# NEWS 02 2015

## Improved Bioavailability through cGMP super critical fluid atomization.

Cerbios-Pharma SA (from now on "Cerbios") has invested in a cGMP atomization plant for particle engineering using super critical fluid technology capable of generating micro and nano APIs particles with very narrow particle size distribution.
By the end of 2015 the plant will be fully operative for the handling of HPAIs (High Potency Active Ingredients) at 200 grams cGMP scale.

"I am very excited about this latest addition to Cerbios' available technologies for the production of outstanding HPAIs (Highly Potent Active Ingredients)" says Gabriel Haering, Cerbios' CEO.
"By using this technology, potent compounds with dosages lower than one milligram may potentially become ultra-potent, since nanoparticles are known as an attractive solution to improving bioavailability of poorly soluble compounds. This may eventually result in an improved clinical profile.
Lower dosage options have, in fact, several positive advantages ranging from improved drug tolerability to cost-savings for dosage-form makers, healthcare Institutions and patients" states Andrea Tam, Cerbios' Chief Commercial Officer.

Particle engineering Bioavailability enhancement via supercritical fluid atomization may impact on several pharmaceutical preparations profiles.

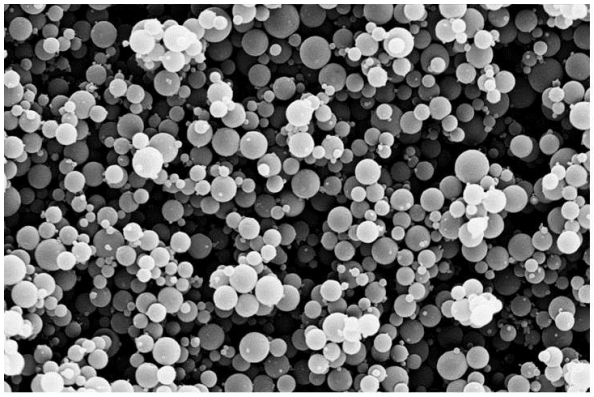
- solid oral
- injectable
- suspensions
- Inhalable powders

Typical therapeutic areas where this could have an important impact on HPAI becoming even more potent are

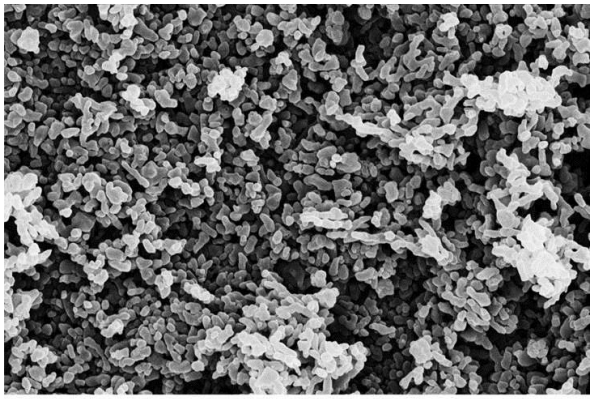
- Oncology
- Respiratory
- Dermatology
- Ophthalmology

And many others

The technology and services Unlike traditional methods used for particle size reduction, supercritical fluid-processing techniques offer advantages ranging from superior particle size control to clean processing.
The powders obtained from the process of atomization using supercritical CO2 display an extremely limited Particle Size Distribution (see figures below), with particles in the submicron or few micron range.




Amorphous HPAI




Semicrystalline HPAI

The possibility to choose among different atomization technologies (SAA or SAS) provides more options to achieve unique particle features including particle size distribution and specific surface area as well as superior formulation performance.
Technology selection criteria are based on product affinity for carbon dioxide and the solvent to be used during processing

This technology will expand Cerbios' contract manufacturing services platform in the area of HPAIs, either in conjunction with the production of the HPAI itself or as a standalone option. Typically,the initial project development phase will confirm its technical feasibility, not only at PSD or particle design level but also the product stability in terms of its impurity profile and solid state form.
The scale-up in the cGMP plant will enable 50 – 200 grams of output capacity per batch of HPAIs.

Based on interest shown in the project, an upgrade of the unit to process larger batches as well as the construction of a large-scale unit for batches of up to 100x the present scale (20 kgs per batch) can be foreseen as options for the future.

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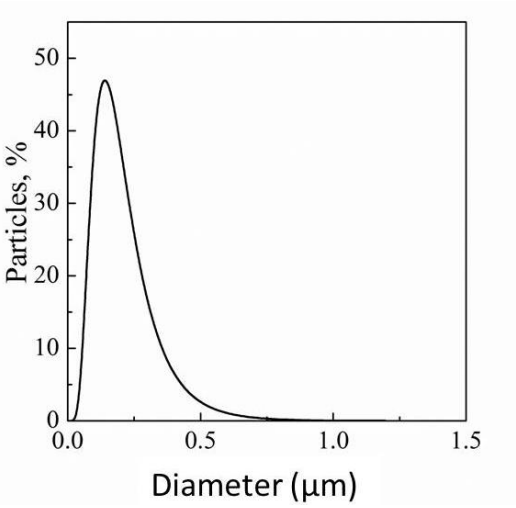
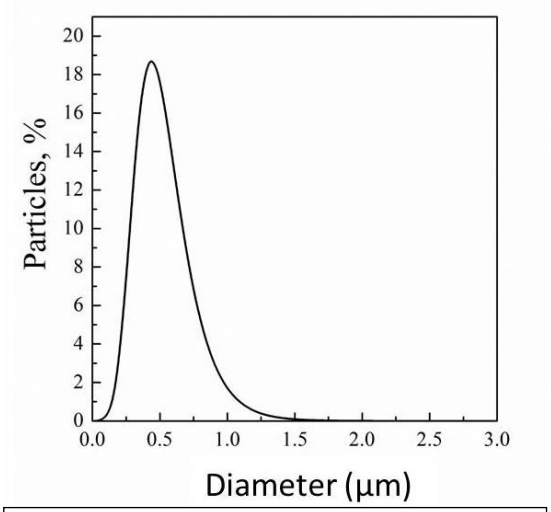



Nanonized API obtained by SAA technology (Supercritical Assisted Atomization)




Micronized API obtained by SAS technology (Supercritical Anti Solvent).

*About Cerbios-Pharma SA*
Cerbios is a privately held company located in Lugano, Switzerland, that specializes in the development and manufacture of both chemical and biological APIs for its partners world-wide.
Exclusive, third-party manufacturing services are offered by the Chemical Division for HPAIs and by the Biological Division for monoclonal antibodies, recombinant proteins and pharma probiotics.
Cerbios provides full CMC support to its world-wide partners, including the supply of cGMP clinical batches, registration/validation material and commercially manufactured APIs. Paramount to this is the ability to supply all of the technical documentation and support necessary for a successful registration. Cerbios' commercial products are marketed worldwide but primarily in Europe, USA, Japan and India