



Research & Investment Services

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Company Insight!

Industry: Biotechnology, Cardiac Medical Device MIV Therapeutics Inc. US\$0.2125

VERY ENCOURAGING 9-MONTH FIRST IN MAN STUDY DATA

For any medical device company, approval of its products for use in humans is an enormous corporate development. Currently, MIVT has two CE Mark bare metal stents (BMS) on the market and is targeting one of the fastest growing markets worldwide – India. After showing excellent results in preclinical studies, MIVT commenced its human clinical trials in May 2007 for its first polymer-free, nanoscale, microporous, hydroxyapatite-based product – the VESTAsync™ Coronary Drug Eluting Stent System. Excellent safety data, with no Major Adverse Coronary Events (MACE) and good efficacy data in a nine-month follow up of First-In-Man studies were reported on March 31, 2008. This positive study allows MIVT to continue to the next phase of human clinical trials, with the prospect of commercializing its drug eluting technology within 18 months. After a short period of explosive growth, the market for drug eluting stents (DES) experienced a correction. Uncertainties regarding the risk of late stent thrombosis due to the use of the device led to a decline in the use of DES. MIVT's goal is to restore confidence in drug-eluting stents with VESTAsync™ by combining the safety profile of bare metal stents with the efficacy of a drug-eluting stent. MIVT is an undiscovered company with a huge opportunity in a very large market. MIVT is significantly undervalued and we reaffirm our speculative buy rating and 12-18 month target price of \$2.50.

MIV Therapeutics Inc.

Consolidated Statements of Operation in US\$ ('000)

	FY06A 2. Qtr.	FY06A 3. Qtr.	FY06A YE	FY07A 1. Qtr.	FY07A 2. Qtr.
Revenues	0	1	191	302	250
G&A	832	1,371	6,595	1,780	1,930
R&D	767	698	3,731	1,160	1,201
Loss from Operation	1,779	2,436	10,478	3,241	3,590
Net Loss	1,779	2,383	10,499	3,135	3,424

Source: Company reports, business plan, SEC filings

Financial Data

FY 2008	Ends May 31, 2008
Market Capitalization	US\$ 23.9 million
Shares outstanding (01.11.2008)	112,309,004
Book Value/ Share (February 2007)	\$0.08
Price/Book Ratio	2.7 x
Est. 5 Year Earning Growth	N/A

Stock Data

52-Week Range	\$0.70 – 0.21
Symbol / Exchange	OTCBB: MIVT
1-Year Return	-64.4 %



INVESTMENT HIGHLIGHTS:

- ◆ **In November 2007**, MIVT received regulatory approval in India for the GenX™ Stainless Steel Coronary Stent and the GenX™ CrCo Chromium Cobalt Coronary Stent. This regulatory achievement permits MIVT to enter into one of the world's fastest growing stent markets. These products will be manufactured and sold through third party distributors in India, where coronary heart disease is a major health problem. According to a global study by the World Health Organization (WHO), India has the highest number of deaths from coronary heart disease in the world, exceeding 1.5 million in 2002. The WHO has predicted a cardiac epidemic for India by 2010.
- ◆ **On March 31, 2008, MIVT announced positive results from the nine-month follow up of its First-In-Man (FIM) study with its VESTAsync™**, a polymer-free hydroxyapatite-coated sirolimus-eluting stent system. This stent system achieved excellent safety and efficacy data, which is very remarkable in that these results were obtained with sixty percent less drug delivered from an ultra-thin, 0.6 micron coating that is entirely polymer-free. The data compares very favorably with FIM data generated by the currently available drug eluting stents, both in the US and worldwide. The positive results from the study allow MIVT to continue to the next phase of human clinical trials, with the prospect of commercializing its drug eluting technology within eighteen months. Uncertainties regarding the risk of late stent thrombosis due to the use of polymer coated stents led to a decline in the use of DES. Polymer coated stents may cause allergic reactions and place patients at a higher risk of heart attack. The VESTAsync™ stent system is definitely a candidate in restoring confidence in drug-eluting stents by combining the safety profile of bare metal stents with the efficacy of a drug-eluting stent.
- ◆ **Two months ago, MIVT received the 2008 Frost & Sullivan North America Award for Technology Innovation.** MIVT received this award primarily because the Company has innovatively leveraged a polymer-free approach to tackle the present day limitations of first- and second-generation stents to develop a product characterized by excellent biocompatibility, flexibility, and optimal drug delivery. The award acknowledges the importance of the future of advanced biocompatible coatings for drug-eluting applications using hydroxyapatite (HAp) on cardiovascular stents, as well as for a broad range of other implantable medical devices.
- ◆ **Today, MIVT is a undiscovered company with huge opportunities in very large markets.** The Company could solve a very large safety issue that is now becoming a public issue with drug eluting stents. If MIVT succeeds in bringing its technology to the market, the Company then has the potential to become a larger market player in a very large industry. The acquisition of Biosync helped the Company to immediately realize cash flow – a very important milestone, and combined with positive news from human clinical trials, further drives the Company's valuation. Despite very encouraging achievements during 2007 and 2008, MIVT currently trades at a market cap of only \$23.9M, 64.4% below its stock price one year ago and is therefore still massively undervalued. We reaffirm our twelve-month target price of \$2.50, but still maintain our Speculative Buy/4 rating.

