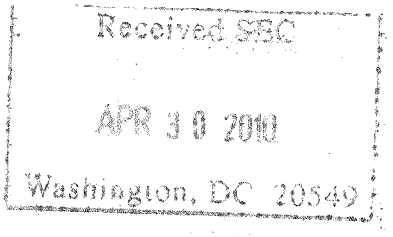
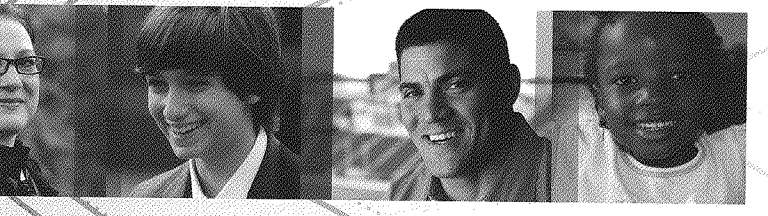
AGA Medical Corporation

2009 Annual Report

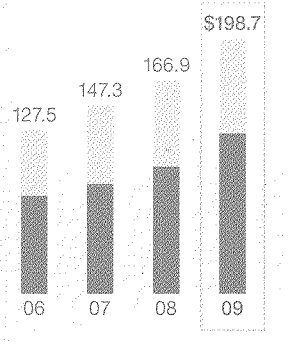




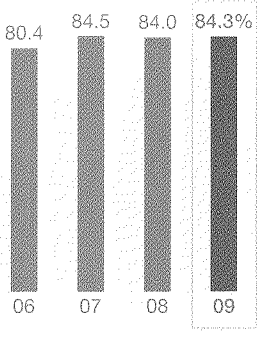
changing lives through medical innovation

Welcome to AGA Medical

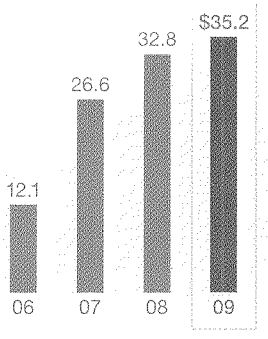
AGA Medical (Nasdaq: AGAM) is a global innovator and manufacturer of medical devices used to treat structural heart defects and abnormal blood vessels. AGA Medical's AMPLATZER® occlusion (closing or sealing) devices offer minimally invasive transcatheter treatments clinically shown to be highly effective in defect closure. All of its products are designed using nitinol braiding. AMPLATZER devices are recognized for ease of use, leading to good clinical outcomes for the patient. Interventional cardiologists, interventional radiologists, vascular surgeons and electrophysiologists use AMPLATZER devices, which are sold in 112 countries through direct sales and distributors. The company is a market leader with more than 400,000 devices shipped as of the 2009 year-end, and more than 1,650 peer-reviewed articles published in medical literature supporting the benefits of AMPLATZER devices.



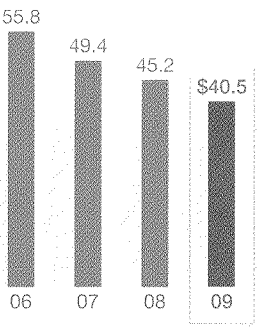
Net Sales
dollars in millions



Gross Margin
percentage



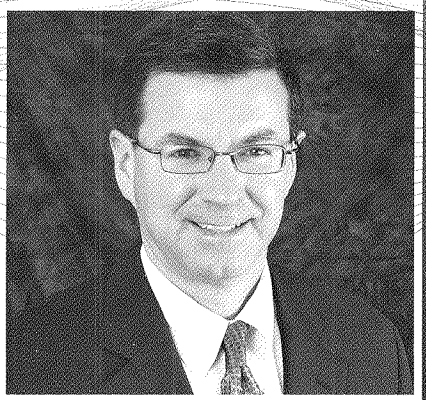
Research & Development Expense
dollars in millions



EBITDA*
dollars in millions

International United States

*EBITDA is defined as Earnings Before Interest, Taxes, Depreciation and Amortization.
Please see the inside back cover of this annual report for a reconciliation of EBITDA to net income for the periods presented.*



John Barr
President and Chief Executive Officer

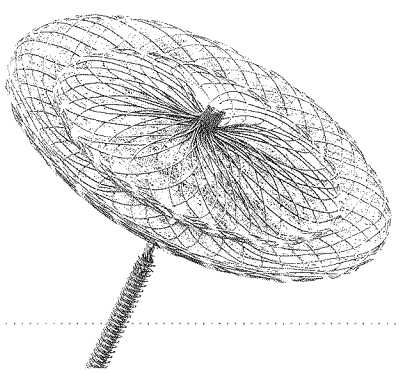
"Changing the lives of our patients drives us and is at the core of our mission — to develop innovative products that address significant unmet medical needs and become the standard of care."

To Our Shareholders:

As we enter our first full year as a public company, I want to welcome new shareholders to AGA Medical. You join our founding shareholder Franck Gougeon and his partner — Welsh, Carson, Anderson & Stowe — who together have shepherded our growth to where we are today. We pioneered the development of occlusion devices for structural heart defects, and today, are the premier structural heart company with a rapidly expanding vascular business.

Structural Heart Defect:
An unwanted communication or pathway (typically a hole) in the heart that affects normal blood flow and function.

AMPLATZER® Septal Occluder



Our goals for the future are equally ambitious: to change the standard of care for additional structural heart defects and vascular abnormalities.

Our current success would not be possible without the passion and drive of one of our co-founders and scientific leader, Dr. Kurt Amplatz. In 1998, Dr. Amplatz introduced a transcatheter structural heart device to treat an atrial septal defect, a hole between the right and left atrium in the heart's upper chambers. His innovation eventually changed the standard of care for the treatment of this defect, which is one of the most commonly diagnosed and treated structural heart defects.

In fact, before Dr. Amplatz's invention, most people diagnosed with an atrial septal defect faced the prospect of open heart surgery to correct the problem.

Today, most of these patients need only a minimally invasive procedure using AGA Medical's devices to close or occlude this hole in the heart. All of our occlusion devices proudly carry the AMPLATZER® name, a brand recognized by interventional physicians worldwide.

Thanks to Dr. Amplatz's research and leadership, we have a strong history of developing and commercializing products that deliver outstanding value to patients, physicians and the health care system. Today, AGA Medical is a strong, profitable business and on course for substantial growth, leveraging our expertise in nitinol braiding, our reputation for device ease of use, our highly efficient manufacturing operations, and our global sales and distribution organizations. Our progress is demonstrated by our strong 2009 results, which are highlighted in this annual report.

Nitinol Braiding: *The use of braiding machines that braid thin nitinol wires into a medical device. Commonly used in medical devices, nitinol is a shape memory metal alloy that allows the devices to retain their shape when compressed in a catheter.*

Occluder: *A medical device that is permanently implanted in a defect (typically a hole) that can be present in the heart or in other vascular connections in the body and is used for effective closure of the defect and to block blood flow.*

Leveraging Our Innovative Technology, Occluder Expertise

The sale of occlusion devices, or occluders, to treat atrial septal defects is a significant portion of our business, accounting for 51% of our revenue in the fourth quarter. Building on our success with this device and under the direction of Dr. Amplatz, we have developed occluders to treat other common structural heart defects, including a patent foramen ovale (PFO) which we currently sell outside of the United States and which comprised 16% of our revenue in the fourth quarter. Other structural heart occlusion devices that we sell are used to treat ventricular septal defects (holes between the left and right ventricles) and patent ductus arteriosis (a blood vessel that forms an opening to connect the aorta to the pulmonary artery).

AGA Medical is the only manufacturer with devices approved to occlude seven different structural heart defects, and we have the top position in every product segment in which we participate — we are the unmatched leader in occluders. Our products are the only fully retrievable and repositionable occluders on the market, and offer high closure rates, as well as a history of safety and durability.

