Aurisco turns 25

A talk with Aurisco's founder and chairman

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This year Aurisco turns 25 years old. Aurisco's founder and chairman, Peng Zhien reflects on the company's 25th anniversary, how it all started, the contribution of the business and what lies ahead.

On March 5th, 2023, Aurisco Pharmaceutical celebrated its 25th anniversary in the API industry, serving both generic and innovative pharma with complex small molecules, oligonucleotides and peptides. With 3 cGMP inspected manufacturing facilities and 250 scientists, the company has expanded its portfolio from steroids and complex chiral molecules to mRNA oligonucleotides, modified phosphoramidites and peptides. Milestone anniversaries are a good time to look back and celebrate accomplishments. "We are proud of how the company evolved and our continued success after a quarter century." – says Peng Zhien, Aurisco's founder and chairman.

Which goals did you have in mind when you created Aurisco 25 years ago?

PZ – As a team of chemists back in 1998, we wanted to produce something special, to use science and develop advanced technology to manufacture challenging products with consistent high quality, that could save lives or significantly improve the lives of patients.

What thoughts and emotions come to mind when you think about that?

PZ - We recognize how hard it was to build Aurisco's international business reputation and how technical competence, GMP compliance and customer centricity were key elements to attain success. We feel proud and humble as we didn't walk this road alone. We must thank our employees, customers and partners, who have helped building this successful business story.

What does it mean to you to carry on this successful business for such a long time and what do you see as the biggest accomplishments since your start in 1998?

PZ - Our team's success comes from being innovative and playing ahead of the competition. We were the first pharmaceutical company in China to produce steroids from phytosterols and became the best, vertically integrated manufacturer of Flumethasone in the world, contributing to saving millions of lives among asthma and COPD patients across the globe. In 2020 we got listed in the Shanghai Stock Exchange and launched Shanghai Aurisco Biotech, a CRDMO to support customers developing RNA-based therapies. We are again taking a leading role in bringing affordable new therapies to patients, launching our first generic oligonucleotides and peptides in 2023, and that makes me feel very satisfied.

Shanghai Aurisco Biotechnology – a fast CRDMO for Oligonucleotides and Peptides

You work with both innovators and generics. How do you manage IP and how much innovation is necessary to make a copy of an existing molecule?

PZ – We work under Non-Disclosure Agreements, with confidential information for each project being coded and kept secret. As a science-based company, we need to protect our know-how and Aurisco files its own patents, but when working in the CRDMO model, all generated IP belongs to the customer. Innovation is a pillar of our success.
Regarding your second question, a generic API needs to be the same as the innovator's molecule, but a lot of innovation is required to make it affordable, safe and more sustainable, while respecting existing patents. Besides having to fully characterize both the generic and reference listed drug to demonstrate sameness, we also need to ensure that, if a different route of synthesis or starting material is used, we keep the same impurity profile, maintaining the critical product attributes and safety profile. This is particularly challenging for complex generics.

Can you give us an example of how you're using science to make APIs more affordable?

PZ – While most manufacturers make steroids like betamethasone and dexamethasone by fermentation of Yam (a root similar to sweet potato), Aurisco invested significant R&D resources to become the 1st company in China to develop a sustainable alternative route, using Phytosterols to produce key intermediate 9-OH-AD by fermentation and then to convert that into regulatory starting materials like 3-TR, 8-DM, Dexamethasone, DB-11, Betamethasone, etc.

Why is that process more sustainable?

PZ – Using Phytosterols we are adding value to by-products of agriculture, instead of using Yam, which is a basic food ingredient. The industrial demand of yam made prices double between 2000 and 2006 and we're presently going through another price peak, making it more difficult for people to access this essential food product in low-income countries. I can give you other good examples of using science to achieve environmental targets: We use industrial scale photochemistry to avoid using toxic reagents and developed advanced asymmetric catalysis and biocatalysis to increase selectivity, avoiding the need for expensive chromatography steps and reducing waste, water use and energy consumption.

