Zacks Equity Research

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INVO Bioscience

(IVOB-OTC)

IVOB: INVOcell Launched In Canada Through Exclusive Agreement…

UPDATE

This morning INVO Bio announced its INVOcell device has been launched in Canada through an exclusive distribution agreement with Invaron Pharma. We see this as a significant near-term opportunity for the company. The INVOcell device has been elegantly designed to provide several advantages when compared to interuterine insemination (IUI) or in vitro fertilization (IVF). These advantages include lower risk of ovarian hyperstimulation syndrome, lower risk of anesthesia complications, and wider applicability and availability for infertile couples. New reimbursement policies in Canada should help drive uptake of INVOCell over the next several years.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	05/24/2010
Current Price (10/05/10)	$0.08
Target Price	**$0.25**

SUMMARY DATA

52-Week High	**$0.51**
52-Week Low	**$0.03**
One-Year Return (%)	**-83.80**
Beta	**-0.96**
Average Daily Volume (sh)	**121,134**
Shares Outstanding (mil)	**63**
Market Capitalization ($mil)	**$3**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2010 Estimate	**N/A**
P/E using 2011 Estimate	**N/A**
Zacks Rank	**3**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**45 of 138**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	0.04 A	0.02 A	0.00 A	0.01 A	0.06 A
2010	0.02 A	0.01 A	0.02 E	0.02 E	0.07 E
2011					0.10 E
2012					0.16 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	$0.01 A	-$0.01 A	-$0.06 A	-$0.00 A	-$0.09 A
2010	$0.01 A	-$0.01 A	-$0.01 E	-$0.01 E	-$0.01 E
2011					-$0.03 E
2012					-$0.03 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

INVOcell Launched In Canada…

On October 5, 2010, INVO Biosciences announced that it has signed an agreement with Canadian-based Invaron Pharmaceuticals for the exclusive distribution of INVOcell in Canada. We believe this could represent a meaningful near-term revenue driver for INVO Bio given the growing infertility rates and Canada and recently implemented reimbursement policy that dramatically improves patient access to assisted reproductive procedures. INVO Bio received Health Canada Regulatory Approval in 2009. The device is CE Mark approved in Europe and Canada and conforms to all consumer health and safety requirements. INVOcell is currently marketed and sold in Austria, Cameroon, Columbia, the Dominican Republic, Guatemala, Nicaragua, Pakistan, Panama, Peru, Spain, Togo, Turkey, and Venezuela. Regulatory procedure is underway in additional areas including China, Russia, and India.

There are approximately 27 fertility centers in Canada licensed to perform assisted reproductive procedures. INVO Bio's more natural alternative to IVF is an attractive option for the estimated 1 million infertile couples in Canada. Plus, with approval and now distribution in place, the door is open to the estimated 8 million infertile couples in the U.S. and 10 million Europe to travel to Canada should they chose to seek INVOcell.

Recently, the provincial government of Quebec has initiated the funding of up to three assisted reproductive cycles for residents of the province. Fertility centers in Quebec are currently administering approximately 1,850 cycles annually. By 2014 provincial officials predict that the annual number of embryo-implant cycles administered will grow to between 7,000 and 10,000 in the Quebec province alone due to the new reimbursement policy. INVO Bio's INVOcell device represents an excellent low start-up-cost alternative to help these centers meet the potential surge in demand for assisted reproductive procedures.

INVESTMENT THESIS

Sales of the INVOcell device have underwhelmed to date. Management continues to run into the problem where existing IVF centers are viewing the INVOcell device as a competitive threat. These centers, due to the difficult economic environment, are seeing demand decline significantly. However, most IVF centers still have a backlog, albeit smaller, as the number of infertile couples seeking treatment continues to rise. Instead of viewing INVOcell as a competitive threat, if these centers viewed the product as a low-cost alternative to target a significant population of the infertile couples currently not being treated by IVF, sales of INVOcell would soar. This is management's chief goal in the coming quarters – to work with the doctors and the IVF centers, and educate them on how INVOcell can help expand their business and grow their revenues. However, this costs money; money to attend conferences, travel to IVF centers and meet with doctors in South America, Europe, and Asia, and to educate and train potential users on INVOcell. This is money the company did not have to spend in the second quarter, and that is why we believe sales disappointed. If the company can secure funding in the next few months, we expect the situation to improve.

We note that the company plans to attend the American Society of Reproductive Medicine (ASRM) in late-October 2010 in Denver, CO. This could be a significant opportunity to increase education and awareness in the U.S. for the INVOcell device.

…Looking For Funding…

As of June 30, 2010, INVO BioSciences reported only $571 in cash on the balance sheet. Operating burn for the second quarter was $108k, one of the lowest in a while and further evidence of the lack of marketing and promotional spending during the quarter. We believe the company needs an estimated $250k to fund operations in the third quarter, and another $300 to $400k for the fourth quarter. During the second quarter, the company funded operations by issuing convertible notes and restricted stock. We expect this to continue in the third and fourth quarter. In August 2010, the company raised $50k by issuing 1.25 million shares of common stock to Mazuma Funding of New York, a private investor. The company used the proceeds to pay off a $50k working line of credit with Century Bank. We anticipate future PIPE deals to come, however the overall dilution through the end of the year should be less than 10%.

The company is also looking to tap its reserve equity financing (REF) agreement with AGS Capital Group LLC. INVO Bio and AGS entered into the REF in October 2009, which allows the company to issue common stock for cash consideration of up to $10 million. We expect that INVO to access this REF in the fourth quarter.

The opportunity exists for the company to secure funding from the Federal R&D Tax Credit. These options include either a tax credit for R&D expenses, or a research grant that would pay for up to 50% of the total research or related expenses for new product development. We estimate that INVO could qualify for a federal research grant between $500k and $1 million to fund the U.S. regulatory trial for INVOcell. Management has applied for these funds and expects to hear back in September or October.

Finally, management is in discussions with potential development and commercialization partners in Europe, Asia, and the U.S. These talks may be early-stage, but the potential exists that something gets done to provide additional funding for expansion of the marketing and promotional effort behind INVOcell in 2011. We highlight the recent agreement with Invaron Pharmaceuticals in Canada as a positive step forward on INVOcell distribution.

Management is currently in the process of launching INVO around the world. The device is ISO-13485 certified and CE Mark approved for sale in Europe and Canada. Key markets where the device is available include Canada, Austria, Columbia, Pakistan, Peru, Brazil, and Argentina. For these territories where registration has been complete, management has signed distribution partners and is working with physicians to train them on the procedure. The company is in talks with potential distribution partners in India, China, Russia, and South Africa. Management just recently got some good news from the State Food and Drug (SFDA) agency in China, classifying INVOcell as a Class 2 medical device without requiring a human clinical trial. The next step for potential marketing in China is for management to secure a Certificate of Free Sale for a European contract manufacturer, which will allow for marketing in China through the company's distribution partner, Progressive Group.

In the U.S., INVO Bioscience has completed the first step for medical device companies who manufacture Class 2 devices and the filing of a Premarket Notification with the FDA. The FDA has reviewed the 510(k) application and requested human clinical trial. INVO is currently focusing on the international market while is seeks funds to conduct the U.S. registration program. We believe this program could begin in 2011 once funds are secured, perhaps in the form of a federal grant.

According to the European Society of Human Reproduction and Embryology (ESHRE), in 2007 there were an estimated 150 million couples worldwide with infertility. Based on the significant limitations discussed above for IUI and IVF, only around 0.5% seek treatment, leaving an estimated 149 million couples untreated. In the U.S., there are an estimated 7.5 million couples battling infertility. The number in Europe stands around 10.0 million.

Assuming a blended worldwide price of around $250 per device, plus the costs of the warming blocks, if management were able to capture just 10% of the current market, peak sales of the device are $15 million. At the current market value of only $3 million, we believe that this opportunity at INVO Bio is dramatically under-appreciated by Wall Street.

Staying Positive

In June 2010, we initiated coverage of INVO Biosciences with an 'Outperform' rating and price target of $0.25 per share. We are maintaining our positive rating following the disappointing second quarter. Despite the tough times, we believe that the company has built a superior device for the treatment of infertility. The INVOcell device has been elegantly designed to provide several advantages when compared to interuterine insemination (IUI) or in vitro fertilization (IVF). These advantages include lower risk of ovarian hyperstimulation syndrome, lower risk of anesthesia complications, and wider applicability and availability for infertile couples. Additionally, the INVO procedure provides The INVO procedure also provides a far more personalized and natural approach to conception than IVF. Recent trial results demonstrate the INVO procedure has a clinical pregnancy rate similar to that of in vitro fertilization (IVF) and about half the cost.

