NeXtGen™ Biologics Inc.
13800 Tech City Cir, #200
Alachua, FL 32615
Phone: (800) 209-7190
https://www.nextgenbiologics.com/

THE AXOLOTL

NEXTGEN'S NEOMATRIX® ECM PRODUCT

NEOMATRIX®: INDICATIONS FOR USE

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undermined wounds
- Surgical wounds
- Trauma wounds
- Draining wounds

Source: NeXtGen Biologics Inc.

COMPANY DESCRIPTION

NeXtGen™ Biologics Inc. is a medical device company that possesses a collection of patents covering **extracellular matrix (ECM)†** platform technology sourced from the **axolotl**, a rare paedomorphic salamander closely related to the tiger salamander. Leveraging the Company's innovative biotechnology, NeXtGen is seeking to unravel the mysteries of regeneration and scar-free healing using the ECM of the axolotl, as this species is capable of regenerating organs and complex tissues (including its nervous system). The Company is currently developing platform solutions to address and enhance the treatment of various intricate conditions found in wound care, general surgery, trauma, plastic surgery, cardiovascular diseases, neurosurgery, orthopedics, and ophthalmology. NeXtGen's first FDA-cleared device, NeoMatriX® Wound Matrix, is indicated for partial and full thickness wounds, pressure venous diabetic and chronic vascular ulcers, surgical wounds, trauma wounds, **Mohs surgery**, and burns. NeoMatriX is provided as sheets in various sizes for placement on wound beds to help manage the wound environment.

KEY POINTS

- The global medical device market for wound healing is expanding rapidly due to the increasing prevalence of chronic diseases (such as diabetes and obesity) and the surge in surgeries and injuries. Advanced wound care products, such as those which use ECM technology, are essential due to their effectiveness in promoting wound healing.
- NeoMatriX uses a material from nature that has long been studied for its benefits of regeneration.
- NeXtGen owns a portfolio of trade secrets, including U.S and foreign issued and pending patent rights, for medical devices coatings, cosmetics, biologics, pharmaceuticals, and nutraceuticals.
- The Company is currently generating roughly $100,000/month.
- NeXtGen is led by an experienced team with proven success in pharmaceutical research, development, and commercialization.
- The Company has received $16.2 million of funding, including a $1.3 million SEED round (closed); $7.9 million raised through convertible notes (8% interest and 20% discount in "qualified equity financing"); and $6.4 million Common Stock (with $0.5 million remaining to reach convertible note). It currently seeks to raise an additional $5 million.
- The Company's current cash position provides three months of runway with additional investment inflows expected to be imminent.

Table of Contents

Executive Overview

NeXtGen Biologics Inc. ("NeXtGen" or "the Company") is at the forefront of medical device innovation, developing advanced platform solutions to treat and manage a wide range of complex conditions, including wounds, general surgery, trauma, plastic surgery, cardiovascular diseases, neurosurgery, orthopedics, and ophthalmology. The Company holds a suite of patents covering an extracellular matrix (ECM) platform technology derived from the axolotl, a paedomorphic salamander closely related to the tiger salamander, which is capable of regenerating organs and complex tissues (including its nervous system). NeXtGen's flagship product, NeoMatriX® Wound Matrix, is fabricated from the dermal ECM of the axolotl and is provided as sheets of various sizes for placement on wound beds to help manage the wound environment. Specifically, the product addresses the management of various wound types, including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post Moh's surgery, post-laser surgery, podiatric, and wound **dehiscence**), and trauma wounds (abrasions, lacerations, partial thickness burns, and skin tears).

Problem

Every year, approximately 12 million individuals in the U.S. experience traumatic lacerations that require treatment in the emergency room; globally, roughly 250 million people undergo surgical incisions. Chronic wounds affect 6.5 million people in the U.S. alone and can carry the risk of scar formation, adhesions, incomplete healing, and infection. Despite significant technological advancements, both surgical and chronic wounds remain challenging to effectively manage. Additionally, these conditions may lead to non-closure, dehiscence, and recurrence, causing suffering for patients and imposing substantial costs on payors.

Solution

NeXtGen has identified a key to regeneration and scar-free healing, which may lie in investigating the characteristics of an animal called the axolotl. This amphibian is one of the rare vertebrates that is capable of regenerating organs and complex tissues, including its nervous system, throughout its entire lifespan. The axolotl also remains as a neotenic organism, preserving juvenile traits throughout adulthood. Humans, like most mammals, lose the ability to heal without scarring during the second trimester of fetal development. Axolotls stand apart by retaining the unique ability to regenerate limbs and heal without scarring both in their juvenile and adult stages.

The process of axolotl regeneration follows the same four general phases observed in human wound healing: hemostasis, inflammation, proliferation, and tissue remodeling, albeit with some differences in timing. Following a full-thickness excisional (FTE) wound, axolotls exhibit reduced hemostasis and inflammatory responses, along with rapid re-**epithelialization**. However, they demonstrate a slower deposition of new ECM compared to humans. Unlike human wound healing, where the provisional matrix and ECM form quickly after an FTE wound, axolotls postpone ECM formation for up to 10 days after re-epithelialization.

Leveraging its ground-breaking technology, NeXtGen is seeking to unravel the mysteries of regeneration and scar-free healing using ECM derived from the axolotl. The axolotl has innate attributes for scar-free healing of skin wounds, can regenerate limbs and organs, and is one of only a few vertebrate animals capable of regeneration throughout its life. Axolotl-derived ECM has been shown to promote cell migration, proliferation, and differentiation and has been used in various preclinical models to promote tissue regeneration. Because it retains juvenile traits into adulthood, the axolotl, when coupled with NeXtGen's patented and proprietary technology, has the potential to positively influence human capacity for complex tissue repair.

The Company exclusively owns a portfolio of trade secrets, U.S and foreign issued, and has pending patent rights for medical devices coatings, cosmetics, biologics, pharmaceuticals, and nutraceuticals. Its first FDA-cleared device, NeoMatriX® Wound MatriX, is indicated for partial and full thickness wounds, pressure venous diabetic and chronic vascular ulcers, surgical wounds, trauma wounds, Mohs surgery, and burns.

NeoMatriX Wound Matrix Technology

NeXtGen's NeoMatriX® Wound Matrix (Figure 1) received FDA clearance in 2018 as a **510(k) medical device** and subsequently for its proprietary in-house process in 2021. The Company's proprietary manufacturing process removes elements that may otherwise cause a reaction in a patient after application while retaining native structural ECM constituents. Animal studies indicate that using axolotl-derived tissue as a wound management device may initially elicit a regeneration-like response, with clinical usage of NeoMatriX showing encouraging outcomes when employed by physicians for use on chronic and challenging-to-heal wounds. Examples of these initial patients' successes are provided on pages 20-25. NeoMatriX is currently available in sterile sheets of various sizes to place on the wound bed. The device is terminally sterilized using low dose gamma **irradiation** and is intended for one-time use. Future alternate forms and uses for the product may include a particulate, an injectable, as a coating, as a gel, as a tube for neural or vascular repair, as a hemostatic dressing, and it is expected to be studied for its potential antimicrobial and **fibrosis**-reducing properties.

Figure 1
NEOMATRIX®

Source: NextGen Biologics Inc.

The Company performs its entire process in-house from start to finish (besides irradiation). This includes raising the animal, recovering raw material, and decellularizing the material. The only time the material leaves NeXtGen's facility is when the Company sends it out for irradiation, a process by which the material is exposed to low dose gamma irradiation to ensure sterility.

With the product selling for an average sales price of $1,000, the Company is generating approximately $100,000/month in top line revenue. Importantly, NeXtGen is running margins in excess of 80% on small batch production runs (several hundred units at a time) and only utilizing the skin of the species right now; eventually the Company believes that it can use the bone, organs, or remnants for its products. Once this occurs, margins should continue to increase upwards of 90% by utilizing more of the animal, combined with completing larger runs at an increasing scale.

Status

NeXtGen's first application for NeoMatriX is within the wound care market, where it is targeting acute wounds, such as surgical wounds, traumatic wounds (including burns and lacerations), as well as chronic wounds. The Company is unaware of any product that has been able to successfully address the obstacle of scar-free healing. NeoMatriX is available for commercial distribution through select distributors. There are currently over 6,000 hospitals, approximately 120 burn care facilities, and over 1,000 outpatient wound centers in the U.S. (not including the wound care provided by physicians in their offices, inpatient, or long-term facilities). Additionally, the Veterans Health Administration is the largest integrated healthcare system in the U.S. providing care at 171 VA Medical Centers and 1,112 outpatient sites of care to over 9 million veterans. The product is reimbursed by Medicare and assigned to the high-cost bundle. Covered sites of service include hospital outpatient departments, physician office, ambulatory surgical center, outpatient wound clinics, and hospital inpatient services, such as surgery.

Patents have been granted in the U.S. and Japan and are validated in 7 foreign territories, including but not limited to issued claims directed to a decellularized, immuno-privileged extracellular matrix (ECM) xenograft derived from a highly regenerative animal source (further described on page 9).

Physician Experience

Physicians have reported positive outcomes with NeoMatriX in use with a variety of patient wounds with severe disease states or non-compliance, noting rapid tissue generation and effective wound healing. NeXtGen's initial use, involving approximately 150 recalcitrant patients, have shown remarkable success at achieving wound closure and reducing recurrence. In the future, studies can be designed to evaluate these encouraging outcomes.

Preliminary Experience Using Axolotl Dermis Devices as a Biologic Agent for Wound Management After Neurosurgical Procedures

Specifically, as it relates to neurosurgical procedures, which can carry risks of surgical site infections and challenging patient recovery, current wound management options face limitations, which has prompted the exploration of alternatives, such as axolotl derived NeoMatriX. NeXtGen studied 13 neurosurgical patients treated with axolotl dermis, recording comorbidities, treatment rationale, and outcomes. In this study, no postoperative complications were observed, with minimal scarring noted in all patients. These findings highlight the potential of utilizing axolotl dermis in neurosurgical wound management, particularly for high-risk patients, though further research is warranted to validate these results and compare them to existing wound management practices. Nonetheless, axolotl-derived materials offer hope for improved outcomes and reduced healthcare costs. Greater details of NeoMatriX for neurosurgical wound management are provided on pages 19 and 25.

Market Opportunity

The global wound care market is projected to reach $25 billion by 2024, with a compound annual growth rate (CAGR) of 6.7% from 2019 to 2024. This surge is attributed to the escalating incidence of chronic diseases like diabetes and obesity, an aging population, and an uptick in surgeries and injuries. Advanced wound care products, particularly regenerative medicine products, are anticipated to experience the most substantial growth. Furthermore, the global medical device market for wound healing is rapidly expanding, predicted to hit $22.01 billion by 2025, with a CAGR of 5.1% from 2018 to 2025. Chronic diseases, notably diabetes and obesity, are driving this growth, resulting in a higher prevalence of chronic wounds. Advanced wound care products, such as ECM technology, are gaining traction due to their efficacy in promoting wound healing.

NeXtGen's cutting-edge platform for wound care and associated technologies aligns with the rapidly expanding global regenerative medicine market, estimated at $66 billion in 2022, and recognized as the medical device sector's fastest-growing segment. The surge in merger and acquisition deals and IPOs in recent years underscores the enthusiasm in this market, as depicted in Figure 16 (page 26). Beyond wound care, NeXtGen is exploring properties related to anti-microbial and anti-inflammatory, vascularization, and fibrosis, which could further enhance its market reach and value proposition. Potential other indications may include surgical mesh, plastics, orthopedic (tendon and bone), cardiovascular, gastrointestinal, and neurosurgery (nerve cuff, dura replacement).

Funding

The Company has received $16.2 million of funding to date, including a $1.3 million SEED round (closed); $7.9 million raised through convertible notes (8% interest and 20% discount in "qualified equity financing"); and $6.4 million Common Stock (with $0.5 million remaining to reach convertible note). NeXtGen is currently seeking to raise an additional $5 million, to be used to expand manufacturing, grow raw materials, for new regulatory filings, for key opinion leader (KOL) adoption, to expand its pipeline, and to grow sales.

Corporate Information (Headquarters, Employees, and History)

The Company has headquarters in Alachua, FL (Figure 2) and employs 12 individuals.

Figure 2
HEADQUARTERS

Source: NextGen Biologics Inc.

Company Leadership

The Company is led by a highly experienced management team and Board of Directors with proven success in pharmaceutical research, development, and commercialization. Biographies of these individuals are provided in the accompanying section. NeXtGen co-founders, Jamie Grooms, Chairman (biography on page 8) and Jonelle Toothman, CEO (biography on page 7), share a mutual interest with regard to advancing healthcare science, with their initial meeting sparking the Company's inception as a medical device company pioneering a groundbreaking approach to regenerative medicine by harnessing the healing potential of a naturally derived extracellular matrix (ECM).

Management

Jonelle Toothman, Director, Chief Executive Officer, President and Secretary

Jonelle Toothman has over 20 years of experience in leadership roles commercializing medical device products and positioning companies for acquisition and has been a part-owner of several ventures. She has been President and Secretary at NeXtGen Biologics Inc. from 2014 to present. As CEO, President, and Secretary at NeXtGen, Jonelle's responsibilities include fundraising and operations. Her trajectory into healthcare was catalyzed by personal loss and a newfound commitment to the field. Following her journalism and mass communications studies, she delved into various facets of healthcare at Pfizer, Inc., immersing herself in everything from sales and marketing to the intricacies of disease pharmacogenetics. Her journey led her to operating rooms and a deep understanding of neurosurgery and medical devices. Eager for a leadership role aligned with her passion, Jonelle's introduction to Jamie marked the beginning of a transformative partnership. She has a B.A. in journalism and mass communications from Marshall University (2003).

Dayna Healy, Business Development

Dayna Healy previously ran NeXtGen business development and since retirement in August 2022, continues to act in an advisory role for sales and marketing activities. She has over 25 years of experience in regenerative companies; product development, clinical studies, and commercialization of multiple novel products.

Guy Grover, VP Operations

Guy Grover has 20 years of experience in tissue and medical device R&D, engineering, manufacturing, and project management.

Joann Ocampo, Raw Materials Facility Manager

Joann Ocampo has 10 years of experience in front office management and working in research and the commercialization of new technologies.

Kerry Pearson, Regulatory/Quality Consultant

Kerry Pearson has over 15 years' experience in GxP, Regulatory Compliance & Quality Management for biotechnology, medical device, and pharmaceutical products.

Gerard Bencen, General and Legal Counsel R&D

Gerard Bencen is an entrepreneur with extensive experience in pharmaceuticals, biotechnology, and autograft/allograft/xenograft. While retired, he is accessible for patent support and historical context on prior work in event of new issues.

Board of Directors

Jamie Grooms, Chairman

Jamie Grooms has over 20 years of experience as a successful entrepreneur co-founding two regenerative startups and leading them to IPO. Jamie embarked on his healthcare journey over three decades ago armed with a bachelor's degree in biology. His career trajectory began with roles in human tissue donation and grafting, where his intrigue with tissue healing and bone reconstruction developed. Transitioning into the realm of health and medical products, Jamie played pivotal roles in the success stories of Gainesville startups like RTI Surgical, Inc., and AxoGen, Inc. His journey taught him that the essence of successful technology development lies in its intrinsic calling—a capacity to offer substantial value beyond existing market offerings. Jamie's interest piqued when encountering a presentation on a novel ECM material. His extensive experience in the ECM market has affirmed the significance of this emerging technology, leading him to secure its patent for future development.

Jonelle Toothman

See page 7.

Dr. Gerald Kluft

Dr. Gerald Kluft is a retired oral surgeon who practiced in Tampa for 36 years. He is a distinguished alumnus for his achievements in dentistry as well as a distinguished Professor, University of Florida.

