

Daré Progresses Women-Centric Drug Pipeline

BIOPHARMA: Sildenafil Cream Study Reports Positive Topline Data

■ By JENNIFER KASTNER

San Diego's **Daré Bioscience** (NASDAQ: DARE) announced it achieved milestone positive results from a study evaluating the effects of a targeted female sexual arousal cream made with sildenafil, the generic form of erectile dysfunction (ED) medication Viagra. Details were shared in the company's second quarter 2023 financial results which went public this month.

"Sildenafil Cream, 3.6% is an investigational proprietary topical formulation of sildenafil being developed as a potential first-in-category treatment for sexual arousal disorder in women. There are no FDA-approved treatments for any form of arousal disorder in women," President & CEO **Sabrina Martucci Johnson** said. "The group receiving Sildenafil Cream in the [study] demonstrated improvements in arousal lubrication, orgasm and sexual desire, which persisted through the end of study assessment."

The biopharma company name comes from the Italian word "dare" which means "to give." In English, it means "to be bold." Its researchers have been working steadily on accelerating innovations to address a myriad of women's health concerns, including arousal disorder.

"It's a condition in women that is as prevalent as ED is in men. Specifically, market research suggests that 16% of women in the U.S. ages 21 to 60, or approximately 10 million women, are distressed from experiencing no or low sexual arousal, and are actively seeking solutions to improve their condition. In comparison, the prevalence of complete ED in men is estimated to be about 5% of men at age 40, increasing to about 15% at age 70," she added.

Daré plans to change that.

"For context, **Pfizer** secured an FDA approval for Viagra in 1998 and March 2023 marked the 25th year since Viagra was first approved" Martucci Johnson said. "In the intervening years, there have been no FDA approvals for the treatment of [female sexual arousal and interest disorders]. Viagra sales peaked at \$2 billion in 2012."

Pre-Term Birth Prevention

In another move to empower women's healthcare needs, the company announced in July that it was awarded a federal grant to support the development of potential new therapeutics to prevent pre-term births. The \$385,000 award comes from the **Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)** of the **National Institutes of Health (NIH)**. Daré plans to collaborate with the nonprofit **University of South Florida Research Foundation** to find novel solutions to prevent and treat pre-term births.

It's widely known that premature babies often suffer from serious health issues.

"These problems can vary in severity and the earlier a baby is born, the higher the risk of health-related complications, including difficulty maintaining normal body temperature, difficulty breathing or feeding, and susceptibility to severe infections and brain disorders," Martucci Johnson said.

For more than a decade, Makena was the only drug available that was aimed at preventing preterm birth, but it was

voluntarily pulled off the market this year after the FDA expressed reservations about whether it was effective.

"Since the removal of the only FDA-approved product indicated to reduce the risk of preterm birth in women with a history of history of spontaneous preterm birth, this area has re-emerged as an area of great unmet need," she explained. "We view this grant as an acknowledgment that more innovation is required, and we are honored that the NICHD is funding this important collaboration."



Sabrina Martucci Johnson
President & CEO
Daré Bioscience

More Product Developments

Aside from its efforts to prevent premature birth, Daré is actively working with commercial collaborator **Organon** to achieve a 2023 launch of its FDA-approved XACIATOTM, a gel to treat bacterial vaginosis.

In Daré's second quarterly earnings report, Martucci Johnson stated that the company is anticipating its first commercial sale of XACIATO, triggering a \$1.8 million milestone payment from Organon. Daré received a \$10 million upfront payment from Organon when the two companies entered into the commercial license agreement in March 2022. Daré is eligible to receive potential milestone payments of up to \$182.5 million and tiered double-digit royalties based on net sales.

Daré is also expecting to soon enroll subjects in the third phase of its study on Ovaprene®, an investigational hormone-free monthly intravaginal

contraceptive. U.S. commercial rights are under a license agreement with **Bayer**. In that agreement, which the two companies entered into in 2020, Daré may be entitled to up to \$310 million in commercial milestone payments plus tiered royalties on net sales in the double-digits.

Also later this year, Daré expects to announce the topline findings from its Phase 1 trial of DARE-PDM1 - a new development program targeted at treating primary dysmenorrhea (better known as menstrual cramps and pain) by delivering the nonsteroidal anti-inflammatory drug diclofenac in a novel way. Prevalence rates of dysmenorrhea vary but range from 50% to 90%. Recent market research suggests that the global market for dysmenorrhea treatment was valued at \$13 billion in 2022 and is expected to increase to \$28.5 billion by 2029, Martucci Johnson said.

"We are working to identify and advance new therapies that provide additional choices and improve outcomes so that we can make a difference in the lives of women everywhere," she added. ■

Daré Bioscience



FOUNDED: 2015 as Daré Bioscience Operations
PRESIDENT & CEO: Sabrina Martucci Johnson
HEADQUARTERS: La Jolla
STOCK: DARE (NASDAQ)
REVENUE: \$10 million (FY 2022)
EMPLOYEES: 30
BUSINESS: biopharma
WEBSITE: darebioscience.com
CONTACT: innovations@darebioscience.com
NOTABLE: President & CEO Sabrina Martucci Johnson was named one of FiercePharma's Most Influential People in Biopharma in 2023.

