# Sonoma Pharmaceuticals, Inc.



May 2023

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Sonoma



## **About Sonoma**

Sonoma Pharmaceuticals is a global healthcare leader for developing and producing stabilized hypochlorous acid (HOCI) products for a wide range of applications, including dermatology, wound care, eye care, nasal care, oral care, podiatry, animal health and non-toxic disinfectants. Sonoma's products are clinically-proven to reduce infections, itch, pain, scarring, and harmful inflammatory responses safely and without damaging healthy tissue. Invitro and clinical studies of HOCI show it to have impressive antipruritic, antimicrobial, antiviral and anti-inflammatory properties. Sonoma's stabilized HOCI kills pathogens and breaks down biofilm, does not sting or irritate skin and oxygenates the cells in the area treated, assisting the body in its natural healing process. Sonoma's products are sold either directly or via partners in 55 countries worldwide and the company actively seeks new distribution partners.

# **Investor Highlights**

#### **Diverse global healthcare leader**

- Focused on billion-dollar markets in Rx and OTC dermatology, wound care, eye, oral and nasal care, podiatry, animal health and non-toxic disinfectants, treating common injuries, infections and irritations
- Over 20 years of experience with over 100 clinical studies and continual product innovation
- 21 U.S. FDA clearances as 510(k) medical devices, CE marks for over 39 products, and extensive worldwide regulatory clearances means products can be commercialized faster
- Robust and diverse international partner network selling into over 55 countries
- Pharmaceutical-grade manufacturing capabilities in Mexico lowers COGS and creates opportunities for volume plays

#### Unique, patented and FDA-cleared, CE and ISO approved Microcyn® Technology

- HOCl is known to be among the safest and most effective ways to relieve itch, inflammation, redness and irritation while stimulating natural healing through increased oxygenation and eliminating persistent microorganisms and biofilms
- Microcyn effectively treats common everyday irritations, such as rashes, and chronic conditions, such as diabetic foot ulcers, making it a flexible treatment appealing to everyone. Unlike other common treatments such as steroids or antibiotics, Microcyn can be used long-term with no reported serious adverse effects and no contraindications. Microcyn is extremely safe and all-natural.
- Proven antipruritic, antimicrobial, antiviral and anti-inflammatory properties
- Non-toxic disinfectant approved in the U.S. and Australia for use against COVID-19





## **Expand distribution**

# **Growth Strategy**

- Expand Rx and OTC reach in U.S. in the dermatology, wound care, eye, oral and nasal care, podiatry, animal care and non-toxic disinfectants markets via direct-to-consumer sales and distribution partnerships
- Increase sales of dermatology products through the direct dispense model that generates Sonoma's highest margins by leveraging Sonoma's existing relationships with dermatologists and skin care professionals
- Increase direct-to-consumer marketing in niche markets to generate greater overall margins, while continuing to grow successful distribution partner network
- Expand non-toxic disinfectant sales; have recently secured EPA clearance in the U.S. and expect to commence sales in summer 2023



## Invest in R&D to expand commercialization opportunities

- Introduce new technology to new markets by leveraging expertise of existing distribution partnerships
- Fully commercialize robust pipeline of new products via direct-to-consumer sales or distribution partnerships, and seek additional regulatory clearances for new indications and in high-value markets; currently pursuing new 510(k) clearances for facial dermatology and oral rinse indications



**Continue to introduce new high margin products** 



Manufacturing capabilities can support significant future growth, leading to improved





## **Robust International Distribution Network**

Established and growing distribution network with OVER 40 GLOBAL PARTNERS generating strong revenues internationally and in the U.S.

- Expand presence in new markets by replicating what works in existing markets
- Continue to add new distribution partners and grow existing relationships
- Continue co-development of innovative new products with partners in the U.S. and internationally
- Work with partners to seek new approvals and certifications