OVERVIEW

INFERTILITY

Infertility primarily refers to the biological inability of a person to contribute to conception. Infertility may also refer to the state of a woman who is unable to carry a pregnancy to full term. There are many biological causes of infertility, some which may be treated with medical intervention. Reproductive endocrinologists and infertility specialists typically consider a couple to be infertile if the couple has not conceived after 12 months of contraceptive-free intercourse and the female is under the age of 34. For women over the age of 35, infertility may be classified after only 6 months of contraceptive-free intercourse due to declining egg quality.

There are two types of infertility, primary infertility and secondary infertility. Primary infertility is designated for a couple that has never been able to conceive. Secondary infertility results when a couple has difficulty conceiving after already having conceived once – whether or not the pregnancy has gone to term. Generally, it is estimated that one in seven couples (~15%) have problems conceiving, with the incidence varying slightly in most countries independent of the level of the country's development.

Infertility is caused by many factors, although for almost a quarter of the couples the cause remains unexplained. Age of the potential mother is the single biggest factor in infertility. However, in almost half of the reported cases of infertility in the U.S., the male is the underlying cause. Health problems that may result in infertility are: ovulation problems, tubal blockage, low-sperm count, uterine problems, tuberculosis, hypospadias, endometriosis, and polycystic ovarian syndrome. More general causes include: diabetes, thyroid disorders, adrenal disease, environmental factors, smoking, or alcohol abuse.

Treatment Options

Treatment methods for infertility may be grouped as medical or complementary and alternative treatments. Conservative options include medications designed for ovarian stimulation or cervical caps designed to collect the sperm and hold it in place against the cervical os for up to six hours. This type of conception device is particularly useful in males with low sperm count or low sperm motility. Fertility drugs primarily include medications to enhance ovarian activity, such as gonadotropins, estrogen antagonists, follicle-stimulating hormones (FSH), or gonadotropin releasing hormones (GnRH).

One such common drug is clomiphene (Serophene or Clomid), a selective estrogen receptor modulator (SERM) that increases the production of gonadotropins for ovarian stimulation. Clomiphene is taken orally, but many other drugs are administered by subcutaneous injection in the abdomen or thigh or intramuscular injection in the buttocks. Response to these drugs is monitored by frequent vaginal ultrasounds and blood estrogen determinations. At a time in the cycle when the ovarian follicles reach a designated size and estrogen levels are appropriate, an injection of the hormone human chorionic gonadotropins (hCG) is given to trigger ovulation. Ovulation usually occurs 36-48 hours after the hCG injection, and intercourse or artificial insemination or oocytes retrieval is timed accordingly.

…Interuterine Insemination (IUI)…

Interuterine insemination (IUI), or artificial insemination (AI), is the process by which sperm is placed after preparation into the reproductive tract of a female for the purpose of impregnating the female by using means other than sexual intercourse. The fresh sperm can be placed in the cervix for intracevical insemination (ICI) as well. In humans, it is used as an assisted reproductive technology (ART), primarily to treat infertility using sperm from the woman's partner, or sperm from a donor (donor sperm) where the male partner produces no sperm. It is also increasingly used to enable women without a male partner to produce children by using donor sperm.

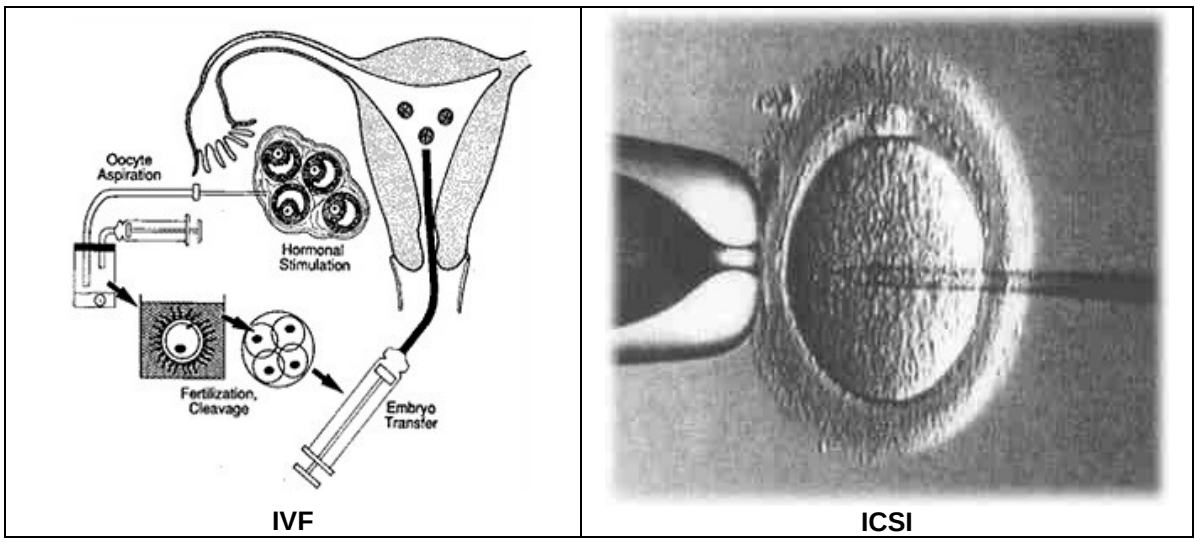
Success rates, or pregnancy rates, for artificial insemination vary widely based on many factors, including the age and health of the female patient. For couples whose infertility is unexplained, un-stimulated IUI is no more effective than natural means of conception. IUI is among the first options that couples seeking assisted reproductive technologies (ART) because of the low cost. An IUI cycle will run approximately $1,000 in the EU and $1,500 in the U.S. Between Europe and the U.S., there was an estimated 800k IUI cycles in 2009. However, generally speaking, approximate pregnancy rates are low at only 10 to 15% per ovulatory cycle. The average couple requires 2 to 3 cycles to achieve clinical pregnancy through IUI. The overall aggregate pregnancy rate for couples attempting IUI is around 25%. Thus, for most couples, the cost to try IUI will be around $3,000 to $4,000, and only a quarter will succeed. Therefore, the overall cost per pregnancy for IUI is roughly $12,000 (in the EU) to $16,000 (in the U.S.).

…In Vitro Fertilization (IVF)…

The procedure of *In Vitro* Fertilization (IVF) is a process by which egg cells are fertilized by sperm outside the womb as a treatment for infertility. IVF is often used when less invasive methods of assisted reproductive technologies (ART) have failed. The process involves hormonally controlling the ovulatory process, removing oocytes (eggs) from the woman's ovaries and letting sperm fertilize them in a culture medium outside of the womb.

Ovarian stimulation typically starts on the third day of menstruation and consists of a regimen of fertility medications discussed above to stimulate the development of multiple follicles of ovaries. These medications are usually given for period of up to ten days. The FSH stimulates growth of immature ovarian follicles in the ovary. It is a complex process that requires close monitoring of estradiol and follicle growth by means of gynecologic ultrasonography. GnRH antagonists may be used during the last days of stimulation to block the natural surge of luteinizing hormone (LH) and allow the physician to initiate the ovulation process by using medication, usually injectable hCG. The egg retrieval procedure takes place using a transvaginal technique involving an ultrasound-guided needle piercing the vaginal wall to reach the ovaries. Through this needle the follicular fluid can be aspirated and is handed to the IVF laboratory to identify eggs. It is common to remove between ten and thirty eggs during one procedure. The retrieval procedure takes about 20 minutes and is usually done under general anaesthesia. In the laboratory, eggs are identified, stripped of surrounding cells, and prepared.

In the meantime, sperm of the partner or donor is prepared through a procedure called sperm washing. Fertilization usually takes place in a Petri dish containing a culture medium or organic material in the case of coculture. The sperm and the eggs are then incubated together at a ratio of about 75,000:1 for about 18 hours. In some cases, where male infertility is a problem due to low sperm count or low sperm motility, physicians can attempt an intracytoplasmic sperm injection (ICSI). ICSI is a procedure where a single sperm is injected directly into an egg using a sharp glass pipette under guidance of a high powered microscope. The zygotes are then incubated for an additional 48 to 60 hours under close monitoring. When ready, the embryos are graded by the embryologist based on cell growth, evenness of growth, and degree of fragmentation. The embryos judged to be the most suitable are transferred to the patient's uterus through a thin, plastic catheter, which goes through cervix into the uterine cavity.



