

**Medical Devices**  
**January 20, 2005**

**CABG Medical, Inc.**

**(CABG - \$5.94)**

**Initiating coverage**

**BUY**

## Financial Summary

Rev(mil)	2004E	2005E	2006E
Mar	\$	\$	\$
Jun	\$	\$	\$
Sep	\$	\$	\$
Dec	\$	\$	\$
FY	\$ 0	\$ 0	\$ 0
P/Sales	na	na	na

EPS	2004E	2005E	2006E
Mar	\$	(\$0.08)	(\$0.20)
Jun	\$	(\$0.09)	(\$0.22)
Sep	\$	(\$0.11)	(\$0.23)
Dec	\$	(\$0.16)	(\$0.25)
FY	(\$0.30)	(\$0.44)	(\$0.91)
P/E	na	na	na

Price:	\$5.90
52-Week Range:	\$6.98-\$5.35
Target:	na
Rating:	BUY
Shares Outstanding:	16.6 mil
Mkt. Capitalization:	\$99 mil
Ave. Volume:	49,000
Instit. Ownership:	10%
BV / Share:	\$1.88
Debt / Tot. Cap.:	0%
Est. LT EPS Growth:	na

## Company Description

*CABG Medical is an early stage medical device company that has designed the Holly Graft System, an artificial graft for coronary artery bypass surgery. The first human implant of the Holly Graft System was completed on November 30, 2004 in Brisbane, Australia.*

## Key Points:

- CABG Medical is an early stage medical device company that has designed the Holly Graft System (HGS), an artificial graft for coronary artery bypass surgery. **Coronary artery bypass grafts represent a market opportunity in the U.S. approaching \$1.5 billion** and possibly double that on a worldwide basis. Currently there is no approved, artificial graft for coronary applications that is on the market.
- According to the American Heart Association, there were over **500,000 coronary artery bypass graft procedures done on 305,000 patients in the U. S during 2001**. While the number of procedures had been declining since the late 1990's, current industry statistics suggest that this downtrend has stabilized.
- The **first implant** of CABG Medical's artificial graft **was completed on November 30, 2004** in Brisbane, Australia.
- **Preparations are being made to begin clinical trials** in Australia and Europe over the next three to six months and the Company intends to **apply for an Investigational Device Exemption (IDE) in the second half of this calendar year** to begin trials in the U. S. by the end of the year.
- CABG Medical **raised \$27.0 million net after expenses in an initial public offering** of 5.5 million shares at \$5.50 per share on December 7, 2004. The over-allotment of 825,000 shares was exercised on January 14, 2005 raising an additional \$4.2 million.
- Even under the most optimistic assumptions, **CABG Medical will not be generating product revenues outside the U.S. until 2007 and in the U.S. until 2008**. This may necessitate additional needs for capital before commercialization of the product.
- While revenues are not expected in the near term, we believe the timely commencement of clinical trials in Australia and Europe, completing additional animal studies and obtaining an IDE for clinical trials in the U. S. and the start of clinical trials in the U.S. are **milestone events that should positively influence the share price over the next twelve months**.

## Investment Recommendation:

We are initiating coverage of CABG Medical with a **BUY** rating for speculative investors who understand and can tolerate the risks of investing in an early stage medical device company. In our opinion the HGS works, but the clinical effectiveness and safety of the device remain to be proven in widespread human clinical trials.

Our strategy for investing in CABG Medical is to establish an initial position at, or near, current prices and to add to that position as progress towards commercialization is made and the clinical and regulatory risks are reduced. This strategy will not produce the greatest gains assuming successful commercialization of the product, but recognizes that the risk of owning the stock is reduced as these milestones are successfully met.

## Company Description:

CABG Medical is an early stage, medical device company that has designed and developed the Holly Graft System, an artificial graft for coronary artery bypass surgery. The Company was incorporated in Minnesota on December 3, 1999. A pilot study to test the feasibility of the HGS was initiated in January of 2001 and a formal, preclinical animal evaluation of the HGS was started in January 2003.