# **Recent Business Developments**

## Continuously expanding our distributor network

- Entered into a distribution agreement with Daewoong Pharmaceutical Co., Ltd., one of the largest pharmaceutical companies in South Korea, in January 2023 for the marketing and distribution of Primocyn<sup>TM</sup> Skin Solution products
- Sonoma's Microcyn® Rx products, including wound care, prescription dermatology products Celacyn® and Levicyn®, and prescription eye care Acuicyn®, received a Distribution and Pricing Agreement (DAPA) in January 2023 for distribution by the Defense Logistics Agency (DLA), enabling our partner, EMC Pharma, LLC to enter into distribution agreements for these products with federal customers
- In April 2023, our partner Te Arai BioFarma Limited launched BabySoothe for diaper rash applications in Taiwan
- Our partner Microderm Technologies recently launched Dermodacyn for wound care applications in Thailand
- Signed a new partner, TPVN Pharmaceuticals Company Limited, for distribution of Endocyn Root Canal Irrigation Solution in Vietnam
- Our partner Brill Pharma SL is now selling Sonoma's eye care products in Italy, Spain and Portugal and plans to sell in Germany and France next year
- Our MicrocynAH® products are now available through Pets at Home, with 453 stores across the UK, through our partner Manna Pro Products, LLC



# **Recent Business Developments**

## **Expanding commercialization opportunities by investing in R&D**

• In March 2023, Sonoma announced new EPA claims for its Nanocyn® Hospital-Grade Disinfectant for effective use against MRSA, Salmonella, Norovirus, Poliovirus, and as a fungicide. Nanocyn was previously approved for use against COVID-19 as well as emerging pathogens including Ebola virus, Mpox, and SARS-CoV-2. Nanocyn also received the esteemed Green Seal® Certification after surpassing a series of rigorous standards that measure environmental health, sustainability and product performance.

## Introduction of new products using our Microcyn® technology

- On April 11, 2023, Sonoma launched Podiacyn<sup>TM</sup> Advanced Everyday Foot Care direct to consumers for over-the-counter use in the United States.
- On January 4, 2023, Sonoma launched a line of office dispense products exclusively for skin care professionals, including two new
  products, Reliefacyn® Plus Itch-Burn-Rash-Pain Relief Hydrogel and Rejuvacyn® Plus Skin Repair Cooling Mist. Along with
  Regenacyn® Plus Scar Management Hydrogel, these office dispense products are targeted to dermatology practices and medical spas.



# **New Market Opportunities**

Sonoma is expanding its partnerships and product offerings in the all-natural skin care and medical spa industries.

- The global **natural skin care** products market size was valued at \$6.7 billion in 2021 and is expected to expand at a compound annual growth rate (CAGR) of 6.6% from 2022 to 2030.<sup>1</sup>
- The global **medical spa** market size was valued at \$16.4 billion in 2022 and is expected to expand at a compound annual growth rate (CAGR) of 14.97% from 2023 to 2030.<sup>2</sup>
  - North America dominated the medical spa market with a share of 41.5% in 2022, attributable in part to increasing demand for minimally invasive aesthetic procedures.<sup>3</sup>

Sonoma also continues to expands its presence in the global **animal health** market that was valued at \$39.9 billion in 2021 and is expected to witness a compound annual growth rate (CAGR) of 10.0% from 2022 to 2030.<sup>4</sup>

- 1. Grand View Research, Natural Shin Care Products Market Report, 2022-2030, available at https://www.grandviewresearch.com/industry-analysis/natural-skin-care-products-market
- 2. Grand View Research, Medical Spa Market Size, Share & Growth Analysis Report 2030, available at https://www.grandviewresearch.com/industry-analysis/medical-spa-market
- 3. *Ibid.*
- 4. Grand View Research, Animal Health Market Size & Share Report, 2022-2030, available at https://www.grandviewresearch.com/industry-analysis/animal-health-market



# Sonoma's Microcyn® Technology

#### **Stable triple-action topical technology**

- A powerful anti-microbial reduces microbial load, including destruction of biofilms
- Anti-inflammatory agent reduces itch and pain
- Anti-pruritic activity
- Tissue healing (increased blood/oxygen flow to wound)

#### <u>Unparalleled safety – No drug-to-drug interaction or contraindications</u>

- Millions of patients treated worldwide without single report of serious adverse effect
- 30+ human clinical trials with over 1,500 patients
- Over 100 clinical papers available on our website

#### No mutations or resistance

Overused antibiotics may cause deadly epidemics such as MRSA

#### **Cost effective**

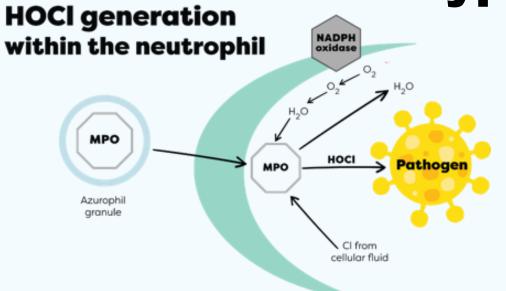
- Preventative reduces hospital/physician visits
- Medicare/hospital savings faster healing reduces hospital stays







What is Hypochlorous Acid?