COMPANY OVERVIEW

MIV Therapeutics, Inc., headquartered in Atlanta, Georgia was established in 1999 and today is a diversified advanced stage research and development company. The Company is aggressively pursuing commercialization of a third generation of biocompatible polymer-free coatings for cardiovascular stents and other implantable medical devices and drug delivery systems in collaboration with the University of British Columbia (UBC). MIVT has developed two HAp coatings that range in thickness from 100 to 500 nanometers. The first coating is non-porous and can be used as a biocompatible surface coating to protect the surrounding tissue from potential side effects caused by metals used in implantable medical devices. The second coating is porous and can be used as a biocompatible surface coating capable of delivering drugs to local tissue. MIVT's lead product incorporating this novel technology is a drug eluting stent (DES) aimed at addressing the drawbacks of the currently available DES and is in early human testing. Preclinical studies in late 2006 of two of the Company's novel biocompatible polymer-free drug-eluting stent coating technologies showed their performance matched or even outperformed Cordis' and Boston Scientific's polymer-based drug-eluting stents. The four-week porcine study, independently conducted at the Erasmus University Medical Center in the Netherlands, compared stents coated with MIVT's polymer-free drug-eluting technologies to the industry's benchmark, the J&J Cypher stent, one of the world's best selling drug-eluting stents. Three variations of MIVT's polymer-free sirolimus eluting coatings were at least as effective as – and in some cases, better than – Johnson & Johnson's Cypher drug-eluting cardiovascular stent. New encouraging data was released in November of 2007 from a previously presented animal study comparing the safety and efficacy of the Company's VESTAsync™ HAp coronary stent coating with low-dose sirolimus to the Cypher® Stent. The hydroxyapatite coating, eluting low dose sirolimus, showed less delayed healing but equal efficacy to Cypher in porcine coronary arteries. Summarized, hydroxyapatite is a safe coating and effectively releases sirolimus. These excellent results from preclinical studies have paved the way towards human trials, which began in May 2007.

Positive results from the four-month First-in-Man Angiographic and IVUS Follow-Up on thirteen patients in the fifteen-patient study were announced in October 2007. The results include excellent safety data, as all patients were thrombosis-free with zero restenosis and very good efficacy. This encouraging data compares very favorably with FIM data generated by the currently available drug-eluting stents both in the US and overseas. The patients' follow up with angiographic and IVUS data was completed and reported nine months after stent insertion on March 31, 2008.