IVF **ICSI**

Several embryos may be placed into the uterus to improve chances of implantation and pregnancy. This can often lead to multiple births. In fact, according to a study conducted by the Jones Institute for Reproductive Medicine, multiple births occur in roughly 24% of IVF pregnancies, with triples or more accounting for roughly 3% of the successful outcomes. As such, strict limits on the number of embryos that may be transferred have been enacted in some countries (e.g. England) to reduce the risk of high-order multiples (triplets or more), but are not universally followed or accepted.

Typical cost of an IVF cycle in the U.S. is roughly $12,400 (range: $7,000 to $15,000). Prices outside the U.S. are typically lower, and can be as low as $4,000 in Japan, with the average cost around $10,000. However, most couples will require more than one cycle to achieve pregnancy. The average is around 2.2 cycles, with many couples paying for several cycles of IVF before ultimately giving up seeking a new alternative such as adoption. Thus, a typical cost per pregnancy for IVF is approximately $25,000 (range: $17,000 to $35,000).

The first successful IVF birth occurred in 1978. Since that time, physicians have been able to improve IVF successful pregnancy rates, which now stand around 38 – 40% per cycle. The live birth rate for IVF, slightly lower due to miscarriages, stands around 28 – 30%. The live birth success rate is directly correlated to age, health, and demographic of the prospective mother. IVF attempts also correlate to success rate. One published study in the New England Journal of Medicine (NEJM) on 6,164 patients undergoing 14,248 cycles (Cumulative Live-Birth Rates after In Vitro Fertilization; NEJM, Vol. 360:236-243, January 15, 2009) reported 49% to 52% for three attempts, and 70% to 74% for six attempts. In 2009, there was an estimated 600k IVF cycles between the U.S., Europe, and Asia / Japan.

…Risks and Limitations of IVF…

In vitro fertilization does not come without risks or limitations. With respect to the limitations, IVF is not cheap. As noted above, a typical IVF cycle in the U.S. can cost over $12,000. And with the average couple requiring at least 2 cycles, an IVF pregnancy will run around $25,000. The bulk of the costs of IVF are in the hormones used to obtain mature oocytes. Human recombinant gonadotropins and gonadotropin-releasing hormone (GnRH) analogues account for at least 50% of IVF costs. The remaining costs of an IVF procedure go to cover the cost of the ultrasonographic equipment suitable for monitoring ovarian follicular development and retrieving oocytes, as well as overhead costs that include the incubator unit, the monitoring and alarm system necessary to keep close watch of the incubator, power system backups, air filtration units, quality control systems, and maintenance. An IVF center can cost upwards of $500,000 to build.

Finally, IVF has substantial human costs, including a highly trained laboratory embryologist and an endocrinologist. The high capital cost of an IVF center limits the demographic and socioeconomic target market for IVF. The centers are usually large and located in major cities. There are only roughly 430 U.S. fertility clinics in the U.S. that can provide IVF services. Compare that to the more than 300 hospitals and IVF centers in Japan, a country with one-third of the population and less than one-fourth of the land mass. It is clear that cost plays a major role in the decision to try IVF.

Also noted above, the potential for multiple births is also high with IVF. It is common to remove between ten and thirty eggs during one harvesting procedure, and to have multiple embryos created. Most centers will not implant more than 2 to 3 embryos at one time to limit the potential for multiple births. If multiple embryos are generated, patients may choose to freeze embryos that are not transferred. The Society for Assisted Reproductive Technology estimates there are currently 500,000 frozen embryos in the U.S. The growing “embryo dilemma” is a hot area of contention for political and religious rights groups around the country.

However, potentially the biggest risk to IVF is ovarian hyperstimulation syndrome (OHSS), a rare but severe and potentially life-threatening complication. It results as a side-effect of human chorionic gonadotropins (hCG) use, which causes the ovaries to undergo extensive luteinization, releasing large amounts of estrogen, progesterone, and cytokines that induce vascular hyperpermeability (leaky capillaries). OHSS has been characterized by the presence of multiple luteinized cysts within the ovaries leading to ovarian enlargement and secondary complications. Severe OHSS can result in blood clots, abdominal pain and distension, decreased urine production, pleural effusion, and respiratory distress. It can be further complicated by ovarian torsion, ovarian rupture, and thrombo-phlebitis and renal insufficiency. Incidence of severe OHSS is around 2 – 4% for patients undergoing IVF. Once OHSS develops, it is prudent to postpone embryo transfer until the condition reverses, either naturally or through supportive care. Physicians typically look to monitor estradiol levels as a warning sign to developing OHSS. This adds to the workload and costs associated with IVF.

Besides the high capital costs and potentially life-threatening side-effects of ovarian hyperstimulation, IVF is also a rather tedious process that results in high emotional stress. Administration of GnRH agonists and gonadotropins (the most commonly used stimulation protocol) usually involves as many as ten office visits to complete a cycle. Specialized ultrasound monitoring and need for frequent blood estrogen determinations are required, meaning a typical office visit can run two hours long. Once a treatment cycle has begun, daily drug administration and monitoring are necessary until ovulation occurs. IVF also often creates significant psychological stress associated with prolonged treatment. The stress can result from lack of success (multiple cycles), lack of funding to continue, or negative reaction to the hormonal injections.

A study conducted by the Ninewells Hospital & Medical School, in Dundee, Scotland, and published in The Journal of Human Reproduction (Vol.21, No. 2:358-363,2006) concluded that behind discontinuing IVF as a result of a successful live birth (52%), discontinuing due to psychological stress (36%) was the number two reason why couples stop the process. Lack of funding (23%) was third.

A Wide Open Market…

As a result of the risks and limitations noted above for IVF or the relatively low pregnancy rate for IUI/ICI, many couples go left untreated for their infertility. In fact, according to the European Society of Human Reproduction and Embryology (ESHRE), in 2007 there were an estimated 150 million couples worldwide with infertility. Only around 0.5% seek treatment, leaving an estimated 149 million couples untreated.

In the U.S., there are an estimated 7.5 million couples battling infertility. The number in Europe stands around 10.0 million. For the U.S. and Europe, treatment rates are higher thanks to the availability of IVF centers and access to medical care for diseases that could lead to infertility. Areas outside of the U.S. and Europe do not fare as well. For example, in the Middle East, Russia, India, and Pakistan, infertility rates are 20% due to widespread and untreated sexually transmitted disease (STDs), and a lack of IVF centers. In Pakistan, a country with 172 million people and 25% infertility rates, there are only 5 main IVF centers. India is a country with 1.1 billion people and 20% infertility rates, there are an estimated 30 million people that could benefit from a low-cost and effective option. Russia, a country with 140 million people has seen its population decline in recent years thank in part to its high infertility rate. Countries like Russia and Australia have instituted progressive tax advantages to couples for having more than one child. Between the U.S., E.U., Australia, Japan, and developed areas of India, China, Russia, Pakistan, the Middle East, and South America, we estimate there are 80 to 100 million couples that could be potential users of an alternative procedure.

INVOcell – A Better Solution



INVOcell is a small plastic gas permeable capsule that is used in infertility treatment for the incubation of eggs and sperm for embryo development. Unlike conventional infertility treatments such as in vitro fertilization (IVF), where the eggs and sperm develop into embryos in a laboratory, the INVOcell utilizes the women's vagina as a natural incubator to support embryo development. This novel INVOcell technology offers patients a more personal approach to achieving pregnancy, decreases the risk of multiple births and reduces the chance for creating unused embryos. This can help to lower the psychological stress noted above with IVF.

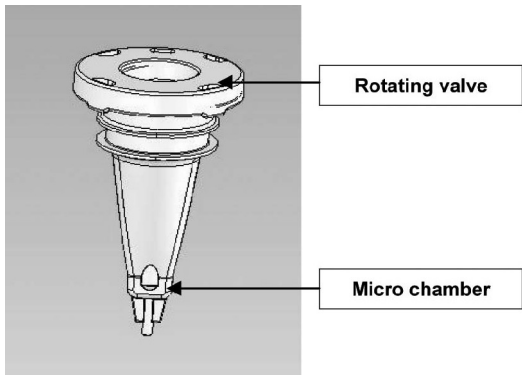
Using the maternal vaginal cavity for incubation inside the INVOcell creates a simpler and reproducible procedure. It eliminates the need for expensive, high-tech monitoring of incubators, which often require power backups, air filtration, alarm systems, and instrument maintenance, and quality control technicians. The procedure takes less than 90 minutes and can be performed in a physician's office or in a satellite facility of an IVF center.