Brian Lipke

Brian Lipke is a retired chairman of the board and former CEO of Gibraltar Industries, Inc. and founding partner of Buffalo Capital Partners with multiple acquisitions and divestitures over the last 20 years.

Dr. Elad Levy

Dr. Elad Levy is a professor and chairman of neurosurgery at the State University of New York at Buffalo. Dr. Levy is actively involved with clinical studies of new technologies with several successful exits in biotechnology.

Rick Wassel

Rick Wassel is executive director strategy office for the Florida Division of Adventist Health System and Managing Director, IQ Orlando.

Daniel Hamister

Daniel Hamister is the CEO of Hamister Group, a hospitality and healthcare investment and management company. He has been instrumental in doubling the size of the company since returning in 2007.

Intellectual Property

NeXtGen's intellectual property (IP) is based on the extracellular matrix (ECM) derived from a **urodele** axolotl species. This IP encompasses anything that utilizes ECM from this species of animal and is decellularized, where it can be used in pharmaceuticals, nutraceuticals, medical devices, biolologics, etc. The Company's IP is unique, with the urodele species relatively unknown; however, many people are aware of the axolotl, with this being the species from which the Company sources its material. NeXtGen exclusively owns a portfolio of Trade Secrets and U.S. and foreign issued and pending patent rights for medical devices, implants, coatings, cosmetics, biologicals, pharmacological, and other therapeutic technologies, as listed in Figure 3 and summarized in Figure 4 (page 10).

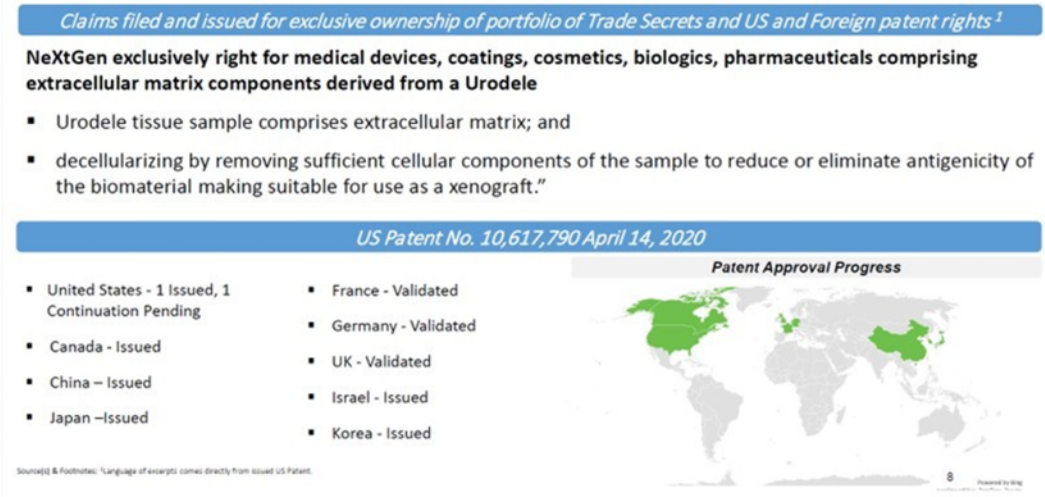
Figure 3

U.S. AND FOREIGN PATENTS, PATENT APPLICATIONS, AND REGISTERED TRADEMARKS

Application or Registration #	Title	Description	File Date	Grant Date	Country
US10,617,790	Decellularized Biomaterial from Non-mammalian Tissue	US Patent	1/9/2014; NB: Priority date 1/9/2013 (US61/750,555)	04/14/2020	U.S.
JP6606429	Decellularized Biomaterial from Non-mammalian Tissue	Issued Patent	As with WO2014110269	08/20/21	Japan
EP2943209: validated in FR, DE, & GB	Decellularized Biomaterial from Non-mammalian Tissue	Issued Patent	As with WO2014110269	02/24/2021	EU (GB, DE, FR)
IL239828	Decellularized Biomaterial from Non-mammalian Tissue	Issued Patent	As with WO2014110269	09/01/21	Israel
CN105246495	Decellularized Biomaterial from Non-mammalian Tissue	Issued Patent	As with WO2014110269	07/28/21	Korea
USSN 16/801,956	Biomaterial from Non-mammalian Tissue	Pending US Application	2/26/2020	Prosecution has initiated	U.S.
CA2897662	Biomaterial from Non-mammalian Tissue	Pending Canadian Application	01/09/2014	Final fee paid for patent to issue	Canada
WO2014110269	Decellularized Biomaterial from Non-mammalian Tissue	Published PCT Application expired; basis for priority claim in foreign filings	01/09/2014 claiming 01/09/2013 priority	N/A	PCT International application as basis for foreign filings.
US61/750,555	Decellularized Biomaterial from Non-mammalian Tissue	Expired priority provisional patent application	Filed on 01/09/2014; Domestic priority claimed on 01/09/2013	N/A	Expired provisional priority application
5449020	NEOMATRIX®	Standard Character Mark	04/05/2016	04/17/2018	U.S.

Source: NextGen Biologics Inc.

Figure 4
ROBUST IP PROTECTION ISSUED



Source(s) & Footnotes: [1] Language of experts comes directly from issued U.S. Patent.

Milestones

Recent Milestones

- FDA clearance of NeoMatriX® Wound Matrix
- Coverage by Medicare (which represents over 65 million lives)
- Approved skin substitute code A2021
- Listed in RedBook
- Signed 1st large distributor partner
- Increased Raw Material and Manufacture capacity to support production demand into 2026 with materials on hand today

Potential Milestones

- Working to penetrate the $1.7 billion wound care market with its current indication. Market penetration may be driven by additional FDA clearances;
- Seeking to raise an additional $5 million, to be used to expand manufacturing, further grow raw materials, for new regulatory filings, for key opinion leader adoption (KOL), to expand its pipeline, and to grow sales;
- Seeking contracts with hospital networks; and
- Pursuing active R&D pipeline with additional clearances anticipated in 2025.

Core Story

NeXtGen™ Biologics Inc. is a medical device company that holds a collection of patents covering extracellular matrix (ECM) platform technology sourced from the axolotl, a rare vertebrate capable of regenerating organs and complex tissues (including its nervous system). Leveraging its innovative biotechnology, the Company is seeking to unravel the mysteries of regeneration and scar-free healing using the ECM of the axolotl. Because it retains juvenile traits into adulthood, when coupled with NeXtGen's proprietary technology, the axolotl has the potential to reignite human capacity for complex tissue repair. The Company is currently developing technology that can provide surgeons with platform solutions to address and enhance the treatment of various intricate conditions found in wound care, general surgery, trauma, plastic surgery, cardiovascular diseases, neurosurgery, orthopedics, and ophthalmology. NeXtGen's first FDA-cleared device, NeoMatriX® Wound Matrix, is indicated for partial and full thickness wounds, pressure venous diabetic and chronic vascular ulcers, surgical wounds, trauma wounds, Mohs surgery, and burns.

Neoteny and the Axolotl

Figure 5
THE AXOLOTL

Source: NextGen Biologics Inc.

Neoteny is a biological phenomenon where an organism reaches sexual maturity without undergoing the typical metamorphosis seen in its species. In simpler terms, neoteny is when an organism retains juvenile characteristics into adulthood. The axolotl is a prime example of neoteny in the animal kingdom. Native to Mexico, these fascinating amphibians belong to the salamander family. While most amphibians undergo metamorphosis from larvae to adults, axolotls remain in their larval form, making them neotenic. This can manifest in a variety of ways, such as the retention of larval traits, like gills in amphibians, or maintaining a juvenile appearance, as illustrated in Figure 5. Moreover, axolotls exhibit remarkable regenerative abilities, capable of regrowing its entire organ system, limbs, organs, and even parts of their brain. For example, if a part of its spine is crushed, it can regenerate the injured spinal cord; if a piece of its brain is removed, it regrows portions of brain tissue. This physiology offers insights into fundamental biological processes which hold so much promise for medical research.

Part of the urodele species, the axolotl has been studied for hundreds of years as scientists continue to attempt to understand its regenerative capabilities. Specifically, this regenerative ability has led to extensive studies aimed at understanding the underlying mechanisms, with the hope of applying this knowledge to regenerative medicine in humans. One notable application of axolotl research in medicine is limb regeneration. The regenerative properties of axolotls make them valuable models for studying wound healing and tissue regeneration. Scientists have been particularly interested in the cellular and molecular processes involved in axolotls' ability to repair and regenerate damaged tissue. Specifically, a promising avenue of research involves extracting certain proteins or molecules from axolotls that are involved in their regenerative processes and applying them to wound healing in humans.

The Fascination of the Axolotl: Studied for Over 200 Years

NeXtGen's results to date in its 150 treated patients are fascinating (a sample of which are described and illustrated on pages 20-25) and speak to the reason the axolotl has been so well studied for over 200 years. To date, while is not entirely understood why it works so well, the use of extracellular matrix from this unique species is not rejected or treated like a foreign body (versus alternatives, which may create an inflammatory response). The Company chose the axolotl as its target material given its regenerative capabilities, specifically that of the ECM.

The Problem

In the U.S. alone, over 6.5 million individuals are afflicted by chronic wounds annually, with approximately 12 million lacerations requiring treatment in emergency rooms each year, and an additional 480,000 burns requiring medical attention, of which 50,000 demand hospitalization. Globally, the demand is even more acute, with over 250 million surgical incisions and an additional 11 million burns requiring treatment annually. As the population ages, the prevalence of debilitating diseases and injuries is expected to rise, amplifying the need for soft tissue repair surgeries. These surgeries often require the use of skin substitutes and replacement scaffolds to facilitate tissue repair and wound closure. Despite advancements in engineered and biological skin, as well as significant research efforts, a substantial clinical gap persists since no existing technology has been able to achieve complete scar-free healing.

The Extracellular Matrix (ECM) Platform Technology

The ECM is a complex network of proteins and other molecules that provide structural and functional support to cells, with ECM-based therapies having shown promise in regenerative medicine. The use of ECM technology involves the use of ECM derived from animal tissues to promote tissue regeneration and wound healing. The axolotl, known for its remarkable regenerative abilities in its native state, is rich in **antimicrobial polypeptides (AMPs)** and other bioactive peptides, such as growth factors and adhesion proteins. The decellularized ECM from the axolotl is now being used to support wound care and is the area of predominant focus, as the loss of skin integrity due to illness or injury can lead to chronic, life-threatening complications. ECM plays a crucial role in wound healing, conveying blood, blood products, and proteins into the void formed at the wound. Scaffold products have been developed that mimic tissue structure and mechanical behavior to promote tissue repair, serving as a temporary replacement for damaged, diseased, or absent tissue.

Utilizing Axolotl-Derived ECM for Wound Healing Purposes

Axolotl-derived ECM presents a promising avenue in wound healing applications, showcasing its efficacy in repairing damaged skin and underlying tissue. Serving as a biological scaffold, the ECM supports tissue repair by providing essential structural cues and support. Its versatility allows for various applications, such as wound dressings, scaffolds, gels, and more, tailored to meet specific wound care needs. In clinical settings, axolotl-derived ECM has demonstrated notable success in treating challenging wound types like diabetic foot ulcers, venous leg ulcers, and pressure ulcers. Studies reveal significant improvement in wound healing rates, with one wound dressing featuring axolotl-derived ECM showcasing a 50% enhancement in healing compared to standard care. Moreover, this ECM has been integral in addressing a substantial unmet clinical need, especially in cases where scar-free healing remains elusive despite extensive research efforts and investment.

Platform Technology: NeoMatriX

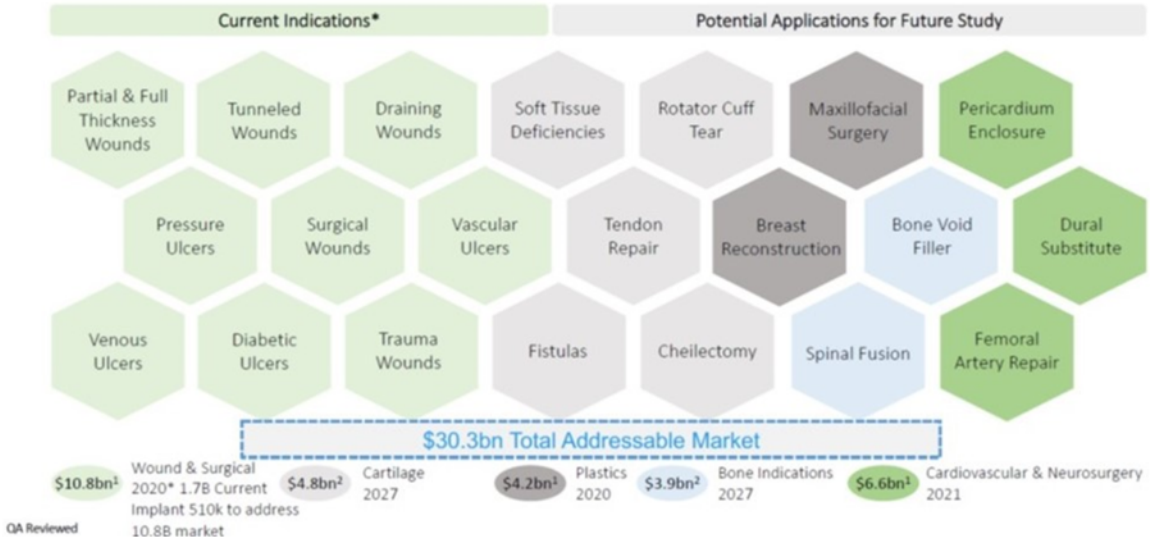
NeXtGen's first FDA-cleared device, NeoMatriX Wound Matrix (Figure 6), is targeting acute wounds, such as surgical wounds, traumatic wounds (including burns and lacerations), as well as chronic wounds. The Company's intellectual property (IP), as shown in Figure 3 (page 9), is based on the ECM derived from a urodele axolotl species in its neotenic form. Future applications may expand to include collagen powders, medical devices, dural regeneration, skin regeneration, nerve regeneration, heart regeneration, and coatings on stents for endothelization—where all these applications may be suitable for the Company's platform technology.

Figure 6
NEOMATRIX®

Source: NextGen Biologics Inc.

In the beginning, NeXtGen did not plan to go into wound care; the original business plan was to go directly into the surgical markets, specifically in the neuro space as a dural implant. However, when looking at the regulatory requirements (with the axolotl having never been approved by the FDA), the Company chose to take a more direct path as a medical device for the indications of wound care. The wound care indications are broad, with NeXtGen's FDA clearance being for a variety of acute and chronic wounds. This may include full thickness wounds, partial thickness wounds, tunneling wounds, diabetic foot ulcers, venous ulcers, and essentially most surgical wounds. Within a total addressable market of $30.3 billion, a summary of the current indications for NeoMatriX, as well as potential applications for future study, is provided in Figure 7.

Figure 7
NEOMATRIX® PLATFORM APPLICATIONS



Source: NextGen Biologics Inc.

NeXtGen holds a platform technology with IP that is unique and different. The Company's first FDA cleared device in wound care is a differentiator in the market as the axolotl is the only regenerative species that has been cleared. Importantly, while the Company is able to market the product based on its FDA clearance, NeXtGen expects that physicians will study NeoMatriX in their labs to understand its capabilities for untreated applications or applications that have been unsuccessfully treated with other options.

Global Market for Wound Healing Devices

The global wound care market is projected to reach $25 billion by 2024, with a compound annual growth rate (CAGR) of 6.7% from 2019 to 2024. This surge is attributed to the escalating incidence of chronic diseases like diabetes and obesity, an aging population, and an uptick in surgeries and injuries. Advanced wound care products, particularly regenerative medicine products, are anticipated to experience the most substantial growth. Furthermore, the global medical device market for wound healing is rapidly expanding, predicted to hit $22.01 billion by 2025, with a CAGR of 5.1% from 2018 to 2025. Chronic diseases, notably diabetes and obesity, are driving this growth, resulting in a higher prevalence of chronic wounds. Advanced wound care products, such as ECM technology, are gaining traction due to their efficacy in promoting wound healing.

