Regenerative Medicine Newsletter

Research Report
CardioVascular BioTherapeutics Inc.

Stock Trading Symbol: CVBT

Closing Price as of 4/14/05	$5.50	52 Week Range:	High $15.20 Low $5.50
Market Capitalization:	$660,990,000	Shares Outstanding	120,180,000
Public Float:	2.1%	Average Daily Volume:	N/A
Exchange:	OTCBB		

Executive Summary

CardioVascular BioTherapeutics Inc., trading under the symbol CVBT is a new stock issue we highly recommend watching. The sharp investor who investigates emerging Biotech growth companies will keep a close eye on this one. The results of numerous clinical medical trials must be analyzed so logical investment conclusions may be drawn.

CVBT has a protein drug under trial with a multitude of medical applications trademarked under the name Cardio Vascu-Grow. As stated many times in this report, there is no guarantee the FDA will approve this drug. However, if approved, the sales and earnings per share potential can be no less than staggering.

To determine whether CVBT is to be maintained in ones investment portfolio, one must first believe in the medical science associated with Cardio Vascu-Grow, otherwise looking at the potential sales numbers is virtually a waste of time. This report will contain a number of forward sounding statements. Sources to support and substantiate such statements will be provided. Additional research by the savvy investor is a necessity before moving forward.

The Regenerative Medicine Newsletter presents the initial research report. It is our mission to present in clear and concise language a report without prejudice containing medical and financial information to help the reader determine if CVBT represents a long term investment opportunity. From time to time updates and revisions to this report will be forthcoming.

Please feel free to contact this office if you have specific questions.

Sales@rmnewsletter.com

Thank You
Robert Volin President,
Regenerative Medicine Newsletter

Introduction

April 14, 2005
Las Vegas, Nevada

Diseases of the cardiovascular system are the leading cause of death and suffering in the developed world. In the United States alone an estimated 18 million people suffer from cardio vascular disease of the heart. An estimated 8 million suffer from vascular disease in their legs and an additional 6 million people suffer from vascular disease affecting blood vessels supplying the brain that can lead to a stroke. Millions of diabetics suffer from cardiovascular disease which can affect almost every artery in their bodies, while a high percentage of our aging population suffer from vascular disease in their kidneys, intestinal tracts and stomach. Now there is compelling evidence that lower back pain may also be directly related to blockages of blood vessels supplying the back muscles leading to lumbar ischemia.

CardioVascular BioTherapeutics Inc. (stock symbol CVBT) is a company that has stated through various public disclosures that it is developing a novel and potentially breakthrough medical therapy to treat a wide array of diseases affecting the cardiovascular system. These are diseases that kill almost 40% of U.S. citizens.

The company states that the medical developments of CVBT should be of importance to everyone, especially those over the age of 55 with a family history of:

- **Heart Disease**
- **Stroke**
- **Diabetes**
- **Back Pain**
- **Intestinal Pain**
- **Vascular disease of the legs**

CVBT has developed a protein drug with the trademarked name of Cardio Vascu-Grow™, which when injected into the diseased human heart stimulates the growth of new and healthy blood vessels, a biological process that is referred to as "Angiogenesis." The protein triggers the growth of new coronary blood vessels in areas of the heart where the blood flow has been restricted or blocked by atherosclerosis. This blockage causes heart muscle cells to suffer from a lack of oxygen and nutrients which can lead to diminished function, pain, and even death. CVBT's protein drug therapy, with its ability to grow new blood vessels around blockages in the heart, functions in a practical sense as a pharmaceutical heart by-pass. This new therapy could potentially be applied to the 18 million Americans that suffer from crippling chest pain and angina.

Just as restricted blood flow to the heart leads to heart attacks, blockages of blood vessels in the brain or supplying the brain lead to stroke. Stroke is the third highest cause of death in the United States, and an estimated 7 million people suffer from the long-term effects of strokes in this country. It has been reported that Cardio Vascu-Grow™ has shown very good potential in pre-clinical animal studies to reduce the size of damaged brain tissue after a stroke and thus, could be a potential new therapy to treat this condition, a condition which currently has no effective treatment.

It has been clearly established that diabetics suffer more from cardiovascular diseases than non-diabetic individuals. For example, blockage of blood vessels in the legs is estimated to affect 8 million Americans. The overwhelming majority are diabetic. Vascular disease of the legs is the leading cause of amputations in the U.S. and a major cause of disability in this country.

Diabetics also make up a disproportionate share of patients who suffer from an impaired ability to heal wounds leading to bedsores, foot and leg ulcers, and surgical incisional wounds that will

not heal. These problems, again, can be directly tied to poor blood perfusion in the affected area. Cardio Vascu-Grow™ with its ability to promote new blood vessel growth and increase blood perfusion has the potential to permanently heal these lesions, a fact which the company has disclosed, has already been amply demonstrated in animal studies.

Finally, medical researchers are now demonstrating that blocked blood vessels can lead to problems in a way that no one suspected in the past. Chronic back pain, which is reported to affect 26 million Americans, has recently been shown to be triggered, or caused by blockage of the blood vessels in the lower back, leading to a condition referred to as lumbar ischemia. European medical researchers have speculated that chronic back pain resulting from blockage of blood vessels in the lower back precedes the blockage of coronary arteries in the heart by ten years.

A second finding reported at a recent medical conference in Maui, Hawaii is that many medical experts believe the blockage of the small arteries of the digestive system affects almost everyone over the age of 70. This leads to a condition referred to as intestinal ischemia. While major blockages of blood vessels supplying the intestinal tract can result in death in a relatively small number of patients, the blockage of smaller blood vessels in the digestive system is a major cause of pain, constipation and malnutrition affecting perhaps up to 30 million elderly Americans.