Fertilization of the oocytes (immature egg) and early embryo development takes place inside the INVOcell device, which is placed in the mother's upper vaginal cavity for incubation for three days. The upper vaginal cavity provides the necessary physiological characteristics, specifically with respect to pCO_2 concentration and pH, to facilitate development. This is a significant cost and procedural advantage over traditional IVF where the early embryo development is taking place inside a Petri dish in monitored incubators at the IVF center.

…The Device…

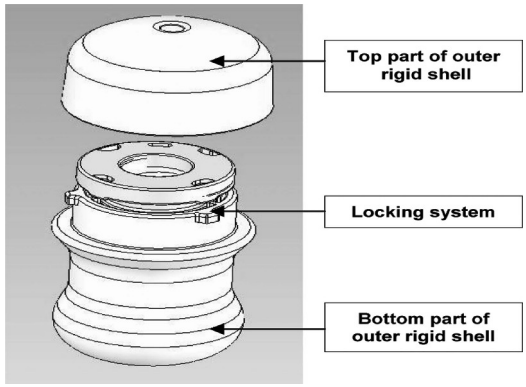
The INVO (intravaginal culture of oocytes) device is a two inch plastic capsule with an inner chamber, an outer rigid cover, and a gas permeable retention system membrane that maintains normal flow of vaginal secretions.

The device has been elegantly designed for both form and function. The rotating valve allows for access to the inner chamber without introduction of air or contamination of the culture medium. The valve also has a small orifice to help protects against variation in pH and potential medium overflow and the loss of gametes.



The micro-chamber (1.1 mL) collects the embryos after incubation and allows for observation with a microscope while still inside the chamber. This is a significant advantage because the physician can transfer the embryos directly from the device into a catheter for transplant into the uterus of the patient.

The outer rigid shell of the INVOcell device is smooth to prevent lesions or irritations in the vagina or the cervical epithelium during the three days of vaginal incubation. The outer wall is also permeable to CO_2 to allow for the ideal physiologic condition for embryo development. The rigid wall protects the inner chamber, but still allows the physician to grasp the device with a forceps for implantation or remove it from the vagina.



The device also has a locking system to prevent an unexpected opening of the outer shell. Finally, holes have been perforated in the membrane of the diaphragm (retention system) for elimination of the vaginal secretions during the incubation period.

The INVOcell device is ISO-10993 tested to assess toxicity, biocompatibility, comfort and retention within the vagina. Clinical and empirical data shows INVOcell to be well-tolerated with no meaningfully significant level of serious adverse effects observable during use. The device is ISO-13485 certified and CE Mark approved for sale in Europe and Canada. It is also available in South America, Africa, and the Middle East. In the U.S., INVO Bioscience has an open investigation drug exemption (IDE) to begin U.S. clinical trial testing. This trial has been requested by the U.S. FDA following a review of the company's 510(k) application.

…How It Works…

INVOcell was rationally developed to be a superior incubator of the growing embryo than with traditional IVF. The procedure is also less tedious and provides a far more personalized and reproducible approach to conception.

The procedure requires only mild ovarian stimulation instead of the conventional stimulation used in to IVF. Mild stimulation can be accomplished through injection of lower levels of hormones, such as 100mg of clomiphene for five days, or 75 IU of hMG or FSH without starting GnRH antagonists until later in the cycle. Through mild stimulation, physicians can recruit anywhere between five to ten eggs during one procedure. This is far less than the ten to thirty eggs typically recruited during conventional stimulation. The far quicker procedure also results in less discomfort for the patient. It can also be done under a conscious sedation rather than a general anaesthesia. Finally, less GnRH agonist and hCG levels during the cycle provide for a lower risk of overstimulation, and risk of OHSS. It is also a meaningful cost advantage, as the hormones used usually account for up to 30% of the total cost for IVF.

- ✓ Less egg recruitment
- ✓ Less risk of OHSS
- ✓ Lower cost
- ✓ Conscious sedation
- ✓ Less discomfort to patient
- ✓ Quicker procedure

Sperm collection is similar between INVOcell and IVF, although because of the movement of the INVOcell device (inside the patient) a small fraction of sperm is used to inseminate the few (usually three to five) selected oocytes. Usually a ratio of about 10,000:1 is sufficient, which provides a meaningful benefit to couples where the male has low sperm count or low sperm motility. All this can be accomplished without a highly trained embryologist, and without the need for complex lab equipment, so the costs to run the procedure are far lower than with IVF. Also, no pre-incubation of the oocytes are necessary, so the procedure can be initiated at the same time of the collection; this is another time-saving benefit to the couple.

Once the transfer of prepared sperm and eggs in the device is complete, the INVOcell device is closed, placed into a protective outer rigid shell and then positioned into the upper vaginal cavity for 2 or 3 days. A retention system is used to secure the device in the vagina during incubation. This is the ideal physiological condition for embryo incubation. Because the embryos are not stored in the fertility facility in an incubation chamber, there is no need of room air filtration with positive pressure, no need for an alarm or monitoring system, no need for a battery backup, and no need for an embryologist to be on call every night. This potentially allows for a remote facility in more rural areas. Again, this is far fewer costs to the patient and the facility.

After incubation the retention system and the device are removed from the vagina in the physician's office. The outer rigid shell is removed, the device is opened and the contents observed under microscope to find the embryos. The two best embryos are loaded into a catheter and transferred immediately into the uterine cavity. Ultrasound guidance is used in order to improve the quality of the transfer. The entire INVO procedure takes approximately 3 hours over the course of two visits.



…Advantages of INVOcell vs. IVF & IUI…

In our opinion, INVO Bioscience has created a better mousetrap for in vitro fertilization. There are numerous potential advantages of using INVOcell vs. conventional IVF.

1) **Mild Ovarian Stimulation:** Besides the obvious safety advantage of using far less hormonal treatment, which leads to lower risk of developing ovarian hyperstimulation syndrome (OHSS), there is also a big cost advantage. Roughly 50% of the costs of IVF are the hormonal treatments required to stimulate the ovaries. Reducing the medications reduces the cost of the procedure.
   - ✓ Less risk of OHSS
   - ✓ Lower costs

2) **Conscious Sedation:** With INVOcell, retrieval of the oocytes can be performed in the physician's office under a conscious sedation rather than a general anesthesia. Serious risk or complications from general anesthesia include toxic effects on the heart, lungs, liver, and kidneys, or nerve damage. And since the procedure is conducted by the OB/GYN, it limits the need for an endocrinologist, and an embryologist, or an anesthesiologist. This saves the patient both time and money.
   - ✓ Less risk of anesthesia complications
   - ✓ Significant convenience advantage for patient and physician.
   - ✓ Lower costs of procedure and skilled staff

3) **Targeted Procedure:** With conventional IVF, it is common to remove as many as fifteen to twenty eggs at one time. Often more than two to three eggs are fertilized, created an ethical dilemma of what to do with non-selected embryos for implantation. According to SART, there are 500,000 frozen embryos in the U.S alone. Implanting more than two embryos leads to high potential for multiple births. The multiple births rate for IVF is roughly 25%. INVO Biosciences has designed the INVOcell procedure to be as effective as IVF with only removing three to five eggs, and creating one to two embryos. INVOcell does not contribute to the growing embryo dilemma, and has a significantly lower multiple births rate.
   - ✓ Lower egg removal
   - ✓ Low risk of multiple births (about 50% reduction based on clinical data)
   - ✓ Potential ethical advantage

4) **Personalized Approach:** With conventional IVF, the fertilization and incubation of the embryo takes place outside of the womb in a Petri disk or another type of organic material, inside a desktop incubator. The incubator may hold the developing embryos of more than one couple, potentially creating the opportunity for error. With INVOcell, the device is placed in the upper vaginal cavity of the female, creating a far more personalized and interactive approach for the couple.
   - ✓ Less risk for embryo error
   - ✓ More personalized / interactive approach for the couple