NeXtGen's Key Differentiators Within the Wound Care Market

The wound care market is quickly changing, particularly as it relates to the regulatory changes in human products. Several years ago, the FDA put some companies with certain human products on notice that they will need to go through a **biologics license application (BLA)** process, which is a higher burden than the medical device process. NeXtGen's product utilizes a species of animal that has FDA clearance under a medical device. This is particularly important as other entities confront issues stemming from human-based products. NeXtGen has a clear differentiator in the market in which it is focused with NeoMatriX as it is building the foundation to address the surgical market—specifically the future of tendon wraps, nerve wraps, **dermoplasty**, and a bone void filler.

Due to changes within the marketplace of publicly traded companies using human products, MIMEDX Group, Inc. being one of the largest (as further described on page 31), is that these companies need a xenograft product—which is an animal-based product. Other products which may compete include placental-based technology products, as well as advanced wound care and traditional wound care products, among others. This market is roughly $1.7 billion, with MiMedx and Organogenesis each reporting approximately $400 million in sales, annually, representing approximately $800 million of the $1.7 million market. NeXtGen is working to penetrate this market with its current indication, which may be driven by additional FDA clearances, where they are the only company utilizing this species of animal.

Key Benefits

Figure 8 (page 16) summarizes some of the attributes which differentiate NeXtGen's axolotl ECM from alternative solutions. The current shelf life of NeoMatriX is 18 months. Additionally, in the first quarter 2024, NeXtGen began its real time aging, where this is expected to increase the shelf life up to two, three, or five years. However, 18 months is likely to be sufficient for the Company to gain access to hospital shelves.

Figure 8
AXOLOYTL ECM COMPARED TO ALTERNATIVE SOLUTIONS

Source: NextGen Biologics Inc.

Reimbursement and Market Penetration: How to Go from Being FDA Cleared to Revenues

NeXtGen currently has a hybrid salesforce in place, with CEO, Jonelle Toothman (biography on page 7) and another employee acting in this role. By the end of 2024, sales are expected to be done via distributor networks for the first six to eight months, with three of these distributor networks currently signed on to primarily cover physician's offices as well as other hospital side networks as these are quite different call points in terms of reimbursement. Similar to regulatory changes regarding all allograft products, reimbursement of tissue based medical devices has a higher standard when compared to allograft products. In analyzing reimbursement levels, many of the human products will not be on reimbursement scales for as long. As a result, NeXtGen's hybrid salesforce intends to capitalize on being a xenograft in a physician's private practice office setting as well as penetrating the hospitals under the DRG setting.

Key service sites are expected to be physician office settings for podiatry; physician's office settings for Moh's surgery (which will be dermatologists); as well as the hospital setting for any medical professional who will be closing a surgical wound (i.e., neurosurgery, orthopedics, plastic surgery, etc.). Once NeXtGen receives approval through the hospital administration side, the Company seeks to access the hospitals through wound care clinics and through podiatry, and then be available for all other surgical applications within the surgical market—all of which is expected to drive revenue. Currently, NeXtGen is generating revenue of approximately $100,000/month, with the Company successfully penetrating these accounts.

The Company seeks to stay at a price of approximately $1,000 per square centimeter, with most companies running between $300-$400 per square centimeter. The reason for the higher pricing is due to reimbursement strategy and volume discounts that certain high throughput physician practices may qualify for. The Company seeks to keep its price per square centimeter higher until it gets its **average sale price (ASP)** established.

Currently, NeXtGen has reimbursement through Medicare, Medicaid, and is in the highest bucket of reimbursement for Medicare and Medicaid as of April 2023. The Company's A code, which is a reimbursement code by The Centers for Medicare & Medicaid Services (CMS), is A2021. Many of NeXtGen's competitors are likely to be Q codes, which is used for skin substitutes; however, they are moving xenografts to A codes, which are Device codes.

Production Process

The Company performs its entire process in-house from start to finish (besides irradiation). This includes raising the animal, recovering the raw material, and decellularizing the material. The only time the material leaves NeXtGen's facility is when the Company sends it out for irradiation, a process by which the material is exposed to radiation to ensure sterility.

Once the material returns to the Company, it is packaged and then shipped to the customers, where it can be used off the shelf without the need for refrigeration, lyophilization, or the need to be kept in a specific area within the hospital since it is classified as a device (versus a human product, which requires specific storage). Furthermore, it is easier for hospitals and physicians to use the product since they do not have to document or trace the origin of the donor human from which the product came. This adds to the unique benefits to this product in terms of scalability, production, as well as ease of use since it is classified as a medical device.

Supply Chain

The main vendor of NeXtGen's raw material is its own laboratory, with access to an out of state laboratory. One of the Company's larger vendors is Fisher Scientific, who supplies chemicals and non-consumable and consumable supplies. A variety of items are also currently purchased through many companies approved on NeXtGen's approved supplier list (ASL).

Scalability, Manufacturing, and Commercialization

NeXtGen initially seeks to scale revenues to $20 million by 2026. To do this, the Company will need to expand its facilities. In terms of animals on hand, NeXtGen believes that it has approximately $8 million worth of product, which can readily be generated by the VP Operations, Guy Grover (biography on page 7), along with one other technician in the Company's clean room (which the Company has demonstrated is able to run at approximately $1 million worth of product per month). A bottleneck in the Company's process, however, may come down to reliability, as the Company requires financing for redundant equipment and additional staff to support growth plans.

In the Company's last production run, NeXtGen produced approximately $3 million worth of product within three weeks, which has all been irradiated and is back in the Company's hands. The Company must find outlets for the product that keep it at $1,000 per square centimeter, where NeXtGen can match demand. As the Company begins to run through its $8 million worth of raw material stock that it currently has on hand, it has been working on its animal husbandry practices, which allow it to successfully spawn and grow more animals to maturity for additional raw material. Importantly, this process involves caring for the animals in a humane and environmentally friendly way until they reach the point of sacrifice for the product.

Like a giant store with aquariums, the Company's facilities have little tanks, where the animals are fed and cared for as a very stable mature colony that can be spawned at will. One spawn provides anywhere from 300 to 800 animals that can be harvested within nine months. The Company is scalable on both the raw material side as well as the manufacturing-throughput side and has the facilities in place to expand beyond its stated $20 million revenue milestone. Furthermore, NeXtGen believes that it has a clear understanding of what it would take to scale both the raw material and manufacturing side to surpass this milestone.

From a manufacturing and scalability standpoint, the Company believes that it can breed animals quickly enough and that it has enough empty tanks to refill those animals at every production run—where it will not run out of product. The goal is to maximize its current facility at almost 2,500 animals, where NeXtGen will always have enough product on hand to produce between $10-$15 million in sales at any one point. Furthermore, the Company expects that it can eventually reach between $20-$25 million in revenues at half of the current available capacity. At that point, should NeXtGen become a potential acquisition target, it could start production runs every week and reproduce its animal line with enough product starting in 2025. The Company's current facilities have scalability available to them by staffing up and adding additional equipment.

Importantly, NeXtGen is running in excess of 80% margins on small production runs (several hundred units at a time) and currently only utilizing the skin of the species; eventually the Company believes that it can use the bone, organs, or remnants for its products. Once this occurs, margins should continue to increase by utilizing more of the species, combined with completing larger runs at an increasing scale.

Product Limitation

NeoMatriX can be made to scale, however, is currently limited in size where the largest size available is 2x3cm Ellipse (which is 4.5 square cm). This is a limitation, specifically for areas on the leg, foot, hand, ear, face, abdomen, back, or larger burns, etc., where the product currently available is not large enough to cover certain areas. NeXtGen expects to be releasing two additional sizes in 2025—a 3x5cm Ellipse and a 3x7cm Ellipse. As such, NeXtGen is not currently able to use its product to treat larger sized wounds. However, the next product line is expected to be a particulate, which can be sprinkled into the wound to cover a large surface area, which should help expand the market significantly in 2025.

Additional Prospective Indications

Following the Company's Series A financing, expected to close in 2025, NeXtGen expects to develop a gel-like slurry that can be cut to certain sizes to get bigger sheets. Until that time, NeXtGen's focus is on NeoMatriX, where it may be able to use the same product for additional FDA indications, including for an implant, a nerve wrap, or a tendon wrap, without changing its manufacturing, dyes, etc. Thus, there are several different areas that can be penetrated without the need for a big research and development effort.

In addition to wound healing, axolotl-derived ECM has potential applications in tissue engineering and regenerative medicine. Biomaterial scaffolds (tissue-derived and collagen-based) can promote and expedite wound healing and regeneration. Immune cells may be targeted as an alternative strategy, as they are the first responders to traumatic wounds and can interact directly with biomaterial scaffolds.

Potential Side Effects

Importantly, in the 150 patients who have been treated with NeoMatriX, there has not been any foreign body reaction, no immunological response, no allergic response, nor has there been any response that has stopped the procedures. The axolotl does not transmit diseases to other animals or to humans. As well, the axolotl is 300 times less likely to get cancer than any other animals. NeXtGen chose the axolotl because it was known to be the most regenerative species, specially produced by nature (versus a synthetic material).

Physician Experience

Physicians have reported positive outcomes with NeoMatriX in use with a variety of patient wounds with severe disease states or non-compliance, noting rapid tissue generation and effective wound healing. NeXtGen's initial use, involving approximately 150 recalcitrant patients, have shown remarkable success at achieving wound closure and reducing recurrence. In the future, studies can be designed to study these encouraging outcomes.

A significant part of what is being studied is not only wound closing but also wound re-opening because while there is technology available to close wounds, up to 40% to 60% of those these closed wounds re-open over time, which can happen within three months to a year. The reason this happens is that while the body absorbs the product and acts as a signaling response to heal itself, some available products do not have enough of the proteins for specific patients. Specifically, the body of a diabetic, smoker, or a patient with venous disease may not completely absorb and re-use the product.

Leg Wound Case: Supporting The Human Skin Healing Response

An Advent Health patient with a venous ulcer who was at risk of amputation with a large leg wound was given the Company's NeoMatriX as part of an evaluation, in which approximately 7 grafts were applied to demonstrate the product's capabilities. After a period of 12 weeks, this patient was completely closed. In this patient, the individual received product once weekly until he was completely closed in seven applications, with a total of seven different weeks of applications, in which NeoMatriX played a key role in supporting the human skin healing response.

Worth noting is that in podiatry wounds, such as for a venous ulcer or leg ulcer, patients are typically treated once per week for up to 12 weeks, where weekly, the patients visit a physician and has a new graft applied, which becomes incorporated into the body as it begins the healing process. Because the graft is incorporated into the body, it cannot be seen in a patient as it has been incorporated into their skin. Thus, a patient will receive a new application weekly until that wound has shrunk down or closed—beginning, for example, with four grafts, then three in the next application, then two, and closure with smaller sized grafts.

Neurosurgical Procedures: Preliminary Experience Using Axolotl Dermis as a Biologic Agent for Wound Management

Neurosurgical procedures are known for their intricate nature and the potential risk of surgical site infections, which pose significant challenges to patient recovery and healthcare systems. Current wound management options, while diverse, are often hindered by drawbacks, which include material rejection and disease transmission risks. However, the advent of regenerative medicine, including the use of axolotl derived NeoMatriX Wound Matrix, presents a promising alternative.

In the Company's study, 13 patients with a mean age of 61.1 years underwent neurosurgical wound closure using axolotl dermis. Comorbidities, such as diabetes and obesity, were prevalent among the patient cohort. The product was applied based on surgeon discretion, typically in cases of wound dehiscence or immunocompromised states. Data on patient characteristics, antibiotic regimens, and postoperative outcomes were meticulously recorded.

Results showed that there were no postoperative complications, such as infections or wound dehiscence. Minimal scarring was noted in all patients, suggesting promising wound healing potential. These findings underscore the utility of axolotl dermis in neurosurgical wound management, particularly in patients with comorbidities traditionally associated with poor wound healing.

The observed benefits of axolotl dermis, including biocompatibility and effective wound healing properties, offer promising avenues for further research, with larger trials needed to validate these preliminary findings and compare them with existing wound management strategies. Even so, the use of axolotl-derived materials shows considerable potential in improving neurosurgical wound closure outcomes and reducing healthcare costs associated with postoperative complications.

Patient Experience

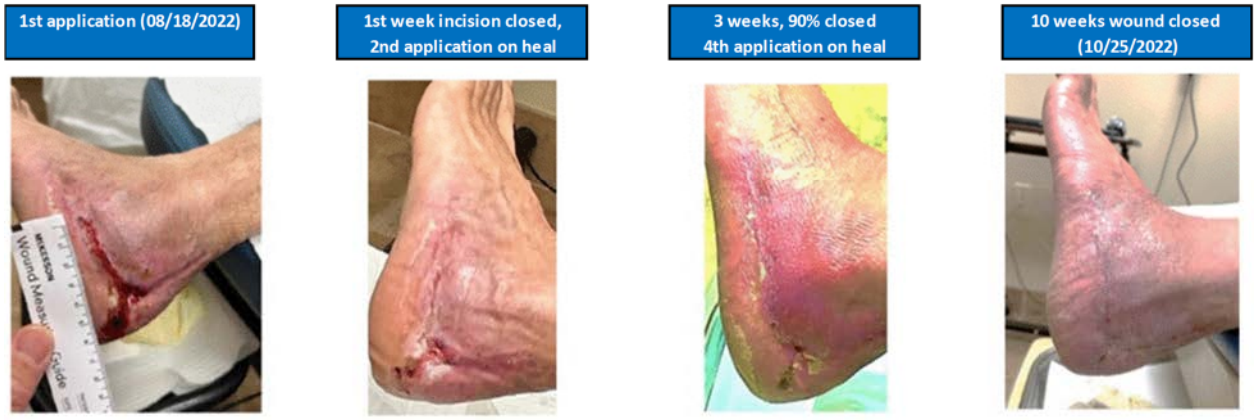
NeoMatriX Wound Matrix was first cleared by the FDA as a 510(k) medical device in 2018 and again for in-house process in 2021. Animal performance studies suggest axolotl-derived tissue used as a wound management device may lead to a regeneration response. The Company's proprietary manufacturing process removes elements that may otherwise cause a reaction in a patient after application, while retaining native structural ECM constituents. Currently, NeoMatriX is available in sterile sheets of various sizes for placement on the wound bed. Clinical use of NeoMatriX demonstrates promising results when used by physicians for patients suffering from chronic and difficult to heal wounds, as further described in the accompanying section (pages 20-25),

NeoMatriX for an Open Wound (First Patient Case)

Figure 9 shows the first patient's use of NeoMatriX of an open wound, which was not healing correctly post-surgery. This patient experienced an infection after calcaneus fracture repair with hardware, which progressed to surgical dehiscence. He had an open wound for 18 months (75 weeks) and was on IV antibiotics. This patient participated in the trial, receiving his first application on August 18, 2022, and within 1 week had the incision closed, and within 10 weeks had a complete healing of his wound.

Figure 9
PATIENT USE TESTIMONIAL: RICK NELSON

"I can not express how much NeXtGen Biologics has improved my life. I had an open wound on my heel for 1 1/2 years. I had two skin grafts and months of using a Wound VAC after surgery on my heel. The emotional pain was often more than the physical pain. Not knowing if I would ever heal. The wound allow the hardware and bone to become infected. The hardware had to be removed. Following the surgery to remove the hardware, the wound still was not healing right. I was asked if I would participate in a trial of a new product. Within 60 days of using this new product my heel wound completely healed up, providing my mobility back. We live on a 300 plus acre horse and cattle ranch and it has been very difficult not being able to help my wife on the ranch. Not sure I will ever be able to repay my wife for her care and patience."