During the activation of neutrophils, respiratory bursts generate hydrogen peroxide  $(H_2O_2)$  and the activated granule enzyme myeloperoxidase converts  $H_2O_2$  to hypochlorous acid (HOCI)

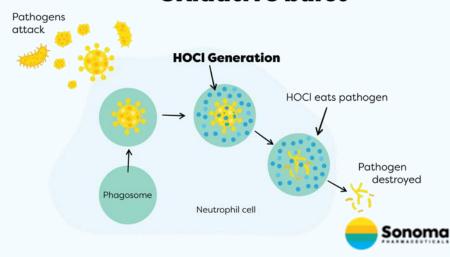


#### Produced by neutrophils in the body as part of its defense mechanism

**Phagolysome** 

- Highly active against bacterial, viral, and fungal pathogens
- Shown to rapidly kill spore-forming and non-spore forming bacteria and have significant activity against biofilms

# Phagocytosis & Oxidative burst



## Over 100 research articles and case and clinical studies showcasing both the efficacy and safety of our Microcyn® technology

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REVIEW ARTICLE



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Topical stabilized hypochlorous acid: The future gold standard for wound care and scar management in dermatologic and plastic surgery procedures

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IntraDerm Pharmaceuticals Grant/Award

review was suppor

Background: Hypochlorous acid (HOCI), a naturally occurring molecule produced by the immune system, is highly active against bacterial, viral, and fungal microorganisms. Moreover, HOCI is active against biofilm and increases oxygenation of the wound site to improve healing. Natural HOCI is unstable; through technology, it can be stabilized into an effective topical antiseptic agent

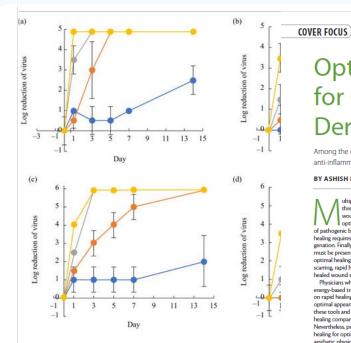
Aim: This paper focuses on the use of topical stabilized HOCI in wound and scar management for pre-, peri-, and postprocedures—including its ability to reduce the occurrence hypertrophic scars and keloids. The role of the product in other skin conditions

Methods: A panel comprising clinicians with experience in cosmetic and surgical procedures met late 2018 to discuss literature search results and their own current clinical experience regarding topical stabilized HOCI. The panel of key opinion leaders in dermatology and plastic surgery defined key insights and consensus statements on the direction of use for the product.

Results: Topical stabilized HOCI provides an optimal wound healing environment and, when combined with silicone, may be ideal for reducing scarring. Additionally, in contrast to chlorhexidine, HOCI, used as an antiseptic skin preparation, raises no concerns of ocular- or ototoxicity.

Conclusions: For wound care and scar management, topical stabilized HOCI conveys powerful microbicidal and antibiofilm properties, in addition to potency as a topical wound healing agent. It may offer physicians an alternative to other less desirable wound care measures

hypertrophic scars, keloid scars, scar management, stabilized hypochlorous acid, wound care



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Figure 1. Stability of severe acute respiratory syndrome SARS-CoV. (a) Stability of SARS-CoV-2 in dried form. ( solution. (c) Stability of SARS-CoV in dried form. (d) St Blue line, 4°C; orange line, 20-25 °C; grey line, 30 °C;

## Optimizing Wound Healing

#### for Cosmetic and Medica Dermatologic Procedures

Among the options for wound management is hypochlorous acid, a broad-action antimic anti-inflammatory agent.