A common thread in all of our occluders is our proprietary know-how and patent-protected manufacturing methods in braiding nitinol. Commonly used in medical devices, nitinol is a shape memory metal alloy that allows the devices to be compressed in a catheter and then return to the original shape when deployed at the defect. The braiding process involves the use of machines that braid thin nitinol wires into a medical device. Our proprietary expertise in nitinol braiding coupled with our extensive knowledge of occluders and delivery methods — and understanding of the heart and vasculature anatomy — have allowed us to extend our product line into the vascular market. Our line of vascular plugs — our fastest-growing segment — currently represents 8% of our fourth quarter revenue.

Today, the standard of care to treat patients who need to close or occlude an abnormal blood vessel involves placing small metal coils that are individually threaded through a catheter and packed together to block blood flow. Typically, physicians use between six and 10 coils, which can be challenging and time consuming to place at the right position in the blood vessel. In contrast, a physician usually needs only one AMPLATZER vascular plug, resulting in rapid occlusion and shorter procedures times.

Longer range, we are developing a new product line of vascular grafts to treat vascular aneurysms, which occur in the body when a weakened vessel wall expands. Today, the standard of care for vascular aneurysms requires a large incision to allow the relatively large catheters (delivery systems) to be inserted into an appropriate-sized blood vessel. Leveraging our expertise in braiding nitinol and our experience in developing easy-to-use delivery systems, we believe we can introduce vascular grafts that can be delivered through a smaller catheter, resulting in a truly minimally invasive procedure. Our vascular graft pipeline is another example of delivering our core technology through smaller delivery systems.

Growing Strong Revenue, Gross Margins

We reported strong financial results for 2009, and we are excited about our future. Our full-year 2009 net sales were $198.7 million, a 19% increase over the prior year. Our sales growth was driven by our investment in developing strong direct sales and marketing channels. Over the last three years, we have converted all but one country in Europe and Canada to a direct sales force that is better positioned to sell our products, while developing close relationships with our customers.

As a result, we have experienced strong growth in our core products. For example,

sales of our AMPLATZER PFO Occluder, available outside the United States, grew 23% on a unit basis in the fourth quarter. In addition, our vascular business — our fastest-growing segment — increased 38% on a unit basis worldwide during that time. Finally, our 2009 growth was fueled by introducing new products, including our AMPLATZER Cardiac Plug and AMPLATZER Vascular Plug 4, in Europe.

Our gross margins are exceptional for the industry, reflecting the high value of the products we deliver combined with efficient manufacturing. In 2009, our gross margin was 84.3%, providing the dollars to invest back into our business and product pipeline. As mentioned above, we are already benefiting from the investment in our sales and marketing channel, which helped drive record sales in the fourth quarter. Our investments in our product pipeline are critical to our ability to continue to bring innovative, clinically relevant products to market. Going forward, we now have the infrastructure to support a larger company.

Our profitability is strong. With just under $200 million in revenue — and with significant investment in our product pipeline — our EBITDA (earnings before interest, taxes, depreciation and amortization) was $40.5 million in 2009. And as we begin to complete key clinical trials and continue to see the impact of our direct sales organizations, we expect significant operating leverage to help us become even more profitable over the next four to five years.

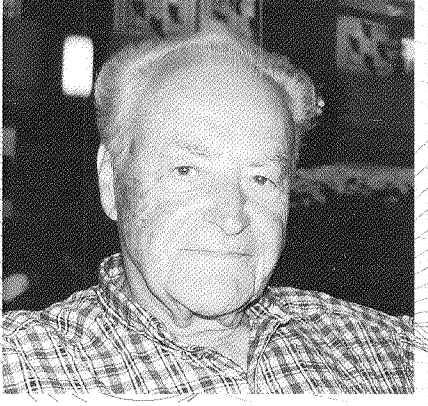
Our successful initial public offering in October 2009 demonstrates the strength of our current business and the market opportunities ahead. We are extremely proud to have been the only medical device company to complete an IPO in 2009. As a result, our financial profile is more solid than ever. We used the IPO net proceeds of $88.2 million to improve our balance sheet.

Expanding Our Opportunities Through New Indications

At our core, AGA Medical is an evidence-based medical device company. We invest in developing new products and new indications for existing products where there is a significant unmet medical need and a desire to improve the standard of care. Our current clinical programs focus on two products sold outside the United States today: the AMPLATZER PFO Occluder and AMPLATZER Cardiac Plug.

The AMPLATZER PFO Occluder is designed to close a patent foramen ovale (PFO), a tunnel between the upper chambers of the heart that allows blood unfiltered by the lungs to flow to the brain. A PFO is a common defect that can be found in up to 25% of the population; however, not all PFOs are clinically significant and need occlusion. Currently, we have three randomized, prospective clinical trials under way, each intended to confirm scientific theories about a relationship between PFO and cryptogenic stroke (stroke of unknown origin) or PFO and certain types of migraine headaches.

The RESPECT trial in the United States is studying whether PFO closure using our AMPLATZER PFO Occluder is superior to current medical management in preventing recurring stroke. AGA Medical's clinical team, along with our



Dr. Kurt Amplatz: AGA Medical Founder and Inspiration

Dr. Kurt Amplatz — a legendary cardiovascular researcher and pioneering medical device inventor — founded AGA Medical in 1995, and continues to lead its R&D efforts.

Dr. Amplatz discovered a way to braid nitinol wire into occluders that would regain their shape after passing through a catheter, creating the foundation for AGA Medical's AMPLATZER devices. Dr. Amplatz started AGA Medical at age 70, convinced these devices had a big future.

He was right. Dr. Amplatz completely changed the way we care for children born with heart defects. The life-changing innovation was just one milestone in the doctor's illustrious and prolific career. Dr. Amplatz's name is associated with fundamental tools in interventional radiology and pediatric cardiology, technology that was revolutionary at the time. Hundreds of published scientific papers carry his name, along with multiple honors from leading medical associations and the 13 U.S. patents that line the halls of AGA Medical.

Soon, another groundbreaking achievement will bear the esteemed doctor's name — Amplatz Children's Hospital, at the University of Minnesota. His daughter, Caroline Amplatz, pledged $50 million in her father's honor, the second-largest gift in the university's history.

AGA Medical thanks Dr. Amplatz for his vision, leadership and innovation. He has improved the lives of patients around the world and advanced the medical technology industry.

study centers, is making strong progress in recruiting patients. As of January 31, 2010, we have enrolled 667 patients with 1,244 patient follow-up years.

The two other studies — the PREMIUM clinical trial in the United States and PRIMA trial in Europe — are measuring whether PFO closure can result in a meaningful reduction in the number and severity of migraine headache days in patients with a significant PFO. In August 2009, we received FDA approval for a significant protocol change, which allowed us to keep all enrolled patients and reduce by half the projected enrollment. We will update you on our enrollment progress later in the year, as we gain further experience with our new protocol.

The AMPLATZER Cardiac Plug and its potential effectiveness in reducing the risk of stroke is currently the subject of a U.S. clinical trial. Patients with a heart arrhythmia, called atrial fibrillation, face a five-fold higher incidence of stroke. Clinical studies have demonstrated that a stroke in these patients is linked to a small structure, shaped like a pouch, off the left atrium of the heart called the left atrial appendage (LAA). Atrial fibrillation can cause blood to pool in the LAA, increasing the chance of clots that may travel to the brain and lead to stroke. The current standard of medical care is to treat these patients with anticoagulants, which are difficult to tolerate for many people and carry a risk of complications, such as bleeding. Our approach is to permanently seal the appendage using our AMPLATZER Cardiac Plug, sparing patients from spending the rest of their lives on anticoagulants.