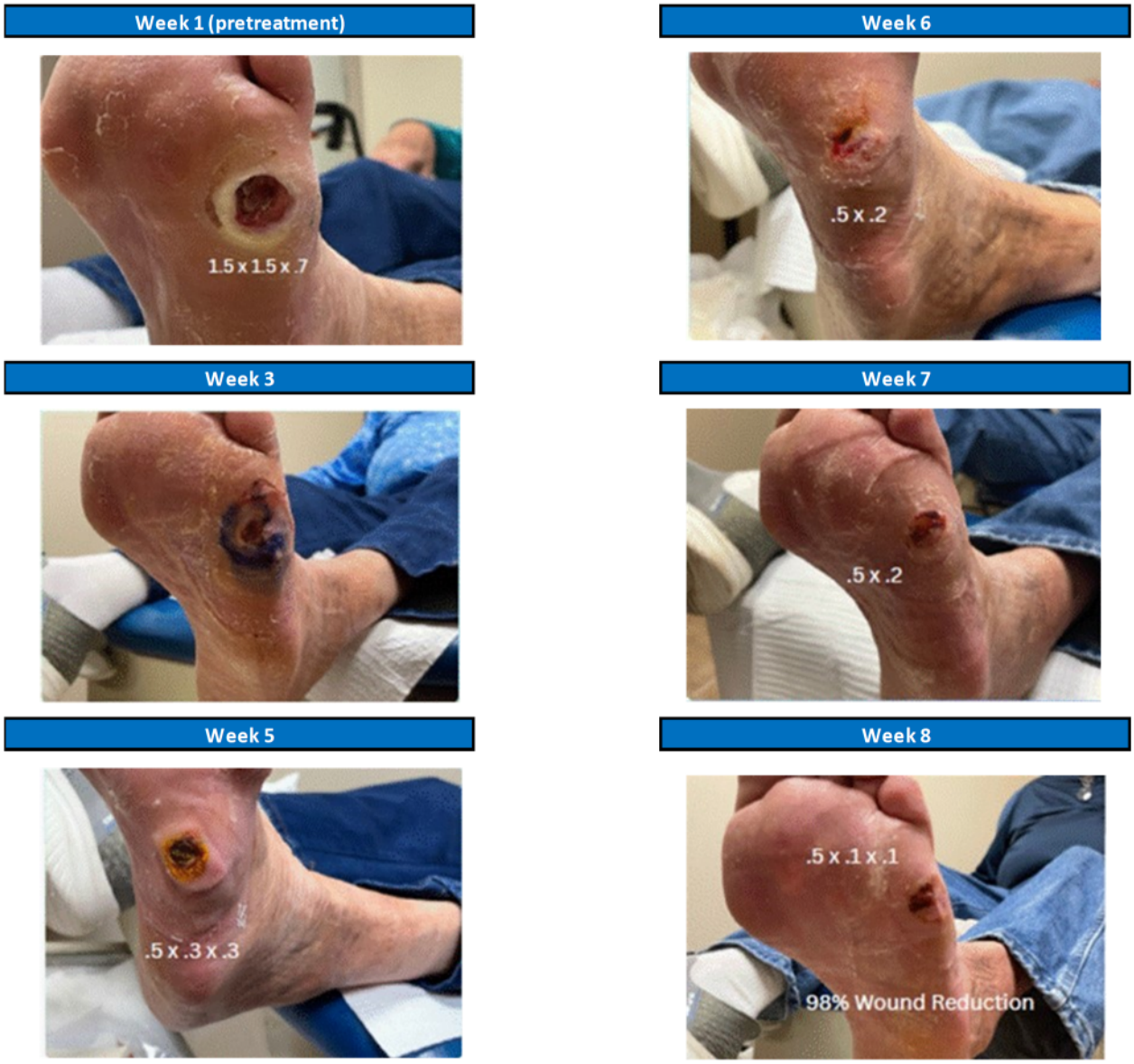


Source: NextGen Biologics Inc.

NeoMatriX for a Diabetic Ulcer

Figure 10 shows a patient's use of NeoMatriX for a diabetic ulcer. This patient received 8 applications (of various sheet sizes) and had a 98% healing of the wound after 8 weeks.

Figure 10
DIABETIC ULCER: 8 APPLICATIONS WITH NEOMATRIX®



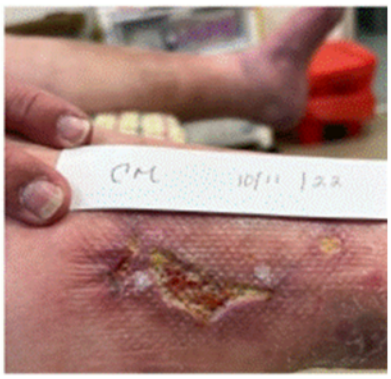
Source: NextGen Biologics Inc.

NeoMatriX for a Venous Stasis Ulcer

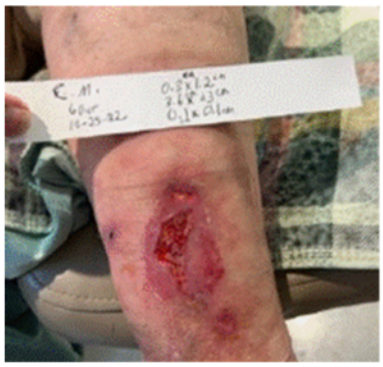
Figure 11 shows a patient's use of NeoMatriX for a venous stasis ulcer. This patient received 4 applications and had closure of the wound after 8 weeks (10/11/2022-12/13/2022).

Figure 11
VENOUS STASIS ULCER: 4 APPLICATIONS WITH NEOMATRIX®

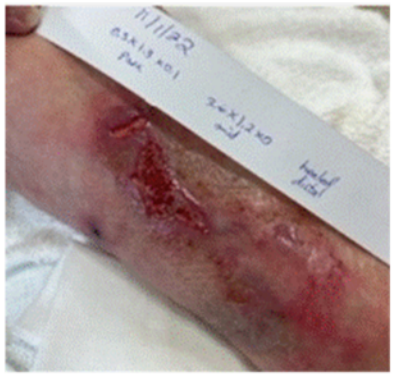
Pretreatment



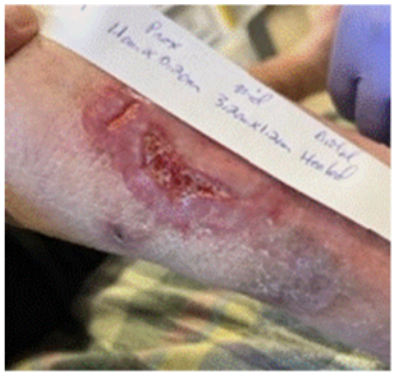
Week 1



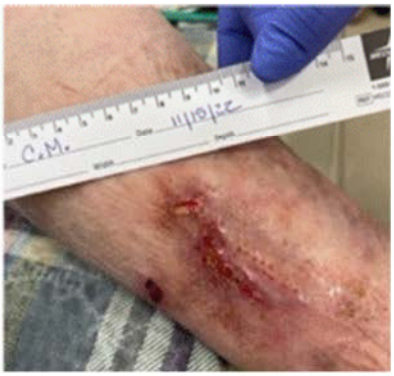
Week 2



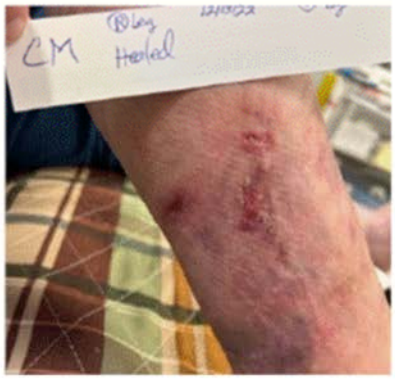
Week 3



Week 4



Closed



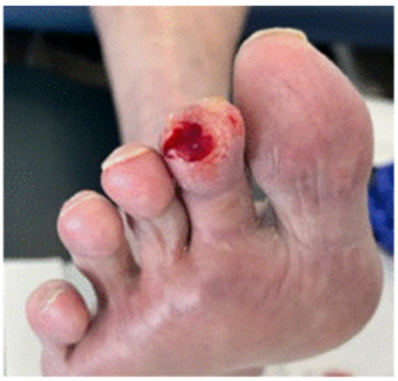
Source: NextGen Biologics Inc.

NeoMatriX for a Second Toe Wound of a Diabetic Patient

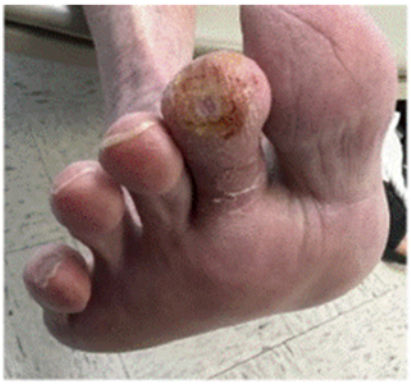
Figure 12 shows a patient's use of NeoMatriX for a second toe wound of a diabetic patient. This patient received 2 applications (8 mm disc applied) and had closure of his wound after 4 weeks (post debridement).

Figure 12
PATIENT JF - R 2ND TOE WOUND – DIABETIC: 2 APPLICATIONS WITH NEOMATRIX®

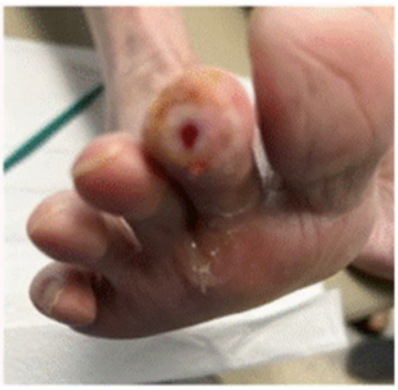
First Treatment 8mm Disk Applied 4/26



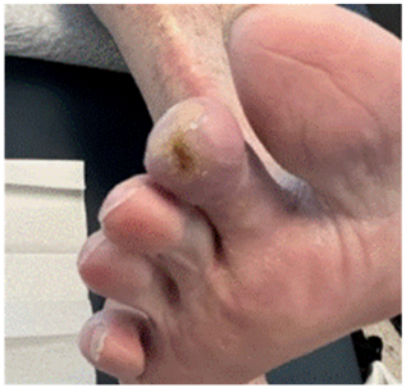
Week 1: Follow-up Pre Debridement



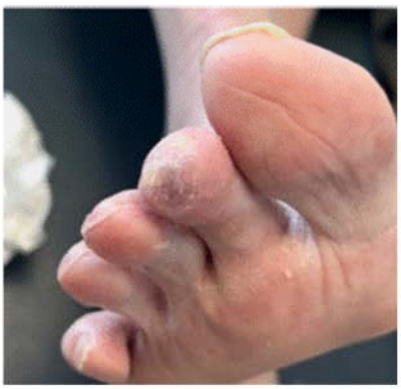
Week 1 Post Debridement: 8mm Disk Applied 5/3

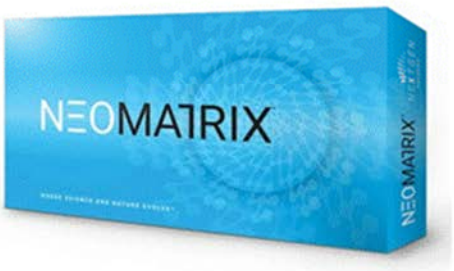


Week 4: Pre Debridement



Week 4 Post Debridement - Closed



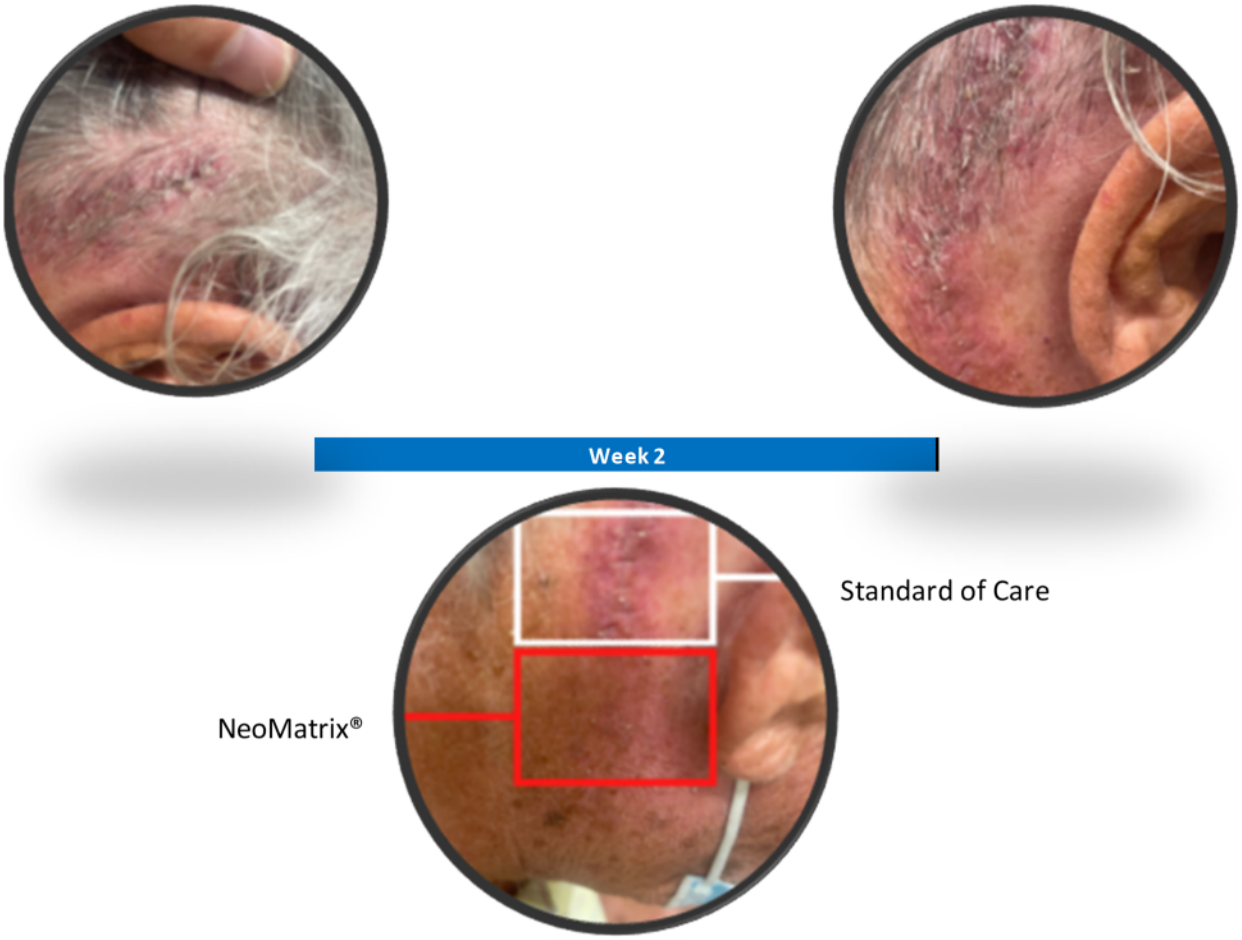


Source: NextGen Biologics Inc.

NeoMatriX for a Compromised Wound Healing Patient

Figure 13 shows surgical use of NeoMatriX for a compromised wound healing patient, post irradiation treatment after two weeks of treatment following the patient receiving a single application (09/07/2022-09/19/2022).