It is clear that a new therapy that could successfully treat this wide array of medical ailments, all resulting from blocked blood vessels, could be a multi-billion dollar business opportunity. Cardio Vascu-Grow™, with its ability to potently induce new blood vessel formation, presents such an opportunity for CVBT.

Cardio Vascu-Grow™ was first tested in 20 humans suffering from severe coronary artery disease in 1995/96. The data from this study was published in the American Heart Associations monthly publication “Circulation” in February 1998, this landmark paper was cited as the most significant development in cardiovascular medicine that year by the American Heart Association.

A second human clinical trial was conducted on 20 individuals suffering from severe coronary artery disease in 1998/99 where the drug was utilized as the sole medical therapy. The results of this clinical trial, published in 2000 in the cardiology journal *Cardiac and Vascular Regeneration*, appear to be successful.

In 2003, CVBT started clinical trials in the United States that had been reviewed and authorized by the FDA. Early results presented at the 2004 American Heart Association’s meeting in New Orleans by the medical researchers at the University of Cincinnati Hospital, were very well received at the Conference.

This Research Report should examine two questions:

> ***Question One: Does this medical treatment really work, and will it be approved by the U.S. FDA?***
>
> ***Question Two: If it is real, what does it mean economically for potential investors who purchase shares of CVBT?***

The answer to Question One is in the future and that question will only be answered when and if the U.S. FDA approves the drug. However, what can be analyzed in this Research Report are the possible economic scenarios following a positive outcome, approval by the U.S. FDA to sell Cardio Vascu-Grow™.

In Section I of this Research Report, entitled "The Medical Science Behind CVBT", the research and development activities behind Cardio Vascu-Grow™ will be examined. If one believes that a positive outcome and approval is likely from the investigation of the medical science supporting Cardio Vascu-Grow™, then the second question becomes very relevant. What does FDA approval to sell Cardio Vascu-Grow™ mean economically to a potential investor? As often seen in the past with other biotech companies, great science does not always mean great business success. The issue of the business potential of Cardio Vascu-Grow™ will be addressed in Section II, "The Marketplace Potential."

Section III of this report will present possible "Economic Model Outcomes." In this section financial details will be provided on what the economic and financial outcomes could be for an investor in CVBT if the drug is approved by the FDA.

The analysis of CVBT is difficult and complex, and a positive outcome is completely dependent upon U.S. FDA approval of Cardio Vascu-Grow™. Without FDA approval the drug has zero value, and CVBT is a worthless company. What this Research Report will attempt to do is understand is what it the likelihood that Cardio Vascu-Grow™ will be approved, and secondly, if the drug is approved, what could it mean to the investors in CVBT shares.

Investing in CVBT shares is a high risk investment. An investor has to be prepared to lose 100% of their investment if the drug is not approved by the U.S. FDA.

The following Research Report analysis covers the Medical Science behind CVBT, the Marketplace Potential, and the Possible Economic outcomes underlying CVBT.

Section I- Medical Science Which Supports CVBT

It should be noted that the author of this research report obtained information regarding the medical science which supports CVBT from the following sources:

- The website of CVBT at www.cvbt.com
- Dr. Thomas Stegmann's book, "New Vessels for the Heart." published in 2005.
- Research and clinical papers from reputable medical journals or medical organizations such as the American Heart Association.
- Medical and scientific presentations discussed at the "2nd Annual Regenerative Medicine Conference" in Maui, Hawaii, February 2005.
- Informational sources available to the general public including patents from the U.S. Patent Office.
- The Annual Report of CVBT

Based on information from the above sources, CVBT has divided the medical applications of their drug into different tissue categories. The primary tissue groups for possible medical applications are Muscle Tissue, Wound Healing Tissue, Nerve Tissue, Intestinal Tissue, Kidney, and Other Medical Indications. This Research Report will be structured similarly to those categories.

Much of the specific medical science supporting CVBT can be read at the company's website www.cvbt.com, so for that reason this report will not go into great details of the medical science.

This report will address the main points in summary and for those interested parties who wish to do a more detailed analysis they can go to the company website and have the detailed studies made available to them.

Muscle Tissue Group

Heart

Since heart disease is the number one cause of death in the developed world, a major cause of medical expenditures, and the area where CVBT has advanced the furthest, it will be addressed first.

For blockage of the larger blood vessels, patients have several medical options including (1) do nothing; (2) have a balloon angioplasty performed; or (3) have heart by-pass surgery performed.

For blockage of the smaller blood vessels there is currently nothing that can be done to help this condition.

While most people think of heart disease as blockage of the larger coronary arteries, many doctors believe that in addition to this, blockages of smaller blood vessels are just as significant. The reason that few people realize this, is that currently there is no interventional treatment to treat blockage in smaller blood vessels. Therefore, the problem is not talked about among non-experts.

In 1995, Dr. Thomas Stegmann after years of medical research, animal studies, and investigation and analysis, obtained permission from his hospital's Institutional Review Board (IRB) to conduct the first human trial to attempt to grow new blood vessels with Cardio Vascu-Grow™ in the hearts of no-option heart patients undergoing a by-pass procedure. Several major medical questions existed at that time, some of those were:

Would Cardio Vascu-Grow™ grow blood vessels?

If the blood vessel growth occurred, would it be uncontrollable?

Could this trigger any cancers?

Would the new therapy benefit patients?

These questions and others were addressed in the first clinical trial and the answers are now known.

Would it grow blood vessels?	***Answer: Yes***
Would the growth be uncontrollable?	***Answer: No***
Could this trigger cancer?	***Answer: No***
Would the patients benefit?	***Answer: Yes***

Details of this first clinical study can be read in the journal, *Circulation,* published by the American Heart Association or at the CVBT website.

A second clinical trial was conducted in 1998/99 where 20 no-option heart patients received Cardio Vascu-Grow™ as the sole therapy. That study was completed and the details published in the cardiology journal, *Cardiac and Vascular Regeneration*. The detailed report is also available at the CVBT website.