The patients' follow up, with angiographic and IVUS data, was completed and reported nine months after stent insertion on March 31, 2008. The nine-month results from the FIM MIVT Pilot Trial of its VESTAsync™ drug-eluting stent suggest that the stent has the potential for superior safety and equivalent efficacy when compared with currently available drug-eluting stents. The study concluded that there were no significant differences between the four- and nine-month results and that the observed degradation was uniform across all patients with no outliers. No late acquired incomplete stent apposition, stent thrombosis, or major adverse coronary events were reported. This preliminary nine-month data of the MIVT Pilot Trial is very encouraging, and the data compare favorably with FIM data of drug-eluting stents now available in the United States and abroad. More remarkable is the fact that these results were obtained with sixty percent less drug delivered from an ultra-thin, 0.6 micron coating that is entirely polymer-free.

Based on this nine-month follow up data, the VESTAsync™ polymer-free HAp sirolimus-eluting stent system is sufficiently safe and effective to warrant testing in a larger human study. MIVT plans further human testing during the first half of 2008.

NEW TRENDS IN CARDIOLOGY DEVICES – DRUG ELUTING STENTS

When the FDA approved the use of drug-coated stents on April 24, 2003, it was hailed as a landmark advance in the treatment of blocked arteries. Before that time, the only stents in use were bare metal stents (BMS). These devices were used to prop open clogged arteries after angioplasty and had met with much success. However, according to the FDA, roughly fifteen to thirty percent of stent patients suffered from restenosis (re-clogging of the artery) within a year of the procedure and had to be treated again with another angioplasty or bypass surgery. The drug-eluting stent was developed to solve the problem of restenosis. By releasing a drug to retard cell growth and stop scar tissue from forming within arteries that have been opened, the new device was designed to prevent the arteries from becoming blocked again. Those devices now significantly reduce the rate of re-blockage that occurs with existing stents. In early 2003, patients and medical professionals were so excited about the drug-coated stent that angioplasty procedures were being delayed specifically to await the FDA's approval of the Cypher stent, Cordis' revolutionary sirolimus-eluting coronary stent. Patients had heard the news about drug-eluting stents, and suddenly, nobody wanted a bare metal stent anymore. The drug-coated stents have become so popular; nearly ninety percent of all stent procedures in 2005 in the US made use of the drug-coated stent. Last year, approx. 990,000 heart patients received the devices.

IT DIDN'T TAKE LONG FOR THE MOOD TO CHANGE

In early July of 2003, less than three months after it approved the Cypher stent, and after more than 50,000 patients had received a Cypher stent, the FDA had received forty-seven Medical Device Reports (MDRs) of stent thrombosis occurring at the time of implantation or within a few days of implantation. Cordis immediately informed healthcare professionals, notifying them of the incidence of thrombosis and reminding them to make use of an adequate antiplatelet regimen to reduce the risk of clot formation. Blood clotting became a key element in the implantation and maintenance of drug-coated stents. While the safety of the DES may still have been questioned, the efficacy of the product was almost universally accepted: drug-coated stents were instrumental in reducing the need for second surgical procedures. By the end of 2005, more than ninety percent of all stents implanted in heart patients were drug-eluting stents. Medical professionals were so thrilled that drug-coated stents reduced the risk of restenosis they were, perhaps, willing to overlook the fact that the risk of stent thrombosis may have been growing. Several studies released in 2006 have brought the safety concerns back to the forefront of the discussion. A significant Swiss study presented in March 2006 indicated that stent patients who stopped using the anti-clotting drug sold under the brand name Plavix after one year were twice as likely to suffer late stent thrombosis as those treated with bare metal stents. Researchers also concluded that the risk of cardiac death or heart attack with the use of drug-eluting stents was "significantly higher" than the risk with the use of bare metal stents. In September 2006, Boston Scientific announced that its own internal research had found a slightly higher risk of blood clotting in patients who received its Taxus drug-eluting stent when compared with those who'd been implanted with bare metal stents. Boston Scientific's review looked at 3,500 patients and included four years of data to determine the risks of late stent thrombosis (blood clotting in the stent area from the period beginning six months after implantation). The use of DES has decreased from eighty-nine percent in the US, down to an estimated seventy-eight percent in 2007, driven by concerns over stent thrombosis causing heart attacks and confidence in bare metal stent (BMS) safety. According to a new report from Medtech Ventures, the current market for drug eluting stents is estimated at \$3.9 billion, accounting for seventy-eight percent of the total global coronary stent market. The US accounted for forty-six percent of the global market, followed by Europe, accounting for twenty-six percent, and Japan, accounting for twelve percent. In-stent thrombosis has marred the use of the DES within the clinical community, which have come under scrutiny since that time.

