INVO Bioscience Management Letter to Shareholders

Key Developments and Future Initiatives Position INVOcell® Within the Severely Underserved Fertility Market

SARASOTA, Fla., Jan. 7, 2021 /PRNewswire/ — **INVO Bioscience, Inc.** (NASDAQ: INVO) **("Company") ('INVO"),** a medical device company focused on commercializing the world's only in vivo Intravaginal Culture System, INVOcell®, an effective and affordable treatment for patients diagnosed with infertility, is pleased to provide a year-end letter to shareholders.

Dear Shareholders,

As we begin the 2021 calendar year, we wanted to take the opportunity to wish you all a Happy New Year and to provide a brief summary of our recent progress at INVO, which we feel has been transformative to the business. We would also like to provide an outline of our key initiatives moving forward.

It goes without saying that 2020 was truly a unique year. The COVID-19 pandemic negatively impacted the entire world economically, physically, and psychologically. We are optimistic that as new treatment modalities and vaccines come to market that we can begin to return to some sense of normalcy throughout 2021.

Similar to many other medical device companies that support discretionary procedures and treatments, our commercialization efforts and the general pace of INVOcell's market adoption was certainly impacted during 2020, both with our internal efforts and our key partnering activities. However, we believe our overall market opportunity was not impacted as we believe INVOcell is well suited to address existing lab capacity challenges and provide an affordable and efficacious fertility option for patients in need.

Various market estimates suggest that the current Global Fertility market exceeds $20 billion and is growing, yet it remains severely underserved, with nearly 95% of couples in need of infertility treatment going without care. High costs relative to success, limited access to treatment in many areas, existing lab capacity issues, as well as cultural and religious factors are all contributors to this significant underserved market.

The underserved market is the real opportunity for INVOcell. We believe the value proposition of INVOcell as an affordable and efficient treatment technology with reduced infrastructure requirements can expand capacity and access to care, allowing us to increase adoption as

patients look for alternative and effective solutions with strong clinical outcomes.

Transformative Accomplishments

We believe the Company's progress over the past 18-24 months has proven to be transformational and has positioned us well for future market expansion. These highlighted accomplishments include the following:

- A U.S. commercialization agreement in January 2019 with Ferring Pharmaceuticals ("Ferring"), a multi-national firm and significant player in the global fertility drug market with a direct local marketing presence in more than 50 countries worldwide and distribution in 110 countries.
- Expansion of our operating team with key individuals with extensive fertility industry experience.
- Distribution agreements in eight countries located within Africa, Asia, Europe and the Middle East.
- The additional real market (retrospect) usage data that further demonstrates the understanding of INVOcell's efficacy vs. industry standard conventional IVF treatment options. Having two years of real-world outcomes data provides an extremely important validation of the technology while also providing a new potential pathway for our 5-day label expansion efforts.
- The formation of INVO's joint venture (JV) strategy, with initial partners in India, Mexico, and Malaysia, designed to establish dedicated INVOcell® clinics. We are excited about this additional commercialization method as we believe it will accelerate the awareness of INVOcell within key markets, enable us to benefit in the market development around our technology beyond a device sale alone, and potentially build the overall market for INVOcell at an accelerated pace. We anticipate additional JV arrangements in select markets, including in the U.S., in 2021. We intend to pursue these activities in a prudent and appropriately measured pace, but believe the return on investment (ROI) is attractive and the upfront investment for an individual facility is reasonable. We believe the key factor to ensure our success is to work with quality partners that have extensive clinical experience in fertility treatment practice.
- The successful implementation of INVOcell within a clinical practice at the America Institute for Reproductive Medicine (AIRM) in Birmingham, Alabama, which demonstrates an effective business model for implementing INVOcell. We believe this model further validates many of the key attributes we highlight with INVOcell, including quality outcomes, patient affordability, addressing the underserved population, and an efficient/streamlined process leading to substantially improved volume potential within existing clinic resources. In our opinion, this also creates a proven and efficient implementation format which we can utilize to operate our planned JV clinics.
- The creation of our new scientific advisory board with four industry experts including:
    - Tony Anderson, DHSc, ELD, multi-site laboratory director for Aspire Fertility as well