Supporting a Scalable Global Company

We are a global company with strong, scalable sales and distribution organizations that sell our products in 112 countries. These organizations contribute to our growth today and will be equally effective in launching our pipeline products as we receive regulatory approvals.

In March 2010, we reorganized our sales leadership and resources around the world to focus on ensuring a high level of customer attention with experienced sales executives who will continue to accelerate our growth. Gianluca Iasci now leads our European sales effort and our distributor relationships in Eastern Europe, the Middle East and Africa. Don O'Hearn oversees our sales organizations in the Americas and Jack Darby manages our worldwide marketing effort, as well as our Asia Pacific distributors. These leaders collectively bring nearly 50 years of experience with large, global medical device manufacturers.

Changing Lives Through Medical Innovation

The medical device industry in the United States is one of the strongest, most innovative and most competitive industries globally. We are proud to be a part of this industry and believe AGA Medical is a great example of how U.S. companies have transformed medical care around the world. We are a net exporter with over 60% of our revenue generated outside of the United States.

Focus on Corporate Sustainability

AGA Medical seeks to operate in an economically, socially and environmentally sustainable manner that is transparent and increasingly satisfying to all stakeholders.

Over the past several years, we have focused on implementing a number of programs in order to actively manage activities that can have a positive environmental impact on our business. These sustainable practices include, but are not limited to:

- Investing in solar energy through the use of photovoltaic arrays to generate building electricity;
- Employing energy-efficient lighting throughout the building;
- Minimizing local environmental impact through reduced grounds development with near-term plans to reduce water use through new irrigation practices; and
- Establishing a recycling program for solid waste materials, including aluminum cans, paper, cardboard and plastic bottles.

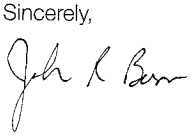
In an effort to make sure that we continue to prioritize these extremely important initiatives, we recently commenced a process to create a five-year corporate sustainability plan. The overarching goal of this plan is to formalize sustainable practices and provide a roadmap to continue using sustainability as a criterion for business decisions company-wide.

Throughout the global economic crisis, we continued to hire and expand our business, creating well-paying jobs and paying our fair share of taxes. We can do this because we deliver high-value and cost-effective products that are clinically relevant, thereby adding tremendous value to the health care system and most importantly — our patients.

Changing the lives of our patients drives us and is at the core of our mission — to develop innovative products that address significant unmet medical needs and become the standard of care. I encourage you to read the patient stories contained in this report — a small sample of the hundreds of thousands of patients who have received an AMPLATZER device. These stories are possible because of the 500 AGA Medical employees around the world. I thank them for their hard work and commitment and for contributing to the success of our company.

As a newly public company, I recognize the investment our shareholders have made in AGA Medical. In the year ahead, we will stick to our knitting: selling high-margin, proven devices that deliver exceptional value to patients and health care systems. We will continue to invest in our exciting pipeline products to deliver even more value, leveraging our existing sales channels and manufacturing capabilities. We look forward to continuing to create value for our shareholders.

Sincerely,



John R. Barr
President and Chief Executive Officer

March 31, 2010

Corporate Information

Board of Directors

Tommy G. Thompson
Chairman
Former Secretary
U.S. Department of Health & Human Services

Franck L. Gougeon
Co-Founder
AGA Medical

Jack P. Helms
Chairman
Lazard Middle Market LLC

Daniel A. Pelak
Senior Advisor
Welsh, Carson, Anderson & Stowe

Paul B. Queally
Co-President
Welsh, Carson, Anderson & Stowe

Terry A. Rappuhn
Project Leader and Consultant
Patient Friendly Billing® Project

Darrell J. Tamosuinas
Independent Consultant
Former Senior Vice President
GE Commercial Finance

Sean M. Traynor
General Partner
Welsh, Carson, Anderson & Stowe

Senior Management

John R. Barr
President and
Chief Executive Officer
(Section 16 Officer)

Brigid A. Makes
Senior Vice President and
Chief Financial Officer
(Section 16 Officer)

Ronald E. Lund
General Counsel and Secretary
(Section 16 Officer)

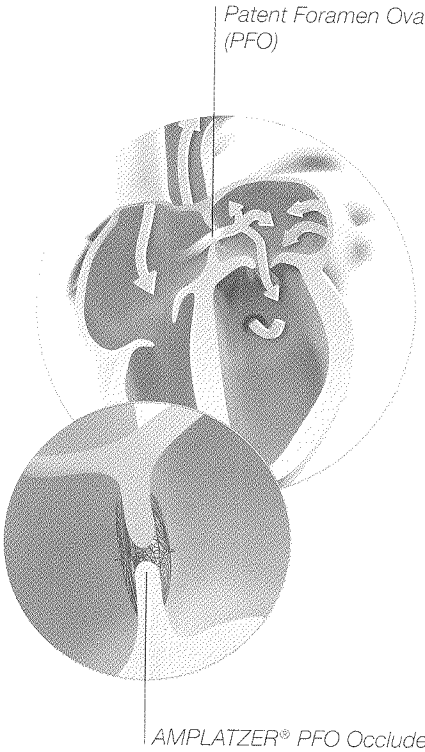
Jack A. Darby
Senior Vice President
Global Marketing and
Distributor Sales

Larry W. Found
Senior Vice President
Human Resources

Gianluca Iasci
Senior Vice President
Europe, Middle East and Africa

Donald J. O'Hearn
Senior Vice President
Americas

What are Structural Heart Defects?



*Not yet commercially available in the U.S.

Structural heart defects are sometimes diagnosed and corrected at birth. Those who grow up with these conditions may only find out about them when health problems arise, such as shortness of breath, fatigue and weakness. At 24, Amber was diagnosed with a hole in her heart. Despite countless routine doctor visits throughout her life, no one had detected the 24-mm hole in her heart. Amber was adamant about avoiding open heart surgery and was thrilled to know she could have her heart repaired with an AMPLATZER device. AMPLATZER devices not only help young adults like Amber, but reach patients across all age groups. Please see the patient stories at the end of this annual report to learn more about the experiences of Amber, Kai and Carmen.

Significant Medical Conditions: Structural Heart Defects

A structural heart defect is an abnormality in the heart and associated vessels, such as the aorta and pulmonary artery. Many structural heart defects result from problems during fetal heart development and are referred to as congenital heart defects. These structural heart defects can be clinically significant and require immediate treatment early in life, or could become an issue later in adulthood. The most commonly diagnosed and treated structural heart defect is an atrial septal defect (ASD), which is a hole between the right and left atrium. Other common defects include ventricular septal defects (VSD), which are holes between the right and left ventricles; patent ductus arteriosis (PDA), which is the result of the failure to close certain embryonic passageways after birth; and patent foramen ovale (PFO), which is a tunnel between the right and left atrium.

Another type of structural heart defect relates to the left atrial appendage (LAA), a structure, shaped like a small pouch, on the left side of the heart. Atrial fibrillation can cause blood to pool in the LAA, increasing the chance of clots that may travel to the brain and lead to stroke. As a result, patients with atrial fibrillation, face a five-fold higher incidence of stroke.

Before Dr. Kurt Amplatz founded AGA Medical, these structural heart defects were generally treated by open heart surgery. Otherwise, the only alternative for patients was to simply wait and see whether they developed clinically significant symptoms. Today, most defects are now closed using minimally invasive techniques with AGA Medical's line of AMPLATZER occluders.

112

AMPLATZER devices are sold in 112 countries through direct sales and distributors.

400,000

AGA Medical is a market leader with more than 400,000 devices shipped as of Dec. 31, 2009.

What is an Occluder?

AGA Medical initially developed occluders to close holes in the heart. These devices are manufactured using a thin nitinol wire that can be braided into many shapes. Occluders have two discs, essentially creating a sandwich around the defect. The devices are connected by a waist, which allows the devices to adjust within the hole the physician is trying to occlude, or close.

