

# NEXT SCIENCE®

## US Medicare accreditation signals growth in Wound Care revenue

**Sydney, Australia, Wednesday, 19 October 2022:** Next Science Limited (ASX:NXS) (**Next Science/Company**) announces the launch of topical collagen products (**Collagen**) to complement the Company's BlastX™ product. To take this product to market more effectively, the Company has established itself as, and been licensed and accredited by US Medicare as, a Durable Medical Equipment (**DME**) provider based in the State of Florida, USA.

### Highlights

- Next Science launches new Collagen products to complement BlastX™ wound gel infection treatment to improve patient outcomes. Sales to commence immediately.
- Next Science is also developing a new integrated BlastX™ Collagen wound product which will be submitted to the FDA for consideration as a 510(k) application in due course.
- Once market traction is established, sales from Collagen are expected to be material.
- Next Science has become accredited as a DME provider to expand its wound care footprint, drive commercial sales and facilitate Collagen reimbursement.

Biofilms are the major underlying problem in chronic, difficult to treat wounds. Next Science's XBio™ technology-derived products disrupt biofilms in wounds and are at the core of its mission to heal patients and save lives. One product at the heart of this commitment is BlastX™, developed for the management of wounds including various forms of chronic non-healing ulcers as well as other general and surgical wound infections.

As part of our research and development program, we continually explore how BlastX™ can complement and strengthen traditional wound healing support. An example at the forefront of this program is the use of Collagen with BlastX™ to enhance patient outcomes.

### **What is the role of Collagen in wound healing?**

Collagen is the most common protein in the human body, and as such has a wide range of biomedical applications. In the healing of chronic wounds, its optimal amount, structure and function are crucial for the reconstruction of a stable skin barrier and wound closure. Topical Collagen supplementation can modulate the chronic wound environment and have a positive effect on healing.

Due to its low antigenicity and inherent biocompatibility, Collagen is often used as a wound dressing for Venous Leg Ulcers, Diabetic Foot Ulcers, Pressure Ulcers, Surgical Wounds, Radiation Wounds, Burns, and as a Post-Operative Dressing. These

dressings have been shown to be practical and have economic advantages over Cell-Based dressings and Growth Factors for the treatment of full thickness wounds.<sup>1</sup>

Adding Collagen dressings to standard of care protocols has been shown to increase the probability of an ulcer healing within 6 months from 11% to 49% and may reduce management costs by 40%<sup>2</sup>.

### **Combining BlastX™ with Collagen**

Next Science is developing technology to combine BlastX™ with Collagen in both powder and sheet forms (the forms in which it is currently administered for wound care). The technology, which will fully preserve the efficacy of both BlastX™ and Collagen, is continuing through development towards submitting a FDA 510k application for an integrated BlastX™ Collagen product.

After much investigation, Next Science has determined that the most efficient and competitive way for a BlastX™ Collagen product to enter the market will be via the US DME structure, explained further below. The Company announces that it has completed the application process and received full accreditation to operate, and be reimbursed through US Medicare, as a DME provider based in the State of Florida, USA. This means that the Company is licensed to bill Medicare / Medicaid for the supply of approved products direct to patients and is now also holding a National Provider Identifier with Medicare. The Medicare registration gives Next Science a licence to sell in 40 US States. We will now review the process for registration in the remaining 10 States.

### **BlastX™ / Collagen User Study**

Next Science announces that commencing immediately, and simultaneously with the ongoing development of the integrated BlastX™ /Collagen product and the 510(k) application process, it will be distributing a Collagen product through the DME structure and undertake a user study on the combination of BlastX™ with Collagen.

The user study will provide strong clinical evidence for the combined use of the two wound care technologies. BlastX™ will be provided to patients enrolled in the user study who are prescribed Collagen treatment in order to add proven infection control to their healing strategy.

Short series case studies have shown that augmenting Collagen treatment with BlastX™ will push a stalled surgical wound or unhealed pressure ulcer back to healing<sup>3</sup> with wound closure shown to occur at between two and four weeks. Standard wound care healing usually takes between twelve and sixteen weeks.<sup>4</sup>

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<sup>1</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601889/>

<sup>2</sup> <https://doi.org/10.12968/jowc.2018.27.2.68>

<sup>3</sup> <https://www.nextscience.com/technology/>

<sup>4</sup> <https://pubmed.ncbi.nlm.nih.gov/29521641/>

In supplementing its portfolio with Collagen, Next Science is providing a complementary product to advance the healing of chronic wounds and at the same time, improving its wound care business economics as the use of Collagen materials is eligible for reimbursement. This means the Company will receive a significant contribution towards marketing, sales, distribution and administration costs for BlastX™.

The medical Collagen market in the US is estimated at over US\$1.4B per annum<sup>1</sup>. Once traction is established, revenues from the sale of Collagen are expected to be material.

By entering the Collagen distribution market as a DME provider, Next Science will also gain significant market information and invaluable experience.

Next Science expects the anticipation of the new integrated BlastX™ / Collagen product will motivate many physicians to engage with Next Science early and prepare for it by switching to Next Science as their Collagen provider prior to the combined BlastX™ / Collagen product being FDA cleared for sale.

## **What is a DME**

A DME is a US company that has been through the relevant accreditation and licensing processes allowing it to provide certain reimbursable medical goods and therapies such as for the treatment of chronic wounds. The products are reimbursed by Medicare/Medicaid and the major insurance companies. The level of reimbursement across the US is set through the US Center for Medical Services (CMS). The reimbursement levels are set through a series of Healthcare Common Procedure Codes, referred to as HCPC codes (A Codes) and Collagen products are part of the Surgical Dressings sections of A Codes.

## **Common A Code reimbursements for Collagen**

The common A Codes<sup>5</sup> for reimbursement are:

- A6021 <16 sq. inches of Collagen sheet
- A6022 >16 sq. inches of Collagen sheet & <48 sq. inches of Collagen sheet
- A6023 > 48 sq. inches of Collagen sheet
- A6010 Powdered Collagen wound filler

Topical Collagen products are prescribed by physicians and podiatrists to treat patients with chronic wounds. A physician or podiatrist would send a prescription to a DME company, and once a patient's insurance eligibility has been verified, the product is shipped as directed by the physician. This could be to the physician's office or the patient's home.

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<sup>5</sup> <https://hcpcs.codes/fee-schedule/dme>

There are over 18,000 podiatrists and 10,000 podiatry offices in the US Market.<sup>6</sup>

Next Science has reorganised its commercial personnel into two teams, one focusing on infection prevention and the other on wound care.

In developing a DME structure and releasing a Collagen product, Next Science can expand its wound care business footprint substantially. This will increase the number of patients we can serve, provide access to the commercial wound care space where our focus to date has been on the Federally funded sites, such as the US Department of Veterans' Affairs (VA), and provide much better sales force economics allowing us to efficiently drive revenue growth.

Approved and authorised by the Board.

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**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](http://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 involved 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.

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<sup>6</sup> <https://www.globenewswire.com/en/news-release/2022/08/04/2492408/0/en/Collagen-Dressings-Market-Expands-with-Rising-Demand-for-Animal-based-Wound-Care-Dressings-Globally-States-TMR-Study>