

November 11, 2024



# Sonoma Pharmaceuticals Receives New FDA 510(k) Clearance for Microcyn(R)-based Wound Care Hydrogel

**BOULDER, CO / ACCESSWIRE / November 11, 2024** /Sonoma Pharmaceuticals, Inc. (Nasdaq:SNOA), a global healthcare leader developing and producing patented Microcyn<sup>®</sup> technology based stabilized hypochlorous acid (HOCl) products for a wide range of applications, including wound care, eye, oral and nasal care, dermatological conditions, podiatry, and animal health care, today announced it has received a new 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its Microcyn technology-based hydrogel, including improved biocompatibility and extended shelf life.

Per this new clearance, Sonoma's Microdacyn<sup>®</sup> Hydrogel can be used under the supervision of a healthcare professional for management of wounds associated with dermal irritation, sores, injuries and ulcers of dermal tissue, for use on first and second degree burns, and diabetic ulcers, and for the management of mechanically or surgically debrided wounds. It is also indicated for OTC use on minor skin irritations, lacerations, abrasions and minor burns, including for the management of irritation from sunburn.

The new 510(k) clearance process also included more rigorous biocompatibility testing, and the clearance applies to 50mL bottles with a shelf life of 24 months.

"This new 510(k) clearance from the FDA demonstrates the superior safety and efficacy of Sonoma's wound care products," said Amy Trombly, CEO of Sonoma. "Our Microcyn technology-based hydrogel is effective for the management of both wounds and skin irritations, and we are pleased to see it has passed the more rigorous testing required by the FDA. Our commitment to innovation and the high standards we set for our products sets us apart in the industry."

## **About Sonoma Pharmaceuticals, Inc.**

Sonoma Pharmaceuticals is a global healthcare leader for developing and producing stabilized hypochlorous acid (HOCl) products for a wide range of applications, including wound, eye, oral and nasal care, dermatological conditions, podiatry, animal health care and non-toxic disinfectants. Sonoma's products are clinically proven to reduce itch, pain, scarring, and irritation safely and without damaging healthy tissue. In-vitro and clinical studies of HOCl show it to safely manage skin abrasions, lacerations, minor irritations, cuts, and intact skin. Sonoma's products are sold either directly or via partners in 55 countries worldwide and the company actively seeks new distribution partners. The company's principal office is in Boulder, Colorado, with manufacturing operations in Guadalajara, Mexico. European marketing and sales are headquartered in Roermond, Netherlands. More information can be found at [www.sonomapharma.com](http://www.sonomapharma.com). For partnership opportunities, please

contact [busdev@sonomapharma.com](mailto:busdev@sonomapharma.com).

## **Forward-Looking Statements**

Except for historical information herein, matters set forth in this press release are forward-looking within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including statements about the commercial and technology progress and future financial performance of Sonoma Pharmaceuticals, Inc. and its subsidiaries (the "company"). These forward-looking statements are identified by the use of words such as "continue," "develop," "anticipate," "expect" and "expand," among others. Forward-looking statements in this press release are subject to certain risks and uncertainties inherent in the company's business that could cause actual results to vary, including such risks that regulatory clinical and guideline developments may change, scientific data may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, protection offered by the company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the company's products will not be as large as expected, the company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to meet the company's cash needs, fund further development, as well as uncertainties relative to the COVID-19 pandemic and economic development, varying product formulations and a multitude of diverse regulatory and marketing requirements in different countries and municipalities, and other risks detailed from time to time in the company's filings with the Securities and Exchange Commission. The company disclaims any obligation to update these forward-looking statements, except as required by law.

Sonoma Pharmaceuticals™ and Microcyn® are trademarks or registered trademarks of Sonoma Pharmaceuticals, Inc. All other trademarks and service marks are the property of their respective owners.

## **Media and Investor Contact:**

Sonoma Pharmaceuticals, Inc.  
[ir@sonomapharma.com](mailto:ir@sonomapharma.com)

Website: [www.sonomapharma.com](http://www.sonomapharma.com)

Follow us on LinkedIn: <https://www.linkedin.com/company/sonoma-pharmaceuticals>

Follow us on Instagram: [https://www.instagram.com/sonomapharma\\_us/](https://www.instagram.com/sonomapharma_us/)

Follow us on Facebook: <https://www.facebook.com/sonomapharma/>

**SOURCE:** Sonoma Pharmaceuticals, Inc.

View the original [press release](#) on [accesswire.com](http://accesswire.com)