

02 Oct 2023 | Analysis

# Opportunities In Fertility: Recognizing Gaps In The Market

by Jo Shorthouse

Ferring Pharmaceuticals' US CSO Elizabeth Garner talks to *In Vivo* about the future of fertility and where investment should be heading to make a dent in this multi-million-dollar market.

At a time when the biopharma industry is still suffering from the financing hangover of 2022, investment in women's health is on the upswing.

While company founders, investors and scientists have been discussing the state of investment, or lack thereof, in women's health for many years, it seems that the wider investment community has started to listen. Investors are seeing the benefit in financing women's health, a benefit to not just women, but to healthcare providers, payers and descendants such as children.

According to the Boston Consulting Group, women's health is on the "cusp of a major buildout." Indeed, in 2022 private equity funds invested \$3.3bn in US women's healthcare companies, an all-time high. In 2021, that figure had settled at \$800m, see Exhibit 1.

Click here to explore this interactive content online

#### **Not So Niche**

"Fifty percent of the population are women, and there are multiple major opportunities in women's health. But somehow, the investor community's mindset is that women's health is a niche. To this day, you still hear that women's health is a niche market and there is no money to be made," Elizabeth Garner, chief scientific officer of *Ferring US*, told *In Vivo*.

Garner refers to the situation in women's health investment as a "vicious circle," that once people believe there is no return on investment, interest and money vacate the space, *see Exhibit* 



2.

## <u>Click here to explore</u> this interactive content online <sup>→</sup>



Approximately 1% of healthcare research and innovation is invested in female-specific conditions beyond oncology, according to McKinsey. Of the \$194bn spent on clinical stage assets in 2020, 4% went on women's cancers, and 1% on all other female conditions.

#### **Much Needed Innovation**

Garner, an OB-GYN and GYN oncologist by training, is by her own admission very lucky to have pursued a career in her passion for women's health. After working at Brigham and Women's Hospital and Dana Farber Cancer Institute as an assistant professor at Harvard Medical School, she moved into industry, first to Merck as a member of the Gardasil clinical team, and then director of the product development team for its next generation HPV vaccine.

Her varied career in big pharma such as at <u>Abbott</u> and small firms such as <u>ObsEva SA</u> and <u>Agile</u> Therapeutics, Inc. have given her a sense of what can be achieved by companies, no matter their size, if the passion and innovation behind the product is there.

As chief scientific officer at Ferring Pharmaceuticals US, her remit is understandably wider than women's health but her aim, to develop innovative products in the reproductive medicine and maternal health arena, is evident.

Stigma was deeply linked to the lack of awareness and understanding around women's health, said Garner. The lack of conversation around topics such as miscarriage, bleeding and infertility adds to the belief that it is an area that holds promise.

The biggest opportunities within women's health come from maternal health (pre-eclampsia, post-partum hemorrhage and preterm labor), fertility and menopause, as well as endometriosis and uterine fibroids. Ferring has products in the late-stage clinic for male and female infertility and is working toward bringing its postpartum hemorrhage medication to the US. It markets a huge swathe of reproductive medicine products from stimulation to implantation in the *in vitro* fertilization (IVF) journey.

"Ferring is one of the first companies that is truly investing in male infertility," Garner told In Vivo. It has a Phase II trial looking at the impact of gonadotropins on It's Time For A Billion-Dollar Women's Health Fund



idiopathic infertility. "If there's a positive effect there, that could potentially change the fertility landscape," she said. In 30% of infertility cases, the issue behind the difficulty to conceive is from the male side.

Established pharma companies still focus their innovation dollars on the female side of infertility, there are smaller biotech firms that are investing in male infertility, but Ferring is the leader among

larger firms in conducting trials for this area of R&D.

By Lucie Ellis-Taitt

24 Jul 2023

Jessica Federer, former chief digital officer at Bayer, talks to *In Vivo* about making the jump into investing and why women's health is a rich and deep market set for change.

Read the full article here

Ferring is also looking to reformulate gonadotropins to an oral formulation to give women an option away from the heavy regime of injectables that many so find so hard to endure.

## The Mysteries That Still Exist

Garner believes that artificial intelligence may have an impact on removing some of the "mysteries that still exist" in fertility treatment despite how far this field has come in the lab. "There has been so much work done in the laboratory to create high-quality embryos," said Garner. "But once the embryo is placed into the uterus, we don't fully understand the key factors that lead to a successful or unsuccessful pregnancy outcome."

