

Next Science receives CE Mark approval for BlastX

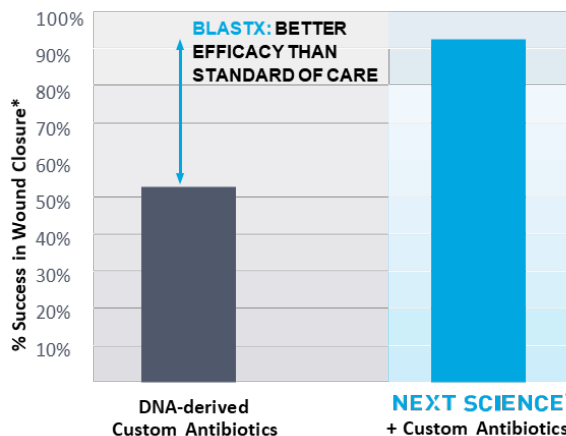
Sydney, Australia, Monday 21 December 2020: Next Science Limited (ASX:NXS) announces that it has received CE Mark approval for BlastX.

This allows Next Science to apply to sell BlastX in each market in the European Union and the UK. BlastX is the second Next Science product to receive a CE Mark, with Bactisure (distributed by Zimmer Biomet globally) receiving a CE Mark in March this year.

BlastX is an antimicrobial wound gel based on Next Science's patented, non-toxic, biofilm-disrupting Xbio™ technology. BlastX deconstructs the bacterial biofilm, the gel envelops and eliminates the bacteria and defends from recolonisation while maintaining a moist wound environment conducive to healing. The product is ideal for the treatment of non-healing wounds (**Chronic Wounds**) such as diabetic foot ulcers, bed sores (pressure ulcers) and venous leg ulcers as well as preventing infections in acute wounds and surgical wounds. Chronic Wounds continue to be a major health issue for patients in all countries in the world. They are very difficult to treat, increase pain and suffering, cause a decline in quality of life and increase mortality.

In a study conducted independently by Dr Wolcott at the South West Regional Wound Care Centre in Lubbock Texas, USA and published in 2015, it was shown that combining Next Science's BlastX with custom antibiotics increased the extent of chronic wound closures by 40% in 4 weeks based on a 45 patient, four week, prospective, randomised, controlled trial compared with customised antibiotic treatment alone¹.

Figure 1 BlastX comparison with customised antibiotics



* Defined as 50% wound closure in 4 weeks

As a collective, the Advanced Wound Care market in Europe is estimated to be valued at US\$2.8 billion per annum and is growing at 4.6% per annum.²

BlastX is currently sold by 3M in the US market with FDA 510(k) clearance for sale as indicated for use on patients with:

- Stage I – IV pressure ulcers

- Partial and full thickness wounds
- Diabetic foot and leg ulcers
- Post-surgical wounds
- First and second-degree burns
- Grafted and donor sites

BlastX is approved in the various markets in the European Union and UK for these same indications.

Managing Director, Judith Mitchell, commented: “The receipt of a CE Mark approval for BlastX represents the successful conclusion of three years of work and marks a major milestone for Next Science as we pursue our mission to heal patients and save lives worldwide by reducing the impacts of biofilms on human health. The CE Mark is a minimum requirement for many other jurisdictions so we can now work on further approvals.”

Other News:

General Market Update

Next Science’s revenue run rates in Q4 have returned to Q4 2019 levels. We look forward to further positive improvement in 2021 with the launch of our XPerience No Rinse Irrigation Solution. Launch of XPerience is dependent upon approval by the US FDA. Progress with the approval process is outlined below.

We continue to examine opportunities to expand commercial activities and establish greater control over distribution with a view to accelerating long term revenue growth.

Negotiations for the licensing of the Company’s surface disinfectant are ongoing and are expected to conclude in 1Q 2021.

XPerience No Rinse Irrigation Solution:

The Company will be resubmitting the 510(k) dossier for XPerience No Rinse Irrigation Solution by year end, on track with timing previously announced, having finalised the extensive additional testing requested by the FDA. Results from the additional testing do not appear to have raised any material issues.

Judith Mitchell, Managing Director, commented: “All of the test results of the product and the packaging show the safety profiles of both the solution and the packaging appear to be within the guidelines set out by the FDA and the ISO standards.”

Recent Publications On Our Science:

The Bone and Joint Journal has accepted Duke University’s submission for its scientific publication on: “Efficacy of Common Antiseptic Solutions Against Clinically Relevant Microorganisms in Biofilm”. Publication date to be confirmed. The study shows the effectiveness of Bactisure.

The Journal for Antimicrobial Agents & Chemotherapy is publishing in December 2020: “Efficacy of Biofilm Disrupters Against *Candida auris* and Other *Candida* species” from the University of Augusta.

The Journal of Wound Care is publishing in December 2020: a paper from Dr Thomas Serena on the “Use of BlastX with Negative Pressure Wound Therapy (**NPWT**) to advance

healing”. This is the culmination of work which commenced in 2019 and was disrupted by COVID-19, which concludes that the addition of BlastX to NPWT can heal patients who have had previously failed NPWT alone.

Managing Director Judith Mitchell commented: “We highly value the relationships we have forged with such strong collaboration partners. Next Science and our partners together seek to improve treatment of patients, save lives and reduce suffering through use of our technology to resolve unmet medical needs.”

Approved and authorised by the Board

Further information:

Judith Mitchell

Managing Director, Next Science Limited
Phone: +61 2 9375 7989
Email: investorqueries@nextscience.com

Michael Brown

Pegasus Advisory
Phone: +61 400 248 080
Email: mbrown@pegasusadvisory.com.au

About Next Science

Next Science is a medical technology company headquartered in Sydney, Australia, with a research and development centre in Florida, USA. Established in 2012, the Company’s primary focus is on the development and commercialisation of its proprietary Xbio™ technology to reduce the impact of biofilm based infections in human health. Xbio is a unique, non-toxic technology with proven efficacy in eradicating both biofilm based and free-floating bacteria. Next Science owns 100% of the patent protected intellectual property relating to its Xbio technology. Website: www.nextscience.com.

Forward looking statements

This announcement may contain forward looking statements which may be identified by words such as “believes”, “considers”, “could”, “estimates”, “expects”, “intends”, “may”, and other similar words that involve risks and uncertainties. Such statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions and other important factors, many of which are beyond the control of Next Science or its Directors and management, and could cause Next Science’s actual results and circumstances to differ materially from the results and circumstances expressed or anticipated in these statements. The Directors cannot and do not give any assurance that the results, performance or achievements expressed or implied by the forward-looking statements contained in this announcement will actually occur and investors are cautioned not to place undue reliance on these forward-looking statements

1. [Disrupting the biofilm matrix improves wound healing outcomes.](#) Wolcott R. J Wound Care. 2015 Aug; 24(8):366-71. doi: 10.12968/jowc.2015.24.8.366. 26562379
2. <https://www.marketdataforecast.com/market-reports/eu-advanced-wound-care-market>