Figure 13
NEUROSURGICAL PROCEDURE: COMPROMISED WOUND HEALING POST IRRADIATION TREATMENT
SINGLE APPLICATION WITH NEOMATRIX®

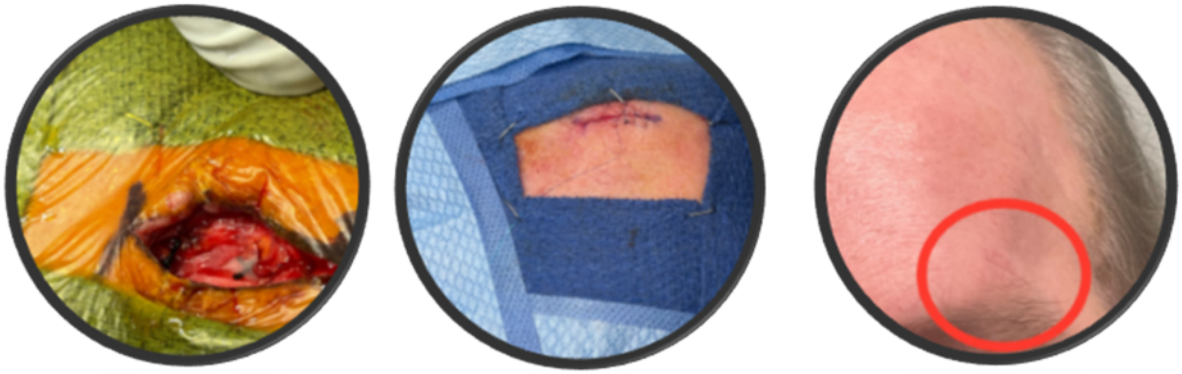


Source: NextGen Biologics Inc.

NeoMatriX for a Neurosurgical Procedure (We would like to add another case study here)

Figure 14 shows surgical use of NeoMatriX for a neurosurgical procedure after three weeks of treatment following the patient receiving a single application (11/29/2022-12/19/2022).

Figure 14
NEUROSURGICAL PROCEDURE: SINGLE APPLICATION WITH NEOMATRIX® (11/29/2022-12/19/2022)

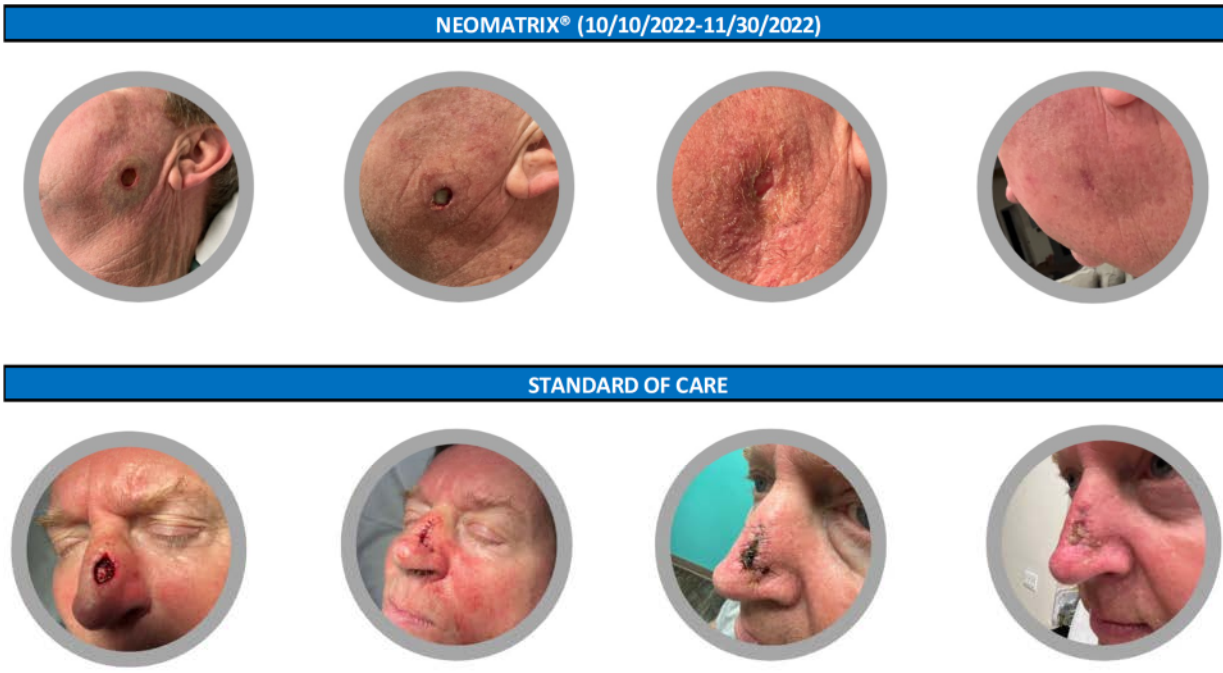


Source: NextGen Biologics Inc.

NeoMatriX for Mohs Surgery Versus Standard of Care

Figure 15 shows use of NeoMatriX for Mohs surgery (top) after six weeks of treatment following the patient receiving a single application (10/10/2022-11/30/2022) versus the standard of care (bottom).

Figure 15
MOHS SURGERY



Source: NextGen Biologics Inc.

Recent Merger and Acquisition Transactions and IPO Activities

There has been a healthy amount of merger and acquisition (M&A) activity taking place within the wound care space, as summarized in Figure 16. NeXtGen seeks to maximize shareholder value by building a high-quality company through its IP and R&D efforts for technology diversification to facilitate a potential exit. The Company's exit opportunities include M&A, licensing, IPO, or remaining as a standalone company. Each of these opportunities will require full board review and appropriate approval, which will determine the Company's future course of action.

Figure 16
M&A ACTIVITY WITHIN THE WOUNDCARE SPACE

Source: PitchBook.

Investment Highlights

- ***NeXtGen Biologics' extracellular matrix (ECM) technology is unique in all aspects of the surgical markets***. The Company's first product, NeoMatriX® Wound Matrix, is the foundation of this platform technology. The product uses the dermis of the axolotl, an animal that has been long studied regarding its inherent regenerative nature.
- ***The neotenic characteristics of axolotls, combined with their remarkable regenerative abilities, make them valuable subjects for scientific research with potential applications in regenerative medicine, including wound healing***. By studying these fascinating amphibians, scientists hope to unlock new insights into tissue regeneration and develop innovative therapies to improve human health.
- ***NeoMatriX was first FDA cleared as a 510(k) medical device in 2018 and again for in-house process in 2021***. The Company's proprietary manufacturing process removes elements that may otherwise cause a reaction in a patient after application, while retaining native structural ECM constituents. Currently, NeoMatriX is available in sterile sheets of various sizes for wound bed placement. Clinical use demonstrates promising results when used by physicians for patients suffering from chronic and difficult to heal wounds.
- ***Every year, approximately 12 million U.S. patients suffer traumatic lacerations that are treated in the emergency room and 250 million people worldwide undergo surgical incisions***. Chronic wounds affect 6.5 million people in the U.S. In many cases, these wounds carry the risk of scar formation, adhesions, incomplete remodeling, and infection.
- ***Despite significant technological advancements, the management of surgical and chronic wounds remains a challenge***. There is no solution available to date that guarantees scar-free healing. Also, surgically treated conditions may lead to complications, such as non-closure, dehiscence, and recurrence, causing distress for patients and imposing substantial financial burdens on payors.
- ***NeXtGen's product offers unique competitive advantages***, including that it can be stored at room temperature (off the shelf); is sterile, where no viruses will be transmissible to humans; is naturally adherent, versatile and durable; provides for easy placement, where it can be used for partial and full-thickness wounds; offers on-demand manufacturing; and has scalable technology that is cost competitive.
- ***NeXtGen is prepared to launch what it considers a genuinely "next generation" platform for wound care and associated technologies into the estimated $13.67 billion 2025 North American target market***. This endeavor takes place within the broader context of the estimated $66 billion worldwide regenerative medicine market of 2022, which is recognized as the fastest-growing sector in medical devices, as indicated by recent merger and acquisition transactions and IPO activities (Figure 16, page 26).
- ***The Company has received $16.2 million of funding to date***, including a $1.3 million SEED round (closed); $7.9 million raised through convertible notes (8% interest and 20% discount in "qualified equity financing"); and $6.4 million Common Stock (with $0.5mm remaining to reach convertible note). It currently seeks to raise an additional $5 million.
- ***NeXtGen is led by a highly experienced management team and Board of Directors with proven success in pharmaceutical research, development, and commercialization***. Jonelle Toothman, Co-founder & CEO, has 15+ years of experience in leadership roles commercializing medical device products and positioning companies for acquisition and has been part owner of several ventures; and Jamie Grooms, Co-founder & Chairman of the Board, has been Co-founder and former CEO of 2 startup regenerative companies (RTI Surgical [NASDAQ: RTIX], and AxoGen, Inc. [NASDAQ: AXGN]).
- ***NeXtGen exclusively owns a portfolio of Trade Secrets and U.S. and foreign issued and pending patent rights for medical devices, implants, coatings, cosmetics, biologicals, pharmacological, and other therapeutic technologies.***

Potential Competition

The markets in which the Company's products are sold are highly competitive. Of all the current options, including traditional, surgical, and advanced products for treating a variety of wounds, no other product is derived from a regenerative source. All other natural collagen wound dressings are made from porcine (pig) intestinal lining and urinary bladder, bovine (cow) skin, fish skin, human cadaveric skin, human skin cells, as well as human placental linings. NeoMatriX provides a wound dressing used in a manner familiar to physicians with the unique characteristic of being the first product made from the dermis of an axolotl. Axolotls have been studied for the past 150 years and have demonstrated the ability to heal without scar throughout their lifespan. There are companies that have products called 'axolotl biologics,' because the axolotl is known for its regenerative capabilities. Competitors compare their placental products to this species, with the end goal being the ability to regenerate or to have a healing response that is like, or as good as the axolotl; NeXtGen is setting the stage to make this a reality. NeXtGen's products compete against similar products of many large and small companies, including well-known global competitors. In many of the markets and industry segments in which the Company sells its products, NeXtGen will be selling its products alongside other branded products as well as retailers' private-label brands. Product quality, performance, value, and packaging are important differentiating factors.

Companies that may be considered competition to NeXtGen include Aroa Biosurgery, ConvaTec Group, ECM Therapeutics, and MIMEDX, with Aroa Biosurgery and MIMEDX having developed wound care products that specifically use axolotl-derived ECM and have patents on their axolotl-derived ECM technology. Other medical device companies with patents for ECM technology include Organogenesis, LifeCell (an Acelity Company), and Cook Medical. These companies are developing ECM-based products for wound healing, tissue repair, and other applications. Additional companies which could compete with NeXtGen include Amniox Medical, Inc., Convatec Group Plc., Integra LifeSciences Holdings Corporation, LifeCell Corp., MiMedx Group, Inc., Organogenesis, and Osiris (which was acquired by Smith and Nephew plc). NeXtGen may also compete with skin substitute products, placental-based technology products, orthobiologics products, other advanced wound care and traditional wound care products, among others. The potential competition that NeXtGen may face is profiled in the accompanying section. While not intended to be an exhaustive collection of the Company's competitors, it is believed to be a selection of the type of competition that NeXtGen may face as it strives to commercialize its technologies and product candidates. Figure 17 provides a broad summary of revenues and market share for some of the leaders within this space.

Figure 17
ECM COMPETITION BY MANUFACTURER

	2021 Revenue	2022 Revenue	2021 Share	2022 Share
Organogenesis	$ 417,650,000	$ 411,600,000	28%	26%
Integra	$ 267,330,000	$ 283,073,333	18%	18%
MiMedx	$ 242,300,000	$ 256,417,333	16%	16%
SNN	$ 155,470,000	$ 171,689,333	11%	11%
All Others	$ 387,211,000	$ 482,793,333	26%	30%
Total	**$ 1,469,961,000**	**$ 1,605,573,333**		

Source: NextGen Biologics Inc.

Amniox Medical, Inc. (a subsidiary of TissueTech, Inc.)

Amniox Medical, Inc., a subsidiary of TissueTech, Inc., specializes in clinical applications of human birth tissue-based products. These products, processed using TissueTech's proprietary CRYOTEK® preservation technology, have found utility in various medical contexts. Amniox offers CLARIX®, which includes cryopreserved umbilical cord and amniotic membrane products, which are used for both surgical and injectable procedures. By harnessing the power of human birth tissue, these products aid in wound healing and pain management. They possess anti-inflammatory and anti-scarring properties, helping patients recover faster and restore their bodies to their original state. Amniox was launched by TissueTech in 2011, with a mission to address unmet patient needs in orthopedic and wound care indications. A recently published study suggests that CLARIX FLO, an amniotic membrane and umbilical cord particulate product, provides benefits in moderate-to-severe knee osteoarthritis. Amniox is headquartered in Atlanta, GA.

Axolotl Biologix

Axolotl Biologix is a biotech company focused on developing and producing human biologics and biological-related products to address various medical conditions. These conditions include orthopedic issues, wound care, and cosmetic concerns. The company's products include Axolotl Graft™ and Axolotl DualGraft™, which utilize a proprietary BioSym™ process for preparation, which includes donor testing and screening, cleaning, preservation, and terminal sterilization of donor tissues. Axolotl Graft™ and Axolotl DualGraft™ are designed to be efficient, effective, and safe for clinical use and do not require special instrumentation and have a low risk of immunogenicity. Axolotl Biologix recently launched AxoBioMembrane™, which expands the human body's regenerative capabilities. This membrane is part of their mission to disrupt traditional, invasive, painful, and costly treatment protocols. By harnessing regenerative human cells and tissues, AxoBioMembrane™ aims to foster tissue regeneration. In July 2023, Carmell Therapeutics Corporation announced a merger with Axolotl Biologix, which combines their expertise in regenerative medicine and promises exciting developments in the field. Axolotl Biologix has headquarters in Phoenix, AZ. Carmell Therapeutics trades on the NASDAQ under the symbol (NASDAQ-CTCX).

Aroa Biosurgery Ltd

Aroa Biosurgery is a soft-tissue regeneration company that develops, manufactures, and distributes medical and surgical products to improve healing in complex wounds and soft tissue reconstruction. Endoform™ Dermal Template, Aroa's first product for chronic non-healing wounds, was launched in the U.S. by Hollister Inc. (USA) in 2013 after obtaining U.S. Food & Drug Administration (FDA) clearance and breakthrough reimbursement from the Centre for Medicare and Medicaid Services for an ECM-based product allowing widespread access in all sites of care. In 2018, Aroa Biosurgery acquired back Endoform™ Dermal Template and formed a joint venture to continue to deliver this product to its customers. The company's first commercial surgical product, a Reinforced Bioscaffold developed in collaboration with Tela Bio Inc. (USA), was cleared by the FDA in December 2014 and clinical studies were initiated in the U.S. in May 2015 for use in ventral hernia repair and abdominal wall reconstruction. Founded in 2008, Aroa Biosurgery is headquartered in Auckland, New Zealand and is listed on the Australian Securities Exchange (ARX-ASX).

BioTissue Holdings Inc.

A company dedicated to regenerative healing, BioTissue harnesses the power of human birth tissue to create trusted products that aid in wound healing and pain management. These products, derived from compassionate mothers' donated birth tissue, possess anti-inflammatory and anti-scarring properties. They help patients recover faster and restore their bodies to their original state. For many, BioTissue offers a second chance at life, whether they are post-op patients or professional athletes aiming for better-than-ever recovery. BioTissue's product offerings for wound healing include Ocular Products: Prokera, a cryopreserved amniotic membrane (AM) that aids in ocular surface healing; AmnioGraf, used for ocular surface reconstruction; and AmnioGuard Surgical, which supports surgical procedures. BioTissue's surgical products are designed to promote healing in various surgical contexts. BioTissue's technology, including their proprietary CryoTek® method, effectively retains the structure and biological properties of natural tissue, orchestrating regenerative healing. The company has headquarters in Miami, FL.