The first human implant of the HGS was completed on November 30, 2004 in Brisbane, Australia. The patient was released from the hospital approximately one week later. The Company does not intend to comment on the progress of individual patients

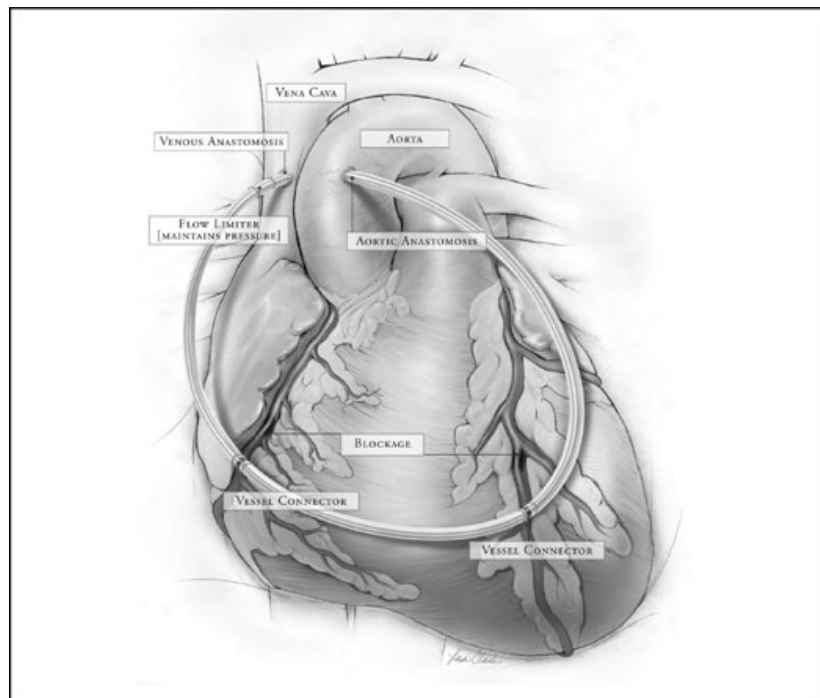
On December 7, 2004, the Company raised \$27.0 million, net of expenses, in an initial public offering of 5.5 million common shares at \$5.50 per share. The underwriter's overallotment of 825,000 shares was exercised on January 14, 2005. This raised an additional \$4.2 million, net to the Company.

The Company's Chairman and CEO, Manny Villafaña, has been involved in the startup of several other medical device companies including Cardiac Pacemaker, Inc. (now Guidant, Inc.), St. Jude Medical, Inc., ATS Medical, Inc. (founded as Helix BioCore) and GV Medical, Inc. (renamed SpectraScience, Inc.).

## The Holly Graft System:

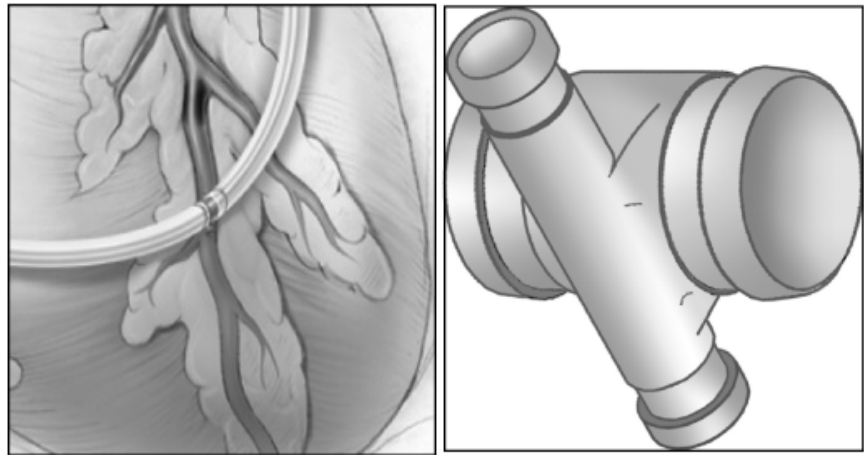
The Holly Graft System is an artificial coronary artery graft designed to treat blockages in single or multiple coronary arteries from a single graft attached at one end to the aorta. Blood flows into the HGS at the aorta and out of the HGS at the superior vena cava. In between, blood will flow to one or more coronary arteries through vessel connections established by surgeons.