A summary of the results of those two clinical trials indicated:

- All of the patients demonstrated new blood vessel growth at the site of the injection, which was still present when it was reviewed three years later.

In addition the following results were observed:

- 80% of the patients showed a significant improvement in their exercise test.
- Perfusion of the heart under stress showed a 5-fold increase in SPECT perfusion score. (i.e. better blood supply to muscle heart)
- No significant adverse effects of the therapy.
- Importantly, 90% of the patients had an improvement in their dominant clinical symptom, angina or chest pain. During stress exercise tests, angina was either completely absent, or began at a much higher levels of exertion.

Given that 6 million Americans suffer from angina this is an enormous marketplace opportunity.

In 2003, CVBT started U.S. FDA authorized clinical trials which are now taking place at six U.S. medical centers including:

- University of Cincinnati Medical Center, Cincinnati, Ohio
- Penn State University Medical Center, Hershey, Pennsylvania
- University of Alabama Medical Center, Birmingham, Alabama
- St. Joseph's Hospital, Towson, Maryland
- St. Vincent's Medical Center, Bridgeport, Connecticut
- JFK Hospital, West Palm Beach, Florida

The company states that the first U.S. clinical trial should be completed in the middle of 2005.

The first results from this trial have been announced and reported by the Cincinnati Enquirer, and ABC Nightly News, May 12, 2004. The initial U.S. medical results that have been reported are positive and are consistent with those obtained by Dr. Stegmann in his earlier clinical trials.

CVBT has divided the medical indications in the heart into four categories:

- No-Option Heart Patients
- Adjunct to By-Pass Surgery
- Diffuse Heart Disease
- Catheter Based Delivery of Cardio Vascu-Grow™

No Option Heart Patients

These are patients who have heart disease which is so advanced that currently no known medical treatments exist; they are therefore defined as "No Option Patients." This is the group of patients on which Dr. Stegmann's second clinical trial was focused, and the group of patients now being treated in the on-going US clinical trials.

Adjunct Therapy for By-Pass Patients

This indication for Cardio Vascu-Grow™ is focused on those people who not only have heart disease in their larger coronary arteries requiring a bypass procedure, but also have the disease in their small vessels as well. The concept is that patients undergoing a heart by-pass will also be injected with Cardio Vascu-Grow™ into areas of the heart where smaller vessels are blocked to

help relieve the ischemia these patients suffer. This is similar to Dr. Stegmann's first clinical trial performed in 1995/6.

Diffuse Heart Disease – Angina

Diffuse heart disease is when smaller blood vessels are blocked in the absence of blockage of larger coronary arteries. These people have pain in their chest, which is referred to as angina. However, the vessels are too small to be treated by balloon catheter or by-pass surgery. It is virtually impossible to direct a 1 millimeter diameter catheter down a blood vessel with an internal diameter of only ½ millimeter. For these estimated 6 million people in the United States who suffer chest pain from diffuse coronary artery disease, the company believes that Cardio Vascu-Grow™ could be a way to cure the underlying disease by growing new blood vessels. Existing therapies, such as nitroglycerin tablets merely treat the symptoms of this disease.

Catheter-based delivery of Cardio Vascu-Grow™

CVBT is working on delivery of the drug into the heart muscle by a catheter introduced into the body via the femoral artery. The company states that this less invasive application could dramatically lower the cost of the treatment and dramatically expand the marketplace applications. The drug would be delivered in a manner so that surgery would be avoided for most people. It is obvious that most people would seek to avoid surgery if possible.

While great progress has been made in applications of Cardio Vascu-Grow™ to treat ischemic heart muscle, the management of CVBT has stated that there is very good reasons to believe that Cardio Vascu-Grow™ will also induce the growth of new blood vessels in ischemic muscles outside the heart. Towards that objective, CVBT is working on two other medical applications in muscle tissue that has become ischemic due to blockage of blood vessels supplying those muscles.

Peripheral Vascular Disease of the Legs

It is estimated that 8 million Americans suffer from Peripheral Vascular Disease (PVD). Many of these sufferers are diabetics, who seem to have a propensity towards this medical problem. PVD occurs when blood vessels that feed the legs, become blocked by atherosclerotic lesions resulting in pain while walking in milder cases, and evolving to more severe forms of the disease where circulation to the foot and leg become so reduced that amputation of the toes, foot, or legs is the only alternative. This disease increases in prevalence as people age.

CVBT has started testing Cardio Vascu-Grow™ in scientifically accepted models of peripheral vascular disease. They have targeted the 3rd quarter of 2005 to submit to the U.S. FDA an application for an Investigational New Drug (IND). The Phase I study is simply a safety study for the injection of Cardio Vascu-Grow™ into the legs and this type of trial should be completed quickly permitting a Phase II efficacy trial authorized by USA FDA to begin next year.

PVD is a major medical problem and is essentially the same condition in arteries supplying the leg as is seen in diseased coronary arteries in the heart. As CVBT has had success in treating heart patients they are anticipating the same success in treating peripheral vascular disease patients.

Lumbar Ischemia

It has been reported that 26 million Americans suffer from chronic back pain. The cause of this pain is undetermined. Some medical researchers believe that when the blood vessels of the lower back (the lumbar area) become blocked (similar to arteries in the heart or legs) that this causes a cascade of events which generates chronic back pain. Studies from Europe have presented very

compelling data that blocked lumbar arteries lead to chronic back pain and this could be a compelling target treatment area for Cardio Vascu-Grow™.

CVBT is participating in proof of concept clinical trial in Europe in the second half of 2005 to test whether Cardio Vascu-Grow™ can successfully treat chronic back pain. This trial should take approximately nine months to complete. If the results are positive then by the middle of 2006, CVBT will be able to file an IND application to the U.S. FDA to study the use of Cardio Vascu-Grow™ to treat chronic back pain in U.S. patients. If successful, the use of Cardio Vascu-Grow™ to treat the millions of Americans suffering from chronic back pain would be a major medical breakthrough.

