

ASX Release

Manufacturing Update

ArTiMist™ First Manufacturing Scale-Up Batch Successfully Completed

SUDA LTD (SUDA) is pleased to inform its shareholders that another significant milestone in the development of ArTiMist™ has been achieved.

Therapex have informed us that the first of the manufacturing scale-up batches has been successfully completed and the product manufactured has passed its quality assurance testing and is within the agreed specifications. This is an important step in the commercialisation process.

The ability to take a product from the laboratory to pilot scale batches, then through to commercial size manufacture, is not an easy process. Scale-up of any pharmaceutical manufacturing process entails a skilful combination of art, experience, science and engineering. It is well understood that the pace of new drug introductions has slowed, and many new drug candidates ultimately prove to be "unmanufacturable," wasting hundreds of millions of R&D dollars each year, so the Management at SUDA is happy with the news that through intensive planning and an effective technical transfer process our product has been scaled-up effectively.

During the scale-up process there is a need to apply effective quality and design procedures to ensure minimisation of the risk of failure, as well as to take into account the future cost of the product. Process development is one of the last and most important areas to play a role in ensuring the cost structure is as competitive as possible. The work carried out in Canada has addressed these areas and we look forward to the completion of the follow-up batches.



Further information:
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