The HGS is designed to create a high volume of blood flow through the main conduit to provide a supply for each of the coronary arteries to which a connection is made. To maintain appropriate pressure in the system to feed the coronary arteries, a flow limiter is incorporated at the outflow end to restrict the flow of blood into the vena cava.



The graft is manufactured using expanded polytetrafluoroethylene, or ePTFE. This material is commonly used as a peripheral vascular graft conduit. The flow limiter and vessel connectors are made of titanium.

The HGS vessel connector is coated with a combination of drugs to limit thrombus and the buildup of tissue at the ends of the connector in the vessel in the same manner that drug-eluting stents prevent restenosis in stenting procedures. The titanium used in the vessel connector and flow limiter is approved by the FDA as an implantable alloy. The connector utilizes the same drug, paclitaxel, that is currently used in an FDA approved drug eluting stent (see risk factors). The vessel connector is attached to the graft and the target vessel using standard suture material. An implanted vessel connector and the vessel connector and are shown at the left and right below:



The existence of an unmet clinical need is what ultimately drives innovation in cardiac surgery and creates markets, as in all other medical device areas. While traditional bypass procedures have produced acceptable results, there are a number of issues with traditional the procedures that an artificial graft could solve; i.e., saphenous vein harvesting is an invasive procedure subject to complications, the anastomosis (connection) of the graft to the artery is difficult and time consuming, there are a significant number of patients who have previously undergone bypass surgery in whom grafts have either failed or suffered other blockages and a significant number of patients who have no other option.

The HGS addresses many of these issues by:

- Reducing the need for and cost of an invasive surgery to harvest vessels in the arms or legs that can lead to patient discomfort, scarring and complications;
- Significantly, reducing the time and skill required for the anastomosis of the SVG to the coronary artery. In animal trials, the vessel connector has been sutured into the coronary artery in two to three minutes versus 12-20 minutes for a SVG;
- Providing a source of graft material for patients who have already had a SVG procedure or who are not candidates for bypass surgery due to co-morbidities such as diabetes and/or obesity that make vessel harvesting difficult or impractical;
- Using materials in the graft and connector and the drug combination that are readily available and have been approved by the FDA in other applications.

## **Intellectual Property:**

There have been numerous efforts to develop an artificial coronary graft using materials that mimic the natural structure of the coronary artery. To date, none of these efforts has been approved by the FDA or made it to the market. CABG Medical believes that focusing on the mechanics of blood flow and the corresponding influence on graft patency are the critical elements for developing a successful graft particularly when coupled with drug combinations to minimize or eliminate clotting and tissue growth.

To date, CABG Medical has obtained two U. S. patents; applied for four additional U. S. patents on various aspects of the HGS, and has filed foreign applications in several countries. Additionally, it has obtained non-exclusive licenses from several suppliers for critical components. However, the Company is in continuing discussions on necessary licenses from Angiotech Pharmaceuticals Inc. relating to the use of paclitaxel that is used as a coating on the vessel connector in the HGS. While the Company can continue to use paclitaxel in its clinical trials, it will need to negotiate a license with Angiotech before commercializing the HGS. CABG has begun to evaluate alternative drugs, but there is no guarantee that they will be as effective as paclitaxel.

Assuming the Company is correct that it is the mechanics of blood flow in combination with drugs that limit clotting and tissue growth, we believe it will be difficult for competitors to get around CABG Medical's intellectual property portfolio (both issued and applied for) since the patents address these issues. This should provide a competitive advantage for the Company.

## **Industry Background:**

Cardiovascular diseases (CVD) of all types, including high blood pressure, coronary heart disease, congestive heart failure, stroke and congenital cardiovascular defects, affect over sixty million people and are the leading cause of death in the United States. In 2004, the estimated direct and indirect cost of CVD approached \$400 billion.