All AMPLATZER occluders have a screw attachment that connects the device to the catheter delivery system — this feature is key to making AMPLATZER devices easy to use. The screw attachment allows physicians to retrieve and reposition the devices during a procedure. Today, AGA Medical can manufacture occluders using various wire sizes that can be braided into multiple shapes featuring single-layer or multi-layer techniques.

AMPLATZER occluders are delivered into the body in a minimally invasive procedure through a catheter, requiring only a small incision to access a blood vessel for catheter placement. Physicians use x-ray and ultrasound imaging technologies to monitor and place the device using an AMPLATZER delivery system. Following the procedure, most patients can return home the same day or the next day.

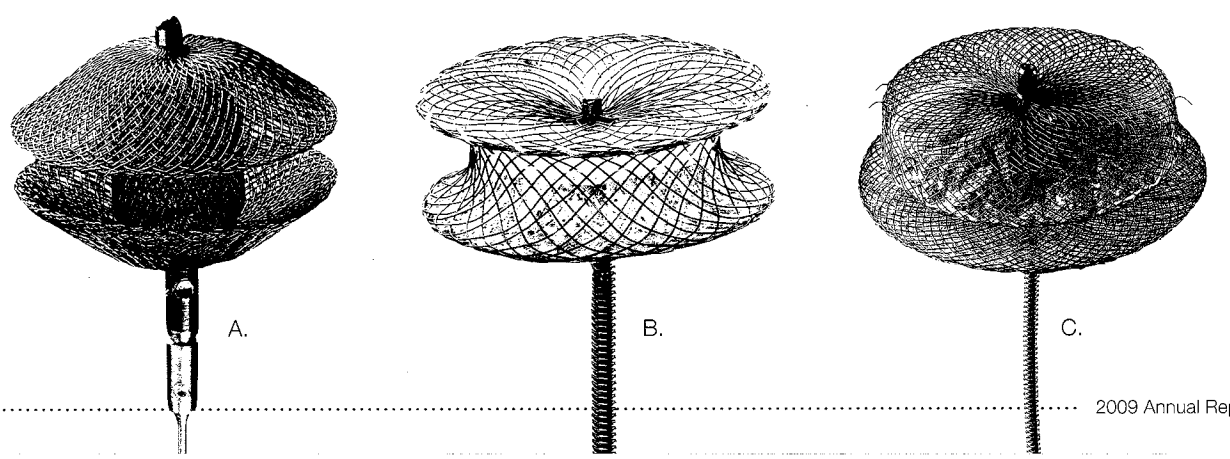
Structural heart defects have had a major impact on the health and quality of life of people with these conditions. Advances in correcting these defects using AMPLATZER occlusion devices have had significant positive impacts on morbidity, mortality and improved quality of life for infants, children and adults with these conditions.

*A. AMPLATZER® Duct Occluder II**

B. AMPLATZER® Muscular VSD Occluder

*C. AMPLATZER® Cardiac Plug**

**Not yet commercially available in the U.S.*



Strong Track Record of Commercializing Occluders

Since the development of the original AMPLATZER Septal Occluder used to treat atrial septal defects, the company has leveraged its experience with occluders and associated delivery systems, as well as its nitinol braiding expertise to develop additional occluders. AGA Medical has received product approvals and regulatory clearances for 13 different structural heart occluders and vascular plugs worldwide. The company is able to leverage this strong clinical and regulatory position for future product development and growth.

AGA Medical sells its occlusion devices to treat structural heart defects to interventional cardiologists and electrophysiologists and its line of vascular plugs to treat abnormal blood vessels to interventional radiologists and vascular surgeons. AGA Medical has invested resources to significantly strengthen its worldwide distribution channels over the last several years. As a result, the company now has strong and scalable distribution organizations that are contributing to the growth of its business today. These organizations will be highly effective in launching its pipeline programs upon completion of clinical trials and subsequent regulatory approvals without the need for significant incremental investments.

Advancing AGA Medical Through R&D Investment

AGA Medical lives its mission through continuous research and development of new devices to address heart defects and vascular abnormalities. Dr. Amplatz continues to lead its research and development efforts, working closely with a team of engineers who are helping him develop the next generation of AMPLATZER devices. AGA Medical is undertaking several clinical trials — RESPECT, PREMIUM and PRIMA — to determine the possible connection between a structural heart defect called a patent foramen ovale and certain types of stroke and migraines.

In addition, the AMPLATZER Cardiac Plug is being sold in Europe and used to close the LAA. In patients with atrial fibrillation, which affects approximately 4.5 million patients in the United States and Europe, this defect is believed to play a significant role in the occurrence of stroke. People with atrial fibrillation have a five-fold higher incidence of stroke than those without the condition. Clinical research has shown that the risk of stroke could be reduced if the LAA is closed, because 90% of blood clots are associated with the LAA. Last year, a pivotal clinical trial sponsored by another company established proof-of-concept that closure of the LAA is as good as the current gold standard, an anticoagulant called Warfarin, in preventing stroke for these patients. This product is already sold outside of the United States and AGA Medical has received conditional Investigational Device Exemption approval from the FDA to begin its U.S. clinical trial to support product approval in America.

Each of these opportunities, if proven in these clinical trials, represents significant patient populations, and therefore, offers market opportunities of $1 billion or greater for AGA Medical.

Amber

I truly owe my life to the AGA Medical family.

During a routine examine in spring 2000, a nurse detected a murmur in Amber's heart. Tests confirmed the 24-year-old woman had an atrial septal defect (ASD). At the time, open heart surgery was the only FDA-approved procedure to close the hole in her heart. But Amber wanted other options. She was in good health and active.

One year after her diagnosis, Amber's health began to deteriorate. She was constantly tired. Her 20-minute weekend naps turned into four hours and water retention in her feet made walking painful. She also experienced frequent, painful heart palpitations. She was running out of time. Amber needed to have the hole in her heart closed.

One afternoon, by chance, she was watching a Discovery Channel feature on the Cleveland Clinic's use of the AMPLATZER device for ASD closure. The next day, she spoke by phone to the Cleveland Clinic doctor, who assured her the device would work for her. And it did.

The AMPLATZER device was implanted on March 26, 2002. After a few days of recovery and a couple months for the symptoms to subside, Amber resumed living a happy, active and full life. In fact, she took a 26-mile hike in the mountains of her native Alaska just a year later.

Carmen

I felt like a new person.

For most of her adult life, Carmen endured terrible back pain, shortness of breath and dizziness. Her pain eventually became debilitating. She no longer could join her husband in their favorite activities — camping, walking the dogs and riding bikes with their grandchildren. She could not even make it up the stairs without a break and often slept sitting up. Carmen convinced herself she just needed a new mattress.

After several new mattresses and a couple of physicians, Carmen saw a cardiologist. Her angiogram revealed a pulmonary arteriovenous malformation (PAVM), a rare, congenital vascular malformation. Delighted and relieved to know the cause of her symptoms, Carmen happily accepted a referral to an interventional radiologist.

After evaluating the options with his patient, the physician scheduled Carmen for a catheterization lab procedure and implanted the AMPLATZER Vascular Plug II to block the malformation in her lungs. Carmen experienced relief from her back pain as soon as the device was implanted. In fact, during the procedure Carmen asked the doctor what he had done — she was lying down with no back pain.

The day after her procedure, Carmen was running up and down her stairs, fascinated that she felt like a new person. Now she races around the neighborhood with her grandchildren and husband, enjoying the Arizona sunshine.

Leveraging Platform to Treat Vascular Conditions

While occluders were first used to treat structural heart defects, AGA Medical has also developed a line of occluders, called vascular plugs, which can be used to block or reroute blood flow in abnormal blood vessels. Vascular occlusion can lessen pressure on malformed, weakened or leaking blood vessels and can also be used to reduce blood supply to benign or malignant tumors, as well as to organs or other areas of the body prior to procedures.