ConvaTec Group PLC

One example of a medical device that has received clearance from the U.S. FDA is ConvaTec Group PLC's InnovaBurn® placental ECM medical device. This device is used for the management of complex surgical wounds and burns, including partial-thickness second-degree burns. According to the American Burn Association's AmeriBurn.org, almost 500,000 people seek medical treatment for burn injuries each year, with about 40,000 being hospitalized for their burn injuries. The company has headquarters in Paddington, London, England, UK and trades on the London Stock Exchange under the symbol (CTEC-LON).

Cook Medical LLC

Cook Medical is a global manufacturer of medical devices, specializing in various fields, such as interventional cardiology, gastroenterology, and urology. Their products are designed to enhance patient care and improve medical procedures. The company markets the Biodesign® 4-Layer Tissue Graft, which is designed for use in various surgical procedures. The product consists of four distinct layers, each serving a specific purpose: layer 1 (epithelial layer), provides a barrier to prevent adhesions and promote healing; layer 2 (submucosal layer), offers strength and support; layer 3 (muscular layer), enhances durability and stability; and layer 4 (serosal layer), facilitates tissue integration. Surgeons use this graft for applications such as hernia repair, wound closure, and tissue reinforcement, where its versatility and biocompatibility make it a valuable tool in the field of surgery. Cook Medical has headquarters in Bloomington, IN.

ECM Therapeutics

ECM Therapeutics is a regenerative medicine company utilizing naturally occurring ECM-based signaling molecules. The company capitalizes upon findings generated from the intersection of regenerative medicine and matrix biology research, which provide an in-depth understanding of how ECM changes with homeostasis, injury, or disease. This understanding allows for the formulation of medical devices and drugs specifically designed to address unmet clinical needs, both broadening the scope of ECM-based therapeutics as well as providing better outcomes. The company seeks to develop products for various clinical markets, including gastrointestinal, musculoskeletal, optic, and central nervous system, among other areas. ECM has headquarters in Warrendale, PA.

Integra LifeSciences Holdings Corporation

Integra LifeSciences Holdings Corporation is an integrated medical device company that offers a diverse range of products for various medical specialties. Within orthopedics, Integra provides implants, instruments, and equipment for orthopedic surgery. Their orthopedic product offerings include devices and implants for foot and ankle, hand and wrist, tendon and peripheral nerve protection and repair, wound repair, and spine. Within neurosurgery, the company is a leader in cranial neurosurgery, offering a comprehensive portfolio of implants, devices, instruments, and systems used in neurosurgery, neuromonitoring, neurotrauma, and related critical care. For general surgery, Integra's products extend to general surgery, providing surgical instruments to hospitals, surgery centers, and alternate care sites, including physician and dental offices. The company's proprietary CRYOTEK® preservation technology ensures the effectiveness and safety of their products. The company is headquartered in Plainsboro, NJ and trades on the NASDAQ under the symbol (IART-NASDAQ).

Kerecis (Sold to Danish company Coloplast A/S in July 2023 for $1.2 billion USD)

Kerecis, which was sold to Danish company Coloplast A/S in July 2023 for $1.2 billion USD, is an Icelandic company that pioneers the use of fish skin in cellular therapy and tissue regeneration. The company has developed innovative products using intact fish skin to treat various wounds, burns, and other complex acute and chronic injuries. Specifically, Kerecis utilizes wild Atlantic cod skin, sourced sustainably from pristine Icelandic waters. The intact fish skin is processed using renewable energy and is used to treat burns, as well as other complex acute and chronic wounds, including diabetic, venous, trauma, and surgical wounds. The company recently introduced Shield Standard, which combines a fish-skin graft with a silicone backing for an efficient wound healing environment. This fish-skin graft is homologous to human skin and is used for tissue regeneration. It also acts as a natural microbial barrier. Importantly, Kerecis' products offer improved clinical performance and pose no disease transfer risk to humans. The company's U.S. headquarters are in Arlington, VA, with offices in Iceland and Germany. The company trades on the

Nasdaq Copenhagen, formerly known as the Copenhagen Stock Exchange under the symbol (COLO B / CPH) and under the OTC markets under the symbol (CLPBF-OTCMKTS).

LifeCell Corp. (a part of Acelity)

LifeCell Corporation specializes in regenerative medicine and biotechnology. It is now part of Acelity, a global market leader in advanced wound therapeutics and regenerative medicine. LifeCell focuses on developing and commercializing acellular tissue matrices for use in general and reconstructive surgical procedures. Their portfolio includes products like ALLODERM™ Regenerative Tissue Matrix (launched in 1994) and STRATTICE™ Reconstructive Tissue Matrix (launched in 2008). In 2012, they expanded with the launch of ALLODERM™ Ready to Use. In 2013, the REVOLVE™ System was introduced for efficient fat transfer processing. In 2014, LifeCell, along with other companies, became part of the global medical technology brand known as Acelity, which is a global healthcare company headquartered in Houston, Texas that develops and manufactures advanced wound care products.

MIMEDX Group, Inc.

MIMEDX is a pioneer and leader in placental biologics focused on delivering innovative solutions to patients and the healthcare professionals who treat them. With more than a decade of helping clinicians manage chronic and other hard-to-heal wounds, MIMEDX has provided a leading portfolio of products for applications in the wound care, burn, and surgical recovery sectors of healthcare. Specifically, MIMEDX has patented methods for producing axolotl-derived ECM for use in wound healing. AXIOFILL® is a biocompatible acellular human placental extracellular matrix (ECM) derived from the placental disc. It is intended for use in the replacement or supplementation of damaged or inadequate integumental tissue. Clinical use examples include deep, tunneling, or irregular soft tissue deficits and incision management in surgical applications. As a particulate, AXIOFILL presents a versatile option for various clinical applications and is easy to apply dry or hydrated to use in paste form. The company has headquarters in Marietta, GA and trades on the NASDAQ under the symbol (MDXG-NASDAQ).

Organogenesis Holdings Inc.

Organogenesis Holdings Inc. is a leading regenerative medicine company offering a portfolio of bioactive and acellular biomaterials products in advanced wound care and surgical biologics, including orthopedics and spine. With its bioactive wound healing, the company offers innovative solutions for wound care, including products that aid in tissue regeneration. The company's soft tissue regeneration products address soft tissue repair and regeneration, helping patients recover from injuries and surgeries. Some of the company's notable products include: Apligraf®, a bioactive wound care product that promotes healing in chronic wounds, such as diabetic foot ulcers and venous leg ulcers (with the product consisting of living human cells embedded in a collagen matrix); Dermagraft®, another bioengineered product for wound care used to treat diabetic foot ulcers (with the product containing fibroblast cells on a bioabsorbable scaffold); PuraPly®, an acellular dermal matrix used in surgical procedures for soft tissue repair and reconstruction, which provides a scaffold for tissue regeneration; and ReNu®, a product line that includes ReNu® Matrix, ReNu® Surgical, and ReNu® Sports, which are designed for soft tissue repair and orthopedic applications. The company had headquarters in Canton, MA and trades on the NASDAQ under the symbol (ORGO-NASDAQ).

Osiris Therapeutics (which was acquired by Smith & Nephew plc)

Osiris Therapeutics, Inc., which was later acquired by Smith & Nephew plc, is known for its regenerative medicine products. These products include skin, bone graft, and articular cartilage substitutes. One of their notable product lines is the OASIS Matrix Products, which are naturally derived scaffolds of ECM. These products, composed of porcine small intestinal submucosa (SIS), are indicated for managing a wide range of acute and chronic wounds. The ECM components in OASIS attract endogenous cells (cells already present in the patient's body) to the wound site and help to regulate the inflammatory response, promoting a balanced healing environment. It encourages the formation of new blood vessels (angiogenesis), which is crucial for wound healing and, over time, undergoes remodeling as the patient's cells replace it with their own tissue. OASIS is used for chronic wounds, such as diabetic foot ulcers, venous leg ulcers, and pressure ulcers. The acquisition of Osiris by Smith & Nephew was completed for approximately $660 million in cash, and it is expected to accelerate growth within Smith & Nephew's Advanced Wound Management franchise. The company trades on the NYSE under the symbol (SNN-NYSE).

Historical Financial Results

Figures 18, 19, and 20 (pages 32-34) provide a summary of NeXtGen's most recent key unaudited financial statements for the quarter ended March 31, 2024.

Figure 18
NEXTGEN BIOLOGICS INC.
PROFIT AND LOSS
January - March 2024

	JAN 2024	FEB 2024	MAR 2024	TOTAL
Income				
65410 Revenue - Sale of Product	60,733.75	44,416.25	30,450.00	$135,600.00
Total Income	**$60,733.75**	**$44,416.25**	**$30,450.00**	**$135,600.00**
GROSS PROFIT	**$60,733.75**	**$44,416.25**	**$30,450.00**	**$135,600.00**
Expenses				
51600 Consolidated Overhead, MFG				$0.00
51160 Supplies & Materials MFG	2,899.58	4,189.32	7,286.38	$14,375.28
51624 Facility, MFG	10,231.81	4,161.70	4,256.38	$18,649.89
51640 General Administrative, MFG	42.99	6,768.00	56.93	$6,867.92
51691 Payroll Expenses MFG	9,277.44	9,249.55	12,091.92	$30,618.91
Total 51600 Consolidated Overhead, MFG	22,451.82	24,368.57	23,691.61	$70,512.00
61600 Consolidated Overhead, RM				$0.00
61161 Supplies and Materials, RM	9,962.20	3,087.20	5,368.07	$18,417.47
61610 Travel , RM		17.97		$17.97
61624 Facility, RM	9,332.32	7,245.74	7,680.13	$24,258.19
61640 General Administrative, RM	175.92	145.32	491.00	$812.24
61650 Professional Fees, RM	2,395.17	3,869.36	2,825.13	$9,089.66
61692 Payroll, RM	13,807.39	14,251.80	16,878.16	$44,937.35
Total 61600 Consolidated Overhead, RM	35,673.00	28,617.39	33,242.49	$97,532.88
63600 Consolidated Overhead, R&D				$0.00
63161 Supplies and Materials, R&D	503.90	246.86	105.54	$856.30
63624 Facility, R&D	403.17	392.01	394.71	$1,189.89
Total 63600 Consolidated Overhead, R&D	907.07	638.87	500.25	$2,046.19
64600 Consolidated Overhead, REG/QUAL				$0.00
64161 Supplies and Materials, REG/QUAL		108.68		$108.68
64650 Professional Fees, REG/QUAL	5,900.00	3,300.00	4,000.00	$13,200.00
64692 Payroll, REG/QUAL	4,090.81	4,089.36	4,146.50	$12,326.67
Total 64600 Consolidated Overhead, REG/QUAL	9,990.81	7,498.04	8,146.50	$25,635.35
65600 Consolidated Overhead, SALES				$0.00
65610 Travel, SALES	11.40	75.61		$87.01
65640 General Administrative, SALES	8.00			$8.00
65650 Professional Fees, SALES	11,050.00	0.00	2,775.00	$13,825.00
Total 65600 Consolidated Overhead, SALES	11,069.40	75.61	2,775.00	$13,920.01
68600 Consolidated Overhead, CORP				$0.00
68161 Supplies and Materials, CORP	49.48		55.32	$104.80
68601 Advertising and Promotional, CORP	4,550.00	235.37		$4,785.37
68610 Travel, CORP	2,805.17	2,672.22	3,888.10	$9,365.49
68636 Insurance, CORP	7,537.62	3,933.18	2,562.16	$14,032.96
68640 General Administrative, CORP	2,670.16	6,030.76	14,685.08	$23,386.00
68650 Professional Fees, CORP	2,520.20	13,325.60	17,728.10	$33,573.90

	JAN 2024	FEB 2024	MAR 2024	TOTAL
68692 Payroll, CORP	18,062.44	17,539.70	18,120.28	$53,722.42
Total 68600 Consolidated Overhead, CORP	38,195.07	43,736.83	57,039.04	$138,970.94
Total Expenses	$118,287.17	$104,935.31	$125,394.89	$348,617.37
NET OPERATING INCOME	$ -57,553.42	$ -60,519.06	$ -94,944.89	$ -213,017.37
Other Income				
68700 Other Miscellaneous Income, CORP	592.64	615.39	494.42	$1,702.45
Total Other Income	$592.64	$615.39	$494.42	$1,702.45
Other Expenses				
51800 Consolidated Other Expense, MFG	17,763.75	2,520.84	2,520.84	$22,805.43
61800 Consolidated Other Expense, RM	7,721.88	7,721.88	7,721.88	$23,165.64
63800 Consolidated Other Expense, R&D	7,760.70	7,760.70	7,760.70	$23,282.10
68800 Consolidated Other Expense, CORP	81.58	81.58	14,800.31	$14,963.47
Total Other Expenses	$33,327.91	$18,085.00	$32,803.73	$84,216.64
NET OTHER INCOME	$ -32,735.27	$ -17,469.61	$ -32,309.31	$ -82,514.19
NET INCOME	$ -90,288.69	$ -77,988.67	$ -127,254.20	$ -295,531.56

Source: NextGen Biologics Inc.

Figure 19
NEXTGEN BIOLOGICS INC.
BALANCE SHEET
As of March 31, 2024

	JAN 2024	FEB 2024	MAR 2024
ASSETS			
Current Assets			
Bank Accounts			
10101 Bank of America - Operating	182,764.61	215,503.61	215,296.86
10103 FLCU 066-0008	537,358.08	398,554.68	304,844.86
10104 FLCU 066-0000	5.85	5.85	5.85
10105 Merrill Lynch (02194)	0.00	0.00	0.00
Total Bank Accounts	**$720,128.54**	**$614,064.14**	**$520,147.57**
Accounts Receivable			
10120 Accounts Receivable	182,147.50	226,563.75	255,813.75
Total Accounts Receivable	**$182,147.50**	**$226,563.75**	**$255,813.75**
Other Current Assets			
1012030 Other Receivable	43,796.79	43,796.79	21,301.65
10130 Undeposited Funds	0.00	0.00	0.00
10140 Inventory Asset	0.00	0.00	0.00
1014020 Inventory - Manufacturing Supplies	0.00	0.00	0.00
Total 10140 Inventory Asset	**0.00**	**0.00**	**0.00**
10150 Prepaid Expenses	-0.40	-0.40	-0.40
1015020 Prepaid Rent	0.00	0.00	0.00
1015030 Prepaid Other (Insurance, Advertising etc.)	0.00	0.00	0.00
1015050 Legal Retainer	15,000.40	15,000.40	15,000.40
Total 10150 Prepaid Expenses	**15,000.00**	**15,000.00**	**15,000.00**
1015099 Uncategorized Asset	0.00	0.00	0.00
Total Other Current Assets	**$58,796.79**	**$58,796.79**	**$36,301.65**
Total Current Assets	**$961,072.83**	**$899,424.68**	**$812,262.97**
Fixed Assets			
10170 Property, Plant and Equipment			
50180 Location - Manufacturing	34,598.30	32,077.46	29,556.62
61180 Location - Raw Materials	138,174.28	130,452.40	122,730.52
63180 Location - Research and Development	59,381.14	59,331.64	59,282.14
68180 Location - Corporate	9,015.16	8,933.58	9,011.90
Total 10170 Property, Plant and Equipment	**241,168.88**	**230,795.08**	**220,581.18**
1019020 Patents	601,474.55	601,474.55	601,474.55
1019950 Accumulated Amortization	-212,057.56	-219,768.76	-227,479.96
1300 Inventory Cost - Raw Material Department	0.00	0.00	0.00
1520 Leasehold Improvements	0.00	0.00	0.00
1530 Machinery and Equipment	0.00	0.00	0.00
1540 Computer Equipment	0.00	0.00	0.00
1550 Furniture and Supplies	0.00	0.00	0.00
1600 Accumulated Depreciation	10,890.00	10,890.00	10,890.00
Total Fixed Assets	**$641,475.87**	**$623,390.87**	**$605,465.77**

	JAN 2024	FEB 2024	MAR 2024
Other Assets			
51187 Secuity Deposit	2,600.00	2,600.00	2,600.00
Operating Lease Right of Use Asset	625,932.00	625,932.00	625,932.00
Total Other Assets	**$628,532.00**	**$628,532.00**	**$628,532.00**
TOTAL ASSETS	**$2,231,080.70**	**$2,151,347.55**	**$2,046,260.74**
LIABILITIES AND EQUITY			
Liabilities			
Current Liabilities			
Accounts Payable	$1,075,414.49	$1,045,339.34	$1,045,902.18
Credit Cards	$31,043.33	$25,896.13	$47,258.00
Other Current Liabilities	$72,417.00	$72,417.00	$72,117.00
Total Current Liabilities	**$1,178,874.82**	**$1,143,652.47**	**$1,165,277.18**
Long-Term Liabilities			
10213 Notes Payable - SBA/FLCU PPP Loan	0.00	0.00	0.00
10216 Note Payable Investors 2016	1,318,873.00	1,318,873.00	1,318,873.00
10217 Note Payable Investors 2017	1,666,521.00	1,666,521.00	1,666,521.00
10218 Note Payable Investors 2018	3,590,500.00	3,590,500.00	3,590,500.00
10219 Note Payable Investors 2019	0.00	0.00	0.00
10299 Investor Interest Payable	2,645,147.00	2,645,147.00	2,645,147.00
Crowdfunding Liability	218,377.54	218,377.54	218,377.54
Operating Lease Liability	520,822.00	520,822.00	520,822.00
Total Long-Term Liabilities	**$9,960,240.54**	**$9,960,240.54**	**$9,960,240.54**
Total Liabilities	**$11,139,115.36**	**$11,103,893.01**	**$11,125,517.72**
Equity	$ -8,908,034.66	$ -8,952,545.46	$ -9,079,256.98
TOTAL LIABILITIES AND EQUITY	**$2,231,080.70**	**$2,151,347.55**	**$2,046,260.74**

Source: NextGen Biologics Inc.