More narrowly defined, coronary artery disease (CAD) - myocardial infarction (heart attack); angina pectoris (chest pain) or both - affects over 13 million people in the U. S. according to the Centers for Disease Control and Prevention and the National Center for Health Statistics. In 2001, over 300,000 patients had bypass surgery and more than 500,000 grafts (procedures) were implanted. However, based on a study published in the Journal of the American Medical Association in April 2004, CABG Medical believes the number of procedures (grafts) may be closer to 900,000 per year. It is generally assumed that the rest of the world represents an opportunity roughly equal to the size of the U.S. market.

Advancements in treatment, including devices and drugs, have led to a decline in CVD death rates, but an aging population and increases in obesity and diabetes is expected to lead to increased incidence of chronic diseases including coronary artery disease, heart failure and stroke in the coming years. While the number of bypass procedures has been declining since the mid-1990s due the adoption of angioplasty and stenting, preliminary data for 2002 and estimates through 2004, suggest that the annual number of procedures may have stabilized.

There is also a less well defined pool of patients that cannot be conventionally revascularized and are therefore treated with palliative medical therapies. These patients have severe CAD and are not candidates for interventional or surgical procedures because of their risk profile, co-morbidities, diffuse disease, poor target vessels, lack of conduits and/or lack of an acceptable target site. The HGS could provide clinicians with a revascularization procedure that would address many of these patients as well.

Since pricing for the HGS has not been established, the potential size of the market for an artificial coronary bypass graft is difficult to pinpoint at the present time. We believe that CABG Medical's objective is to realize approximately \$4000 to \$5000 per artificial bypass

procedure (multiple grafts). Assuming the number of patients remains relatively constant in the future, the potential market for the Holly Graft is \$1.2 to \$1.5 billion. However, it is unlikely that an artificial graft would capture this entire potential due to the use of internal mammary arteries and physician preferences for traditional bypass graft methods. Still, we believe that a sizeable, and very profitable company can be built in this area.

### **Reimbursement:**

In the U. S., healthcare providers generally rely on third-party payors, including Medicare, Medicaid, private health insurance carriers and managed care organizations to reimburse all or part of the cost and fees associated with the procedures in which devices are used. The commercial success of the HGS will depend on the ability of the health care providers to obtain adequate reimbursement from third-party payors for the surgical procedures in which the devices are used.

CABG Medical intends to pursue reimbursement for the vessel connector component with a drug coated stent as a predicate device and for the graft component of the device under existing codes for ePTFE vascular grafts. Assuming the American Medical Association adopts those specific procedure codes for the HGS, we believe that reimbursement would be adequate to support the pricing assumptions outlined above.

The mean average charge in the U. S. for a bypass procedure is approximately \$61,000. CABG Medical believes that potential procedure cost savings and facility economics should be attainable from the utilization of the HGS based on reductions of operating room time due to the ease of use of the HGS and the elimination of the expense of and complications from harvesting vessels from a patient's legs and arms. Under existing codes a hospital may currently charge up to \$7000 for vessel harvesting in a bypass procedure. Without calculating other potential cost savings due to less time in the operating room or the elimination of infection or other complications from vessel harvesting, the HGS could appear to make economic sense just by eliminating vessel harvesting.

### **Regulatory and Commercialization Plan:**

The first human implant of the HGS took place in Brisbane, Australia on November 30, 2004 under a Special Access Scheme provision of Australian law. The Company intends to expand its trial in Australia and commence human clinicals in Europe in the first half of this calendar year. Assuming that there are no delays in the process, the earliest that the Holly Graft could be introduced into Europe or Australia is 2007.

Depending on the results of current and future preclinical animal testing and assuming the initial human implants and clinical trials to be conducted in international venues are successful, CABG Medical plans to file an application for an Investigational Device Exemption, or IDE, with the FDA seeking to initiate human clinical trials for the HGS in the United States this calendar year. The HGS is a Class III Device that will require Pre-Market Approval, or PMA, by the FDA.