Industrial photochemistry is a quite unique capability. We tend to see this more in flow-chemistry academic papers. Do you use it as a specific application or is it a broader capability?

PZ – Aurisco adopted photochemistry because it is more sustainable and more selective. We have installed continuous flow photochemistry units at lab, pilot and commercial scale, where we can produce tens of tons of APIs with this technology. We already commercially produce generic Budesonide, Dydrogesterone and Nicergoline using photochemistry, but we also offer this as part of our CRDMO toolbox.

And why did you get into oligonucleotides and peptides? How do you differentiate yourself from your competitors in this space?

PZ - Our expertise is in making APIs. We support customers who make complex drug products and decided to grow by broadening our offer into new modalities instead of going upstream and compete on the finished product. We have very good technology, great people and excellent equipment. We hired very experienced scientists to provide our innovative customers a contract research, development and cGMP manufacturing service (CRDMO) with top quality, high speed and reasonable price.

We offer modified phosphoramidites for RNA manufacturing and we're developing a pipeline of generic oligonucleotides such as Nusinersen and Inclisiran (where we produce our own GalNAc) and generic peptides such as Semaglutide and Tirzepatide. First DMFs should be filled in 2023 and 2024.

Aurisco Biotechnology is a recent entity, but you seem to be working fast to meet timelines. How have you achieved this?

PZ – Our Aurisco Biotech subsidiary was launched by experts with 10 to 20 years of experience, who had worked in Europe, North America and China. However, we have been using biotechnology for a long time, to develop and manufacture enzymes, peptides and small molecules and we have a very experienced analytical and regulatory team, that is a critical success factor in this space.

Aurisco was the first Pharmaceutical company in China to pass a RX360 audit for supply-chain security. How important is that for your customers, in times where security of supply is a hot topic?

PZ - We care for life. We work every day with the health and safety of our patients as the priority. This means that our operations must be sustainable, that our colleagues work safely, our factories are safe and compliant, we and our supply-chain partners operate under a code of conduct that is aligned with the Industry's best practices. Besides RX360, we passed every GMP inspection from FDA, EU-GMP and NMPA and we welcome our customer's audits. This is how we guarantee peace of mind and stability to our customers.

Regarding sustainability and ESG, how do you see Aurisco contributing to a better Pharmaceutical supply chain?

PZ - Aurisco has stable ownership, stable employees, stable systems from development to manufacturing and a stable supply chain. We are ethical, responsible and accountable, doing the right thing even when nobody is looking. We abide to applicable anti-corruption laws and implemented a code of conduct for our suppliers in line with the guidance from the sustainable procurement pledge. We will continue to focus on sustainable development. We have joined initiatives like Energize and Manufacture 2030 to reduce carbon emissions and adopt renewable energy sources and invest continuously to improve our processes. The company's commitment to EHS and sustainability has been recognized in multiple occasions and awards and through our Ecovadis ranking.

When you look forward to the next years for Aurisco, what are your expectations for the company?

PZ - Aurisco will remain as a customer oriented reliable API partner, investing in the best technologies from chemistry, biology and pharmaceutical sciences to consistently offer high-quality, safe and affordable complex products. We will keep pioneering in the adoption of best manufacturing practices, digitalization and automation, and maintain high standards in GMP, HSE and ESG compliance, and reinforce our commitment to sustainability.

In the coming years, Aurisco will become an international company, by setting up or acquiring facilities in EU and North America. We will bring more international colleagues on board, increasing our diversity and broadening our experience to provide worldwide customers more products, services and higher value. With our patients and next generations in our mind, we will use science, collaborating with our customers and partners every day, to bring new drugs to market faster, reducing cost and making them available to a broader population in the most sustainable way.

We see a bright future ahead of us but, no matter how global and successful we get, we will keep being the same flexible and humble business partner as we are today.