As an interesting side note, at the 2nd Annual Regenerative Medicine Conference in Maui, Hawaii in March 2005, Dr. Leena Kauppila of Helsinki University Central Hospital in Finland stated that it appeared from her research that chronic back pain precedes heart disease by approximately ten years.

The above discussion covers applications of Cardio Vascu-Grow™ to treat ischemic muscle disease which CVBT has disclosed. Individuals interested in learning more should obtain a CVBT Annual Report or visit the website at www.cvbt.com

Wound Healing

Wound Healing has been defined by CVBT as a tissue group, because the wounded tissues require new blood vessel growth to accelerate the healing process. Often people with diminished healing abilities such as diabetics, older people, or people with a suppressed immune system (perhaps resulting from cancer treatments) would benefit from an angiogenic agent that could stimulate the growth of new blood vessels in the wounded area, thus accelerating the healing process.

The first medical application being addressed is to accelerate the healing of diabetic ulcers. This affects millions of diabetics, and the failure or delay of proper healing and closure of a wound can lead to great pain and suffering, more severe infection, and greater medical cost to care for these patients.

CVBT has indicated that the company anticipates filing an IND application to the U.S. FDA by the middle of 2005 for a Phase I clinical trial in diabetics with foot and leg ulcers, and will hopefully start a Phase II clinical trial by the start of 2006.

CVBT, who has been working diligently on getting Cardio Vascu-Grow™ approved for use by no-option heart patients, actually believes that approval for the wound healing indication may come first. This is due to the fact that the drug is applied topically on the skin, where there is much less risk of side effects. Additionally, as the diabetics who enroll in this trial can apply the Cardio Vascu-Grow™ salve at home, it should be easier to identify and obtain volunteers for this clinical trial.

Other important areas of wound healing for Cardio Vascu-Grow™ that CVBT has disclosed include:

- Bed Sores
- Surgical (incisional) wounds
- Anastamosis (Organ repair and transplants)

CVBT has indicated that these areas should be advancing through animal testing and submission of IND applications to the U.S. FDA in 2005 and 2006.

Nerve Tissue Group

CVBT has announced that it is working in the nerve tissue group in two major areas. One is the treatment of stroke, and the second is neuropathic pain suffered by many diabetics.

Stroke

CVBT has been conducting animal testing, some of which was reported in Dr. Stegmann's book "New Vessels for the Heart." The initial data appears quite impressive.

CVBT has indicated that they hope to file an IND application to the U.S. FDA by the second half of 2005, to start clinical trials in stroke patients in 2006. As there is no current effective treatment for stroke, a positive outcome for Cardio Vascu-Grow™ in a stroke trial would be a major advancement and should be followed closely.

Neuropathy (peripheral leg and arm pain)

Neuropathy is a new area for CVBT. This is a new area because it is attempting to address the question of growing new nerve cells with Cardio Vascu-Grow™, instead of growing new blood vessels. Numerous reports in the scientific literature indicate that Cardio Vascu-Grow™ is a potent neuroprotective agent and can stimulate the growth of nerve cells. This additional property of Cardio Vascu-Grow™ indicates that it may have utility in medical conditions where nerve loss has occurred such as neuropathy and stroke. This is a new area for CVBT, and the management has been very cautious in their expectations. However, as this is again an unmet medical need in this country, a drug that could successfully treat these conditions would be a major breakthrough.

CVBT has indicated that they hope to know more in 2006 following the completion of animal studies in this area, and this information could be a material development for the company.

Digestive System

The management of CVBT announced at the "2nd Annual Regenerative Medicine Conference," in Maui, Hawaii in Feb 2005, that a new potential application for Cardio Vascu-Grow™ is in the growing of new blood vessels in the digestive tract to address the medical problem of intestinal ischemia and pancreatitis. From analyzing reports it appears that while these diseases are seldom life threatening, they are responsible for a great deal of pain and suffering. Smaller blood vessels that feed the intestines or pancreas can become blocked by the same atherosclerotic process that affects the coronary arteries in the heart. A restricted blood flow to the digestive tract can lead to pain, reduced absorption of nutriments, and diminished clearance of waste. What makes this interesting for CVBT in a business sense, is that it is estimated by various physicians that this disease will affect, to some degree, almost everyone over the age of 70. This would mean that an estimated 30 million potential patients with some degree of intestinal ischemia could be treated with Cardio Vascu-Grow™. There is currently no real medical treatment for these patients, making this an enormous opportunity for CVBT.

This is a new area for CVBT. The company has indicated that they will know more in early 2006.

Kidneys (hypertensive renal disease)

CVBT has been studying the application of its drug to ischemic kidney disease. It is estimated that 3,000,000 Americans suffer from this disease. CVBT has stated that this application is in the early stages and that it will be mid-2006 before they will have any proof of concept data from planned animal experiments. There is no current therapy for ischemic renal disease, often caused by chronic hypertension and it therefore represents a major marketplace opportunity.

Other Medical Indications for Cardio Vascu-Grow™

From reading Dr. Stegmann's book and from the data presented at the 2005 conference in Maui, Hawaii, research and development activities for more novel indications seem to be focused in the following areas:

The Central Nervous System
Connective Tissue/Bone

Little has been disclosed concerning these areas of CVBT's activity, however, over the next 12 to 24 months, CVBT should reveal more

SUMMARY ON THE MEDICAL SCIENCES BEHIND CVBT

CVBT has provided a wealth of information on its research and development activities at its website www.cvbt.com, and through public disclosures at conferences and in the scientific and patent literature. A person should investigate this information carefully and come to their own conclusions. The company has made forward-looking statements in their disclosures, but it appears that these statements are based on sound scientific and medical evidence. It is up to the individual to decide how much risk is involved in CVBT obtaining approvals for various medical indications.