Based on CABG Medical's analysis of the FDA's review of relatively similar medical devices, the Company anticipates the primary endpoints of the pivotal FDA clinical trial will be a six-month angiographic follow-up to assess patency and a twelve-month clinical follow-up. These trials could commence in 2005 and the earliest they will end is the fourth quarter of 2007.

If the Company has completed enrollment and obtained sufficient clinical data, it anticipates filing an application for PMA in late 2007 or early 2008. Under current guidelines, the FDA has an objective of responding to PMA submissions in ten months. This could allow the Company to begin commercial sales in the U. S. before the end of calendar 2008, assuming no delays in the process.



As is typical in the medical technology industry, CABG Medical plans to seek regulatory approvals to market the HGS in certain international markets before seeking FDA approval in the United States. The Company will likely market the product in international markets with a network of experienced cardiovascular surgery representatives. In the United States, the HGS will be marketed using a combination of a direct sales force and independent representatives.

### **Competition:**

Besides traditional coronary artery bypass graft procedures, the principal competition in cardiac surgery arena comes from the large medical device companies. CABG Medical believes these companies may be working on products similar to its artificial graft as well as expanding the complement of competing products or therapies including stenting, angioplasty and drug therapies. While there have been many efforts by companies to develop an artificial coronary graft, to date there has been no artificial graft for coronary applications on the market.

Currently, we are aware of three publicly disclosed, directly competitive efforts. CardioTech International, Inc. is in clinical trials in Brazil evaluating an artificial coronary bypass graft (the CardioPass). CardioTech has implanted three patients who have passed the one-year threshold with the device. This device is a coated, polyurethane-based biomaterial implanted using a traditional bypass approach. CardioTech is currently planning to expand its clinical trial in Brazil and commence clinical trials in Europe this calendar year.

Percardia, Inc. has developed a myocardial implant system that infuses the coronary artery by way of a direct connection through the wall of the ventricle into the blocked artery using a stainless steel stent. A clinical evaluation (ADVANTAGE) of the Company's device had been started in Europe in late 2003, but preliminary results presented last year were disappointing. Percardia has raised a total of \$55 million in several rounds, including a Series D financing of \$23.5 million in the fourth quarter of 2003.

Kensey Nash Corporation (KNC) has identified a model for graft development that imitates the physiological situation of wound surroundings to provide a platform for *in vivo* arterial generation. Based on this model, KNC is developing a graft technology that incorporates resorbable and non-resorbable biomaterials as well as biologically active agents into a porous device to promote uninterrupted tissue connection throughout the entire prosthesis to improve graft compliance matching and patency. This technology is in the pre-clinical development stage at the current time.

While CardioTech's device has been implanted in a limited number of human's for over one year, they do not have a clear-cut lead in terms of human clinical trials in Tier 1 countries such as in Australia, Europe, Canada or the U.S. Consequently, the first to market advantage is still open to CABG Medical.

### **Outlook:**

Since CABG Medical is an early stage company just entering human clinical trials for its first product, our income statement projections in this report include only spending totals over the next two years. They are not adjusted for any expense accruals, as opposed to cash expenditures, and do not include a working capital needs over the period in question. Our estimates are primarily meant to illustrate potential cash burn over the next two years. Investors should recognize that these estimates are subject to considerable variability depending on the timing and pace of clinical trials.

We estimate that CABG Medical had approximately \$27.5 million of cash on hand at the end of calendar 2004. On January 14, 2005 the underwriter's overallotment of 825,000 shares was exercised. This raised an additional \$4.2 million net to the Company.

Management expects to burn \$7-\$8 million of cash in calendar 2005 and up to \$15 million in calendar 2006. Based on the timetable for the expansion of clinical trials in Australia, Europe and the U. S., we would expect to see the burn rate on quarterly basis going from approximately \$1.0 million plus in the current quarter to over \$4.0 million by the end of calendar 2006. This would result in cash declining to \$10 million, or less, by the end of 2006. Consequently, while there is a prospect for sales outside the U. S. in calendar 2007 and in the U. S. by the end of calendar 2008, we would expect the Company to raise additional capital before the end of 2007, assuming the clinical trials are producing positive results.