5) **Wider Applicability:** During the fertilization procedure for conventional IVF, sperm is mixed with the eggs at a rate of approximately 75,000:1. This could be an issue in couples where the male has a low sperm count or poor sperm motility. For these couples, physicians can attempt an intracytoplasmic sperm injection (ICSI). However, statistics show a higher incidence of birth defects for children born through ICSI-IVF by 2:1 (NEJM, Vol. 346:725-730, March, 2002). During the INVO procedure, only a small fraction of the amount of sperm is used to inseminate the oocytes. Usually a ratio of about 10,000:1 is sufficient.
   - ✓ Advantage for couples where the male has low sperm count
   - ✓ A more natural insemination
   - ✓ Lower potential for birth defects

6) **Lower Capital Requirement:** Besides the lower cost of less pharmaceuticals and on-call physicians, the INVOcell procedure requires far less in terms of sophisticated equipment than conventional IVF. An IVF center requires high-tech ultrasonographic equipment suitable for monitoring ovarian follicular development and retrieving oocytes, an incubator unit, the monitoring and alarm system necessary to keep close watch of the incubator, power system backups, air filtration units, quality control systems, and maintenance. An IVF center can cost upwards of $500,000 to build and maintain. As such, IVF centers are found primarily near major hospitals in large cities. INVO allows these large IVF centers to establish satellite offices that offer INVO as an alternative. Plus, there are an estimated 5,000 OB/GYN physicians in the U.S. who offer infertility services such as IUI, but lack the facilities to offer IVF. INVO offers these physicians an opportunity to expand their in-house services at a low cost.
   - ✓ Broader geographic reach
   - ✓ Lower cost of the center allows for wider socioeconomic availability

7) **Lower Cost:** Adding in all the above factors, including the costs of the hormonal medications, the bill from the endocrinologist, the embryologist, the anesthesiologist, and covering the cost of the equipment, and a typical IVF cycle will cost $12,500 per cycle in the U.S., $6,500 in Europe. The average couple requires 2.2 cycles, meaning the cost per IVF pregnancy is around $30,000 in the U.S, and around $15,000 in the EU. For INVOcell, with applying a similar 2.2 cycles per pregnancy rate, the costs are roughly half that level.
   - ✓ Lower overall cost in the U.S. & EU by about 50%.
   - ✓ Similar cost to IUI with greater efficacy

…Clinical Data…

Paramount above the cost of the procedure is the key question for infertile couples, "Does INVOcell work?" None of the above advantages would truly interest an infertile couple if in the end INVOcell was an ineffective method for achieving pregnancy. Accordingly, we are encouraged by the fact that the clinical and real world data presented by the company so far demonstrated INVOcell helps couples to achieve a pregnancy rate similar to that of conventional IVF. Since the initial development of the device in the mid-1980's, there have been numerous clinical trials testing the effectiveness of INVOcell alone or head-to-head versus conventional IVF. Below are data presentations from peer-review journals demonstrating the results of these programs, including fertilization rates and clinical pregnancy. These data are from the pre-commercial prototype INVOcell device. We also note, back in the late 1980s when these studies were done, pregnancy rates for conventional IVF was approximately 21%.

Study	Center	Data*
# 1	Port Royal University Clinic, Paris France (1985 – 1986) 100 cycles Fertility and Sterility, Vol. 49, No. 4:654-657, 1988	INVO Fertilization rate = 52% Clinical pregnancy rate = 20% PR Live Births = 15%
# 2	Port Royal University Clinic, Paris France (1986 – 1987) 80 INVO cycles vs. 80 IVF cycles Journal of In Vitro Fertilization and Embryo Transfer Vol. 7, No.1:6-8, 1990 Later supplemented 20 additional INVO and 20 additional IVF.	INVO = Fertilization rate = 60% = Clinical pregnancy rate = 22% PR = Live Births = 15% IVF = Fertilization rate = 58% = Clinical pregnancy rate = 23% PR = Live Births = 15%
# 3	Women's Hospital, Liverpool, England (1989 – 1992) 375 INVO cycles Bombay Hospital Journal, Vol.35, No.2:155-160, 1993	INVO = Fertilization rate = 52% = Clinical pregnancy rate = 18% PR = Live Births = 12%

# 4	University of Ulm, Germany (1998) 22 INVO couples vs. 23 IVF couples Human Reproduction, Vol.4,Sup:83-86, 1989.	INVO = Fertilization rate = 70% = Clinical pregnancy rate = 23% PC IVF = Fertilization rate = 63% = Clinical pregnancy rate = 17% PC
# 5	New England Fertility and Endocrinology Associates (1992) 51 INVO cycles (43 couples) Obstetrics and Gynecology, Vol.80, No.5:888-891, Nov. 1992	INVO = Fertilization rate = 84% = Clinical pregnancy rate = 10% PC
# 6	Eindhoven, The Netherlands (1990) 55 INVO cycles (40 couples) Elsevier Science Publishers, B.V. (Biomedical Division), pp. 349-351, 1990.	INVO = Fertilization rate = 50% = Clinical pregnancy rate = 14% PR
# 7	Institute of Reproductive Medicine, Santiago, Chile (1989) 23 INVO cycles (21 couples) Journal of In Vitro Fertilization and Embryo Transfer Vol.8, No.6:360-361, 1991	INVO = Fertilization rate = 50% = Clinical pregnancy rate = 14% PC
# 8	University of Arkansas, Little Rock, Arkansas (1993 – 1997) 106 INVO cycles Poster Presentation (P-156), Annual Meeting of the American Society for Reproductive Medicine, Oct. 1997.	INVO = Fertilization rate = 62% = Clinical pregnancy rate = 23% PT

** PC = per cycle, PR = per retrieval, PT = pre transfer*

The clinical data above show remarkable consistency in the fertilization rate, with an average of around 60%, and a clinical pregnancy rate of around 15% per cycle (around 25% per transfer). In total, more than 800 cases of the INVOcell procedure have been documented in peer-reviewed journals since the 1980s. All of these studies are over a decade old; some are two decades old. Since the time of this data, IVF has undergone many scientific improvements in culture media, ovarian stimulation drugs, and control of the timing of ovulation. These improvements have also been positive for the INVO procedure, and have allowed management at INVO Bio to improve the outcome from the 15% clinical pregnancy rate noted above.

For example, recently, management released data from 65 patients in an ongoing study begin conducted by the Center of Fertility and Sterility located in Bogota, Colombia (CECOLFEF). The data showed that 37% of the study participants achieved clinical pregnancy (fetal heartbeat at seven weeks). This clinical pregnancy rate of 37% compares favorably to the 39% rate we noted above for IVF. Additionally, the data showed only a 12% multiple births rate, about half that of what is typically seen with IVF.

…Commercial Data…

In August 2009, management provided an update on the commercial success of INVOcell based on 85 cycles around the world. The data demonstrated a 24% clinical pregnancy rate, showing improvement over the original pre-approval studies conducted in the 1980s and 1990s.

Counties	# of Cycles	# of Clinical Pregnancies	Success Rate
Austria	5	2	40%
Columbia	6	2	30%
India	3	1	33%
Pakistan	60	12	20%
Peru	4	1	25%
Spain	3	1	33%
Venezuela	4	1	25%
Total	**85**	**20**	**24%**

There is clearly more data to come. Recently, both the US National Institute of Health (NIH) and the World Health Organization (WHO) have approved a planned 100 patient study in Pakistan. This program started during the first quarter 2010, and is being conducted by Galaxy IVF in three INVO centers. We expect an update on this program later in 2010.

…Regulatory Status & Manufacturing…

INVO Bio has contracted out the manufacturing for the INVOcell device in an effort to keep overhead costs down. Packing and labeling, as well as sterilization of the device have also been contracted out to an ISO certified manufacturers. At the end of 2009, the company had 300 INVOcell devices ready for sale, and another 9,000 devices molded and ready for assembly, sterilization, and packing.

In May 2008, INVO Bioscience has obtained a CE Mark "Declaration of Conformity" certification that permits the sale of the INVOcell devices in the European Union, Canada, Australia, New Zealand, and other countries that recognize the CE Mark, subject to local registration requirements, including Latin America and the Middle East. The device is also ISO 13485 registered, which represents a comprehensive quality control and management system for medical devices and in-vitro diagnostic devices.

