Zacks Equity Research

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INVO Bioscience

(IVOB-OTC)

IVOB: Focusing On South America, But Sledging Remains Tough…

UPDATE

Although sales of the INVOcell device have been low, the clinical data begin generated by post-approval marketing studies around the world has been impressive. The company is specifically focusing on South America right now, recently having made shipments into Bolivia and Brazil. Data flow should improve over the next several quarters, and thus we believe sales will start to trend higher. However, priority number one for management is to secure funding over the near-term for operations and the filing of the U.S. 510(k) application. We are waiting for an update on this and recommend investors keep INVO on their radar for potential good news later this year. Our target is 10 cents.

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	01/26/2011
Current Price (01/26/11)	$0.04
Target Price	**$0.10**

SUMMARY DATA

52-Week High	**$0.17**
52-Week Low	**$0.03**
One-Year Return (%)	**-71.50**
Beta	**1.37**
Average Daily Volume (sh)	**107,215**
Shares Outstanding (mil)	**66**
Market Capitalization ($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	**88 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 A	0.02 E	0.05 E
2011					0.06 E
2012					0.09 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	-$0.00 A	-$0.01 E	-$0.00 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

Moving Forward In South America

…Brazil…

On January 25, 2011, INVO Bio announced it had commenced a 40 patient clinical study in Rio de Janeiro, Brazil to establish safety, efficacy and comparative in-vitro fertilization (IVF) measures of its INVOcell device. The trial design has been submitted to the Federal Ethics Committee in Brazil for approval. Once completed, clinical study will be submitted to the National Health Surveillance Agency (ANVISA) for the purpose of gaining registration and approval for the sale of the INVOcell device in Brazil. INVOcell has been designated a Class-2 device in Brazil, which requires clinical data obtained in Brazil for submission, registration and approval of the device by ANVISA.

We note that this 40-patient trial is being sponsored and conducted by Dr. Francisco Augusto Colucci Coelho of the Center of Infertility and Fetal Medicine of North Rio de Janeiro, Brazil. Along with the announcement of the trial, management also noted the first trial patient has been treated utilizing the INVOcell device and procedure. An ultrasound exam performed eight weeks after the INVO procedure detected a fetal heart beat confirming a clinical pregnancy. Enrollment for the remainder of the trial population is expected to be completed within four months. Final results of the Brazilian clinical trial, along with the recently announced clinical trial results from Dr. Elkin Lucena of the Colombian Fertility and Sterility Center (CECOLFES) in Colombia, South America, will be submitted to ANVISA for registration and approval.

South America represents the ideal market opportunity for INVO Bio – high infertility rates, access to IVF centers, low-cost, and potential for rapid adoption among doctors and couples given a desire for a more natural approach to fertilization. In Brazil, there are more than 125 fertility centers licensed to perform assisted reproductive procedures. According to the Brazilian Ministry of Health there are more than 15 million infertile couples in Brazil, with less than 1% of these couples actively seeking treatment.

…Columbia…

Studies conducted by Dr. Elkin Lucena of the Columbian Fertility and Sterility Center (CECOLFES LTDA) in Bogota, Columbia, recently offered up impressive data at the 66th American Society of Reproductive Medicine (ASRM) meeting in late October 2010. The results were impressive, demonstrating a 43% clinical pregnancy rate per INVOcell cycle and 48% clinical pregnancy rate when an embryo was transferred. The data was taken from first 95 women ages 21-45 that have enrolled in the program at CECOLFES.

