Drug Delivery Technology®

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Increasing Bioavailability of Poorly Soluble Drugs

The science & business of drug development in specialty pharma, biotechnology, and drug delivery

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DSM BIOMEDICAL: PROVIDING SOLUTIONS FOR THE BIOPHARMA & MEDICAL DEVICE INDUSTRIES

Mr. Donato Di Biase
Business Director
DSM Biomedical

"Basically, when working with DSM Biomedical, our partners are not given a single product option (a square hole) and left to assess which drug in their portfolio happens to be the square peg that may be compatible with the delivery material. DSM Biomedical's partners are offered access to a vast portfolio of IP-protected materials, as well as access to the full range of competencies and services of one of the world's largest materials science companies."

DSM Biomedical is a global leader in biomedical materials that provides proprietary materials-based solutions, designed to enable new and more effective patient treatments for the medical device and biopharmaceutical industries. Building on the expertise and strengths of DSM and its 2008 acquisition of The Polymer Technology Group (now known as DSM PTG), DSM Biomedical's product portfolio includes coatings, drug delivery platforms, and a wide range of biomedical materials for use in short- and long-term implantable medical devices. Leading the company's charge in the drug delivery industry is Business Director Donato Di Biase. Drug Delivery Technology recently interviewed Mr. Di Biase to discuss DSM Biomedical's drug delivery business unit, what makes its technology unique, and what the future holds for the company.

Q: Can you provide some insight into DSM Biomedical's Drug Delivery unit?

A: DSM is unique to the world of drug delivery. Given that we are part of a leading life science and materials science company, our drug delivery business is built on the best practices in polymer science, which we have employed to develop uniquely designed systems for the biopharmaceutical and medical device industries. Through strategic alliances and co-development programs, we strive to enable our partners to maximize value from their products by introducing novel drug delivery technology into their pipeline. DSM Biomedical seeks to partner for the co-development of next-generation products in the ophthalmology, cardiovascular, orthopedic, and pain management therapeutic areas.

Q: Can you provide more specifics about your unique product portfolio?

A: On a macro level, our Trancerta™ Drug Delivery platforms encompass both our portfolio of novel, fully bioresorbable

material platforms as well as our extensive in-house library of synthesis methods, formulation, and processing techniques. All of our materials are designed to handle specific drug payloads, to release and degrade based on a requisite profile, and are easily introduced to the target tissue alone or in combination with a device. The Trancerta Drug Delivery platforms include materials suitable for delivery of both small molecules and complex biologics.

More specifically, the Trancerta Drug Delivery portfolio offers a range of material platforms, including both hydrolytically and enzymatically degrading materials, which are able to be processed into various forms from injectable nanoparticles or rods, to gels and coatings. These materials include novel proprietary linking technologies, such as polythioesters and novel polyurethanes. For example, our polythioester linking technology allows customized solutions with well-established building blocks, such as the lactic/glycolic acid polymer family. In addition to the polythioester and novel polyurethane based materials, DSM Biomedical has expanded the portfolio with the addition of a novel amino acid-based material.

Q: Please tell us more about this new family of amino acid-based polymers.

A: In March 2009, DSM Biomedical obtained an exclusive worldwide license for a unique delivery system developed by MediVas LLC. The technology, known as PEA or Polyester amide technology, has an IP portfolio containing more than 60 issued or pending patents. The polymers are bioresorbable, biocompatible, and allow for greater control over the rate and duration of release of their therapeutic payload.

Q: How is DSM Biomedical's drug delivery technology different from other technologies on the market?

A: In addition to being backed by a strong IP portfolio, our materials (and more notably, our materials science expertise) offer flexibility from a molecular level (ie, changing monomer building blocks to interact with a specific portion of a drug molecule) to a larger dosage form level (ie, designing a new processing technique in order to extrude a polymer into an injectable rod). Basically, when working with DSM Biomedical, our partners are not given a single product option (a square hole) and left to assess which drug in their portfolio happens to be the square peg that may be compatible with the delivery material. DSM Biomedical's partners are offered access to a vast portfolio of IP-protected materials, as well as access to the full range of competencies and services of one of the world's largest materials science companies. Instead of being offered a square hole, we ask our Partners, "What are you trying to achieve in your patient populations, and what type of delivery system would you like us to design?"

Q: What are the clinical benefits of products delivered with Trancerta Drug Delivery?

A: We are always amazed at the number of therapeutic compounds in biopharma's

arsenal, and it is a shame that many do not make it into the clinic due to safety issues. If delivery science can help bring a compound to the market because its release is being controlled, or because the new dosage form allows for an optimized administration method, then one benefit may be simply the availability of otherwise unapprovable drugs. Looking at dosing as an example, because we are able to optimize both the loading processes and the total drug loading of the material, our systems by result are ideally designed for the individual drug at hand. This then allows for smaller total doses of drug to be administered to the patient.

Q: Why should biopharma companies choose Trancerta Drug Delivery to deliver their products?

A: As part of a global life sciences and materials sciences company with leading positions not only in polymer sciences but also in pharmaceutical products manufacturing, DSM Biomedical offers partners bench-to-bedside product and service offerings. In the development stages, we build on the expertise and strengths of DSM, extracting the top design and processing methods needed to develop superior drug delivery systems. When it's time to scale-up, we involve our DSM Pharmaceutical Products business units, who are world leaders in pharmaceutical products manufacturing, including that of the API itself, formulations development, fill and finish services, and even final packaging.

Q: The biomedical industry is a highly competitive one, with innovations constantly being developed. What sort of intellectual property is DSM building in drug delivery?

A: First, our intellectual property assets are based on very strong, internal material science competences. This results in a continuously growing patent estate on materials and processing technologies. Second, and most importantly, we develop new IP in close cooperation with our partners, believing that these multidisciplinary innovations have the best economic impact for all parties.

Q: What do you expect to see in the way of future developments for DSM Biomedical's drug delivery portfolio?

A: Today, we will continue increasing the number of partnerships in our core strategic areas of ophthalmology, cardiovascular, musculoskeletal, and pain management. Going forward, we will expand our delivery science into other therapeutic areas where our technology can provide value in helping to improve the treatments and quality of life for patients worldwide. ◆