In August 2010, management began the commercial registration process with the State Food and Drug Administration (SFDA) of the Peoples Republic of China (PRC). The company's exclusive distribution partner in the PRC, the Progressive Group, has determined after meetings with the SFDA that the regulatory agency may confer a Class 2 medical device classification on INVOCell, thereby exempting INVO Bioscience from conducting clinical trials to complete the approval process. To begin sales in China, the company must receive a Certificate of Free Sale from the country of origin. Since not yet approved in the U.S., INVO is looking to work with a contract manufacturer in Europe where the device is CE Marked. We anticipate that the device could be on the market in China by 2012. China represents an attractive opportunity for the company. There are an estimated 30+ million infertile couples with access to IVF centers in China. However, use of IVF in China is limited due to the high cost and potential for multiple births. The introduction of INVOcell could greatly enhance the market and provide meaningful revenues in the future.

In October 2010, INVO announced that it has signed an agreement with Canadian-based Invaron Pharmaceuticals for the exclusive distribution of INVOcell in Canada. We believe this could represent a meaningful near-term revenue driver for INVO Bio given the growing infertility rates and Canada and recently implemented reimbursement policy that dramatically improves patient access to assisted reproductive procedures. INVO Bio received Health Canada Regulatory Approval in 2009. The device is CE Mark approved in Europe and Canada and conforms to all consumer health and safety requirements.

There are approximately 27 fertility centers in Canada licensed to perform assisted reproductive procedures. INVO Bio's more natural alternative to IVF is an attractive option for the estimated 1 million infertile couples in Canada. Plus, with approval and now distribution in place, the door is open to the estimated 8 million infertile couples in the U.S. and 10 million Europe to travel to Canada should they chose to seek INVOcell.

Recently, the provincial government of Quebec has initiated the funding of up to three assisted reproductive cycles for residents of the province. Fertility centers in Quebec are currently administering approximately 1,850 cycles annually. By 2014 provincial officials predict that the annual number of embryo-implant cycles administered will grow to between 7,000 and 10,000 in the Quebec province alone due to the new reimbursement policy. INVO Bio's INVOcell device represents an excellent low start-up-cost alternative to help these centers meet the potential surge in demand for assisted reproductive procedures.

In the U.S., INVO Bio is currently seeking U.S. regulatory clearance from the FDA for the INVOcell device. The company has completed the first steps in the process for filing of a Premarket Notification with the FDA, which include completing all developmental testing and pre-trial testing for the 510(k) submission. The FDA has requested a clinical study to be conducted in the U.S. prior to granting final clearance in the U.S. We expect that this program will enroll roughly 75 patients once it begins. Management has an open Investigation Device Exemption (IDE) and can begin this study at any time. However, since the study will costly, we estimate roughly $1 to $1.5 million, management remains focused on growing product sales in the international market and securing additional funding prior to initiation. One option for additional funding is to apply for a federal R&D tax credit research grant. This grant could pay for up to 50% of the development costs.

We believe that once initiated, the study will take 12 months to complete, with another 3 months to prepare and file the 510(k) application. Assuming 3 to 6 months for the FDA to respond, it is possible that if management begins this study in 2011, we could be looking at U.S. regulatory action during the second half of 2012.

…Distribution & Pricing…

The company's strategy is to target markets based on size, availability of alternative treatment options, access to medical care, pricing and reimbursement for assisted reproductive technologies (ART). Other factors, including medical device regulatory requirements and gamete handling regulations also play an import role in determining which markets to target for distribution and sales of INVOcell.

Typically, the first step in to targeting a country or region is to begin the process for obtaining regulatory clearance. Management begins by finding a distribution partner and key opinion leaders (KOL) in the area of infertility, and then working to train the sales staff and KOLs on use of the device for the initial clinical studies. Once the data has been collected from the clinical studies, it is packaged and filed to the regulatory authority. Once cleared for sale, the product is launched with the backing of the distribution partner and the KOLs.

Management has shown that greater the number of physicians trained and comfortable with the device, the steeper the ramp in sales. Typically it takes 9 to 12 months before INVO recognizes meaningful sales in a territory. Management's goal is to obtain a 5% market share in 5 years. However, to do this, awareness and physician education must be high (>70%). Dr. Claude Ranoux, CEO, has traveled extensively in 2009 to train physicians and distributors, hold workshops, and participate in conferences. Dr. Ranoux has had training, information workshops, interviews and articles, and lectures in Columbia, Peru, Venezuela, Argentina, Guatemala, Togo, Austria, Turkey, Pakistan and India throughout 2009.

Much of the initial marketing and advertising to increase awareness for the device is done at medical conferences. Recent events in which the company has attended include the European Society of Reproduction and Embryology, the American Society of Reproductive Medicine, The Middle Eastern Fertility Society, The Latin America Reproductive Association, and The First Congress of GIERAF in Africa.

In 2009, INVO Bio made significant progress in expanding its sales and distribution for the INVOcell device in territories recognizing the CE Mark certification. The company has also been working to gain final regulatory clearance in areas where additional work was required to supplement the CE Mark. In total, INVO Bio has begun to establish a presence in more than 30 countries on 5 continents. South America represents the ideal initial market opportunity for the company. The populations of countries such as Columbia and Peru have high infertility rates and limited access to IVF due to cost. Of note, the company has the following distribution agreements:

Distributor	Countries	Status
Nacer	Peru	1 center open, 4 more trained
CGA/Medicult	Italy, Spain	Negotiations and Registration
Delfran Pharma	Southern Africa	Negotiations, no Registration needed
Biogenini	Bulgaria	Training scheduled
Daxley Group	Brazil, Argentina, Colombia, Venezuela, Ecuador, Panama, Guatemala, Chile, and Uruguay	8 centers started, 12 more trained
Medek Medikal	Turkey, Cyprus, Kosovo, Albania, Uzbekistan, Azerbaijan, Bulgaria, Kazakhstan	Clinical trials
Galaxy IVF	Middle East, Pakistan, Egypt	4 centers open, 8 more trained
EnviMed	Thailand	Registration
PIK Progressive Group	China, Taiwan, Hong Kong	Registration
Invaron Pharma	Canada	Launched!
None	Togo, Cameroon, Benin	Finding distributor / Ship direct
None	Spain, Austria	Finding distributor / Ship direct
None	India	Negotiations, Registered
None	Greece	Negotiations, Registered
None	South Africa	Negotiations, Registered
None	Russia	Negotiations and Registration

The price for the INVOcell device is determined through discussions with an advisory board of physicians and strategic partners in each country or region. Management factors in savings in physician's laboratory fixed costs and the amount that a physician will receive from patients to perform INVO. The company's goal is to have the INVO procedure offered to infertile couples as a lower cost alternative with comparable success rates to IVF, but still reflect the innovative features of the device. The price of the INVOcell device and its retention system varies significantly from market to market, ranging between $75 and $400 per unit. IVF centers or Ob/Gyn groups purchasing a large number of devices and promoting the INVO receive discounted prices and a limited amount of free advertising for their facility on the INVO Bioscience website.

It is expected that the INVOcell will sell for $400 in the U.S., which grants a single-use license under the company's patents. In Central and South America and Europe, the price of the device is between $100 and $300 to reflect a generally lower cost of infertility procedures in most of these countries and to make INVOcell available to populations with lower incomes. The holding blocks are sold as a tool for viewing and retrieving the embryos from the inner chamber. Each physician will need a minimum of two blocks depending on the number of cycles he/she performs. The blocks cost approximately $200 per block.

The fixed laboratory equipment used in the INVO procedure (microscope with video system, bench centrifuge, incubator without CO_2, bench warmer and laminar flow hood) is readily available in the market. Management has had initial discussions with an international equipment supplier that has a mobile bench and hood with all the required equipment. The company intends to establish an agreement with this company to provide customers with a discount and financing to facilitate new entry into the INVO market in the future.

…Sales…

Above we noted the market opportunity for the INVO procedure is significant. In markets where the device has been cleared via CE Mark certification (Europe, Canada, Australia, New Zealand, Latin America, and the Middle East), we estimate there are at least 60 million couples battling with infertility.

In the next few years, the company hopes to penetrate into two of the largest markets for infertility, India and Russia. India is an extremely attractive opportunity for INVO with an estimate 15 million infertile couples. India has yet to adopt IVF due to a lack of physician support, funding, and an unreliable electric power infrastructure. The INVO procedure, with its localized Ob/Gyn focus and lack of reliance on electric power could be a significant share gainer in India. In Russia, a country losing approximately 7% of its population each year has one of the highest infertility rates in the world. There are an estimated 10 million infertile couples in Russia. The Russian government is giving incentives to couple to have children and is looking for a low cost infertility treatment. Above we noted the potential to enter China is 2012, another highly attractive market.