If the reader of this report believes Cardio Vascu-Grow™ has a chance of obtaining FDA approval then they should continue reading this report and learn what the economic possibilities are for CVBT if FDA approval of Cardio Vascu-Grow™ is granted.

Section II- MARKETPLACE POTENTIAL FOR CARDIO VASCU-GROW™

In the first section of this report, publicly disclosed information from CVBT concerning the scientific and medical progress being made by the company was analyzed. The progress CVBT has made in advancing their drug through multiple medical indications appears excellent. However, from a business point of view, good science does not necessarily mean good business. The question that will be addressed in this section of the report is; if the medical science is good and the drug is approved, what is the Marketplace Potential for Cardio Vascu-Grow™?

Statistical data for the pharmaceutical marketplace in the United States is readily available and, generally, of high quality. For this reason this report will use the United States marketplace data for its analysis and then use that data to extrapolate an estimated worldwide marketplace potential for Cardio Vascu-Grow™.

To study this topic in a systematic way, this report will follow the same medical indications for Cardio Vascu-Grow™ as defined in CVBT's Annual Report and in Section I of this report where the indications are grouped according to tissue groups.

The first area is the Muscle Tissue Group and consists of several sub groupings.

Heart Applications

1. ***No Options Heart Patients***
   The estimated number of American No Option Heart Patients ranges from 100,000 to 200,000 people per year.

2. ***Adjunct Treatment to a Heart By-Pass***

   The estimated range of potential patients indicates that 60% to 70% of all people under going a heart by-pass operation also suffer from blockage in the smaller blood vessels of their heart. With the American Heart Association reporting that 700,000 heart by-passes occur annually, then 60% to 70% of that number would equate to 420,000 to 490,000 individuals per year that would be eligible for possible treatment with Cardio Vascu-Grow™.

3. ***Diffuse Heart Disease (Angina Pectoris)***

   ABC Nightly News on May 12, 2004 reported that 6 million Americans suffer from this medical problem. If CVBT's drug lessened or eliminated their pain, reduced the risk of damaging their hearts, or possibly avoided death for these patients, it is estimated that between 1-3 million of these patients would seek Cardio Vascu-Grow™ as a treatment for this medical condition.

Mr. Montano, the President of CVBT, has stated that he believes the drug will sell for around $2,000 per injection. He has also stated that he believes that patients will need between two to four injections of Cardio Vascu-Grow™. If each patient receives on average, 2 ½ injections per procedure, then at $2,000 per injection, treating the average patient would result in $5,000 in drug sales for CVBT.

Using the above figures the following calculations can be made:

1. ***No Option Heart Patients***

   The no-option heart patient marketplace potential at the lower estimate of 100,000 potential patients (and assuming a cost of $5000 to treat each patient) would generate $500 million in annual sales. Using the higher estimate of 200,000 potential patients at $5,000 each would generate $1 billion in annual sales

2. ***Adjunct to a Heart By-Pass***

   If 420,000 patients having a heart by-pass procedure elected with their doctors to seek the additional treatment with Cardio Vascu-Grow™ to grow blood vessels in the areas of the heart where the smaller heart blood vessels are blocked, then the annual revenue potential would be $2.1 billion per year.

3. ***Diffuse Heart Disease (Angina Pectoris)***

   If one million Americans sought this treatment, then the revenues for the drug could be $5 billion per year. If three million Americans sought this treatment then the annual revenues could be $15 billion per year.

SUMMARY ON THE MARKETPLACE POTENTIAL FOR THE HEART APPLICATIONS:

If only the no-option heart patients are treated then the marketplace potential would be $500 million to $1 billion in revenues per year. If all medical indications for the heart are approved and one uses the higher end of potential patients, then revenues would be over $18 billion per year.

Peripheral Vascular Disease of the Legs

An estimated eight million Americans, largely diabetics, suffer from blockages in vessels supplying the legs. An approved treatment to lessen their pain and possibly save toes, feet, and legs from amputation would be highly sought after. It is estimated that one to three million suffers would seek this treatment. Given that there are multiple places in the leg where blockages

could occur, CVBT has estimated that most patients would receive between 2-4 injections in various regions of the leg to stimulate new vessel formation. Using an average of 2 ½ injections per patient then the marketplace for the drug's usage could be $5,000 per patient. If one million patients sought the treatment annual sales would be $5 billion per year, and if three million patients sought the treatment annual sales would be $15 billion per year.

Chronic Back Pain Due to Lumbar Ischemia

With a reported 26 million Americans suffering from chronic back pain, the first question asked must be, "What percentage of those people would seek this treatment to alleviate their pain and suffering?" While it is reported that 26 million Americans suffer from back pain, the author of this report believes that there is a wide range in the severity of the pain experienced. Some people may suffer from mild, temporary back pain, while others may experience chronic, severe back pain. It could be assumed that those with severe pain would seek relief first, and it is estimated that perhaps 20% of the 26 million total patients with back pain experience the severe, chronic form. That represents over 5 million potential patients.

For purposes of estimating a potential marketplace for Cardio Vascu-Grow™ in chronic back pain patients, it can be speculated that a range of 10% to 40% of patients with severe back pain would seek the CVBT treatment if it was approved and effective. This represents a potential patient population of between 500,000 to 2 million patients per year. Since the lumbar area has four feeding arteries on each side of the spine (total of 8), again it is speculated that a patient could have as few as one, or as many as five, blocked areas. Using 2 ½ injections per patient as an average, it would equal $5,000 per patient in potential revenues for the drug. If 500,000 people sought the treatment at $5,000 each, then revenues would be $2.5 billion dollars per year. If 2 million people sought the treatment then the potential annual marketplace revenue stream could be $10 billion per year.