Clinical Pregnancy Rate	
…per INVOcell Cycle (all women)	43%
…per Cycle (when embryo was transferred)	48%
…per Cycle (women < 40 years)	46%

The data compares fantastically well to clinical pregnancy rates per cycle when *in-vitro fertilization* (IVF) is used. Data compiled by the U.S. Center for Disease Control (CDC), the Society for Assisted Reproductive Technology (SART), and Canadian Health Ministry show clinical pregnancy rates for IVF range from 35% to 45%. What is impressive for the CECOLFES results is that multiple pregnancies occurred in only 10% of the patients in the study, compared to 25-30% multiple pregnancies that occur in more traditional fertility treatment regimes such as IVF. Multiple pregnancies can cause very serious and expensive complications, especially for women above the age of 35 years. Pregnancy using the INVOcell device also eliminates the potentially dangerous need for intra-cytoplasmic sperm injection (ICSI) – where a single sperm is injected into an egg to achieve fertilization – which can result in the injection of potentially unhealthy or low-motility sperm (i.e no natural selection).

…Peru…

During the third quarter 2010, a study being conducted by Dr. Julio Diaz Pinillos at the Lima Center for Human Reproduction in Lima, Peru initiated. The study is looking enroll approximately 100 couples. Dr. Pinillos indicated that he started out slow but has been making significant improvement on enrollment over the past month. We are anticipating completion of this program during the first half of 2011.

...Bolivia…

In December 2010, INVO announced it has completed an initial shipment of the INVOcell device into Bolivia. The initial order of INVOcell devices was purchased by The National Center for Fertility and Sterility (CENALFES). CENALFES is the largest infertility treatment center in Bolivia, having assisted more than 4,000 infertility patients over the past 20 years resulting in more than 1,500 births. Bolivia has approximately 5 fertility centers licensed to perform assisted reproductive procedures. According to the Bolivian Health Ministry there are more than 1.8 million infertile couples in Bolivia, however less than 1,000 couples per year engage in assisted reproductive procedures, largely due to costs.

…More To Follow…

Management reported being in conversation with several other countries around the world on potential marketing studies in 2011. These studies are instrumental in continuing to build awareness and generate data from the company's planned U.S. 510(k) submission in 2011. As a reminder, INVOcell is approved and available for sale in Canada, Colombia, Guatemala, Belgium, Greece, Bulgaria, Turkey, Poland, Spain, Switzerland, Cyprus, Pakistan, Cameroon, Nigeria, South Africa, Peru, Panama, Dominican Republic, Nicaragua Ukraine and India. Management has started the registration process in China, Argentina, Venezuela, Egypt, Russia, and Taiwan.

North America Next

…Canada…

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 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.

Invaron Pharmaceuticals is planning to conduct a marketing study with INVOcell at various centers around Canada in 2011. We are particularly excited about this opportunity because data generated in Canada should be well-received by the U.S. FDA.

…United States…

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. Previously, the FDA had requested a clinical study to be conducted in the U.S. prior to granting final clearance in the U.S. However, since that time the company has been able to collect a significant amount of data from post-approval marketing studies around the world – most notably 95 patients from CECOLFES in Columbia. Management believes that once additional data from the 100 patients in Peru becomes available, it is worth having a conversation with the FDA about filing the 510(k).

Sometimes the best way to get the FDA to formally respond and qualify what is necessary for final approval is through an actual filing. Therefore, we would not be surprised to see the company submit a 510(k) application for INVOcell in the U.S., assuming they can compile the data from roughly 200 patients or so from Columbia and Peru, around the middle of 2011. The FDA should respond in six to nine months, either with outright final approval or through a response letter notifying INVO Bio what clinical data is necessary for the PMA. We remind investors that INVO has an open Investigation Device Exemption (IDE) and can begin a study, if necessary, at any time

Should the FDA still require a U.S. clinical study, we expect that this program will enroll roughly 75 to 100 patients total at IVF centers around the U.S. We believe that once initiated, the study will take 12 months to complete. Unfortunately, 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. We note that management is currently in talks with potential interested parties in the U.S. to potentially help fund the study, either through a co-promotional agreement or an equity stake that supplies the necessary cash to complete the trial.

INVESTMENT THESIS

Although we are disappointed with the lack of sales in the third quarter 2010, we understand the situation has been resolved and orders placed in the third quarter were shipped in mid-October 2010. According to management, this backlog was slightly larger than the $11,000 in total sales during the second quarter 2010. Therefore, we model a total of $15,000 in revenues for the fourth quarter 2010.