Today, physicians generally close these vessels by individually placing small metal coils through a catheter to access the blood vessel. These coils are then packed together in the vessel to block blood flow. Frequently, six to 10 coils are required to occlude the vessel because it is challenging and time consuming to precisely place the coils.

Alternatively, AGA Medical's AMPLATZER vascular plug product line occludes vessels using a nitinol plug design to permanently seal the blood vessel. Because the vascular plug securely places a nitinol mesh across the entire vessel, only one plug is needed in most cases, making it both time and cost effective.

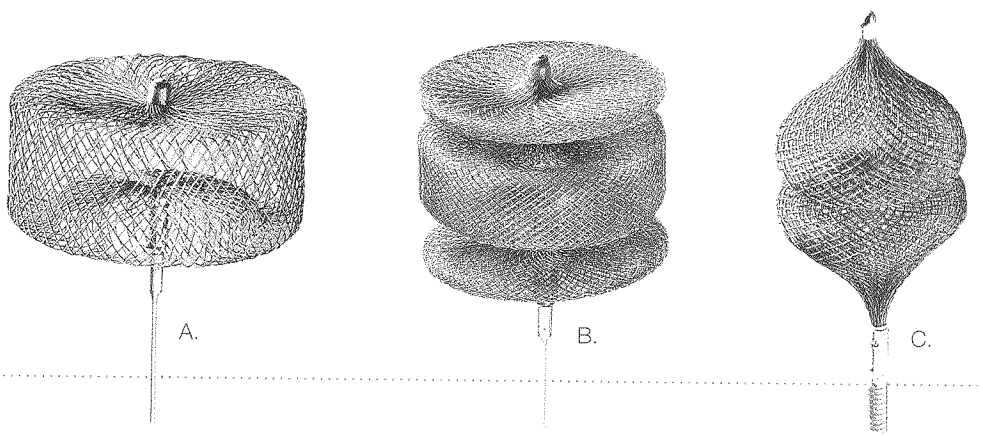
AGA Medical introduced its first vascular plug in 2004. Two versions of the vascular plug have received FDA clearance in the United States and the company has CE Mark approval for four vascular plugs currently marketed outside of the United States. Each device extends the product line and does not replace the previous device.

A. AMPLATZER® Vascular Plug

B. AMPLATZER® Vascular Plug II

*C. AMPLATZER® Vascular Plug 4**

**Not yet commercially available in the U.S.*



Where AGA Medical Does Business

44%

Europe — 44 percent of 2009 sales

Direct sales force in Europe, except Greece. Distributors effectively cover the Middle East and Africa.

37%

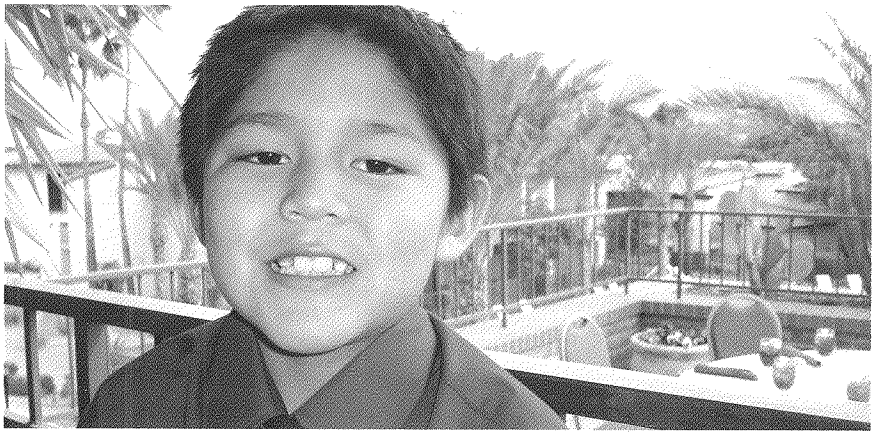
United States — 37 percent of 2009 sales

Direct sales force covers U.S. and Canada. Products marketed through distributors covering every major South American country.

19%

Rest of World — 19 percent of 2009 sales

Products marketed through distributors across the Pacific Rim, covering markets ranging in size from China, Japan and Australia to Singapore.



Kai

I can't believe I have a device inside my heart to help me live forever!

Full of energy and personality, Kai kept up with his two older brothers, running, playing and wrestling. He had no symptoms before being diagnosed with a patent ductus arteriosus (PDA) in fall 2009. But during the boy's annual exam, his pediatrician heard a heart murmur, prompting him to ask the active 6-year-old boy if he ever felt short of breath. Kai's mom, a school teacher on the Navajo Reservation in Kayenta, Arizona, was surprised when her son answered "yes" — she had never heard him complain.

At first, his parents were concerned about the diagnosis. So they went online to read about PDAs and the treatments, and consulted with physicians at St. Joseph Hospital and Medical Center in Phoenix. Afterward, they felt confident that the AMPLATZER Duct Occluder would help Kai.

Immediately following the procedure, Kai was sitting up, asking for food and saying he was ready for school. He wanted to show his friends the sample device his doctor had given him. In short order, Kai was back to normal, rolling on the floor and wrestling with his brothers, and joking around with friends. When asked what he would say to another child who needed to fix a PDA, Kai replied, "It's not that bad. You should do it!"

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2009.

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM TO .

COMMISSION FILE NUMBER: 001-34494

AGA MEDICAL HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**41-1815457**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

5050 Nathan Lane North, Plymouth, MN 55442
(Address and Zip Code of principal executive offices)

(Registrant's telephone number, including area code): **(763) 513-9227**

Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)	**(Name of each exchange on which registered)**
Common Stock, $0.01 par value	NASDAQ Global Market

Securities registered under Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicated by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark if disclosures of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated Filer ☐	Non-accelerated filer ☒ (Do not check if a smaller reporting company)	Smaller Reporting Company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The registrant completed the initial public offering of its common stock on October 26, 2009. Accordingly, there was no public market for the registrant's common stock as of June 30, 2009, the last day of the registrant's most recently completed second fiscal quarter.

There were 50,111,885 shares of the registrant's common stock outstanding as of March 4, 2010.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's definitive proxy statement for its 2010 annual meeting are incorporated by reference into Part III of this Form 10-K.

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PART I

ITEM 1. BUSINESS.

Overview

We are a leading innovator and manufacturer of medical devices for the treatment of structural heart defects and vascular abnormalities. Our *AMPLATZER* occlusion devices offer minimally invasive, transcatheter treatments that have been clinically shown to be highly effective in defect closure. Our devices and delivery systems use relatively small catheters and can be retrieved and repositioned prior to release from the delivery cable, enabling optimal placement without the need to repeat the procedure or use multiple devices. We are the only manufacturer with occlusion devices approved to close seven different structural heart defects, and we believe we have the leading market positions in the United States and Europe for each of our devices, having shipped more than 400,000 devices as of December 31, 2009. We sell our devices to interventional cardiologists, interventional radiologists, vascular surgeons and electrophysiologists in 112 countries through a combination of direct sales and the use of distributors, with international markets representing approximately 62.7%, 59.2% and 57.9% of our net sales in 2009, 2008 and 2007, respectively. Included in the 2009 percentage for international markets is Italy, which represented 12.3% of net sales, respectively.

We received a CE Mark in Europe for our initial occlusion devices and related delivery systems in 1998. In 2001, we received U.S. regulatory approval to commercialize our *AMPLATZER* Septal Occluder, which addresses one of the largest treatment areas of the structural heart defect market. We received U.S. regulatory approval to commercialize our *AMPLATZER* Duct Occluder device in 2003 and our *AMPLATZER* Muscular VSD Occluder device in 2007.