SUMMARY ON THE MARKETPLACE POTENTIAL FOR THE MUSCLE TISSUE GROUP:

Cardio Vascu-Grow™ is currently under development for multiple indications in ischemic muscle tissue. No one can say what the drug will be approved for and whether it will find clinical use in treating blocked vessels in the heart, legs or back. Nevertheless, this marketplace analysis is an attempt to understand what the marketplace potential is should the drug be approved by the U.S. FDA, and Cardio Vascu-Grow™ is embraced as an effective therapy by patients, doctors, hospitals and payors of drugs.

In the Muscle Tissue Group, the marketplace potential ranges from a low of $500 million, assuming only a low end number of no-option heart patients being treated, to a potential high side of $45 billion if Cardio Vascu-Grow™ is approved for heart, leg and back indications.

Wound Healing Group

The Wound Healing Group comprises a number of topical applications of the drug for diabetic foot and leg ulcers, bed sores, and slow healing surgical incisional wounds. Also contained within this group is internal wound healing arising from the surgical joining of tissues (anastomosis), or organ transplants.

Estimated patients for the topical application of Cardio Vascu-Grow™ include 1-2 million foot and leg ulcers and 10 million patients with bed sores. With the advancing age of the U.S. population these numbers should grow materially over the next 20 years. If the average selling price for the topical application was $1,000 per year, then the potential annual revenues could be in the $1 billion to $12 billion per year range. If a successful outcome to the use of Cardio

Vascu-Grow™ in speeding the healing of incisional wounds occurred, then this would have the potential to add significant additional sums of money to this area of CVBT's business.

Excluding at present the possibility of Cardio Vascu-Grow™ being approved for use in healing of incisional wounds, a Wound Healing Group comprising diabetic ulcers and bed sores could provide a potential of $1 to $12 billion per year in annual revenues for CVBT.

Nerve Tissue Group

Stroke

CVBT's President has been very clear in indicating that he believes the chance of success in applying the CVBT drug product to treat strokes is 20% at best. While he has stated the chances of Cardio Vascu-Grow™ ever being approved for this indication are slim, the company has put forward some very compelling evidence that Cardio Vascu-Grow™ can definitely decrease the size of a stroke in animals.

The stroke marketplace potential can be divided in to two classes, either acute or chronic treatment of the patient after the stroke has occurred. Acute treatment would be given to patients who present with a stroke within 6-48 hours of the stroke's occurrence. The treatment would last for, at most, 1-3 days. Chronic treatment of stroke patients would be over a 3-6 month period, where not only would the therapy attempt to limit the size of the stroke, but would actually seek to achieve the restoration of brain function due to the angiogenic and nerve growth-promoting properties of Cardio Vascu-Grow™. CVBT has indicated they are looking at both of these treatment applications, so a simple marketplace potential analysis will be given for both stroke treatments.

Stroke-Acute Treatment

Over 700,000 strokes occur in the USA every year. Many strokes are not identified or go undiagnosed for days, weeks, or months. This makes the acute treatment more difficult to test and to apply to patients who have suffered a stroke. If, however, half of those 700,000 stroke patients were to seek treatment at $4,000 each, it could equal annual revenues for CVBT of $2.8 billion per year.

Stroke-Chronic Treatment

An estimated 400,000 people survive a stroke in the U.S. every year perhaps as many as 6 million people suffer from the effects of a stroke. Perhaps up to half of that number or approximately 3 million persons could benefit from a long term program to rehabilitate the ischemic areas of the brain. This would entail a slow and long-term infusion of Cardio Vascu-Grow™ into the patient with the hopes of establishing new blood flow into the area of the brain affected by the stroke with the subsequent re-growth and connection of new nerve and brain cells allowing the stroke patient to regain important brain and body functions. It was once believed that brains cells did not regenerate; now many medical experts believe they can and do, and what is needed is a reintroduction of blood flow to allow this to happen.

While no economic model has been discussed for chronic treatment of stroke patients with Cardio Vascu-Grow™, it is estimated that such treatment would occur continuously over a 3-6 month period with the drug infused via an intravenous pump, similar to chemotherapy patients. If the cost of this infusion was $4,000 dollars every six months, or $8,000 per year, then the potential marketplace for this indication comprising 3,000,000 stroke patients could be $24 billion per year for CVBT. While declared a long shot by CVBT, because ischemic brain tissue

is more difficult to salvage than muscle tissue, it is an interesting and important area to watch.

Neuropathy

This is a disease common to diabetics where nerves in the extremities slowly die leading at first to tingling in the arms and legs, followed by pain, which can often be excruciating. The scientific literature has reported that Cardio Vascu-Grow™ can stimulate nerve growth in an animal model of neuropathy. Could this same result occur in humans? CVBT has declared that they are in early pre-clinical research in this area, and that it is a secondary priority at present with the company's real effort in this area to begin in early 2006. Because of the many millions of diabetics who suffer from neuropathic pain, this is an area to be watched. No marketplace potential for this indication will be attempted in this report, as it is too early to include it in the company's potential business. However, it is an important area to watch over the next 24 months as the marketplace potential could be very material to CVBT.

Digestive System Group

Most people do not realize that the blood vessels that feed the digestive system can also become blocked by atherosclerosis. The President of CVBT stated at a recent conference in Hawaii that this was a new area for CVBT, which he believed affected 3 million to 30 million Americans. Basically a disease of aging, the blockage can occur at several different places in the circulatory system of the digestive system, which can lead to pain, diminished uptake of nutriments into the body, diminished removal of waste from the body and extreme discomfort to the person.

Mr. Montano stated, "We have just started to investigate this possible new application of the CVBT protein drug, and at present we have no idea if the CVBT drug will work in the intestines, or pancreas. If however it does provide some medical benefit it could be material to CVBT."
The marketplace potential of this area will not be covered at this time, since there is not enough data available. It is simply mentioned here for introductory information, as any medical treatment that could utilize the CVBT drug and be used to treat 3,000,000 to 30 million people would be a large marketplace potential and should be followed over the future.