SoCal Restaurant Design Group Acquires Part of IKONIK

DESIGN: Food Service Division Expected to Raise Revenue 20-25%

■ By KAREN PEARLMAN

Southern California Restaurant Design Group (SCRDG), a design firm out of Encinitas that specializes in turnkey hospitality projects for the restaurant industry, has acquired the food service division of Costa Mesa-based **IKONIK Supply Co.**

The acquisition closed in July, the negotiation and facilitation of the deal was handled by **Ryan Clark of Veld Mergers & Acquisitions**. Neither company would provide details on the purchase price. SCRDRG reported \$40 million in revenues in 2022 and anticipates IKONIK's contribution to boost its gross revenue by 20% to 25% starting in 2024.

Two Industry Giants

The move combines the expertise and resources of two industry giants, providing unmatched benefits to large hospitality groups, independent restaurant owners, golf clubhouses and hoteliers.

IKONIK Supply Co. will continue to operate under its brand name as a division of SCRDRG without any disruption in services to its clients or changes in organizational structure.

Since 2014, SCRDRG has been offering fully designed, built, supplied and installed services to the restaurant industry and serves all aspects of a commercial kitchen design project. Its work includes design services, foodservice equipment and installation work. SCRDRG has offices in San Diego, Orange County, Los Angeles, Houston and Tampa, working with

restaurant owners and chefs to translate their visions into an attractive, efficient and code adherent space.

IKONIK has been in the hospitality supply business since 1969, specializing in diverse project types, from restaurants, hotels and night clubs to country clubs and corporate offices. IKONIK offers a wide range of back-of-house foodservice equipment, front-of-house furnishings and a complete array of customized solutions.

Founded in 2014, SCRDRG is a division of **IFE Group**, a company formed in 2000 by **Michael Benson** to be an independent representative company that focuses on institutional food service equipment sales and services and provides comprehensive solutions to the hospitality industry.

'Tremendous Opportunity'

"This acquisition represents a tremendous opportunity for SCRDRG and IFE Group as a whole," said Benson, president of IFE Group. "With IKONIK added to our portfolio, we increase the already unparalleled value we provide to SCRDRG clients and gain the opportunity to work with new client-partners loyal to IKONIK. We are excited to welcome the talented team at IKONIK into our family and incorporate its 50-plus years of history into our brand story."

As part of the acquisition, IKONIK, which launched in 1969, will rebrand its furnishing



Michael Benson
CEO
Southern California
Restaurant Design
Group

and millwork division under a new name, **Hatch Hospitality Supply**. **Hatch Design Group** will continue to offer full-service kitchen and interior design services as it has been for the past 54 years.

Stephanie Cregg, a Principal of Hatch Hospitality Supply, said that adding IKONIK's foodservice offerings to SCRDRG's lineup "will further elevate its ability to transform spaces into extraordinary dining destinations and commercial kitchens into centers of operational excellence."

Acquiring a company often involves integrating different cultures and teams, but Benson said there will be a smooth transition and collaboration between the two entities.

"The Hatch family sold IKONIK to us because of our shared values and culture," he said. "Our teams have enjoyed a history of working together in the industry and have developed a high respect for one another. Both organizations worked on this deal for over a year, facilitating a smooth transition since the sale closed."

Market Trends, Industry Dynamics

Benson said market trends and industry dynamics played a part in the acquisition decision, and that SCRDRG listened to clients and other leaders in the industry for intel and inspiration.

"Their feedback about industry challenges, including poor service and diminished margins, motivated us to take action," he

said. "The acquisition of IKONIK equips us to deliver highly competitive pricing for hospitality projects while maintaining a dedicated, high-caliber workforce."

He said the combined resources of SCRDRG and IKONIK provide competitive solutions to the hospitality and restaurant industries and noted a growing need since the pandemic for the creation of flexible and multi-use spaces.

"We see more interest from major malls, shopping centers and local strip malls," he said. "They are looking at the restaurant industry as a catalyst for attracting shoppers and repurposing spaces. This aligns with our focus on adaptable, multi-use designs." ■

Southern California Restaurant Design Group

FOUNDED: 2014
CEO: Michael Benson
HEADQUARTERS: Encinitas
BUSINESS: Full turnkey service providers to the restaurant industry and for commercial kitchen design projects.
REVENUE: \$40 million (2022)
EMPLOYEES: 34
WEBSITE: socialrestaurantdesign.com
CONTACT: 760-436-3598
SOCIAL IMPACT: SCRDRG partners with José Andrés World Central Kitchen, a nonprofit founded in 2010 by Chef José Andrés, that provides meals to people in disaster-stricken areas and works toward ending global food insecurity and hunger.
NOTABLE: SCRDRG is a nationally recognized brand but remains closely connected to the San Diego community; it collaborates with two thriving local concepts, Urban Plates and Better Buzz.