INVO Fertility Receives Notice of Allowance for Modified INVOcell Device Patent

SARASOTA, Fla., June 25, 2025 (GLOBE NEWSWIRE) — INVO Fertility, Inc. (Nasdaq: IVF) ("INVO Fertility" or the "Company"), a healthcare company focused on the fertility sector, today announced it has received a notice of allowance on a new patent for a modified version of the Company's proprietary INVOcell device. The new patent extends intellectual property protection on the Company's INVOcell device through 2040 based on a modified design which reflects feedback from leading embryologists to simplify use of the device.

The United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance for U.S. Patent Application No. 16/949,960, titled "Intravaginal Culture Incubation Container and Method." The Notice of Allowance, dated June 17, 2025, indicates that the USPTO has completed its examination and found the claims patentable. Once the issue fee is paid, the patent will be granted and published, providing protection to the claimed invention for 20 years from the filing date.

INVOcell is the world's first FDA-cleared intravaginal culture (IVC) system, a patented medical device that enables fertilization and early embryo development to occur within a woman's body, offering a more natural and intimate alternative to traditional in vitro fertilization (IVF). During the INVOcell procedure, eggs and sperm are placed in the thumb-sized device, which is then inserted into the vaginal cavity, typically, for a 5-day incubation period, utilizing the body's natural environment as an incubator. After incubation, embryos are transferred to the uterus, with any remaining embryos available for freezing. This innovative approach delivers comparable pregnancy rates to IVF-as reflected in the Company's 510k submission that was cleared by the FDA in 2023.

INVOcell was originally granted FDA clearance in 2015 and, in 2023, received clearance from the FDA for a change in labeling that increased the incubation period from 3 days to 5 days. The original INVOcell device included both a main chamber and microchamber. As real-world use cases of INVOcell have occurred over the past number of years, feedback from embryologists highlighted a preference for a singular main chamber without a separate microchamber. The Company redesigned the INVOcell device to reflect the feedback and subsequently submitted a modified device design for patent.

"The INVOcell device has represented a unique and alternative fertility treatment option, offering a more patient-centered approach that empowers couples by allowing fertilization and early embryo development to occur within the woman's body," commented Steve Shum, CEO of INVO Fertility. "The receipt of a new patent for our simplified device expands our intellectual property protection to this innovative approach, which delivers success rates comparable to traditional IVF, helping to make parenthood more accessible and inclusive for those facing infertility challenges worldwide."

About INVO Fertility

We are a healthcare fertility company dedicated to expanding assisted reproductive technology (“ART”) care to patients in need. Our principal commercial strategy is focused on building, acquiring and operating fertility clinics, including “INVO Centers” dedicated primarily to offering the intravaginal culture (“IVC”) procedure enabled by our INVOcell® medical device (“INVOcell”) and US-based, profitable in vitro fertilization (“IVF”) clinics. We have two operational INVO Centers in the United States and one IVF clinic. We also continue to engage in the sale and distribution of our INVOcell technology solution into third-party owned and operated fertility clinics. The INVOcell is a proprietary and revolutionary medical device, and the first to allow fertilization and early embryo development to take place in vivo within the woman’s body. The IVC procedure provides patients with a more natural, intimate, and affordable experience in comparison to other ART treatments. We believe the IVC procedure can deliver comparable results at a fraction of the cost of traditional IVF and is a significantly more effective treatment than intrauterine insemination (“IUI”). For more information, please visit www.invofertility.com.

Safe Harbor Statement

This release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The Company invokes the protections of the Private Securities Litigation Reform Act of 1995. All statements regarding our expected future financial position, results of operations, cash flows, financing plans, business strategies, products and services, competitive positions, growth opportunities, plans and objectives of management for future operations, as well as statements that include words such as “anticipate,” “if,” “believe,” “plan,” “estimate,” “expect,” “intend,” “may,” “could,” “should,” “will,” and other similar expressions are forward-looking statements. All forward-looking statements involve risks, uncertainties, and contingencies, many of which are beyond our control, which may cause actual results, performance, or achievements to differ materially from anticipated results, performance, or achievements. Factors that may cause actual results to differ materially from those in the forward-looking statements include those set forth in our filings at www.sec.gov. We are under no obligation to (and expressly disclaim any such obligation to) update or alter our forward-looking statements, whether as a result of new information, future events, or otherwise.

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