Kidney Group (hypertensive renal disease)

Blockage or destruction of the blood vessels feeding the kidney has been reported to affect 3 million people in American. A new drug that could restore damaged vasculature in the kidney would meet an unmet medical need. CVBT has stated that developing a new treatment for the ischemic kidney is an important area to the company, but it will not be addressed until 2006. Any potential application that has a potential patient population of 3 million people is a good business opportunity for CVBT and will be followed.

Other Medical Indications for Cardio Vascu-Grow™

CVBT has made brief statements concerning other ongoing pre-clinical research. This work is in its early stages and no market potential will be estimated for these projects. From CVBT's public disclosures it has been learned that other tissues have a potential to benefit from Cardio Vascu-Grow™ and include various diseases affecting the central nervous system, connective tissue and bone, and the eyes and ears. While CVBT's work in these areas is in the early pre-clinical stages, the next 24 months should provide a better indication if any of these potential applications will advance to the clinical testing stage.

USA Marketplace Potential for the CVBT Drug Product

CVBT is attempting to apply its drug to many medical indications where the human body's blood supply to a particular tissue or organ has been reduced or blocked all together. The two indications where CVBT has reported the most interesting medical results have been 1) diseases where blood supply to muscle tissue in the heart, legs or back has been blocked leading to tissue ischemia, and 2) wound healing.

For this report only those two areas, the Muscle Tissue Group and the Wound Healing Group will be analyzed for the marketplace potential of Cardio Vascu-Grow™. The other applications, the Nerve Tissue Group, the Digestive System, the Kidney, and Other Medical Indications will be assumed at a zero marketplace potential at this time. The developments in those areas should be followed as they could result in billions of dollars of future business for CVBT however, in this report they will be excluded.

The U.S. Marketplace Potential of the Muscle Tissue Group was given a range from $500 million to $45 billion U.S. dollars. The Wound Healing area was given a Marketplace Potential of $1 billion to $12 billion U.S. dollars. If the drug is approved by the FDA after the completion of ongoing clinical trials, and it should be stressed that there are no assurances the drug will be approved, then the combined Marketplace Potential for CVBT for these two groups of medical indications could be $1.5 billion U.S. dollars to $57 billion U.S. dollars per year.

"What is the Worldwide Marketplace for Cardio Vascu-Grow™, if the drug is approved and accepted?" Again there are no assurances or representations that approval will occur, and this is the single biggest risk factor for CVBT.

Generally the U.S. Marketplace for prescription drugs is 33% to 50% of the world wide marketplace for those drugs, as has been reported in many different publications. While no one can predict with certainty the exact relationship between the U.S. Marketplace for a drug and the worldwide demand for the same drug, some fair assumptions can be made. The first assumption is that diabetes and heart disease are international health issues. Heart disease is reported as the number one cause of death in all developed countries of the world with the exception of Japan, where the number one cause of death is stroke.

Additionally, CVBT's management believes that their treatment could lower the over-all cost of treating these diseases. As an example they cite that if a no-option heart patient's angina and chest pain are relieved by Cardio Vascu-Grow™; then these patients are going to have many fewer visits to the emergency room. Normally new, sophisticated prescription drugs dramatically raise the cost of treatment, not lower it. However, CVBT believes the introduction of Cardio Vascu-Grow™ will dramatically lower the overall cost to treat these patients, and for this reason believes the drug will rapidly gain wide spread acceptance outside of the U.S. following FDA approval. On the conservative side, even though 95% of the world's population lives outside of the U.S., it will be assumed that the U.S. represents one-half of the worldwide market place for Cardio Vascu-Grow™.

Given these assumptions, if the U.S. Potential Marketplace for Cardio Vascu-Grow™ is $1.5 billion in annual sales at the low end and $57 billion in annual sales at the high end, then a Worldwide Marketplace Potential for Cardio Vascu-Grow™ would be double the U.S. Marketplace Potential. This would represent worldwide annual sales of Cardio Vascu-Grow™ of $3 billion at the low end and $114 billion at the high end.

The author of this report must stress that every potential investor in CVBT must do their own critical analysis and challenge every assertion of this Marketplace Potential Analysis.

> *There are no assurances that Cardio Vascu-Grow™ will gain FDA approval, there are no assurances of its acceptance by the medical community if approved, and there are no assurances that the analysis of the marketplace potential represented in this report is an accurate reflection of the future demand for the drug.*

However, if the development of Cardio Vascu-Grow™ progresses as hoped and predicted by the management of CVBT, then there is a very good likelihood that the company could enjoy annual sales of the drug reaching anywhere from $3 billion to as high $114 billion dollars per year.

What this could mean economically for CVBT and its shareholders is covered in the next Section of this report entitled "Possible Economic Models."

Section III- POSSIBLE ECONOMIC MODELS FOR CVBT

It is always difficult to set valuations for biotechnology companies. Generally, most of the younger companies have no products at all, they simply have ideas or interesting pre-clinical data that they are attempting to further develop. CVBT, on the other hand, has advanced its protein drug to the point where it is progressing through U.S. FDA-authorized clinical trials. Will the drug be successful and gain FDA approval is still anyone's guess. However, for certain, if Cardio Vascu-Grow™ is not approved for any therapeutic applications, the company is worth zero dollars.

The purpose of this economic analysis is not to justify a value for CVBT, but to explore what the value could be if the drug is approved by the FDA and is accepted by the medical community, patients, and payors of prescription drugs.

As detailed in Section II of this report, the potential range for annual sales of Cardio Vascu-Grow™, looking at only the Muscle Tissue Group and the Wound Healing Group, were $3 billion at the low end of patients treated, to $114 billion in annual sales at the high end of patients treated.