In addition, we have leveraged our core competencies in braiding nitinol and designing transcatheter delivery systems to develop products for the treatment of certain vascular diseases. Our first products in this area, which we launched in the United States in September 2003 and in Europe in January 2004, are vascular plugs for the closure of abnormal blood vessels that develop outside the heart. A second version of our vascular plug was approved and launched in the United States and Europe in August 2007, and a third version was approved in Europe in May 2008 and we intend to re-file for regulatory clearance in the United States in the second half of 2010. We received regulatory approval for a fourth device in Europe in July 2009 and expect to receive regulatory clearance in the United States in the first half of 2010.

General information about us can be found at http://www.amplatzer.com under the Investors link. Our annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K's, as well any amendments or exhibits to those reports, are available free of charge through our website as soon as reasonably practicable after we file them with the Securities and Exchange Commission.

Our Industry

We operate in the medical device industry, developing and manufacturing products for the treatment of structural heart defects and vascular abnormalities.

Structural Heart Defects

A structural heart defect is an abnormality in the structure of the heart and associated vessels, such as the aorta and pulmonary artery. Many structural heart defects result from problems in normal fetal heart development and are referred to as congenital heart defects. Structural heart defects can be clinically significant and require immediate treatment early in life or can become clinically significant later in life when the child reaches adulthood. Two common categories of structural heart defects are (1) septal defects, which consist of a hole in the wall between the atria or ventricles that causes an errant flow of blood in the heart, and (2) failed closure of embryonic passageways, which reroute blood

around the lungs in the prenatal heart and occur when the foramen ovale or the ductus arteriosus remain open after birth.

Treatment of Structural Heart Defects

In many cases, structural heart defects that show symptoms during childhood or later in life require closure. Historically, open-heart surgery was the most accepted method of closure. Open-heart surgery is an invasive procedure that requires an incision in a patient's chest to gain access to the heart and close the defect using sutures and polyester patches. During the surgery, there is potential for blood loss, trauma and other surgical complications. Open-heart surgery is expensive, requiring long hospital stays and a recovery period of several weeks.

In response to the shortcomings of open-heart surgery, a number of attempts were made as early as the 1970s to develop a transcatheter device to close structural heart defects. These early devices were in some cases difficult to use or had designs that could not withstand the wear and tear of remaining in position in a continually beating heart. Our *AMPLATZER* occluders were one of the first of a number of devices to successfully address the shortcomings of earlier generations of devices and resulted in widespread adoption of a less invasive transcatheter approach to treat structural heart defects. In the transcatheter approach, an interventional cardiologist inserts a flexible catheter into the patient's groin with a small puncture and maneuvers the catheter through the vasculature to the heart. A device is deployed through the catheter.

Commonly Diagnosed Types of Structural Heart Defects

According to the American Heart Association, approximately 36,000, or 1%, of newborn babies in the United States are diagnosed with congenital heart defects each year. The three heart defects that are most commonly diagnosed and treated during childhood or later in life are:

- *Atrial Septal Defect, or ASD.* An atrial septal defect is an abnormal opening in the wall between the left and right atria. Because the right side of the heart receives extra blood, it is forced to bear more than its normal workload. The potential complications of ASDs include high blood pressure in the lung's vessels, which can lead to pulmonary hypertension, damage to blood vessel walls and heart failure. ASDs are increasingly being detected and treated in adults.
- *Patent Ductus Arteriosus, or PDA.* The failed closure of the ductus arteriosus after birth is called a patent, or open, ductus arteriosus. In patients with a PDA, blood that should have traveled through the aorta to nourish the body goes instead back into the lungs, which can lead to difficulty breathing, failure to grow normally and chronic respiratory failure.
- *Ventricular Septal Defect, or VSD.* A ventricular septal defect is an abnormal opening in the wall between the left and right ventricles. Because the left side of the heart receives extra blood, it is forced to bear more than its normal workload. The potential complications of VSDs include heart failure, high blood pressure and failure of a child to grow at a normal rate. Ventricular septal defects can also occur following myocardial infarctions.

We estimate that the global market opportunity for treating these three structural defects is approximately $190 million annually, with ASD repair representing approximately 65% of that opportunity.

Patent Foramen Ovale

The patent foramen ovale, or PFO, is a common structural heart defect in which the foramen ovale does not seal completely. PFOs occur in approximately 20% to 25% of the overall population. While most people never experience any clinical problems related to a PFO, studies have suggested that blood clots that commonly develop outside the heart may pass directly through the PFO from the

right atrium to the left atrium without passing through the lungs, where they are normally filtered out of the blood. These blood clots have been linked to serious neurological events such as types of stroke. In the case of migraine, it is speculated that very small blood clots or other unfiltered chemicals may pass through the PFO and help trigger the migraine attack.

- *Stroke.* Stroke is the third leading cause of death in the United States, affecting approximately 700,000 people in the United States each year, according to the American Heart Association. Ischemic strokes, in which essential blood flow to the brain becomes obstructed, represent approximately 88% of all strokes. Such strokes can be caused by emboli, which are tiny blood clots, caught in the small vessels of the brain. Approximately 40% of all ischemic strokes are cryptogenic, meaning that the stroke occurs in a patient without the normal risk factors. In patients with a PFO, it is believed the foramen ovale opening allows blood unfiltered by the lungs to flow to the brain. The unfiltered blood may contain emboli and therefore block a blood vessel and cause the stroke. A number of articles have been published studying the prevalence of cryptogenic stroke in patients with a PFO. For example, in several studies, PFOs were detected in approximately 40% of cryptogenic stroke patients. Patients are not typically screened for a PFO unless they have actually had a stroke.

- *Migraines.* Migraine headaches represent a large unmet clinical need, affecting approximately 29.5 million people in the United States. Approximately 10% to 20% of migraine patients suffer from migraines with aura, a severe migraine headache preceded by neurological symptoms such as flashing lights, temporary loss of sight, trouble speaking and numbness on one side of the body. Studies have indicated that as many as 50% of the patients that experience migraine attacks preceded by aura may have a PFO, far exceeding the average rate of individuals with PFO in the general population. It is believed that in patients with a PFO the foramen ovale opening allows blood unfiltered by the lungs to flow to the brain, where it acts as triggers for migraine.

Historically, PFOs have not been routinely closed using surgery or transcatheter therapies. Instead, patients with stroke or migraine and a PFO have typically been treated with drug therapy to address the symptoms of the disorder. Drug therapy, however, is often ineffective and can cause serious complications, such as hemorrhagic strokes, which are caused by bleeding in the brain. We estimate that the addressable patient population for PFO closure in the prevention of recurrent cryptogenic strokes in the United States and Europe is approximately 200,000 patients annually, representing a market opportunity greater than $1 billion annually. We estimate that the addressable patient population for PFO closure in the treatment of people with severe migraines in the United States and Europe is approximately 1 million patients annually, representing an even larger potential market opportunity.

Left Atrial Appendage

The left atrial appendage, or LAA, is a small pouch on the left side of the heart, which is the remnant of the original embryonic left atrium that forms during early fetal development. Atrial fibrillation, a condition that results in irregular electrical activity in the upper chambers of the heart, can cause blood to pool and stagnate in the LAA, increasing the chances of forming clots, which may travel to the brain and lead to stroke. Atrial fibrillation is the most commonly diagnosed heart rhythm disorder and affects over 2 million people in the United States and over 2.5 million people in Europe.

Patients with atrial fibrillation are typically treated by blood thinning drugs to reduce the risk of stroke. Common blood thinning medications, such as coumadin, may cause undesirable side effects such as bleeding and require frequent blood monitoring. Studies suggest only approximately 60% of patients can tolerate blood thinners, leaving less effective medications as the only readily available medical treatment. Surgical closure of the LAA is typically only performed when the patient is already

undergoing open-heart surgery for another condition. We estimate that the addressable patient population for LAA closure with a transcatheter approach in the United States and Europe is approximately 200,000 patients annually, representing a market opportunity greater than $1 billion annually.