### **Conclusion:**

In our opinion the HGS works, i.e., the device has shown that it can re-perfuse a blocked coronary artery in animal trials and in the first human implant. However, the long-term safety and effectiveness of the device remain to be proven in widespread human clinical trials.

There is a large unmet clinical need for such a device and CABG Medical could potentially enjoy a first to market advantage, assuming the clinical and regulatory challenges are overcome on a timely basis. While these challenges cannot be minimized, we believe the potential return from owning shares compensates for these risks. Assuming the Company is able to garner a 10% share of the worldwide bypass graft market by the end of the decade CABG Medical could have a very profitable, \$250 to \$300 million business. Based on the current multiples paid for smaller, rapidly growing medical device companies (four to eight times revenues), the upside potential for the stock is considerable. A shorter (less than six years) time horizon outcome could entail the sale to a larger cardiac, oriented device company if the clinical milestones are positive.

Consequently, we are initiating coverage of CABG Medical with a **BUY** rating for speculative investors who understand and can tolerate the risks of investing in an early stage medical device company. Our strategy for investing in CABG Medical is to establish an initial position at, or near, current prices and to add to that position as the clinical and regulatory risks are reduced over time. This strategy will not produce the greatest gains assuming successful commercialization of the product, but recognizes that the risk in owning the stock is reduced as these milestones are successfully met.

### Other Public Companies mentioned in this report:

Advance Neuromodulation Systems, Inc (ANSI \$39.50 not rated)  
ATS Medical, Inc (ATSI \$4.28 not rated)  
CardioTech International, Inc. (CTE \$2.50 not rated)  
Guidant Corporation (GDT \$71.50 not rated)  
Kensey Nash Corporation (KNSY \$33.01 not rated)  
St. Jude Medical, Inc. (STJ \$38.67 not rated)  
SpectraScience, Inc (SCIE \$1.00 not rated)

**CABG Medical, Inc.**  
**Summary Income Statement and Balance Sheet**  
**Fiscal Year ends 12/31**

	Q1	Q2	Q3	Q4E	2004E	Q1	Q2	Q3	Q4E	2005E	Q1	Q2	Q3	Q4E	2006E
<b>Net Sales</b>	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<b>COGS</b>	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<b>Gross Profit</b>	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<b>R&amp;D</b>	\$519	\$473	\$648	\$650	\$2,220	\$1,000	\$1,250	\$1,500	\$2,000	\$5,750	\$2,750	\$3,000	\$3,000	\$3,250	\$12,000
<b>SG&amp;A</b>	\$165	\$236	\$195	\$300	\$896	\$450	\$450	\$450	\$750	\$2,100	\$750	\$800	\$900	\$1,000	\$3,450
<b>Total</b>	\$684	\$709	\$843	\$950	\$3,186	\$1,450	\$1,700	\$1,950	\$2,750	\$7,850	\$3,500	\$3,800	\$3,900	\$4,250	\$15,450
<b>Operating Profit</b>	(\$684)	(\$709)	(\$843)	(\$950)	(\$3,186)	(\$1,450)	(\$1,700)	(\$1,950)	(\$2,750)	(\$7,850)	(\$3,500)	(\$3,800)	(\$3,900)	(\$4,250)	(\$15,450)
<b>Interest Inc</b>	\$5	\$7	\$13	\$0	\$25	\$155	\$148	\$140	\$130	\$573	\$115	\$95	\$75	\$58	\$343
<b>Net Before Tax</b>	(\$679)	(\$702)	(\$830)	(\$950)	(\$3,161)	(\$1,295)	(\$1,553)	(\$1,810)	(\$2,620)	(\$7,278)	(\$3,385)	(\$3,705)	(\$3,825)	(\$4,193)	(\$15,108)
<b>Tax</b>	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<b>Net Income</b>	(\$679)	(\$702)	(\$830)	(\$950)	(\$3,161)	(\$1,295)	(\$1,553)	(\$1,810)	(\$2,620)	(\$7,278)	(\$3,385)	(\$3,705)	(\$3,825)	(\$4,193)	(\$15,108)
<b>Earnings Per Share</b>					(\$0.30)	(\$0.08)	(\$0.09)	(\$0.11)	(\$0.16)	(\$0.44)	(\$0.20)	(\$0.22)	(\$0.23)	(\$0.25)	(\$0.91)
<b>Shares</b>	0	0	0	0	10,500	16,650	16,650	16,650	16,650	16,650	16,650	16,650	16,650	16,650	16,650
<b>Estimated Cash</b>			\$1,426	\$27,500		\$30,405	\$28,853	\$27,043	\$24,423		\$21,038	\$17,333	\$13,508	\$9,315	