This is where AI could make a world of difference. Advanced analytics could study thousands of embryos to find embryo profiles that will have a high likelihood of pregnancy and a live birth. "It is still in its infancy, but I think we may see some meaningful results there, in time," said Garner. The average chance of becoming pregnant through IVF is around 40%, but industry "has not been able to break through that ceiling," said Garner.

The gap between a couple or woman realizing that they are having trouble conceiving and seeking treatment was too long, said Garner. Ferring launched Fertility Out Loud with the support of RESOLVE: The National Infertility Association in 2021. Through the Fertility Out Loud platform, Ferring and RESOLVE



Source: Ferring Pharmaceuticals

hope to continue to elevate the conversation around infertility and encourage those who are



searching for answers to take ownership of their journey by speaking up and seeking help from a fertility specialist sooner.

Creating equity and equality in access to fertility treatment would continue to change the game internationally and closer to home, said Garner. There is an increase in diversity among those seeking IVF procedures. While statistics on ethnic groups are not immediately available, numbers from the Human Fertilisation and Embryology Authority show that in 2018, IVF treatment in the UK was predominantly used by white patients (78%), followed by Asian (14%), black (3%), other (3%) and mixed (2%) patients.

This make up of patients is the traditional portrait of an IVF patient; predominantly Caucasian and able to afford the pricey procedure that is oftentimes a multiple attempt at pregnancy. However, Garner

# 'Femtech' Evolving Beyond Periods, Pregnancy And Postpartum

By Marion Webb

24 Mar 2022

Digital female-centric primary and preventive care and fertility support were top-funded women's health segments in 2021, drawing \$668m and \$330m in investments, respectively. Going forward, experts anticipate innovation to address unmet needs related to menopause, vaginal microbiome, endometriosis, and other chronic conditions, and surgeries such as hysterectomies and mastectomies.

Read the full article here

believes that there is more racial, ethnic and socio-economic diversity among those who are pursuing their fertility.

"At Ferring, we are thinking about ways to reduce the cost burden for patients, as well as helping IVF clinics, physicians and nurses better understand the unique needs of various groups from a cultural perspective, whether that be racial, ethnic, as well as communities such as LGBTQ+ who use assisted reproductive technology services to build their families," she explained. If companies such as Ferring can "figure out" access to affordable IVF treatment, create equality and equity within fertility, this would be a game changer for good, Garner told *In Vivo*.

# Passion for the Plight of Women

Garner was born and raised in Nigeria to an American mother and Nigerian father who met during her mother's time in the Peace Corps. Growing up seeing the discrepancies, "the plight" in women's healthcare stuck, and discussing the situation with her mother made a lasting impact on a teenaged Garner.

Garner was struck, when practicing as an OB-GYN, by the lack of innovation in conditions such as pre-eclampsia, pre-term labor, endometriosis and uterine fibroids. "For example, things



haven't changed much on the labor floor since I left clinical medicine. In this and so many other areas of women's health, we don't understand the science that would enable the development of targeted treatments," she explained.

"The health of women is so important beyond just the woman. A healthy woman means healthy children, healthy families and greater prosperity. We have to think of the bigger picture," Garner said.

## **Further Than Fertility**

Of course, women's health goes far beyond gynecology, fertility and the reproductive system. Even today, there are huge gaps in knowledge around how females react to certain medications as modern medicine has evolved with the view of male biology being the default. Women react differently to cardiovascular disease, for example, and are disproportionately impacted by Alzheimer's disease, rheumatoid arthritis and migraine to name just a few conditions.

Women metabolize drugs differently, female pharmacokinetics can be affected by higher body fat composition, lower body weight, less intestinal enzymatic activity and slower kidney function.

Beyond reactions to medications, males and females have differences in physiology and anatomy which can mean that signs and symptoms of the same disease may look different. One example is in cardiovascular disease; women experiencing a heart attack are more likely than men to complain of nausea, sweating, vomiting and neck or jaw pain.

Women remain underrepresented as healthy volunteers in Phase I trials, making up between 29% and 34% of participants in this early stage of drug testing, according to recent data. For the studies that it funds, the National Institutes of Health requires the inclusion of women, arguing that failing to include women compromises the validity and clinical significance of trial results. To bring those percentages up to 50% would make a huge difference to the future of women's health, and to global health overall.