as the founder of EmbryoDirector IVF Academy USA;
    - Amber Cooper, MD, MSCI, FACOG, a reproductive endocrinologist and medical director of Vios Fertility Institute St. Louis;
    - Karen R. Hammond, DNP, CRNP, IVF Program Director of the America Institute of Reproductive Medicine in Birmingham, Alabama; and
    - Francisco “Paco” Arredondo, MD, MPH, FACOG, recently Chief Medical Officer of the United States largest network of fertility centers, overseeing more than 50 fertility specialists, and currently a partner in a joint venture developing INVOcell clinics in Mexico.
- The addition of new, highly talented and independent board members, including Trent Davis, Barbara Ryan, Matthew Szot, and Jeffrey J. Segal, M.D., creating a majority independence for enhanced corporate governance.
- A successful public offering in November 2020, raising net proceeds of approximately $11.6 million while simultaneously uplisting the company onto the NASDAQ market. We believe that our strengthened balance sheet positions us well to execute on our commercialization efforts while supporting further interest on Wall Street and the investment community. Analysts from both Colliers International Securities and Roth Capital Partners initiated coverage on INVO in December 2020.

Future Initiatives

We have gained a great deal of understanding over the past two years as early adopting clinics have honed their knowledge on how to best implement and utilize INVOcell in their collective practices and the additional information regarding the successful outcomes of INVOcell’s usage has been made available. We intend to leverage this knowledge and understanding to support the ongoing worldwide commercial efforts of INVOcell. As we look ahead in 2021, we are working towards the following objectives:

- Launch the initial INVO clinics through our existing JV agreements and begin to generate revenue from those operations, thus adding to our scalable, recurring, and high gross margin business model.
- Establish the initial 1-2 JV agreements, in Q1, for INVO-only clinics within the U.S. market.
- Begin shipping and generating revenue from the previously executed international distribution agreements.
- Continue to identify quality partners that we feel can best help accelerate the commercialization of INVOcell within a particular market, both in the U.S. and abroad, and execute additional joint venture and distribution agreements.
- Deploy additional resources towards supporting the marketing efforts of partners and distributors while implementing efforts primarily via public relations and social media efforts to increase understanding and awareness amongst physicians and patients. This also involves completing a comprehensive online/virtual training program for clinic

practitioners.

- Complete the work necessary to support the expansion of our U.S. labeling to include 5-day transfers. As a reminder, we recently submitted a 510(k) based on the additional 5-day retrospective data that became available earlier this year.
- Launch a new corporate website in early 2021 to support the adoption and awareness of INVOcell amongst physicians and patients, and provide information for investors and to support current partners.
- Establish additional Key Opinion Leaders and partners within the vast number of physicians within the very large, global OBGYN community, to expand understanding, adoption, and access to care both within the major metropolitan and rural areas.

In conclusion, we are truly excited about INVO's opportunity and our plans and initiatives during 2021 and beyond. On behalf of the entire INVO Bioscience team, we sincerely appreciate the shareholder support and look forward to providing additional updates and progress in early 2021.

Steve Shum
Chief Executive Officer

About INVO Bioscience®

We are a medical device company focused on creating simplified, lower-cost treatments for patients diagnosed with infertility. Our solution, the INVO® Procedure, is a revolutionary *in vivo* method of vaginal incubation that offers patients a more natural and intimate experience. Our lead product, the INVOcell®, is a patented medical device used in infertility treatment and is considered an Assisted Reproductive Technology (ART). The INVOcell® is the first Intravaginal Culture (IVC) system in the world used for the natural *in vivo* incubation of eggs and sperm during fertilization and early embryo development, as an alternative to traditional In Vitro Fertilization (IVF) and Intrauterine Insemination (IUI). Our mission is to increase access to care and expand fertility treatment across the globe with a goal to lower the cost of care and increase the availability of care. For more information, please visit **https://invobioscience.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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