One serious limitation of current DES is the need for patients to comply with a long-term antiplatelet/anticoagulant regimen. Clinicians are under the notion that the blood clot formation results from a combination of too much drug and an inflammatory response to the polymer which delays the healing process, leaving the stent strut's metal alone in the artery to be exposed to the surrounding blood creating a nidus for infection, inflammation, and clotting for a longer period of time. To combat this increased risk for blood clot formation, physicians often prescribe life-long antiplatelet therapy for DES patients, which severely hampers the ability to provide future medical treatment.

POLYMER-BASED DRUG ELUTING STENTS COULD CAUSE IN-STENT THROMBOSIS

There are safety concerns over the current polymer-based drug-eluting stents (DES) regarding possible delayed healing processes and adverse reactions to the polymer when drug elution is complete. In addition, defects in the polymer layers with bare-metal exposure in the loop region as well as peeling of the top-coated polymer layer in the loop could indicate potential risks of thrombosis, late inflammatory, or neointimal reactions. In-stent thrombosis is caused when blood cells become sticky and clump together to form a small mass or clot. When a blood clot forms, it can block the free flow of blood through an artery. If blood flow is severely blocked in an artery that supplies blood to the heart muscle — called a coronary artery — a portion of the heart muscle may be damaged and can cause a heart attack. In addition, delayed healing is a well documented problem of the current generation of approved drug-eluting stents and could lead to an increase in thrombosis rate or an increased need for revascularization. In an MIVT study, there was a clear correlation between the amount of sirolimus eluted and fibrinoid material, which confirmed a strong indicator of delayed healing. The risk associated with drug-eluting stents might be caused by: (a) the polymer in the DES, and/or (b) the quantity of drug delivered by the DES, and/or (c) the method of drug delivery of the DES.

ARE POLYMER-FREE DRUG-ELUTING STENTS THE ANSWER?

Strong interest in polymer-free stents with a microporous surface as an alternative to stents with polymer coatings for local drug delivery is on the rise. This is exactly the space where MIVT is focusing its efforts and the market is driving in the Company's favor. As mentioned before, an independent study conducted in the Netherlands showed MIVT's polymer-free sirolimus-eluting coatings to be at least as effective as — and in some cases better than — Johnson & Johnson's Cypher drug-eluting cardiovascular stent. This is a strong indication that MIVT could bring a drug-eluting stent to the market place that has the same efficiency or effectiveness as a current drug-eluting stent, but one with a safety profile that equals that of a bare metal stent. To have a DES as effective as the current products, with a safety profile as good as a bare metal stent could be huge for the Company. In November 2007, new data from an animal study comparing the safety and efficacy of MIVT's VESTAsync™ hydroxyapatite coronary stent coating with low dose sirolimus showed fewer problems with fibrinoid but equal efficacy to the Cypher stent in porcine coronary arteries. Fibrinoid is a marker of delayed healing. On March 31, 2008, MIVT released the results from its nine-month FIM MIVT Pilot Trial of its VESTAsync™ drug-eluting stent. The results were very encouraging as there were no significant differences between the four- and nine-month results and the data compare favorably with FIM data of drug-eluting stents now available on the market. More remarkable is the fact that these results were obtained with sixty percent less drug delivered from an ultra-thin, 0.6 micron coating that is entirely polymer-free.