Figure 20
NEXTGEN BIOLOGICS INC.
STATEMENT OF CASH FLOWS
January - March 2024

	JAN 2024	FEB 2024	MAR 2024	TOTAL
OPERATING ACTIVITIES				
Net Income	-90,288.69	-77,988.67	-127,254.20	$ -295,531.56
Adjustments to reconcile Net Income to Net Cash provided by operations:				$0.00
10120 Accounts Receivable	-47,933.75	-44,416.25	-29,250.00	$ -121,600.00
1012030 Other Receivable	27.00		22,495.14	$22,522.14
1012040 Short-Term Employee Loans and Advances		-22.13		$ -22.13
1019950 Accumulated Amortization	7,711.20	7,711.20	7,711.20	$23,133.60
5018050 Property, Plant and Equipment:Location - Manufacturing:Accumulated Depreciation - Manufacturing	2,520.84	2,520.84	2,520.84	$7,562.52
6118050 Property, Plant and Equipment:Location - Raw Materials:Accumulated Depreciation - Raw Materials	7,721.88	7,721.88	7,721.88	$23,165.64
6318050 Property, Plant and Equipment:Location - Research and Development:Accumulated Depreciation - Research and Development	49.50	49.50	49.50	$148.50
6818050 Property, Plant and Equipment:Location - Corporate:Accumulated Depreciation - Corporate	81.58	81.58	81.58	$244.74
1020010 Accounts Payable	8,429.15	-30,075.15	562.84	$ -21,083.16
201010 Amex Credit Card -02006	-21,618.45	-794.90	11,011.77	$ -11,401.58
201011 Amex Credit Card -2000	7,720.55	-4,352.30	10,892.78	$14,261.03
1020020 Accounts Payable (Accrued)			-300.00	$ -300.00
1020230 Employee Benefits:401K Deduction Withheld	-1,704.96	0.00	0.00	$ -1,704.96
1020510 Sales Tax Agency Payable:Sales Tax Payable - Florida	0.00	0.00		$0.00
Out Of Scope Agency Payable			0.00	$0.00
Total Adjustments to reconcile Net Income to Net Cash provided by operations:	-36,995.46	-61,575.73	33,497.53	$ -65,073.66
Net cash provided by operating activities	$ -127,284.15	$ -139,564.40	$ -93,756.67	$ -360,605.22
INVESTING ACTIVITIES				
6818010 Property, Plant and Equipment:Location - Corporate:Computer Equipment and Software - Corporate			-159.90	$ -159.90
Net cash provided by investing activities	$0.00	$0.00	$ -159.90	$ -159.90
FINANCING ACTIVITIES				
30320 Additional Paid in Capital Common Stock	359,989.25	33,499.00		$393,488.25
30330 Common Stock	10.75	1.00		$11.75
Net cash provided by financing activities	$360,000.00	$33,500.00	$0.00	$393,500.00
NET CASH INCREASE FOR PERIOD	$232,715.85	$ -106,064.40	$ -93,916.57	$32,734.88

Source: NextGen Biologics Inc.

Recent Events

4/29/2024—In this case report, NeoMatriX® was first applied on December 5, 2023. Subsequently, the patient underwent 7 visits during a 9-week period. Progressive reductions in wound size were observed at each visit, leading to complete closure and minimal scarring. This outcome demonstrates the use of pro-regenerative axolotl dermis for wound management has favorable potential in improving wound closure, preventing poor overall outcomes (Figure 21).

Figure 21

CASE REPORT SHOWCASES A SUCCESSFUL CLINICAL OUTCOME ATTAINED THROUGH THE UTILIZATION OF NEXTGEN™ NEOMATRIX® IN WOUND MANAGEMENT

NEOMATRIX®

NeoMatriX® Wound Matrix is fabricated from the dermal extracellular matrix of axolotl. NeoMatriX® is provided as sheets of various sizes for placement on wound beds to help manage the wound environment.

Rx ONLY Refer to IFU supplied with each device for indications, contraindications and precautions.

ACKNOWLEDGEMENT

Dr. Paul Nasca, MD, DPM
2562 Walden Ave,
Cheektowaga, NY 14225

ABSTRACT

This case report showcases a successful clinical outcome attained through the utilization of NeXtGen™ NeoMatrix® in wound management. A female patient in her late 40's presented with a diabetic ulcer secondary to Charcot joint and diabetic peripheral neuropathy, grade IV.

The patient underwent a 14-week treatment period utilizing other ECM products. Although the wound had closed, an infection manifested one-week after closure, progressing to involve the underlying bone.

RESULTS

NeoMatriX® was first applied on December 5th, 2023. Subsequently, the patient underwent 7 visits during a 9-week period. Progressive reductions in wound size were observed at each visit, leading to complete closure and minimal scarring.

Visit Date	Length Size	Width Size	Depth Size	CM² Treated	% Reduction
12/5/2023	1.5	2.3	0.3	3.45	
12/12/2023	0.8	2.2	0.2	1.76	49%
12/20/2023	0.8	2	2	1.6	54%
12/27/2023	0.6	1.7	0.1	1.02	70%
1/2/2024	0.6	1.7	0.2	1.02	70%
1/24/2024	0.4	1	1	0.4	88%
2/7/2024	0	0	0	0	100%
7				% Reduction	100%

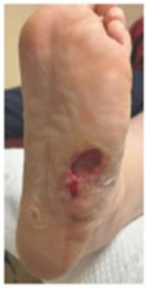
DISCUSSION

This outcome demonstrates the use of pro-regenerative axolotl dermis for wound management has favorable potential in improving wound closure, preventing poor overall outcomes.

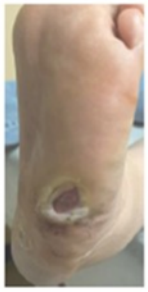
Expressing profound gratitude for reclaiming their optimal quality of life, the patient has indicated the following:

"Because of you, I'm going on a family cruise in a couple of weeks, and I'll be in the water instead of just watching the water. I can't wait!"

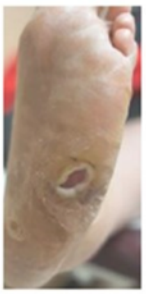
- C.



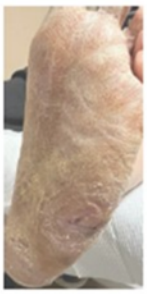
Dec 5th, 2023 1st Application



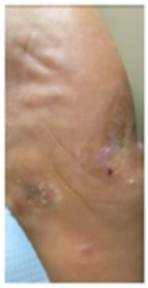
Dec 12th, 2023 2nd Application 1 week



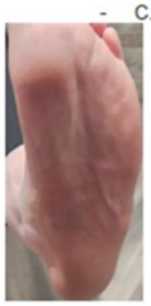
Dec 27th, 2023 3rd Application 4 weeks



Jan 24th, 2024 5th Application 8 weeks



Feb 27th, 2024 Closed 12 weeks



Apr 29th, 2024 20 weeks

Source: NextGen Biologics Inc.

4/10/2024—This case report highlights the successful clinical outcome resultant from treatment of post-lumbar fusion surgical wound dehiscence treated with NeXtGen™. Complete wound closure was achieved at the 28-day follow-up, coupled with the absence of hypertrophic scarring or infections (Figures 22 and 23).

Figure 22

CASE REPORT HIGHLIGHTS THE SUCCESSFUL CLINICAL OUTCOME RESULTANT FROM TREATMENT OF POST-LUMBAR FUSION SURGICAL WOUND DEHISCENCE TREATED WITH NEXTGEN™ NEOMATRIX®

NEW SKIN IN THE GAME

NeoMatriX® Wound Matrix is fabricated from the dermal extracellular matrix of axolotl. NeoMatriX® is provided as sheets of various sizes for placement on wound beds to help manage the wound environment.

FDA Cleared K210024

INDICATIONS FOR USE

NeoMatriX® Wound Matrix is intended for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undermined wounds
- Surgical wounds (donor sites/grafts
- post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, partial thickness burns, skin tears)
- Draining wounds

Rx ONLY Refer to IFU supplied with each device for indications, contraindications and precautions.

ABSTRACT:

This case report highlights the successful clinical outcome resultant from treatment of post-lumbar fusion surgical wound dehiscence treated with NeXtGen™ NeoMatrix®. This will allow clinicians to understand the benefit of NeoMatrix® for the management of post-operative wound dehiscence.

CASE REPORT

A male in his mid-60s, with a medical history significant for previous cervical myelopathy status post C3-6 fusion, presented with a progressive and refractory lumbosacral radiculopathy and spondylolisthesis. Despite conservative treatments such as physical therapy and epidural steroid injections, the patient's symptoms persisted. Consequently, he underwent an elective lumbar L4-5 laminectomy and decompression, L4-5 transforaminal lumbar interbody fusion using an expandable titanium cage, and L4-S1 posterior instrumented fusion. The surgical site was closed meticulously with 3-0 running nylon, and no immediate postoperative complications were observed.

However, on postoperative day 10, the patient was re-evaluated and noted to have wound dehiscence at the inferior aspect of the incision, characterized by dark brown granulation tissue, with no evidence of local or systemic infection. Notably, the patient lacked risk factors predisposing to poor wound healing, such as a smoking history, diabetes, or immunosuppressive therapy.

Following the removal of sutures on postoperative day 14, the patient exhibited persistent wound dehiscence at the inferior aspect of the incision, with subsequent development of dehiscence at the superior aspect. To manage the wound, NeoMatriX® was applied over three treatments.

ACKNOWLEDGEMENT

University at Buffalo Neurosurgery (UBNS)
40 George Karl Blvd.
Williamsville, NY 14221

MKT-018-1 Rev 0 Case Report
CO 2024-044
Effective Date: 05/28/24

Source: NextGen Biologics Inc.

Figure 23

CASE REPORT HIGHLIGHTS THE SUCCESSFUL CLINICAL OUTCOME RESULTANT FROM TREATMENT OF POST-LUMBAR FUSION SURGICAL WOUND DEHISCENCE TREATED WITH NEXTGEN™ NEOMATRIX® (continued)

Source: NextGen Biologics Inc.

04/19/2024—Signed distribution agreement with Samaritan Biologics to bring NeoMatriX to physician offices nationwide (Figures 24 and 25).

Figure 24
SIGNED DISTRIBUTION AGREEMENT WITH SAMARITAN BIOLOGICS TO BRING NEOMATRIX TO PHYSICIAN OFFICES

Source: NextGen Biologics Inc.

Figure 25

SIGNED DISTRIBUTION AGREEMENT WITH SAMARITAN BIOLOGICS TO BRING NEOMATRIX TO PHYSICIAN OFFICES

Source: NextGen Biologics Inc.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by Crystal Research Associates, LLC ("CRA") with the assistance of NeXtGen™ Biologics Inc. ("NeXtGen™" or "the Company") based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in NeXtGen's statements on forms filed from time to time.

The content of this report with respect to NeXtGen has been compiled primarily from information available to the public released by the Company through news releases and other filings. NeXtGen is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by NeXtGen or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, for year one of its Agreement, CRA has been compensated by the Company in cash of fifty thousand dollars for its services in creating this report and for quarterly updates.

Investors should carefully consider the risks and information about NeXtGen's business, as described below and more fully detailed in the Company's recently filed forms with the SEC. Investors should not interpret the order in which considerations are presented in this document or other filings as an indication of their relative importance. In addition, the risks and uncertainties covered in the accompanying sections are not the only risks that the Company faces. Additional risks and uncertainties not presently known to NeXtGen or that it currently believes to be immaterial may also adversely affect the Company's business. If any of such risks and uncertainties develops into an actual event, NeXtGen's business, financial condition, and results of operations could be materially and adversely affected.

This report is published solely for informational purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. For more complete information about the risks involved of investing in the Company, as well as for copies of this report, please contact NeXtGen by calling (800) 209-7190.

RISK FACTORS

Investing in securities involves a high degree of risk and may result in the loss of an investor's entire investment. Before making an investment decision with respect to the Securities, investors are urged to carefully consider the risks described in this section and other factors set forth in the Company's Form C filed with the SEC. In addition to the risks specified below, the Company is subject to the same risks that all companies in its business, and all companies in the economy, are exposed to. These include risks relating to economic downturns, political and economic events, and technological developments (such as hacking and the ability to prevent hacking). Additionally, early-stage companies are inherently riskier than more developed companies. Prospective investors should consult with their legal, tax, and financial advisors prior to making an investment in the securities. The securities should only be purchased by persons who can afford to lose all of their investment.

Risks Related to the Company's Business and Industry

NeXtGen has a limited operating history upon which to evaluate its performance, and accordingly, its prospects must be considered in light of the risks that any new company encounters.

The Company is still in an early phase and is just beginning to implement its business plan. There can be no assurance that the Company will ever operate profitably. The likelihood of its success should be considered in light of the problems, expenses, difficulties, complications, and delays usually encountered by early-stage companies. The Company may not be successful in attaining the objectives necessary for it to overcome these risks and uncertainties.

The amount of capital NeXtGen is attempting to raise in its recent Offering may not be enough to sustain the Company's current business plan.

To achieve the Company's near and long-term goals, NeXtGen may need to procure funds in addition to the amount raised in its recent Offering. There is no guarantee the Company will be able to raise such funds on acceptable terms or at all. If they are not able to raise sufficient capital in the future, NeXtGen may not be able to execute its business plan, its continued operations will be in jeopardy, and it may be forced to cease operations and sell or otherwise transfer all or substantially all its remaining assets, which could cause an Investor to lose all or a portion of their investment.

NeXtGen may face potential difficulties in obtaining capital.

