

In the Competitive World of Pharmaceutical Product Development, Specialty Drug Delivery Company Abon Pharmaceuticals, LLC has Distinguished itself with its Ability to Develop a Product before the Competition

**Healthcare
Specialty Pharma
(Private)**

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**Dr. Salah U. Ahmed
President and CEO**

BIO:

Dr. Salah U. Ahmed is the President & CEO of Abon Pharmaceuticals, LLC. Prior to the establishment of Abon, he was the Executive Vice President of Global Research and Development and Chief Scientific Officer at Barr Pharmaceuticals, Inc. He was responsible for the development of generic and proprietary pharmaceuticals as well as API and biotechnology products. Barr's product portfolio encompassed diverse Drug Delivery Systems (DDS) including parenteral, nasal, ocular, oral, transmucosal, transdermal, and intrauterine routes of administration. The corporation ran its research and development operations in the USA and several countries in Europe.

Dr. Ahmed received his MS in Industrial Pharmacy and PhD in Pharmaceutical Sciences from St. Johns University, New York. He has more than

a quarter century of pharmaceutical experience, of which 16 years were at Barr Pharmaceuticals, Inc. His leadership role in product development significantly contributed to Barr's transformation to a specialty pharmaceutical company and a world leader in the generic pharmaceutical industry.

Dr. Ahmed has a distinguished track record in pharmaceutical research involving special DDS, solid-state interactions, statistical design and mathematical modeling in product development research, and in-vitro/in-vivo performance of dosage forms. His research work in these areas originated more than 40 patents. He authored or co-authored more than 60 research papers, abstracts and book chapters.

Company Profile:

Abon Pharmaceuticals, LLC is a specialty pharmaceutical company focused on drug delivery research and product development. Abon's expertise and flexibility can bring a complex formulation project to clinical or bioequivalence study in a timely manner and within budget. Whether your goal is to improve bioavailability, achieve bio-equivalence, or develop a new product, Abon's innovative approach to formulation development will meet your expectations. Abon's professional team of scientists has a proven track record in a multitude of dosage forms, and has multiple patents in drug delivery.

**Interview conducted by:
Lynn Fosse, Senior Editor**

CEOCFO: Dr. Ahmed, what is the focus at Abon?

Dr. Ahmed: The Company focuses on the development of drugs that have high barriers to entry.

CEOCFO: That is a pretty broad range; what are you focusing on and how have you chosen which particular areas?

Dr. Ahmed: We currently focus on Controlled Release oral and Long Acting injectable drug delivery systems.

CEOCFO: What projects are you working on now?

Dr. Ahmed: We are working on various kinds of products that involve psychotherapeutic drugs, anti-cancer drugs, anti-rheumatic drugs and hormone replacement therapy.

CEOCFO: Are you doing this with partnerships or are you developing these on your own?

Dr. Ahmed: Both. We are developing some products on our own and others in partnership with other pharmaceutical companies.

CEOCFO: What makes you decide to take on a particular project or drug?

Dr. Ahmed: Typically, we select products that have a high degree of difficulty in development, which helps assure good marketability. We evaluate the chemical and pharmacokinetic attributes of the drug in combination with the complexity of the dosage form.

CEOCFO: What are the particular skills at Abon? Why are people working with Abon? What do you bring to the table as a company?

Dr. Ahmed: Abon Pharmaceuticals is a specialty drug delivery company. Our ability to assess in-vivo perform-

ance based on in-vitro characterization provides high assurance in the biostudy success, thereby saving overall development costs and time.

CEO CFO: What can you tell us about Clolar®?

Dr. Ahmed: Clolar is a Genzyme product indicated for the treatment of acute lymphoblastic leukemia in pediatric patients. Abon has filed an ANDA with the FDA and is seeking approval for a generic version. This is a patent challenge product so I will not be able to discuss a lot on that matter, but we believe we are the first and only ANDA filer and could potentially qualify for 180 days of generic exclusivity once approved and launched.

CEO CFO: How do you reach your potential partners?