### **Analyst Certification:**

I, **Ernest Andberg**, certify that the views expressed in this research report accurately reflect my personal views about the subject company and its securities. I also certify that I have not been, am not, and will not be receiving direct or indirect compensation related to the specific recommendations expressed in this report.

### **Important Disclosures:**

The analyst or any member of his/her household **does not** hold a long or short position, options, warrants, rights or futures of this security in their personal account(s).

As of the end of the month preceding the date of publication of this report, Feltl & Co. **did not** beneficially own 1% or more of any class of common equity securities of the subject company.

There **is not** any actual material conflict of interest that either the analyst or Feltl and Company is aware of.

The analyst **has not** received any compensation for any investment banking business with this company in the past twelve months and **does not** expect to receive any in the next three months.

Feltl & Co. **has** been engaged for investment banking services with the subject company during the past twelve months and **does** anticipate receiving compensation for such services in the next three months. Investors should assume that Feltl and Company is seeking or will seek investment banking or other business from the companies in our research universe.

Feltl & Co. **has not** served as a broker, either as agent or principal, buying back stock for the subject company's account as part of the company's authorized stock buy-back program in the last twelve months. Feltl & Co. **may possibly** serve as the company's broker, either as agent or principal, as part of the company's authorized buy-back program in the next three months.

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**Feltl and Company Rating System:** Feltl and Company utilizes a four tier rating system for potential total returns over the next 12 months.

**Strong Buy:** The stock is expected to have total return potential of at least 30%. Catalysts exist to generate higher valuations, and positions should be initiated at current levels.

**Buy:** The stock is expected to have total return potential of at least 15%. Near term catalysts may not exist and the common stock needs further time to develop. Investors requiring time to build positions may consider current levels attractive.

**Hold:** The stock is expected to have total return potential of less than 15%. Fundamental events are not present to make it either a Buy or a Sell. The stock is an acceptable longer-term holding.