#### BY ASHISH BHATIA, MD: JEFFREY HSU, MD: TODD SCHLESINGER, MD: AND ROBERT W

ultiple factors influence wound healing. However, three primary conditions are essential for optimal wound healing with minimal risk of scarring. First, optimal wound healing requires the eradication of pathogenic bacteria and biofilm. Second, optimal wound healing requires an excellent blood supply and proper oxygenation. Finally, the proper immunological healing factors must be present in order for the wound to heal. With these optimal healing "primers" in place, the outcome is minimal scarring, rapid healing, and good structure and function of the healed wound site.

Physicians who perform aesthetic procedures, especially energy-based treatments or injections, are particularly focused on rapid healing, minimum pain, minimum down time, and optimal appearance. A controlled wound, as created with these tools and technologies, is associated with improved healing compared to uncontrolled or traumatic wounds. Nevertheless, proper wound care serves to further support healing for optimal cosmesis. Consider that, in some cases, aesthetic physicians are creating controlled wounds with the intention to revise existing scars, and the need to support

For dermatologists, wound care generally is focused on post-surgical management for biopsy and excision sites or post-procedural skincare following energy-based procedures or peels. At-home skin prep for excisions or Mohs micrographic surgery is not common. However, many patients interested in aesthetic procedures are advised to implement a skincare routine in advance of the procedure. In the aesthetic patient, retinoids and related compounds, botanical ingredients, growth factors, and antioxidants may be recommended individually or in combination, depending on the patient, the procedure, and the physician preference.

Increasingly, evidence suggests that the care o immediately before a surgery or procedure and healing phase can have important effects on hea comes. For years, dermatologists have relied on o ventional" options for peri-procedural skincare: septics to cleanse the skin immediately before a petrolatum ointments immediately after a proc or topical antibiotic ointments to reduce the ris Emerging evidence and experience suggests the may not be ideal.

The antiseptic preparations most commonly surgery in the US are iodopovidone and chlorhe lodopovidone dyes the clothing and the hair. Th and associated irritation are noxious for some pa Chlorhexidine can be toxic to tissues, especially Therefore, procedural dermatologists have grow concerned about its use. However, chlorhexiding tain practical benefits over betadine, and, at leas has been an important option. Chlorhexidine pr hours-perhaps up to 72 hours-of antimicrob it can endure being washed with blood or fluids.

Use of topical antibiotic preparations for wou increasingly unpopular, due to concerns about t ment of bacterial resistance. Furthermore, topica confer no activity against yeasts that reside on the may infect wounds. Additionally, some topical a formulations are associated with risks for allergic dermatitis. The associated inflammation in the v detrimental to wound healing and may contribumation, hyperpigmentation, or hypopigmentatic

Alternative approaches to wound manageme tion prevention have been emerging. The use of rich plasma (PRP), which is increasingly being ad Accepted: 13 February 2017

#### REVIEW ARTICLE



Hypochlorous acid gel technology—Its impact on postprocedure treatment and scar prevention

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Funding information IntraDerm Pharmaceuticals, Grant/Award an educational grant

Background: A pre-and postprocedure regime aimed at prevention of infection reduction of inflammation and risk of scarring, is to enable optimal outcomes

Objectives: The role of a hypochlorous acid containing spray and translucent scar gel formulation that combines modified silicon oil with hypochlorous acid, was explored for pre- and postprocedure treatment and scar management.

Methods: For this purpose a literature review was conducted to explore the value of the technology used in pre-and postprocedural regimes. A panel of dermatologists and plastic surgeons who practice in the United States discussed the summa rized search results, taking into account their current clinical practice. A nominal group process for consensus was used, followed by online reviews of the manu-

Results: Based on panel discussions, consensus was reached regarding clinical recommendations given for postprocedure treatment and scar management. The hypochlorous acid products are produced with electrolysis and are classified among biocidal substances. The technology has demonstrated efficacy and safety for pre and nost procedure use. The safety of hypochlorous solution use demonstrated to be comparable to that of standard local antiseptics. Small studies demonstrated better results with the scar gel compared to silicone gel regarding the appearance of hypertrophic and keloid scars, relief of associated pruritus and pain.