Two major questions for a rational economic analysis of CVBT remain:

> ***When will FDA approval and commercial sale of Cardio Vascu-Grow™ occur?***
>
> ***How will approval affect the valuation of CVBT?***

Question 1- When will Cardio Vascu-Grow™ be approved for sale?
No one knows the answer to this question. The process of obtaining U.S. FDA drug approval is long and difficult. It is not known if the drug will be approved and no one knows once it is approved, how it will be accepted by the medical community. Based on what CVBT has stated in the company's 2005 Annual Report, the company will not be filing an application to the FDA to seek approval to sell Cardio Vascu-Grow™ before the second quarter of 2007. This is approximately 24 months from now. The question that remains open is, if the future U.S. clinical trials continue with similar results as the prior clinical trails, when will the company file for FDA approval? The best estimate on the timing of this submission is late 2007 or early 2008. That would mean the best case scenario has CVBT gaining approval for their drug by late 2007. However, this could be delayed to 2008 or even as late as 2009, if CVBT obtains approval at all.

With the assumption that FDA approval did occur, how long would it take CVBT to build a sales and distribution force, put in place a payment system, and establish an advertising presence such that CVBT could generate the sales of Cardio Vascu-Grow™ discussed in the Marketplace Potential in Section 2 of this report? A good estimate is that, at best, these tasks could take at least one year; but a more likely case is that implementation of these efforts would take two to three years.

If CVBT's drug were approved in 2009 (the latest time estimate if approval is ultimately granted by the FDA) and it did take three years to build the sales, distribution and payments systems, then it is conceivable that in 2012, CVBT could capture the marketplace potential of its drug that has been discussed earlier.

Question 2- What could this mean as far as a value for CVBT?

Attempting to do an economic forecast seven years into the future is very risky and highly unreliable. Given this disclaimer, however, estimates of a company's value can be attempted.

If CVBT reached its marketplace potential in 2012, the range of sales could be between $3 billion per year to $114 billion dollars in annual sales.

Based upon CVBT's SEC filed Form 10-K, the contracted cost for the production of the drug is 10% of sales. Mr. Montano has stated that he believes the Sales and Marketing cost should not exceed 10% of sales, and that he could not foresee the combined General Administrative cost, and R&D expenses exceeding 10% of sales. If this occurred, then CVBT should have a 70% operating profit margin on sales. He has also stated he did not believe overall Income Taxes for CVBT would exceed 30% of Operating profits. A 30% Corporate Tax rate on 70% Operating Profits calculates to a tax which represents approximately 21% of sales. Overall, these figures indicate that CVBT's management believes the company can earn approximately 50% of sales in After Tax, Net Profits.

If CVBT did obtain $3 billion in sales in 2012, does this mean it could earn an After Tax Profit of $1.5 billion? Given that CVBT has approximately 125,000,000 shares outstanding presently; if that occurred then could CVBT earn $12 per share?

If CVBT did obtain $114 billion in sales in 2012, could it earn $57 billion profits after taxes? If so, would CVBT then equal earnings of $456 per share?

What measure of value would be placed upon the earnings per shares figures of CVBT? Would it be a Price to Earnings Ratio (P/E Ratio) of 15 times, 25 times, 35 times, or more? No one knows that answer to this question. Biotechnology shares typically have a wide range of P/E ratios, and a low of 20 times to a high of 60 times is not uncommon. If CVBT had a P/E ratio of 35 times, an average range for the biotechnology industry, and if CVBT earned $12 per share, with a 35 P/E ratio, then, in theory, the shares would be worth $420 each in 2012. If, CVBT earned $456 per share, and had a 35 P/E ratio then the shares would be worth $15,960 per share in 2012.

What does a possible share value of $420 for CVBT shares in 2012 mean to a person who wants to invest in CVBT in 2005? To address this question one can apply a commonly used financial tool referred to as the "The Discounted Present Value." What this tool allows is a calculation, using an estimate of a stock price a number of years in the future, to what an investor should pay in 2005 for that stock. The discount rate of that future value is related to risk, alternative returns, and other market conditions. As an example, suppose a person wanted to earn 50% per year on their money for the higher level of risk they are willing to take. This would equate to an annual Discounted Present Value of 33% per year. To show how this calculation is obtained, a person

would invest $100 and would anticipate it going up to $150 (i.e. a 50% increase in one year). This is the same as getting $150 one year in the future and discounting that back to 2005 by 33% (or $50) and paying $100 now for that investment.

If CVBT shares are estimated to be worth $420 per share in 2012, and an investor wanted a 50% annual return (the same as a 33% discount), what would that value be in 2005. Here is the calculation:

Theoretical Value

2012		$420 per share
2011	(less 33%)	$280 per share
2010	(less 33%)	$186.67 per share
2009	(less 33%)	$124.44 per share
2008	(less 33%)	$82.96 per share
2007	(less 33%)	$55.31 per share
2006	(less 33%)	$36.87 per share
2005	(less 33%)	$24.58 per share

Under this scenario the Theoretical Value of CVBT shares in 2005 is $24.58 per share, based on an estimated price of $420 per CVBT share in 2012. What is important here is not what is the Theoretical Value of CVBT shares is in 2005, but what the value of CVBT shares could be in 2007, 24 months from now when the company will have a much clearer picture on the progress of the various clinical trials being pursued with Cardio Vascu-Grow™. This, in turn, which will permit a much better estimate of the chances of FDA approval for each medical indication that, is being advanced.

Conclusion of Possible Economic Value for CVBT

In this author's mind, CVBT is a company which should be watched and evaluated carefully over the next 24 months to evaluate what progress the company makes towards accomplishing its goals in its clinical trials and its drug approval processes.

No one can predict the future, but the next 24 months should bring clarity as to the likelihood that CVBT will either fail or succeed in gaining approval for its protein drug for use in heart disease or wound healing. It will be an extremely interesting company to watch.