Despite INVO's desperate need for cash, there are clear signs of progress being made. The data from CECOLFES presented by Dr. Elkin at ASRM was fantastic. A 43% clinical pregnancy rate with only 10% multiple births has the potential to take significant market share from in vitro fertilization (IVF) based on cost, personalization, and access.

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. 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. Additionally, the INVO procedure 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%	~40-45%	~35-45%

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 $2.5 million, we believe that this opportunity at INVO Bio is dramatically under-appreciated by Wall Street. We currently have a 'Neutral' rating and $0.10 target while we wait for positive signs on the cash and sales front.

PROJECTED FINANCIALS

INVO Bioscience, Inc.
Income Statement

	2008 A	2009 A	Q1 A	Q2 A	Q3 A	Q4 E	2010 E	2011 E	2012 E	2013 E
Product Revenues	**$0.038**	**$0.063**	**$0.027**	**$0.011**	**$0**	**$0.02**	**$0.049**	**$0.055**	**$0.085**	**$0.125**
YOY Growth	-	*66.3%*	*-27.1%*	*-32.8%*	*-100.0%*	*117.2%*	*-21.8%*	*11.3%*	*54.5%*	*47.1%*
Total Revenues	**$0.038**	**$0.063**	**$0.027**	**$0.011**	**$0**	**$0.02**	**$0.049**	**$0.055**	**$0.085**	**$0.125**
YOY Growth	-	*66.3%*	*-27.1%*	*-32.8%*	*-100.0%*	*117.2%*	*-21.8%*	*11.3%*	*54.5%*	*47.1%*
Goods / Product Costs	$0.011	$0.041	$0.008	$0.004	$0.002	$0.005	$0.018	$0.017	$0.026	$0.038
Product Gross Margin	*100.0%*	*34.5%*	*69.0%*	*67.8%*	*0%*	*68.0%*	*62.7%*	*69.0%*	*69.5%*	*70.0%*
SG&A	$1.838	$1.857	$0.447	$0.318	$0.363	$0.420	$1.547	$1.750	$2.000	$2.150
% SG&A	-	-	-	-	-	-	-	*3181.8%*	*2352.9%*	*1720.0%*
R&D	$0.052	$0.008	$0	$0	$0	$0	$0	$0.150	$0.200	$0.250
% R&D	-	-	-	-	-	-	-	*272.7%*	*235.3%*	*200.0%*
Operating Income	($1.862)	($1.843)	($0.428)	($0.310)	($0.365)	($0.410)	($1.516)	($1.862)	($2.141)	($2.313)
Operating Margin	-	-	-	-	-	-	-	*-3385.5%*	*-2518.7%*	*-1850.0%*
Interest & Other Net	($0.012)	($2.819)	$1.299	($0.081)	$0.130	($0.008)	$1.339	($0.050)	($0.050)	($0.050)
Pre-Tax Income	($1.874)	($4.661)	$0.871	($0.391)	($0.235)	($0.418)	($0.177)	($1.912)	($2.191)	($2.363)
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)	($0.235)	($0.418)	($0.177)	($1.912)	($2.191)	($2.363)
YOY Growth	-	-	-	-	-	-	*-96.2%*	*979.9%*	*14.6%*	*7.8%*
Net Margin	-	-	-	-	-	-	-	*-3476.5%*	*-2577.6%*	*-1890.0%*
Reported EPS	**($0.05)**	**($0.09)**	**$0.01**	**($0.01)**	**($0.00)**	**($0.01)**	**($0.00)**	**($0.03)**	**($0.03)**	**($0.03)**
YOY Growth	-	-	-	-	-	-	*-96.7%*	*865.6%*	*0.3%*	*-4.2%*
Shares Outstanding	36.7	54.7	60.2	61.5	63.6	65.0	62.6	70.0	80.0	90.0