The majority of these couples will start out trying less invasive ART, including hormonal treatments. Most then move to IUI, and then IVF. INVO Bio's goal is to position the INVO procedure as cost-comparable to IUI with superior results. Management's strategy is to not compete directly with IVF, but instead be an alternative treatment to couples who currently do not have access to treatments because of cost or location. Additionally, infertility clinics can expand their businesses by offering INVO in satellite centers that can be opened at a substantially lower cost than an IVF center.

INVO Bio generated $38,000 in revenues in 2008 and $63,000 in revenues in 2009, all from sales of the INVOcell device and holding block outside the U.S. We estimate the total addressable market outside of the U.S. and Europe is roughly 80 to 100 million. If management can achieve their goal of 5% market share, there are an estimated 4 million potential INVOcell users outside of the big two markets. Right now management is focusing on generating sales – and clinical data – in South America. We expect the next target markets for INVOcell will include several Eastern European countries, including Bulgaria, Romania, Albania, Turkey, and Russia. Once management can show progress in these markets, we believe it becomes more likely that a larger (pan-European) distribution partners becomes interested in targeting the big five (UK, France, Germany, Italy, and Spain) countries, and eventually China, Taiwan, and Hong Kong.

Sales in the first quarter 2010 were $26,820, in-line with expectations. However, sales in the second quarter were only $11,172, far below expectations. Management hit somewhat of a funding shortfall in the second quarter. Management was working to repay a working-credit loan with Century Bank, and this along with the tough economic environment, forced management to slow marketing and promotional spend significantly. Sales of the INVOcell device are highly depended on education and awareness. The senior management, including founder Claude Ranoux and CEO Katie Karloff, are the ones travelling around the world to promote the device. When promotional activities fall, sales follow. We expect the funding situation to improve in the second half of the year, and thus the company should be back out on the road promoting the product. This should lead to improved sales in the second half of 2010 and into 2011.

Zacks	**Q1**	**Q2**	**Q3**	**Q4**	**2010**	**2011**	**2012**
	$26.8k A	**$11.2k A**	**$15k E**	**$20k E**	**$69k E**	**$155k E**	**$325k E**

…Intellectual Property…

There are five active patents worldwide that cover the INVOcell device, the INVO process, and the holding block for microscopic embryo inspection. These patents include:

- BIE-113394: U.S.PTO # 5,084,004: Process for intra-uterine fertilization in mammals and device for implementation thereof.
- BIE-114519: U.S.PTO # 5,532,155: Spontaneous cycle fertilization.
- BIE-117061: U.S.PTO # 6,050,935: Container assembly for Intravaginal fertilization and culture and embryo transfer and method of Intravaginal culture employing such a container.
- BIE-117249: Applied No. 10/360,630: Incubation and / or storage container system and method.
- BIE-117771: Applied Nov. 2008: Inspection Block for use in microscopic inspection of embryos or other biologic matter inside a container unit.

VALUATION & RECOMMENDATION

Still Positive Despite Poor Second Quarter…

In June 2010, we initiated coverage of INVO Biosciences with an 'Outperform' rating and price target of $0.25 per share. We are maintaining that recommendation today, despite the poor results in the second quarter. Our expectations are that the company will be able to secure funding in the next few weeks to support greater marketing and promotional spend in the third and fourth quarter, which should lead to greater sales of the INVOcell device.

We believe that the company has built a superior device for the treatment of infertility. The INVOcell device has been elegantly designed to provide improved efficacy over interuterine insemination (IUI) at a similar cost. In fact, recent trial results demonstrate the INVO procedure has a clinical pregnancy rate similar to that of in vitro fertilization (IVF), a procedure that costs twice the price. Additionally, the INVO procedure provides several advantages when compared to IVF, including lower risk of ovarian hyperstimulation syndrome, lower risk of anesthesia complications, and wider applicability and availability for infertile couples. The INVO procedure also provides a far more personalized and natural approach to conception than IVF.

	IUI	INVO	IVF
Cost Per Pregnancy	$12k to $16k	$9k to $16k	$17k to $35k
Pregnancy Rate	~10%	~37%	~39%

The INVOcell device is rationally designed to address the challenges faced by couples with infertility. As noted above, the IVF procedure is rather expensive. INVO provides a lower-cost alternative without significant loss in efficacy. IVF centers are both human and capital intensive; thus, the majority are found in major cities near hospitals. We believe that INVO option is an attractive to couples and physicians because an INVO center can be set up at low cost inside the Ob/Gyn's office. This greatly increases the demographic and socioeconomic reach of the procedure, especially overseas in under-developed counties such as India, Pakistan, South America, and Eastern Europe where infertility rates are above 15%.

Management is currently in the process of launching INVO around the world. The device is ISO-13485 certified and CE Mark approved for sale in Europe and Canada. Key markets where the device is available include Canada, Austria, Columbia, Pakistan, Peru, Columbia, Brazil, and Argentina. Registration activities have begun in China. For these territories where registration has been complete, management has signed distribution partners and is working with physicians to train them on the procedure. The company is in talks with potential distribution partners in India, Russia, and South Africa. In the U.S., INVO Bioscience has completed the first steps for filing of a Premarket Notification with the FDA for a Class 2 medical device. The FDA has reviewed the 510(k) application and requested human clinical trial. INVO is currently focusing on the international market while is seeks funds to conduct the U.S. registration program. We believe this program could begin in 2011 once funds are secured.

According to the European Society of Human Reproduction and Embryology (ESHRE), in 2007 there were an estimated 150 million couples worldwide with infertility. Based on the significant limitations discussed above for IUI and IVF, only around 0.5% seek treatment, leaving an estimated 149 million couples untreated. In the U.S., there are an estimated 7.5 million couples battling infertility. The number in Europe stands around 10.0 million. Areas outside of the U.S. and Europe do not fare as well. For example, in the Middle East, Russia, India, and Pakistan, infertility rates are near 20% due to widespread and untreated sexually transmitted disease (STDs), and a lack of IVF centers. In Pakistan, a country with 172 million people and 25% infertility rates, there are only 5 main IVF centers. India is a country with 1.1 billion people and 20% infertility rates; there are an estimated 30 million people that could benefit from a low-cost and effective option. Russia, a country with 140 million people has seen its population decline in recent years thank in part to its high infertility rate. Between the U.S., E.U., Australia, Japan, and developed areas of India, China, Russia, Pakistan, the Middle East, and South America, we estimate there are 80 to 100 million couples that could be potential users of the INVO procedure.

Assuming a blended worldwide price of around $250 per device, plus the costs of the warming blocks, if management were able to capture just 10% of the current market, peak sales of the device are $15 million. At the current market value of only $3 million, we believe that this opportunity at INVO Bio is dramatically under-appreciated by Wall Street.

MANAGEMENT PROFILES

Kathleen Karloff, Chief Executive Officer, Secretary and Director
Ms. Karloff co-founded INVO Bioscience in January 2007. Since this time, Kathleen has obtained ISO certification and the CE mark for the INVOcell device and has implemented manufacturing and distribution systems. From 2004 until September 2006, Kathleen was the Vice President of Operations for Medelle Corporation. From 2000 through 2003, Kathleen was the Vice President of Operations for a start-up company Control Delivery Systems developing an intra-ocular drug therapy for Uveitis and Diabetic Macular Edema. The Company was acquired by Psivida LTD. Prior to that; she has held various positions at Boston Scientific during 13 years of dynamic growth from 1983 to 1997 her last position being the Director of Manufacturing. Since leaving Boston Scientific, she has been Vice President of Operations on startup teams of three device/pharmaceutical companies. Ms. Karloff earned her B.S. in microbiology from Montana State University and attended Northeastern University for MBA coursework.

Claude Ranoux, M.D., M.S., President, Treasurer and Director
Dr. Ranoux co-founded INVO Bioscience in January 2007. He has more than 30 years of experience in the research and treatment of infertility; he is the inventor and developer of the INVO procedure and INVOcell device. From 2000 through 2005, Dr. Ranoux was president of Medelle Corporation and worked on development of the INVOcell. Dr. Ranoux has built and run 12 IVF centers worldwide and has established 12 reproductive centers worldwide. Before founding INVO Bioscience, Dr. Ranoux had 6 years of experience in creating and finding financing for a start-up company. He has been scientific consultant for a new instrument (Immuno1) from Bayer Corporation. Dr. Ranoux was the founder of several non-profit organizations and foreign trade advisor in the New England area. Dr. Ranoux earned his M.D. and his M.S. in Reproductive Biology from the Medical University of Paris (V & XI) where he was an Associate Professor. Dr. Ranoux has served as a scientific consultant for eight other centers and is the author of numerous scientific publications as first author. He has given numerous invited lectures, conferences and workshops and is the author of five medical and scientific theses and mentor for several others. He is co-author of six scientific and medical films. He received a prize for the one of the best scientific presentation at the Fifth World Congress in IVF, in Norfolk, VA, and is the recipient of several other awards. Dr. Ranoux is the main inventor in six international patents.