MIVT believes to have the lowest dose sirolimus-eluting stent either available or in development. All three doses of sirolimus tested in an animal study produced significantly less fibrinoid material than did the Cypher stent. In the First-In-Man trial, the Company demonstrated both the safety and efficacy of the VESTAsync™ in humans at four months. Applying the findings from this study could help patients experience faster healing. This is another benefit of inert non-

polymeric coatings such as HAp compared with conventional drug-eluting stents that use polymers to attach the drug to the stent. The next twelve months will be very exciting for MIVT, as the Company is in the final stages of preparation for human clinical trials to test a new class of polymer-free drug-eluting stents that could provide patients with superior outcomes.

VESTASync™ ADVANTAGE vs. POLYMER-BASED DRUG ELUTING STENTS

The VESTAsync™ is polymer-free, combining nanothin microporous HAp with low dose sirolimus in a proprietary formulation. Unique features of the VESTAsync™ are: (i) completely polymer-free; (ii) ultra-thin drug coating, which at 600 nanometers is ten times thinner than the Medtronic Endeavor™ and thirty times thinner than Boston Scientific's TAXUS Liberté™; (iii) thin struts, which, at under sixty-six microns are twenty-five percent thinner than the Abbott Vascular's XienceV™, and fifty-seven percent thinner than the Johnson & Johnson Cypher™, and (iv) low drug dose, which at fifty-five micrograms is sixty percent less than the drug on the corresponding Johnson & Johnson Cypher™ and seventy percent less than on the corresponding Medtronic Endeavor™. Bench, animal, and early human testing of the VESTAsync™ shows bare metal stent (BMS) like platelet activation, superior healing when compared to the Cypher™ stent, lower inflammation than Cypher™, and seventy-five percent less fibrinoid deposition (a marker of delayed healing) than Cypher™. Early efficacy results are comparable to current FDA approved DES. These results are a strong reinforcement of the Company's strategy to bring to market a drug eluting stent with the safety profile of a BMS requiring BMS-like antiplatelet therapy.

OUTLOOK

Interventional Cardiology has been perhaps the fastest-growing cardiovascular specialty during the past twenty years. Developments in interventional and minimally invasive treatments of heart disease have created multi-billion dollar markets including angioplasty, stenting, and coronary bypass surgery. MIVT is positioned to take its place in this large and growing market as its next generation drug-eluting stent, **VESTAsync™** is currently undergoing clinical trials to support regulatory approval. The VESTAsync™ polymer-free drug-eluting stent could be on the market within the next eighteen months. MIVT currently has two CE Mark approved bare metal stents on the market — the **GenX™ Stainless Steel Coronary Stent & Stent System** and the **GenX™ CrCo Chromium Cobalt Coronary Stent & Stent System**, both targeting the Indian market, one of the fastest growing markets worldwide. MIVT also received India Regulatory Approval. MIVT is not only involved in the cardiology area, but also entered the orthopedic area by signing a research collaboration agreement with Smith & Nephew, an established market leader in orthopedics to develop new coatings and drug delivery systems for orthopedic devices. MIVT will continue to move forward to evaluate additional opportunities in different therapeutic areas.

We see significant growth potential in lesser developed/regulated markets including China, India, the Middle East, Africa, and Latin America. With the acquisition in India, MIVT added a portfolio of CE Marked products and gained a foothold in this key target market. Since the acquisition, MIVT has achieved close to \$750k in sales of its products. Via acquisition in India, MIVT has already established a regional presence with targets identified or strategies in formation for Asia and Latin America. The Company's network should soon penetrate all of the key unregulated/developing markets where it expects the most attractive DES utilization growth rates. MIVT believes that a strong growth in the drug-eluting stent market will be outside of the US, in the international markets into which MIVT has been expanding its reach.

Following are comments and selected data regarding some of MIVT's key target markets:

United States - According to a new report from Medtech Ventures, the current market for drug-eluting stents in the US is estimated at \$3.9 billion, accounting for seventy-eight percent of the total global coronary stent market. The US accounted for forty-six percent of the global market, followed by Europe, accounting for twenty-six percent, and Japan, accounting for twelve percent.

