Vitrolife
Innovative Cell and Tissue Technology

Press release
December 21, 2010
Gothenburg

The U.S. Food and Drug Administration, FDA, approves Vitrolife's products for cold storage of embryos

Vitrolife has received approval from the U.S. Food and Drug Administration, FDA, the equivalent of the Swedish Medical Products Agency, for the products RapitVit™ Blast and RapidWarm™ Blast. So-called 510(k) clearance has been obtained for these products, which are used for so-called vitrification, the rapid freezing and thawing of blastocysts (embryos days 5-7 after fertilization).
Vitrolife has since before approved products for vitrification of embryos in an earlier stage of the fertilization (embryos day 2-3 after fertilization).

Products for vitrification involve considerable technological progress and open up new opportunities within in vitro fertlization (IVF) treatment. Vitrification involves very rapid freezing, to prevent the formation of ice crystals that otherwise can destroy the cells.

In IVF treatment, the woman has been stimulated with hormones and has more oocytes than normal. The oocytes that are fertilized but not put back in the woman can then be kept in cold storage. Clinical studies have shown that using the vitrification method considerably increases survival after cold storage compared with the previously used method. The chance of the woman getting pregnant again thereby also increases, without her having to undergo new hormone treatment and the removal of more oocytes.

RapitVit™ Blast and RapidWarm™ Blast have been previously approved in Europe and Canada.

The products will be launched on the American market as from the end of December 2010.

"The majority of clinics in the USA that vitrify embryos do so at the blastocyst stage. This approval means that Vitrolife gains both access to yet another non-processed market and opportunities for additional sales to current customers," says Nils Sellbom, Director of Marketing and Sales at Vitrolife.

December 21, 2010
Gothenburg

Magnus Nilsson
CEO

Queries should be addressed to:
Magnus Nilsson, CEO, phone +46 31 721 80 61
Anne-Lie Sveder, CFO, phone +46 31 721 80 13

Vitrolife is a global biotechnology/medical device Group that works with developing, manufacturing and selling advanced products and systems for the preparation, cultivation and storage of human cells, tissue and organs. The company has business activities within three product areas: Fertility, Transplantation and Stem Cell Cultivation. The Fertility product area works with nutrient solutions (media), cryopreservation products and advanced consumable instruments such as needles and pipettes, for the treatment of human infertility. The Transplantation product area works with solutions and systems to evaluate and maintain organs outside the body in order to select usable organs and keep them in optimal condition while waiting for transplantation. The Stem Cell Cultivation product area works with media and instruments to enable the use and handling of stem cells for therapeutic purposes.
Vitrolife today has approximately 220 employees and its products are sold in more than 85 markets. The company is headquartered in Gothenburg, Sweden, and there are subsidiaries in USA, Australia, France, Italy, United Kingdom and Japan. Production facilities are located in Sweden and the USA. The Vitrolife share is listed on NASDAQ OMX Stockholm, Small Cap.