Robert J. Bowdring, Chief Financial Officer
Mr. Bowdring joined the company as its Corporate Controller in October 2008. In January 2009, the Company appointed Mr. Bowdring as its Chief Financial Officer. From April 2003 to August 2008, Mr. Bowdring served as Vice President of Finance and Administration for Cyphermint, Inc., a software development firm. For the fourteen prior years, he was the Controller and Vice President of Lifeline Systems Inc., a public manufacturing and service company (NASDAQ: LIFE) in the personal emergency response market. Mr. Bowdring has a strong history in senior financial management with more than 25 years experience serving in capacities such as chief financial officer, vice president of finance and controller. Rob has been in both public and private manufacturing and service companies during his career. Mr. Bowdring has a Bachelors degree in Accounting from the University of Massachusetts in Amherst.

PROJECTED FINANCIALS

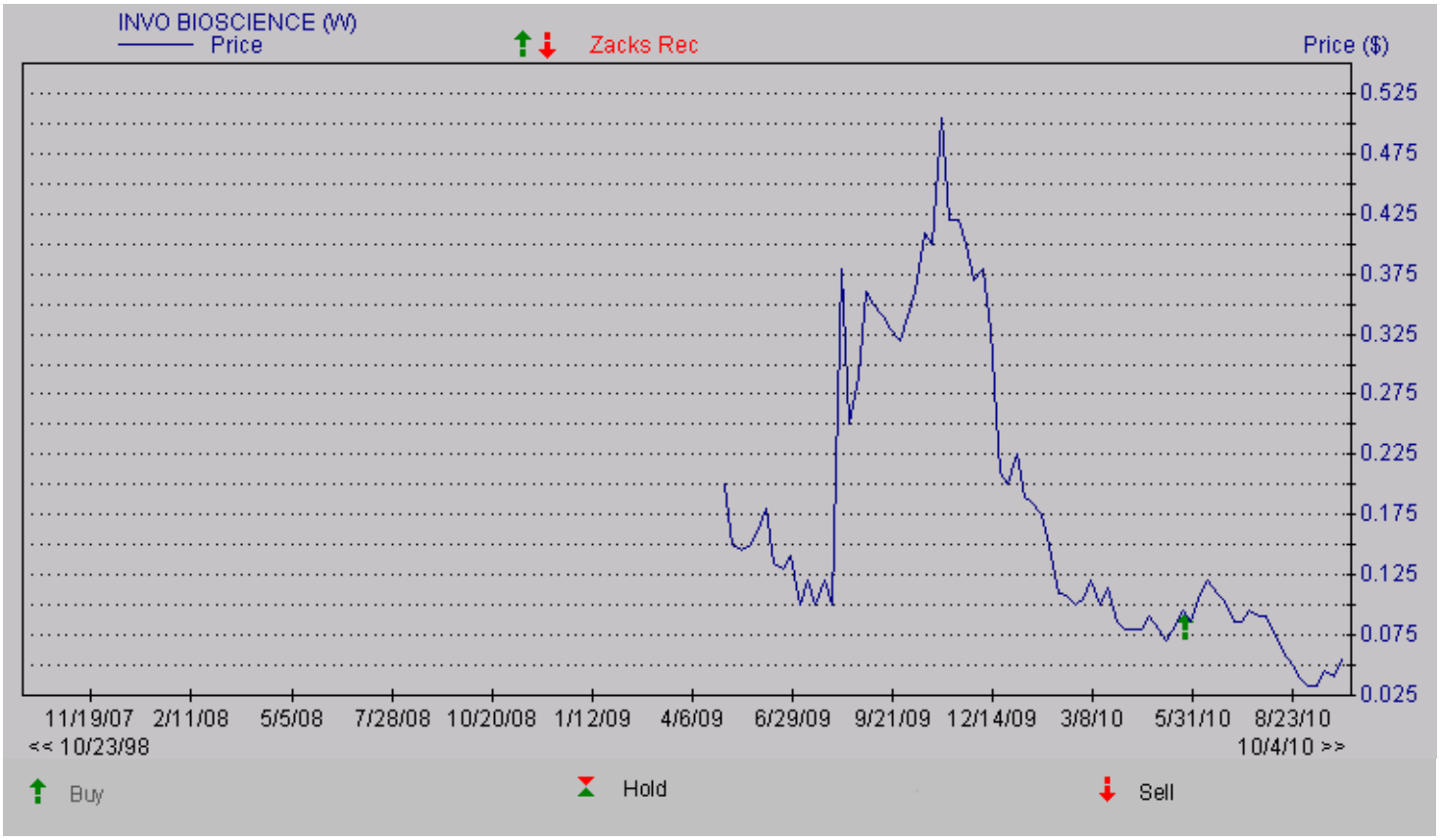
INVO Bioscience, Inc.
Income Statement

	2008 A	2009 A	Q1 A	Q2 A	Q3 E	Q4 E	2010 E	2011 E	2012 E	2013 E
Product Revenues	**$0.038**	**$0.063**	**$0.027**	**$0.011**	**$0.015**	**$0.020**	**$0.069**	**$0.095**	**$0.155**	**$0.325**
YOY Growth	-	*66.3%*	*-27.1%*	*-32.8%*	*425.9%*	*189.6%*	*9.8%*	*36.8%*	*63.2%*	*109.7%*
Total Revenues	**$0.038**	**$0.063**	**$0.027**	**$0.011**	**$0.015**	**$0.020**	**$0.069**	**$0.095**	**$0.155**	**$0.325**
YOY Growth	-	*66.3%*	*-27.1%*	*-32.8%*	*425.9%*	*189.6%*	*9.8%*	*36.8%*	*63.2%*	*109.7%*
Goods / Product Costs	$0.011	$0.041	$0.008	$0.004	$0.005	$0.006	$0.023	$0.029	$0.047	$0.098
Product Gross Margin	*100.0%*	*34.5%*	*69.0%*	*67.8%*	*69.0%*	*68.0%*	*66.9%*	*69.0%*	*69.5%*	*70.0%*
SG&A	$1.838	$1.857	$0.447	$0.318	$0.375	$0.420	$1.559	$1.750	$2.000	$2.150
% SG&A	-	-	-	-	-	-	-	*1842.1%*	*1290.3%*	*661.5%*
R&D	$0.052	$0.008	$0	$0	$0	$0	$0	$0.150	$0.200	$0.250
% R&D	-	-	-	-	-	-	-	*157.9%*	*129.0%*	*76.9%*
Operating Income	($1.862)	($1.843)	($0.428)	($0.310)	($0.365)	($0.406)	($1.513)	($1.834)	($2.092)	($2.173)
Operating Margin	-	-	-	-	-	-	-	*-1931.0%*	*-1349.9%*	*-668.5%*
Interest & Other Net	($0.012)	($2.819)	$1.299	($0.081)	($0.006)	($0.008)	$1.204	($0.050)	($0.050)	($0.050)
Pre-Tax Income	($1.874)	($4.661)	$0.871	($0.391)	($0.371)	($0.414)	($0.309)	($1.884)	($2.142)	($2.223)
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($1.874)	($4.661)	$0.871	($0.391)	($0.371)	($0.414)	($0.309)	($1.884)	($2.142)	($2.223)
YOY Growth	-	-	-	-	-	-	*-93.4%*	*509.6%*	*13.7%*	*3.7%*
Net Margin	-	-	-	-	-	-	-	*-1983.6%*	*-1382.1%*	*-683.8%*
Reported EPS	**($0.05)**	**($0.09)**	**$0.01**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.00)**	**($0.03)**	**($0.03)**	**($0.02)**
YOY Growth	-	-	-	-	-	-	*-94.2%*	*443.7%*	*-0.5%*	*-7.8%*
Shares Outstanding	36.7	54.7	60.2	61.5	63.0	65.0	62.4	70.0	80.0	90.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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