Conclusions: A postprocedure regime using this technology, aimed at preventing infection, reducing inflammation, and promoting healing is proposed to have benefits over current regimes as it appears to be effective, safe, and well tolerated.

hypochlorous add technology, postprocedure care, scar management

#### 1 | INTRODUCTION

Clinician concerns over pre-and postprocedure care and scar management are at the forefront. They are balancing antiseptic properties and cytotoxicity with severity of colonization to assure a proper

naturally produces a compound called hypochlorous acid (HOCL) to eradicate bacteria and other invading pathogens within the body. This compound has also shown antiporritic and anti-inflammatory effects.<sup>1,2</sup> A HOCL containing spray or super-oxidized solution for deansing, infeation, and disinfection of surgical sites (Alevicyn Dermal Spray) may decrease the risk of infection and optimize surgical

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## **Diverse Product Portfolio**

## **United States**

#### Levicyn

**Antimicrobial Dermal Spray** 



Reliefacyn

Itch, Burn, Rash & Pain Care



## **Epicyn**

**Antimicrobial Facial Cleanser** 



Rejuvacyn

**Skin Repair** 



Celacyn

**Scar Management** Gel



Microcyn OTC

**Wound & Skin Cleanser** 



#### Microcyn Rx

**Skin & Wound Care** 



Ocucyn

**Eyelid & Eyelash Cleanser** 



**Everyday Foot Care** 

#### **Podiacyn**







#### Regenacyn

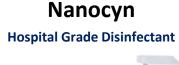
**Scar Gel** 



#### Acuicyn

**Antimicrobial Eyelid** & Eyelash Hygiene

Acuicyn 6







**Pediacyn** 

**Skin Care & First Aid for Children** 

## **U.S. Animal Health Care**

MicrocynAH<sup>®</sup> family of advanced animal healthcare products, safe to use on pets and livestock, and perfect for hot spots, pink eye, scratches, skin rashes and ulcers, cuts, burns, post-surgical sites, irritated skin and lacerations.

• Sold in national pet-store retail chains and specialty stores such as Petsmart, Chewy.com,

Tractor Supply, Cabela's and Bass Pro Shops. Distributed by







MicrocynVS<sup>®</sup> veterinarian-strength animal care for use in vet clinics and animal hospitals.

# U.S. office dispense products exclusively for skin care professionals







- Generates highest margins for Sonoma
- Focused marketing to med spas and dermatology offices, which can resell products to their clients for a substantial margin

Direct-to-consumer products available through Shopify, Amazon and Amazon EU







**U.S. Products** 









Nasal care

**EU Products** 



crodacyn60 Ocu Oral care Eye



## **EU Products**

## Solutions that work naturally for everybody





Exposure to germs and pathogens

Microdacyn60°
Oral Care



Mouth and throat infections

Sinudox<sup>®</sup> Nasal care



Blocked nose or sinuses

Ocudox® Eye lid solution



Blepharitis treatment

**Epicyn**® Dermatology



Keloid or hypertrophic scar

Gramaderm®

Dermatology



Acne treatment

Pediacyn®
Dermatology



Atopic Dermatitis

Microdacyn60® Wound Care





MicrocynAH® Animal Health Care





## **Middle East**

#### Microdacyn

Wound Care





















Face Cool, Anti-Microbial, Baby Cool, Foot Cool, Lady Cool





### Microsafe

**Disinfectant & Sanitizer** 











## **Latin America**

#### Celacyn

Scar Management Gel



#### Gramacyn

**Kit for Acne Skin** 



## **Australia and New Zealand**

#### Microdacyn

Surgical Irrigation and Wound Treatment

#### **Epicyn**

Treat Scars Right from the Start

#### **Microdox**

Super-Oxidised Solution Bladder & Catheter Rinse









## **Asia**

#### Singapore, Malaysia, Thailand, Indonesia

**Wound Care** 



#### China

Microcyn



#### **Hong Kong**

Microdacyn60 Oral Care



#### **South Korea**

**BioDerm** 

**Biodacyn60 Wound Care** 





#### The Philippines

Microdacyn



#### MicrocynAH





## **CUTTING EDGE MANUFACTURING**



Currently operating at 30% capacity, with margin of approximately 35%

- 57,153 square foot state-of-the-art facility
- ISO 9001, ISO 13485 and cGMP certified
- MOH, KFDA, SFDA, KSA, TGA, EN, Biocide and numerous other national listings and approvals
- Shipping to over 55 countries
- Highly trained staff of 153 employees

Flexible operations capable of high/small volume, large/small batch, private label, multiple configurations/packaging



Microcyn

Technology

# **Manufacturing Facility**































## **THANK YOU**

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