



## **Daré Bioscience Announces Exclusive Development and Option Agreement with Orbis Biosciences for Long-acting Injectable Contraceptive**

March 12, 2018

*Advancing 6- and 12- month injectable contraceptive development work carried out to date under a subcontract funded by Family Health International (FHI 360) through a grant from the Bill & Melinda Gates Foundation*

SAN DIEGO, March 12, 2018 (GLOBE NEWSWIRE) -- [Daré Bioscience, Inc.](#) [NASDAQ:DARE], a clinical-stage, women's biopharmaceutical company, today announced that it has entered into an agreement with Orbis Biosciences, Inc. for the development of an injectable etonogestrel contraceptive with 6- and 12-month durations (ORB-204 and ORB-214, respectively). The collaboration represents the Company's first partnership that leverages funds and development work supported to date by investment from a donor and non-profit development community devoted to improving options in women's reproductive health, positioning Daré as a committed industry partner to advance innovation that addresses global gaps in therapeutic options.

The initial development on Orbis' long-acting injectable contraceptive program was carried out under a subcontract funded by Family Health International (FHI 360) through a grant from the Bill & Melinda Gates Foundation. The Bill & Melinda Gates Foundation and FHI 360 are world leaders in the funding and development of novel contraceptive products and programs. In July of 2017, the Bill & Melinda Gates Foundation announced a commitment of \$375 million over three years in support of Family Planning 2020 – a global public/private partnership aimed at providing access to contraception.

Through its Contraceptive Technology Innovation (CTI) initiative, FHI 360 is developing new and strategically important contraceptives that are designed to fill gaps in the market, provide mid-to-long duration of action and have favorable usability profiles.

With this collaboration with Orbis, Daré extends its reach into women's reproductive health and further demonstrates its commitment to identify, develop and advance innovative products that address clear therapeutic gaps. Daré's approach to product identification, validation, and development enable it to quickly identify and secure programs that meet certain market opportunity criteria. This process, along with its development and commercialization expertise, has enabled Daré to establish itself as a partner of choice for women's health innovation.

"Leveraging the prior investment in this technology positions us to make potentially meaningful advances with modest near term investment, which not only helps Daré advance portfolio options in a cost efficient manner, but increases the odds that differentiated products reach women worldwide," said Sabrina Martucci Johnson, President and CEO, Daré Bioscience. "There is a growing preference by women for birth control options that don't require a daily pill or intervention at the time of intercourse. We particularly like the potential of offering a variety of options in monthly increments as they offer flexibility and convenience."

An injectable contraceptive is designed to provide discreet, non-implanted, protection over several months. Limitations of the currently marketed injectable contraceptive is that it provides contraceptive protection for only three months, and can delay the ability to get pregnant for up to ten months after receiving the injection. The target product profiles of ORB-204 and ORB-214 include prolonged duration (6 to 12 months), improved ease of use, with an improved side effect profile and predictable return to fertility.

Pre-clinical studies for the 6- and 12- month formulations have been completed to date, including establishing pharmacokinetics and pharmacodynamics profiles. The collaboration with Orbis will continue to advance the program through formulation optimization with the goal of achieving sustained release over the target time period.

The terms of the agreement with Orbis provide Daré with an option to enter into a license agreement for ORB-204 and ORB-214 should upcoming development efforts be successful.

ORB-204 and ORB-214 are additions to Daré's growing portfolio of novel therapeutic candidates that aims to address unmet needs in women's reproductive health, which includes Ovaprene™, a clinical stage, monthly non-hormonal contraceptive ring and Topical Sildenafil, a potential treatment for female sexual arousal disorder (FSAD).

### **About Orbis Biosciences**

Orbis is a pharmaceutical drug delivery manufacturing technology company focused on licensing its technology to companies to optimize their product portfolios. Orbis develops customized formulations and intellectual property for pharmaceutical product manufacture, leveraging Orbis' novel Precision Particle Fabrication® technology platforms: Optimum® precision encapsulation for oral delivery, Stratum™ precision encapsulation for injectable delivery, and the Unisun® platform for enabling sustained-release otic therapies. Providing industry innovation, the company offers cost-effective reformulation pathways to improve pharmaceutical products for improved health outcomes. For more information about Orbis, visit [orbisbio.com](#).

### **About Daré Bioscience**

Daré Bioscience is a clinical-stage biopharmaceutical company committed to the advancement of innovative products for women's reproductive health. The company is driven by a mission to identify, develop and bring to market a diverse portfolio of novel and differentiated therapies that expand treatment options, improve outcomes and facilitate convenience for women, primarily in the areas of contraception, vaginal health, sexual health and fertility. Daré currently has two product candidates in clinical development. The first is Ovaprene™, a non-hormonal monthly contraceptive ring

intended to provide protection over multiple weeks between menses. The second is SST-6007 (5% Topical Sildenafil Citrate Cream), a potential treatment for Female Sexual Arousal Disorder. SST-6007 incorporates sildenafil, the same active ingredient in Viagra<sup>®</sup>, in a proprietary cream formulation that is specifically designed to locally increase blood flow to the vulvar-vaginal tissue in women, leading to a potential improvement in genital arousal response and overall sexual experience. ORB-204 and ORB-214 are preclinical stage injectable etonogestrel contraceptives with target 6- and 12-month duration.

The company is headquartered in San Diego. For more information please visit [www.darebioscience.com](http://www.darebioscience.com).

#### **Forward-Looking Statements**

*This press release contains "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995 regarding matters that are not historical facts, including statements relating to Daré's expectations regarding the anticipated market demands for its products, the safety and effectiveness of its products, market acceptance of Daré's products and the qualifications and expertise of Daré's management team. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements as a result of various important factors, including the uncertainties inherent in the initiation and completion of clinical trials; availability and timing of data from ongoing and future clinical trials and the results of such trials; whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials, expectations for regulatory approvals; claims of infringement and other risks relating to Daré's owned and licensed intellectual property rights, and other factors discussed in the "Risk Factors" section of Daré's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 13, 2017. Additional information concerning factors that could cause actual results to materially differ from those in the forward-looking statements is contained in Daré's reports to the Securities and Exchange Commission, including Daré's reports on Forms 10-Q, 8-K and 10-K. In addition, any forward-looking statements included in this press release represent our views only as of the date of this release and should not be relied upon as representing our views as of any subsequent date. Daré specifically disclaims any obligation to update any forward-looking statements included in this press release.*

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