Vascular Abnormalities

There are numerous vascular abnormalities characterized by defects in the blood vessel wall or abnormal or inappropriate blood flow.

Abnormal Blood Vessels. Peripheral embolization, a widely accepted treatment option for a large range of vascular conditions outside the heart, reduces or eliminates blood flow to an area of the body by blocking, or occluding, a blood vessel. Vascular occlusion can also be used to reroute blood away from inappropriately formed blood vessels to different blood vessels. Vascular occlusions can be performed by surgery. More commonly, however, occlusions have been performed by releasing small wire coils at the point of occlusion, causing a clot to form, and thus blocking the flow of blood. Rarely is a single coil sufficient to occlude a blood vessel. Six to ten and often times more coils are required to occlude the vessel, which results in a technically challenging, time-intensive and costly procedure with the potential for adverse events if the coils migrate away from the intended location. We believe that there is a significant opportunity for occlusion devices that can address existing shortcomings of coils by having a single device that can more quickly, safely and precisely occlude the vessel through a simple procedure. We estimate that the addressable patient population for peripheral embolization is approximately 300,000 patients annually, representing a market opportunity of approximately $260 million annually.

Aneurysms. Aneurysms develop when the integrity and strength of the vessel wall is reduced, causing the vessel wall to progressively expand or balloon out. Aneurysms are often caused by atherosclerosis, a disease characterized by the thickening and hardening of the arteries. This decreased arterial flexibility can result in weakening of the arterial wall and bulging at sites that are exposed to high blood flow and pressure. Aneurysms are commonly diagnosed in the aorta, the largest artery in the human body, which stems from the heart and carries blood to the body's organs. The aorta is divided into four portions: (1) the ascending aorta, (2) the aortic arch, (3) the thoracic aorta and (4) the abdominal aorta. Aneurysms can also occur in other smaller arteries, such as the iliac arteries, which branch off from the aorta and lead to the legs.

In the United States alone, it is estimated that as many as 1.7 million people have an abdominal aortic aneurysm, or AAA, with only approximately 20%, or 360,000, presently diagnosed and approximately 10%, or 40,000, of those are treated by a procedure to correct the aneurysm. An estimated 21,000 people are diagnosed annually with a thoracic aortic aneurysm, or TAA. We believe that the market opportunity in Europe for technologies that address aneurysms is comparable in size to that in the United States. AAAs and TAAs are among the most serious cardiovascular diseases and, once diagnosed, currently require patients to either be treated through a combination of pharmacological therapy and non-invasive monitoring or undergo a major surgical procedure to repair the aneurysm. After an AAA or TAA develops, it continues to enlarge and, if left untreated, becomes increasingly susceptible to rupture. In a TAA of less than 6 cm, the rupture rate within five years is 16%. In a TAA greater than 6 cm, the rupture rate within five years increases to 31%. In AAAs, the rupture rate within five years for aneurysms in the range of 5-5.9 cm is 25%.

The conventional treatment for an aneurysm is a highly invasive surgical procedure requiring a large incision in the patient's abdomen, withdrawal of the patient's intestines to provide access to the aneurysm and the cross clamping of the aorta to stop blood flow. This surgery has an operative mortality rate of 3% to 5% in elective surgery and approximately 75% if the aneurysm ruptures. In addition, complication rates vary depending upon patient risk classification, ranging from 15% for

low-risk patients to 40% for high-risk patients. The typical recovery period for conventional surgery includes a hospital stay of seven to ten days and post-hospital convalescence of 12 weeks. Given the high rate of complications of open surgery, many physicians choose medical management and "watchful waiting" until aneurysms grow to larger than 4-5 centimeters in size.

Due to the mortality rates, complications and lengthy recovery period described above, physicians have for years sought less invasive methods to treat AAAs and TAAs as alternatives to surgical repair. However, transcatheter devices currently used to repair an aneurysm are often too large to be considered a truly minimally invasive procedure. These devices require very large catheters that can only be introduced into a blood vessel by a procedure known as a cutdown, typically performed by a vascular surgeon. By eliminating the need for a cutdown, a broader range of physicians skilled in minimally invasive procedures would likely be able to perform the procedure with the potential for fewer complications. Currently, less than 15% of patients with AAA are treated for the disease. We estimate that the addressable patient population for a device that could address the shortcomings described above is approximately 240,000 patients annually for AAA, representing a market opportunity of approximately $3 billion annually, and approximately 60,000 patients annually for TAA, representing a market opportunity of approximately $260 million annually.

Corporate History

We were founded as AGA Medical Corporation ("AGA Medical") in Minnesota in 1995 by Dr. Kurt Amplatz, a professor and researcher at the University of Minnesota's Department of Radiology, Mr. Franck Gougeon and Mr. Michael Afremov to capitalize on the attributes of nitinol to make occlusion devices for the transcatheter treatment of structural heart defects. AGA Medical Holdings, Inc. ("AGA") was formed as a Delaware corporation in connection with our July 2005 reorganization as the parent company of AGA Medical. We are currently controlled by Welsh Carson, WCAS Capital Partners IV, L.P. and other individuals and entities affiliated with Welsh Carson, which we collectively refer to as the WCAS Stockholders, and Franck L. Gougeon, our director and co-founder, and other entities controlled by Mr. Gougeon, which we collectively refer to as the Gougeon Stockholders. As part of our July 2005 reorganization, AGA Medical purchased and redeemed all of the outstanding shares of common stock owned by Mr. Afremov, who has not been associated with us since such time. To finance our July 2005 reorganization, AGA Medical (1) issued an aggregate principal amount of $50.0 million of our 2005 notes, which was purchased by one of the WCAS Stockholders at a discount, (2) issued 128,524 shares of Series A preferred stock to the WCAS Stockholders at a purchase price of $1,000 per share and (3) borrowed $107.0 million under a $122.0 million senior credit facility, consisting of a $107.0 million senior term loan and a $15.0 million revolving credit facility. The remaining stockholder, Mr. Gougeon, and new investors subsequently contributed all of their outstanding shares in AGA Medical to AGA in exchange for shares of AGA. Since the July 2005 reorganization, our corporate control has been jointly held by the WCAS Stockholders and the Gougeon Stockholders.

In October 2009, we completed our initial public offering of 13,750,000 shares of common stock. Our common stock is listed on the Nasdaq Global Select market and trades under the symbol "AGAM".

Our Product Portfolio

Our *AMPLATZER* occlusion devices utilize our expertise in braiding nitinol, a metal alloy with superelastic and shape-memory characteristics, and designing transcatheter delivery systems that enable simple and precise implantation of our devices. Our *AMPLATZER* family of devices uses nitinol because its properties allow our devices to be compressed inside a delivery sheath and then return to their original shape once deployed at the implant site. The combination of the use of nitinol and our manufacturing techniques allows us to create device shapes specific to each indication.

We classify our product portfolio into two categories: structural heart defect products, which we market primarily to interventional cardiologists and electrophysiologists, and vascular products, which we market primarily to vascular surgeons and interventional radiologists.

A number of our products are in the early stages of development. In the United States, before we can market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, we must first receive either approval of a PMA application from the FDA, or clearance under section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act, which we refer to as 510(k) clearance, unless an exemption applies. A clinical trial is always a required step to support the PMA application approval and may be required to support the 510(k) clearance. Moreover, sales of our products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. The approval process for occluders is generally more complex in the United States. The regulatory process in Europe generally requires the submission of pre-clinical processes. Our *AMPLATZER* Vascular Plug has been approved through the 510(k) clearance in the United States and with the submission of pre-clinical data only in Europe. The rest of the world, with the exception of Japan, generally accepts approval by the FDA or a CE Mark in Europe as a basis for approval to market. Japan has a regulatory process that generally accepts clinical data from either the United States or Europe which may be supplemented by a small study in Japan to establish experience and confirm safety.

