosystem that will revolutionize the biotechnology industry in Asia.

On the flip side, the most rewarding moment for me is how the disruptive vision has materialized over the past two years. From that initial small conversation with my cofounder and Chief Medical Officer Dr. Harish Dave to today, in the short span of two years, we have grown from an idea to a multinational biotech with a portfolio of first in class targets.

I am also proud that we were recently awarded 2019 Asia-Pacific Biotech Entrepreneurial Company of the Year by Frost & Sullivan, which really recognizes the disruption we are bringing in the Asian biotech industry.

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