The Company may have difficulty raising needed capital in the future because of, among other factors, its lack of revenues from sales, as well as the inherent business risks associated with its Company and present and future market conditions. NextGen's business currently generates limited sales and future sources of revenue may not be sufficient to meet its future capital requirements. The Company will require additional funds to execute its business strategy and conduct operations. If adequate funds are unavailable, NeXtGen may be required to delay, reduce the scope of, or eliminate one or more of its research, development, or commercialization programs, product launches, or marketing efforts, any of which may materially harm its business, financial condition, and results of operations.

The Company may not have enough authorized capital stock to issue shares of common stock to investors upon the conversion of any security convertible into shares of its common stock, including securities.

Unless NeXtGen increases its authorized capital stock, the Company may not have enough authorized common stock to be able to obtain funding by issuing shares of its common stock or securities convertible into shares of its common stock. NeXtGen may also not have enough authorized capital stock to issue shares of common stock to investors upon the conversion of any security convertible into shares of its common stock, including the securities.

NeXtGen may implement new lines of business or offer new products and services within existing lines of business.

As an early-stage company, the Company may implement new lines of business at any time. There are substantial risks and uncertainties associated with these efforts, particularly in instances where the markets are not fully developed. In developing and marketing new lines of business and/or new products and services, NeXtGen may invest significant time and resources. Initial timetables for the introduction and development of new lines of business and/or new products or services may not be achieved, and price and profitability targets may not prove feasible. The Company may not be successful in introducing new products and services in response to industry trends or developments in technology, or those new products may not achieve market acceptance. As a result, NeXtGen could lose business, be forced to price products and services on less advantageous terms to retain or attract clients or be subject to cost increases. As a result, its business, financial condition, or results of operations may be adversely affected.

The Company relies on other companies to provide components and services for its products.

NeXtGen depends on suppliers and contractors to meet its contractual obligations to its customers and conduct operations. The Company's ability to meet its obligations to its customers may be adversely affected if suppliers or contractors do not provide the agreed-upon supplies or perform the agreed-upon services in compliance with customer requirements and in a timely and cost-effective manner.

Likewise, the quality of NeXtGen's products may be adversely impacted if companies to whom they delegate manufacture of major components or subsystems for its products, or from whom it acquires such items, do not provide components which meet required specifications and perform to the Company's and its customers' expectations. NextGen's suppliers may be unable to quickly recover from natural disasters and other events beyond their control and may be subject to additional risks, such as financial problems that limit their ability to conduct their operations. The risk of these adverse effects may be greater in circumstances where NeXtGen relies on only one or two contractors or suppliers for a particular component. The Company's products may utilize custom components available from only one source. Continued availability of those components at acceptable prices, or at all, may be affected for any number of reasons, including if those suppliers decide to concentrate on the production of common components instead of components customized to meet NeXtGen's requirements. The supply of components for a new or existing product could be delayed or constrained, or a key manufacturing vendor could delay shipments of completed products to the Company, adversely affecting its business and results of operations.

NeXtGen relies on various intellectual property rights, including trademarks, to operate its business.

The Company relies on certain intellectual property rights to operate its business. Its intellectual property rights may not be sufficiently broad or otherwise may not provide a significant competitive advantage. In addition, the steps that NeXtGen has taken to maintain and protect its intellectual property may not prevent it from being challenged, invalidated, circumvented, or designed around, particularly in countries where intellectual property rights are not highly developed or protected. In some circumstances, enforcement may not be available to NeXtGen because an infringer has a dominant intellectual property position or for other business reasons, or countries may require compulsory licensing of its intellectual property.

NextGen's failure to obtain or maintain intellectual property rights that convey competitive advantage, adequately protect its intellectual property, or detect or prevent circumvention or unauthorized use of such property, could adversely impact the Company's competitive position and results of operations. NeXtGen also relies on nondisclosure and noncompetition agreements with employees, consultants, and other parties to protect, in part, trade secrets and other proprietary rights. There can be no assurance that these agreements will adequately protect its trade secrets and other proprietary rights and will not be breached, that NeXtGen will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information, or that third parties will not otherwise gain access to the Company's trade secrets or other proprietary rights.

As NeXtGen expands its business, protecting its intellectual property will become increasingly important. The protective steps the Company has taken may be inadequate to deter its competitors from using its proprietary information. To protect or enforce the Company's patent rights, NeXtGen may be required to initiate litigation against third parties, such as infringement lawsuits. Also, these third parties may assert claims against it with or without provocation. These lawsuits could be costly, take significant time, and could divert management's attention from other business concerns. The law relating to the scope and validity of claims in the technology field in which NeXtGen operates is still evolving and, consequently, intellectual property positions in its industry are generally uncertain. NeXtGen cannot assure investors that it will prevail in any of these potential suits or that the damages or other remedies awarded, if any, would be commercially valuable.

The Company's success depends on the experience and skill of the board of directors, its executive officers, and key employees.

NeXtGen is dependent on its board of directors, executive officers, and key employees. These persons may not devote their full time and attention to the matters of the Company. The loss of its board of directors, executive officers, and key employees could harm the Company's business, financial condition, cash flow, and results of operations.

Although dependent on certain key personnel, the Company does not have any key person life insurance policies on any such people.

NeXtGen is dependent on certain key personnel to conduct its operations and execute its business plan, however, the Company has not purchased any insurance policies with respect to those individuals in the event of their death or disability. Therefore, if any of these personnel die or become disabled, the Company will not receive any compensation to assist with such person's absence. The loss of such person could negatively affect the Company and its operations. NeXtGen has no way to guarantee key personnel will stay with the Company, as many states do not enforce noncompetition agreements, and therefore acquiring key man insurance will not ameliorate all the risk of relying on key personnel.

Damage to the Company's reputation could negatively impact its business, financial condition, and results of operations.

NeXtGen's reputation and the quality of its brand are critical to the Company's business and success in existing markets and will be critical to its success as NeXtGen enters new markets. Any incident that erodes consumer loyalty to its brand could significantly reduce its value and damage the Company's business. NeXtGen may be adversely affected by any negative publicity, regardless of its accuracy. Also, there has been a marked increase in the use of social media platforms and similar devices, including blogs, social media websites, and other forms of internet-based communications that provide individuals with access to a broad audience of consumers and other interested persons. The availability of information on social media platforms is virtually immediate as is its impact. Information posted may be adverse to the Company's interests or may be inaccurate, each of which may harm NextGen's performance, prospects, or business. The harm may be immediate and may disseminate rapidly and broadly, without affording the Company an opportunity for redress or correction.

The Company's business could be negatively impacted by cyber security threats, attacks, and other disruptions.

NeXtGen continues to face advanced and persistent attacks on its information infrastructure where it manages and stores various proprietary information and sensitive/confidential data relating to the Company's operations. These attacks may include sophisticated malware (viruses, worms, and other malicious software programs) and phishing emails that attack its products or otherwise exploit any security vulnerabilities. These intrusions sometimes may be zero-day malware that are difficult to identify because they are not included in the signature set of commercially available antivirus scanning programs.

Experienced computer programmers and hackers may be able to penetrate the Company's network security and misappropriate or compromise its confidential information or that of its customers or other third parties, create system disruptions, or cause shutdowns. Additionally, sophisticated software and applications that the Company produces or procures from third parties may contain defects in design or manufacture, including "bugs" and other problems that could unexpectedly interfere with the operation of the information infrastructure. A disruption, infiltration, or failure of the Company's information infrastructure systems or any of its data centers because of software or hardware malfunctions, computer viruses, cyber-attacks, employee theft or misuse, power disruptions, natural disasters, or accidents could cause breaches of data security, loss of critical data, and performance delays, which in turn could adversely affect NeXtGen's business.

Security breaches of confidential customer information, in connection with the Company's electronic processing of credit and debit card transactions, or confidential employee information may adversely affect its business.

NextGen's business requires the collection, transmission, and retention of personally identifiable information, in various information technology systems that it maintains and in those maintained by third parties with whom the Company contracts to provide services. The integrity and protection of that data is critical to NeXtGen. The information, security, and privacy requirements imposed by governmental regulation are increasingly demanding. The Company's systems may not be able to satisfy these changing requirements and customer and employee expectations or may require significant additional investments or time to do so.

A breach in the security of NeXtGen's information technology systems or those of its service providers could lead to an interruption in the operation of its systems, resulting in operational inefficiencies and a loss of profits. Additionally, a significant theft, loss or misappropriation of, or access to, customers' or other proprietary data or other breach of its information technology systems could result in fines, legal claims, or proceedings.

The use of Individually identifiable data by NextGen's business, its business associates, and third parties is regulated at the state, federal, and international levels.

The regulation of individual data is changing rapidly, and in unpredictable ways. A change in regulation could adversely affect the Company's business, including causing its business model to no longer be viable. Costs associated with information security—such as investment in technology, the costs of compliance with consumer protection laws, and costs resulting from consumer fraud—could cause NeXtGen's business and results of operations to suffer materially. Additionally, the success of the Company's online operations depends upon the secure transmission of confidential information over public networks, including the use of cashless payments. The intentional or negligent actions of employees, business associates, or third parties may undermine NextGen's security measures. As a result, unauthorized parties may obtain access to its data systems and misappropriate confidential data. There can be no assurance that advances in computer capabilities, new discoveries in the field of cryptography, or other developments will prevent the compromise of NeXtGen's customer transaction processing capabilities and personal data. If any such compromise of its security or the security of information residing with its business associates or third parties were to occur, it could have a material adverse effect on NextGen's reputation, operating results, and financial condition. Any compromise of the Company's data security may materially increase the costs NeXtGen incurs to protect against such breaches and could subject the Company to additional legal risk.

The Company is not subject to Sarbanes-Oxley regulations and may lack the financial controls and procedures of public companies.

The Company may not have the internal control infrastructure that would meet the standards of a public company, including the requirements of the Sarbanes Oxley Act of 2002. As a privately held (non-public) Company, the Company is currently not subject to the Sarbanes Oxley Act of 2002, and its financial and disclosure controls and procedures reflect its status as a development stage, non-public company. There can be no guarantee that there are no significant deficiencies or material weaknesses in the quality of the Company's financial and disclosure controls and procedures. If it were necessary to implement such financial and disclosure controls and procedures, the cost to the Company of such compliance could be substantial and could have a material adverse effect on the Company's results of operations.

The Company operates in a highly regulated environment, and if it is found to be in violation of any of the federal, state, or local laws or regulations applicable to the Company, its business could suffer.

NeXtGen is also subject to a wide range of federal, state, and local laws and regulations, such as local licensing requirements, and retail financing, debt collection, consumer protection, environmental, health and safety, creditor, wage-hour, anti-discrimination, whistleblower, and other employment practices laws and regulations and NeXtGen expects these costs to increase going forward. The violation of these or future requirements or laws and regulations could result in administrative, civil, or criminal sanctions against the Company, which may include fines, a cease-and-desist order against the subject operations, or even revocation or suspension of its license to operate the subject

business. As a result, the Company has incurred and will continue to incur capital and operating expenditures and other costs to comply with these requirements, laws, and regulations.

Other Investment-Related Risks

In addition to the risks listed above, risks and uncertainties not presently known, or which could be considered immaterial, may also have an adverse effect on the Company's business and result in a total loss of one's investment.

Glossary

510(k) medical device—A premarket submission made to the Food and Drug Administration (FDA) by medical device manufacturers to demonstrate that their device is safe and effective for its intended use.

Antimicrobial polypeptides (AMPs)—A class of small peptides that widely exists in nature and they are an important part of the innate immune system of different organisms. AMPs have a wide range of inhibitory effects against bacteria, fungi, parasites, and viruses.

Average sale price (ASP)—A term that refers to the average price a good or service is sold for. ASP is simply calculated by dividing the total revenue earned by the total number of units sold.

Axolotl—Also known as the Mexican walking fish, the axolotl is an aquatic salamander native to the Xochimilco lake complex near Mexico City. Unlike other amphibians, axolotls exhibit neoteny, meaning they retain their larval features throughout their lives and do not undergo complete metamorphosis. Axolotls are popular as exotic pets due to their unique appearance and relatively low maintenance care requirements. They are also valued in traditional Mexican medicine for various ailments.

Biologics license application (BLA)—A formal application submitted to the U.S. FDA for the approval of a biological product, such as a vaccine, therapy, or diagnostic test. The BLA contains information on the product's manufacturing process, safety and efficacy data, and other relevant information. Once the BLA is submitted, the FDA's review process can take many months to a few years.

Dehiscence—Dehiscence refers to the act of failure of the stitches of a wound to heal properly, resulting in an opening or hole. This condition can occur in various sites of the body, including surgical wounds and postpartum incisions.

Dermoplasty—A minimally invasive cosmetic surgical procedure in which the skin is reshaped using adhesive tapes or threads, instead of surgery. It is used to treat skin irregularities, sun damage, and signs of aging. The procedure involves applying anesthesia and then using specialized instruments to apply slivers of the skin. The skin is then repositioned and secured with adhesive tapes or threads that stay in place for several days.

Epithelialization—The process by which cells produce new epithelial tissue to cover and repair a damaged or exposed surface. This process is important in the healing of wounds, as it helps to restore the integrity of the skin and prevent infection.

Extracellular matrix (ECM)—A complex network of proteins and other molecules that surrounds and supports cells in tissues and organs. It provides physical and chemical cues to cells, regulates their behavior, and helps maintain tissue structure and function. Composition of ECM varies between different tissues and can change during development, aging, and disease.

Fibrosis—The excessive growth of connective tissue in an organ or organism. It is a common condition that affects various parts of the body, such as muscles, tendons, and internal organs. Fibrosis can result from another condition, such as infection or injury, and can lead to chronic pain, fatigue, and reduced mobility.

Irradiation—Refers to the process of exposing something to radiation, such as light, X-rays, or particles. Processes such as irradiation often result in changes in the molecular structure of materials, leading to various effects, such as sterilization, crosslinking, and increased radiance.

Mohs surgery—A minimally invasive surgical procedure performed to remove skin lesions. It is commonly used to treat skin cancer but can also be used for cosmetic purposes. During the surgery, a dermatologist removes the visible portion of the lesion and then checks the underlying skin for any remaining cancer cells. The process is repeated until all cancer cells are removed. Mohs surgery typically results in less scarring than traditional excisional surgery and can be completed in a single day.

Urodele—A type of amphibian that is characterized by its smooth, slimy skin and the presence of a caudal fin. Urodeles are further classified into two groups: salamanders and newts. Salamanders are typically found in freshwater habitats, while newts are adapted to terrestrial environments. Urodele species range in size from small, less than an inch long, to larger animals that can grow up to two feet long. Many urodele species are important ecological indicators, and their habits and habitats provide valuable insights into the health and biodiversity of their environments.

About Our Firm: For the past decade, Crystal Research Associates, LLC (www.crystalra.com) has successfully articulated the exceptional stories of small- and mid-cap companies to the Wall Street investor community. Our methods are well-established and diverse, from compiling and disseminating objective, factual information for both institutional and retail investor audiences to capitalizing on our expansive line of targeted distribution channels, which include industry-leading financial data and information providers. Our distribution efforts are accompanied by the use of prominent social media channels and by strategic and targeted appearances on national news programs and print media.

Crystal Research Associates is led by Wall Street veterans, Jeffrey Kraws and Karen Goldfarb. Together, Kraws and Goldfarb have built a unique business model, capitalizing on decades of experience as an award-winning sell-side analyst team to produce institutional-quality industry and market research in a manner that is easily understood by investors and consumers. Our firm's approach has been proven successful over the years as our products are published and available on Bloomberg, Thomson Reuters/First Call, Capital IQ, FactSet, Yahoo! Finance, and scores of other popular forums.

Office: (212) 851-6685 | www.crystalra.com