China - Cardiovascular stents seems to be the latest trend in the rapidly changing face of China's medical device industry. The prospect of reaching out to more than ten million patients in China is exciting and a growth of up to thirty percent in the stent market in China has been posted. The stent market in China is driven by its huge prevalence of cardiovascular disease. In China's annual health report for the year 2003, there were a total of 1,164,501 hospital discharges due to cardiac disease. Strong economic growth, favorable demographics, and an improving quality of life, particularly in the country's urban areas, will drive this market throughout the next five years.

Asia - Increasing Incidence of Cardiovascular Diseases Fuels Demand for Stents – Cardiovascular disease has been cited as one of the top five causes of growing morbidity in most Asian countries. Boston Scientific estimates the Japanese DES market at \$684 million for 2007.

Latin America - Growth in the Latin American peripheral vascular (PV) device market will be strong as more training centers dedicated to the practice of treating peripheral vascular disease (PVD) are established.

VALUATION

Given that the biotechnology sector is often fraught with uncertain success, the valuation exercise for MIV Therapeutics is not an easy task. However, we believe that MIV Therapeutics can best be compared with Singapore based Biosensors International Group. (Singapore:B20). Biosensors International Group develops, manufactures, and markets innovative medical devices used in interventional cardiology and critical care procedures. Biosensors believes it is well-positioned to be a leader in drug-eluting stents (DES), a therapy for heart disease that is rapidly gaining market share from traditional therapies such as bare metal stenting and open-heart surgery. The company has internally developed technology to address each component of a DES system, including the stent, delivery catheter, polymer, and proprietary drug. In addition to the DES products, Biosensors sells a number of products in the interventional cardiology and critical care markets. These include bare metal stents, stent delivery systems, and a variety of specialty catheters and transducers. During the last twelve months, Biosensors sold products of approx. \$44M and lost approx. \$13.2M. Biosensors market capitalization is approx. \$640M. Currently, Biosensors is trading at a 14.5x price-to-sale multiple. Back in 2007, Johnson and Johnson acquired Conor Medsystems and was willing to pay 39.8 times Conor's DES sales for 2006 in order to acquire that company.

The significant undervaluation of MIVT causes us to take the view that investors are valuing MIVT at the low end of an emerging market premium simply because MIVT targets markets that are, at least initially, low-end markets, i.e., India and China. However, as mentioned before, the outlook for growth in the stent marketplace in both India and China is quite rosy over the long term because of the large emerging middle class.

Today, MIVT is an undiscovered company with a huge opportunity in very large markets. Despite very encouraging milestone achievements during 2007, MIVT currently trades at a market cap of only \$23.9M, 64.4% below its stock price one year ago and is therefore still significantly undervalued. In comparison, in early 2007, Johnson & Johnson acquired Conor Medsystems and gained control over a unique controlled drug delivery technology. This technology had a tag price of \$1.4 billion. The technology is a paclitaxel-eluting cobalt chromium

stent with a bioabsorbable polymer and is sold outside of the United States. The transaction clearly demonstrates the potential for a revaluation of MIVT.

We believe a \$280M market cap for MIVT, which is only approximately twenty percent of what J&J paid for Conors, is a fair valuation. Based on approx. 112 million shares outstanding, we have arrived at a share price of \$2.50. We reaffirm our twelve-month target price of \$2.50, but still maintain our Speculative Buy/4 rating.

ANALYST DISCLOSURE

Analyst: Ernest C. Schlotter

Ernest C. Schlotter has been an analyst since 1995. He is a securities analyst covering companies with SISM Research & Investment Services, Zurich, Switzerland. His areas of focus have included biotechnology and all energy industry sub-sectors, with a focus on independent companies in exploration/production. According to the tracking firm StarMine, based in San Francisco, Ernest C. Schlotter is a four out of five star analyst for EPS estimate accuracy.

Analyst Certification:

I, Ernest Schlotter, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report.