**Sell:** Expect a negative total return. Current positions may be used as a source of funds.

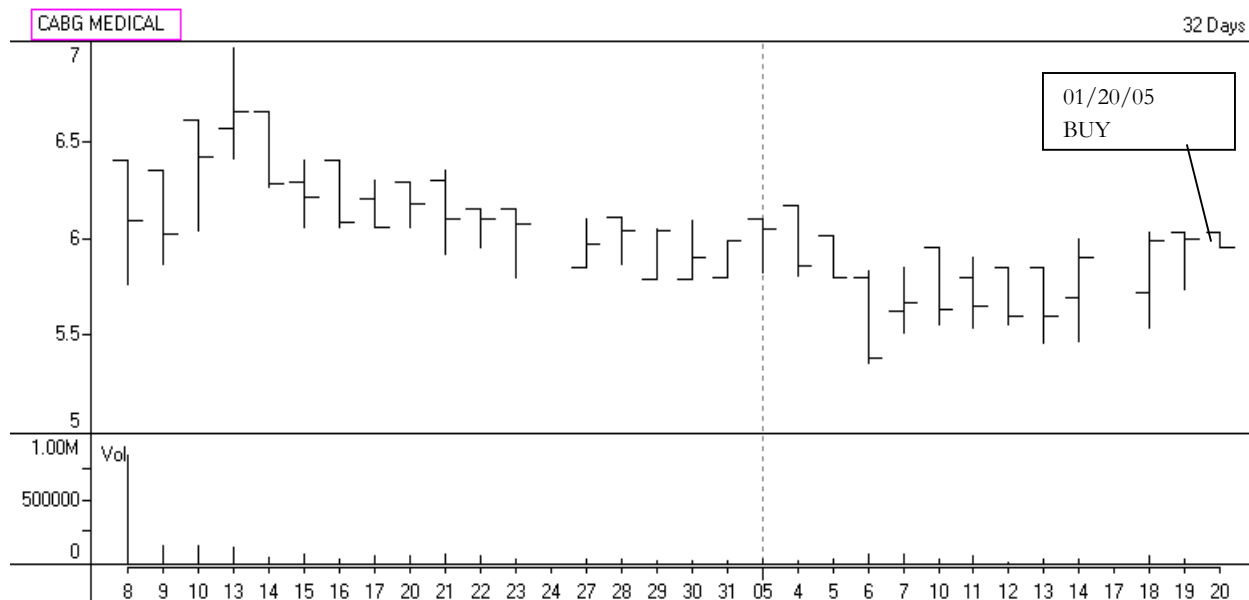
01/01/05

### Ratings Distribution for Feltl and Company

Rating	Number of Stocks	Percent of Total	----- Investment Banking -----	
			Number of Stocks	Percent of Rating category
SB/Buy	20	67%	3	15%
Hold	9	30%	0	0%
Sell	1	3%	0	0%
	30	100%	3	10%

The above represents our ratings distribution on the stocks in the Feltl and Company research universe, together with the number in (and percentage of) each category for which Feltl and Company provided investment-banking services in the previous twelve months.

Note: The above distribution table is current as of January 1, 2005. It does not include CABG Medical for which Feltl and Company acted as the lead investment banker for the Company's initial public offering of common stock.



Date	Nature of Report	Rating	Price Target
01/19/05	Initiation of Coverage	Buy	N.A.

Feltl & Company **does** make a market in the subject security at the date of publication of this report. As a market maker, Feltl & Co. could act as principal or agent with respect to the purchase or sale of those securities.

#### Risks to Achievement of Estimates:

CABG Medical is an early stage company with a limited operating history that is entirely dependent upon the success of the HGS. If the Company is unable to commercialize the HGS, or if it experiences significant delays in doing so, the shares could be impacted negatively.

Any adverse results in the first human implants or human clinical trials could have a material negative impact on the business.

The Company's products are subject to extensive regulation by the FDA and by comparable agencies in foreign countries. The HGS will require a PMA approval in the U. S. The PMA process is expensive, uncertain and lengthy. Significant delay or cost in obtaining, or failure to obtain FDA clearance to market the HGS would have a material adverse effect on the business.

Medicare and/or private insurance set the level of reimbursement for medical devices. The commercial success of the HGS will depend on obtaining adequate levels of reimbursement from third-party payors. There is no guarantee that adequate reimbursement will be achieved. In addition, the Company intends to obtain approval using predicate devices to set the level of reimbursement. If this strategy does not work, reimbursement decisions could be significantly delayed.

To date, CABG Medical has obtained two U. S. patents, applied for four additional U. S patents on various aspects of the HGS, and has filed foreign applications in several countries. Additionally, it has obtained non-exclusive licenses from several suppliers for critical components. However, the Company is in continuing discussions on necessary licenses from Angiotech Pharmaceuticals Inc. relating to the use of paclitaxel that is used as a coating on the vessel connector in the HGS. If the Company were not able to obtain such a license modification of the HGS to avoid infringement would require additional clinical testing in connection with the regulatory approval by the FDA.

Even if the device proves to be safe and effective in clinical trials, the path to regulatory approval in the U. S. and in other countries could take longer than expected. This could necessitate the need for additional capital.

Readers should recognize that the risks outlined above do not represent a comprehensive list of all risk factors that may impact the achievement of our price target.

#### **Other Disclosures:**

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