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

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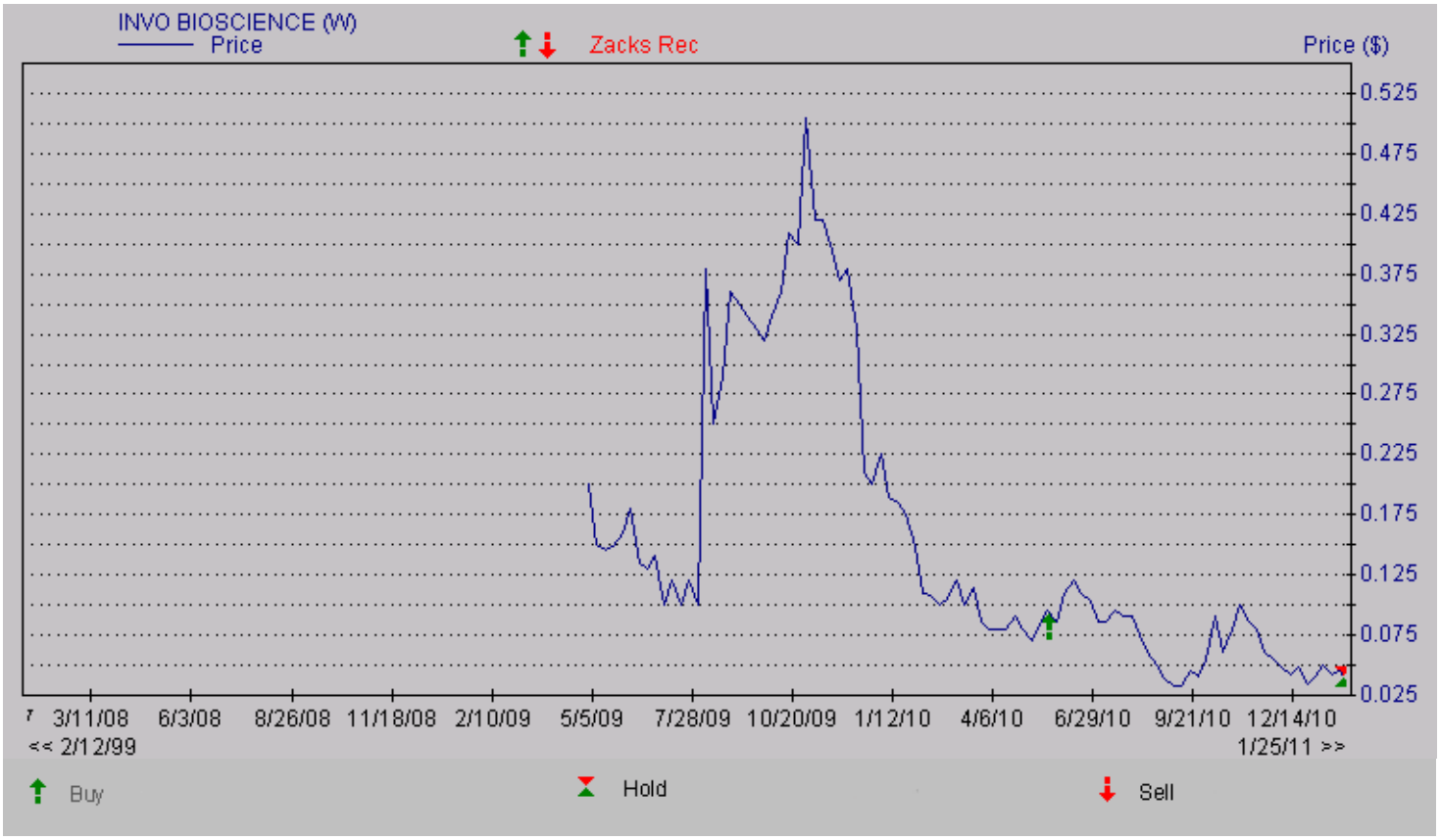

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