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Prosonix Attains International Quality Approval

Prosonix (Oxford, UK) is pleased to announce that it has achieved accreditation to the Quality Management standard ISO 9001:2008 following a recent audit of business systems and procedures by independent external auditors SGS (UK) Ltd.

This covers Prosonix full range of activities from the Research and Development of ultrasonic particle engineering solutions for crystallisation and formulation problems, to the licensing of its proprietary technology for the controlled production of advanced, highly engineered crystalline pharmaceutical materials.

The approval also underpins Prosonix progression following a substantial investment in staff and facilities at the Oxford Science Park to meet rapidly growing demand for its products and services.

Commenting on the achievement, David Hipkiss Prosonix CEO said

“This is an excellent outcome for Prosonix, and is the result of many months hard teamwork by all of the Oxford based staff. The achievement of ISO 9001 certification is an important stepping stone towards the Company’s objective of being capable of providing products manufactured to Good Manufacturing Practice (GMP) to the world’s leading pharmaceutical companies within the next year, and in particular meeting their complex needs for their advanced inhalation products of the future.”

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Notes for Editors Correct as of June 2009

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 core pharmaceutical market.

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 its 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.

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™.I and DISCUS™.M 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™ and UMAX® are proprietary *Solution-to-Particle* sonocrystallization processes technologies with world beating potential for inhalation drug delivery. These build on Prosonix core Prosonitron™ technology. Both processes 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. Prosonix have proven *in-vitro* that the resultant particles have better stability, formulation consistency, eliminates dose-to-dose variation and could 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. UMAX® is a new and proprietary process technology discovered and developed exclusively by Prosonix.

In January 2008 Prosonix in-licensed a novel particle rounding technology process patent (PRT) 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 the post crystallization 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 PRT 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), and Dr Steve Nichols former Head of Inhalation at Sanofi-Aventis UK.

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