

PROSONIX ENTERS NEW AGREEMENT FOR ULTRASONIC PARTICLE ENGINEERING OF INHALED MEDICINE

Prosonix Ltd (Oxford, UK) is delighted to announce a new agreement for the application of its proprietary ultrasonic particle engineering technology in the pharmaceutical industry.

This new agreement has been concluded with Aeropharm (Rudolstadt, Germany) and is concerned with the development and manufacture of a new generation of “*difficult-to-make*” generic products. According to a recent industry report, the market size for inhaled medicines is expected to rise to \$58 billion in 2012. With a significant portion of these revenues available for near term generic substitution, and inhaled drug delivery representing one of the most difficult material science challenges from an equivalence perspective, there is an ideal opportunity to leverage a new ultrasonic particle engineering led approach to generate lasting and significant commercial advantage.

Limitations of conventional crystallization techniques for the manufacture of active pharmaceutical ingredients typically result in the need for milling or micronisation to achieve the small particle size necessary for delivery via inhalation. Such secondary manufacturing destructive based techniques can be unnecessary and more importantly can adversely affect a range of highly important physicochemical properties of the active pharmaceutical ingredient. This can lead to problems in formulation preparation and variability in drug product performance.

Using Prosonix’s sonocrystallization technology can eliminate the need for milling and micronization by enabling the construction and isolation of ideal crystalline particles directly from solution. The particles have optimum size and shape, and can be “*designed for purpose*” to have ideal performance enhancing attributes for delivery by pMDI, DPI, and nebulisation platforms.

Commenting on the deal, Prosonix CEO David Hipkiss said,

“I am delighted to be able to announce this new collaboration with Aeropharm, an affiliate of Sandoz and an acknowledged and emergent leader in the very challenging area of generic inhaled medicines. It provides further validation of the Prosonix business strategy, with our technology offering several significant advantages over current milling and micronization methods. By collaborating with Aeropharm we will ensure the strength and size to see any success through to full commercialization and we look forward to working with them in the months and years ahead.”

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About Prosonix Ltd

www.prosonix.co.uk

Based in Oxford UK and Experts in Sound Science™, Prosonix are acknowledged leaders in the commercialization of proprietary ultrasonic particle engineering technologies and added value ultrasonic process chemistry solutions for the pharmaceutical and related industries.

Prosonix's team of chemists and engineers combine to give Prosonix a unique multidisciplinary approach and competitive advantage to solve customers complex particle engineering process problems, leveraging it's proprietary intellectual property and patented ultrasonic processing equipment to deliver long term and sustainable value added solutions, enabling the cost effective manufacture of better medicines.

Prosonix's core markets are in the Pharmaceutical and Chemical industries, having secured over 50 worldwide customers to date.

Prosonitron™, Prosonix's world leading patented sonocrystallization process and reactor technology is already proven across scale, facilitating the Complete Crystallization Control™ of many aspects of complex pharmaceutical crystallization processes, including control of crystal size, shape, purity, the selective production of polymorphs, enhancing both manufacturing productivity and ultimate formulation performance. New and proprietary process variants include DISCUS™ and UMAX™ for the advanced particle engineering of microcrystalline active ingredients. In addition a new range of small scale SonoLab™ equipment is now available for laboratory and kilo lab use. Prosonitron™ technology is increasingly being recognised as the *defacto* first choice in pharmaceutical API crystallization and isolation. In this regard, Prosonix announced in September 2008 that Pfizer Group Manufacturing had selected the Prosonitron™ technology for implementation at its primary manufacturing Ringaskiddy facilities in Ireland.

SAX™, an award winning Solution to Particle sonocrystallization based technology, is a novel ultrasonic particle engineering and drug delivery technology with world beating potential, which builds on Prosonix core Prosonitron™ technology. SAX™ can produce highly engineered single and combination microcrystalline drug particles that are ideally suited for inhalation, without the need for destructive milling or micronisation processes. SAX™ particles have better stability, formulation consistency, eliminates dose-to-dose variation and exhibit potentially improved efficacy per unit dose than those made by other techniques. Prosonix in-licensed the SAX™ technology from the University of Bath on a world wide exclusive basis in February 2007 and have completed over 20 feasibility studies to date.

In January 2008 Prosonix in-licensed a novel particle rounding technology process patent from Rafael Industries(Haifa, Israel) Importantly the process patent is already granted in key geographies and has wide ranging utility independent of the method of ultrasound delivery in secondary particle engineering, post initial crystallization and isolation. Key applications include particle rounding to improve product flowability and rheology, compressibility, and added concomitant benefits in formulation performance and assurance. Additional opportunities in taste masking, coating, and granulation are also emerging. Used in combination, the Rafael process technology and the proven Prosonix Prosonitron™ process and reactor technology represents an ideal solution to a range of common secondary pharmaceutical manufacturing problems.

Underpinning Prosonix's leadership in commercializable crystallization technology is CrystalGEM™ and SonoLab™. Marketed in partnership with Chiralabs (Oxford, UK) the CrystalGEM™ offering is a unique and award winning predictive crystallization service that significantly enhances crystallization screening productivity in pharmaceutical development. SonoLab™ is a suite of designed for purpose small scale reactors that can be used by the laboratory chemist with confidence, knowing that a proven scale up method already exists. In October 2008, Prosonix announced a worldwide sole marketing partnership with Syrris (Royston, UK) positioning Syrris as the prime channel to market for the new SonoLab™ range.

Complementing its market led internal R&D programs, Prosonix is also actively engaged with several strategic partnerships with leading academic and technology institutions, including the University of Bath, University of Coventry, and the University of Leeds.

Prosonix is further supported by leading industrial and academic consultants including but not limited to Professor Rob Price (University of Bath, UK), Professor Kevin Roberts (University of Leeds, UK) and Professor Tim Mason (University of Coventry).

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