Dr. Ahmed: I was the Chief Scientific Officer and Global Head of Research and Development at Barr Pharmaceuticals. The company was acquired by Teva Pharmaceuticals. After the acquisition by Teva, many of my former colleagues have moved on to leadership positions at other reputable pharmaceutical companies. Some have reached out to me and sometimes I reach out to them. We do not intend to look for too many partners. We look for partners who have similar views regarding the market and product opportunities.

CEO CFO: Why did you decide to establish Abon rather than work for another large pharma?

Dr. Ahmed: During the acquisition of Barr Pharmaceuticals, I decided not to take a position with Teva. I thought that establishing a company would be more challenging and rewarding. I believed founding this company, Abon, would enable me to bring to market generic versions of medications that are difficult to develop, and allow me to develop some advanced dosage forms to better serve patients.

CEO CFO: What surprised you most in the development process?

Dr. Ahmed: Many things were surprising. Establishing a new company

requires much more than developing products in an established research and development company. In the early days of Abon, we needed to set up the business entity and financing procedures, hire the right people, establish supporting departments and job functions, procure and install equipment with the appropriate utilities, for example. The details of such tasks were quite surprising. I had to tackle challenges in areas of expertise that I never knew existed. I learned a lot in the process, and thank God, we are in a strong running position today.

CEO CFO: How is business these days?

Dr. Ahmed: Business is good. Thus far, we have filed five products with the FDA, one of which is our own. Currently, we are working on about a dozen products, of which half of them we intend to file in the next year. We also filed patent applications and

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generated a couple of oral drug delivery platforms, which we believe is a good achievement for the company. We are doing well and we are very happy at this stage. We have achieved some of the capabilities that I believe only a handful of other specialty generic companies may have in the USA, such as the capability of development of long-acting injectable products using biodegradable polymers.

CEO CFO: Is it the polymer that makes it different or is it the knowledge of how to put it all together?

Dr. Ahmed: Both. Some polymers used in long acting injectables have existed before, but using a polymer to form a microsphere is complex. A microsphere is a very small micro particle in which the drug is embedded inside. When injected, the microsphere slowly degrades resulting in a breakdown of the polymer and release of the drug for a prolonged period of time, e.g., weeks or months. We are developing generic products

using this technology and I believe, few, if any, generic companies, are capable of developing products with this technology.

CEO CFO: Why should Abon Pharmaceuticals stand out to investors?

Dr. Ahmed: Among the several reasons Abon stands out, noteworthy to mention is that Abon uses a science based development approach without compromising the speed of development. In this competitive world of pharmaceutical product development, what distinguishes Abon is not the ability to develop a product, but rather the ability to develop a product before the competition does. Another factor that distinguishes Abon is the depth of our knowledge of FDA requirements. The FDA imposes many regulatory requirements on drug developers. Keeping up to date and integrating these requirements into the product development is critical in order to have a product filed, accepted and approved by the FDA. We ensure quality is integrated into the product during each phase of development. Another feature that distinguishes Abon is our ability to predict bio-performance. If

a product fails a bioequivalence or clinical study, the sponsor will suffer from the costs of the study and will lose valuable time. Lost time could mean a significant loss in sales. We have a good track record in predicting bio-performance from our extensive in-vitro studies. These are our internal capabilities. We fully characterize the drug and consider the physicochemical and pharmacokinetic attributes of the dosage form to predict the bio-performance of that product. These capabilities and our successes distinguish Abon from other companies.

CEO CFO: What should people remember most about Abon Pharmaceuticals?

Dr. Ahmed: Abon is a small company with about forty employees. More than 75 percent of our R&D scientists/chemists are PhDs. I believe our lab is probably one of the top in formulation research in the U.S. Our capability to develop multiple types of dosage forms in an organizational structure entirely focused on R&D is

unique. We do not have the inefficiencies typically found in larger pharmaceutical companies. Because

of our experience, pilot plant and lab capabilities, company size and focus,

we can develop products with great speed, accuracy and quality.



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