		Regulatory Status		
Product	**Indication**	**United States Status**		**European CE Mark Status**
Structural Heart Defects:				
AMPLATZER Septal Occluders				
Septal Occluder	Atrial septal defect (ASD) repair for single hole	PMA	12/01—Approved	2/98—Granted
Multi-Fenestrated Septal Occluder (Cribriform)	Atrial septal defect (ASD) repair for multiple holes	PMA	9/06—Approved	9/02—Granted
AMPLATZER Duct Occluders				
AMPLATZER Duct Occluder	Closure of patent ductus arteriosus (PDA)	PMA	5/03—Approved	2/98—Granted
AMPLATZER Duct Occluder II	Closure of patent ductus arteriosus (PDA)	PMA	Clinical Trials	2/08—Granted
AMPLATZER VSD Occluders				
Muscular VSD Occluder	Closure of muscular ventricular septal defect (VSD)	PMA	9/07—Approved	2/98—Granted
Post Infarct Muscular VSD Occluder	Closure of muscular ventricular septal defect (VSD) created as a result of a heart attack	HDE	6/07—Filed for HDE	3/01—Granted
Membranous VSD Occluder	Closure of membranous ventricular septal defect (VSD)	PMA	Safety study completed	2/98—Granted
AMPLATZER Cardiac Plug	Occlusion of the left atrial appendage (LAA)	PMA	8/08—Filed for IDE	12/08—Granted
AMPLATZER PFO Occluders				
Stroke	Closure of patent foramen ovale (PFO) for stroke	PMA	Clinical Trials	2/98—Granted
Migraine	Closure of patent foramen ovale (PFO) for migraine	PMA	Clinical Trials	Clinical Trials

Product	Indication	Regulatory Status		
		United States Status		European CE Mark Status
Vascular diseases:				
AMPLATZER Vascular Plugs				
Vascular Plug	Closure of abnormal blood vessels	510(k)	9/03—Cleared	2/04—Granted
Vascular Plug II	Closure of abnormal blood vessels	510(k)	8/07—Cleared	8/07—Granted
Vascular Plug III	Closure of abnormal blood vessels	510(k)	2/08—Filed for clearance; To be re-filed in second half of 2010	5/08—Granted
Vascular Plug IV	Closure of abnormal blood vessels (delivered through diagnostic catheter)	510(k)	10/09—Filed for clearance	7/09—Granted
AMPLATZER Vascular Grafts				
Peripheral Graft	Treatment of iliac artery aneurysms	PMA	IDE to be filed in first half of 2011	To be filed in second half of 2010
TAA Graft	Treatment of thoracic aortic aneurysms (TAA)	PMA	In development	In development
AAA Graft	Treatment of abdominal aortic aneurysms (AAA)	PMA	In development	In development

We make our regulatory status forecasts, including determining expected dates of filings with, or submissions to, relevant authorities, based on the information currently available to us. The actual timing for any of these regulatory steps may vary, and we may revise any such forecasts as new information becomes available.

All of our implants are sold with our proprietary delivery systems and accessories, which are designed to facilitate proper positioning when our devices are implanted. We believe that our delivery systems are the only systems that can fully retract and reposition an occlusion device during the procedure without having to remove the device from the patient. We also sell a number of complementary accessories including sizing balloons, sizing plates and guidewires. Our sizing balloons and plates enable accurate measurement of the size of the structural heart defect and enable selection of an appropriately sized device to close the defect. All of our delivery systems and accessories have FDA 510(k) clearance and a CE Mark.

The number of *AMPLATZER* occluders sold may differ from the number of delivery systems sold in any given period. We sell our products both directly to hospitals and to distributors. Distributors tend to place bulk orders and do not necessarily balance in any given order the number of devices and delivery sets ordered, which number is largely dependent on their current inventory levels of each type. Hospitals tend to stock more delivery sets than occluders for several reasons. Different delivery sets are used for different types of patients, and it is difficult to predict the mix of patients. For example, adult patients would typically require longer delivery sets. Larger devices require larger diameter catheters. Hospitals stock more delivery sets on average than devices, since often times the selection of the appropriate delivery set is not made until preliminary measurements are made of the patients during the clinical procedure. Delivery sets also have far lower selling prices than devices, which also contributes to the tendency by hospitals to stock more delivery sets than occlusion devices given the uncertainties described above.

AMPLATZER Occlusion Devices for Structural Heart Defects

Our *AMPLATZER* occlusion devices represented approximately 80.8%, 82.6%, and 85.4% of our net sales for the fiscal years ended December 31, 2009, 2008, and 2007, respectively. These have the following common features:

- Our occlusion devices are generally constructed using two discs made of braided nitinol wire, which come in varying shapes and sizes depending on the defect that they are designed to occlude.
- The two discs are linked together by a short connecting waist also made of nitinol wire. In certain defects, the waist helps to center the device.
- The majority of our discs contain thin polyester fabric which aids in closure by promoting endothelialization, a process in which new tissue completely encloses the occlusion device in the septal wall of the heart, essentially becoming a part of the heart and permanently closing the defect. Certain of our current and next generation occlusion devices may not need to contain fabric as we are developing occluder designs using denser and multi-layer braiding that will replace the need for fabric. Occluders without fabric can be delivered through smaller catheters and can more readily conform to the anatomy near the defect.

Our *AMPLATZER* occlusion devices are delivered through small catheters, employ our unique screw attachment mechanism and are fully retrievable until released from the screw which allows for repositioning prior to release of the implant.

Our *AMPLATZER* occlusion devices are typically delivered through a standard percutaneous puncture of the femoral artery or vein, located near the patient's groin. Our delivery systems are used to facilitate attachment, loading, delivery and deployment of our *AMPLATZER* occlusion devices. The devices are connected to a proprietary delivery cable by a screw attachment. In a procedure generally lasting approximately one hour or less, the interventional cardiologist maneuvers our flexible catheter through the vasculature to the heart. For some procedures, we recommend that the interventional cardiologist use our sizing balloons to measure the exact size of the defect in order to select an appropriately sized *AMPLATZER* occlusion device. The physician positions the catheter across the defect and positions the first disc over the hole and against the wall separating the two chambers of the heart, using imaging technology to check for proper placement before deploying the second disc on the opposite side of the defect. The physician then checks one more time that the device is properly positioned and, if satisfied, unscrews the delivery cable used to position the device and withdraws both the catheter and the cable. A unique feature of the *AMPLATZER* occlusion device is the ability to retrieve and reposition the device multiple times, if necessary, prior to unscrewing the device from the wire. The procedure is typically performed on an overnight or outpatient basis, although in certain countries, it is common practice for patients to remain for one to two days in the hospital following the procedure.

AMPLATZER Septal Occluders

We market two occluders for ASDs: our *AMPLATZER* Septal Occluder for closure of single holes and our *AMPLATZER* Multi-Fenestrated Septal Occluder, also referred to as the Cribriform, for closure of multiple holes. The waist connecting the two discs comes in sizes ranging from 4 to 40 millimeters. The appropriate sized waist expands to the width of the hole helping to ensure appropriate positioning of the device.

The *AMPLATZER* Septal Occluder was granted a CE Mark in Europe in February 1998 and FDA PMA approval in December 2001. The *AMPLATZER* Multi-Fenestrated Septal Occluder was granted a CE Mark in Europe in September 2002 and FDA PMA approval in September 2006. In August 2005, our *AMPLATZER* Septal Occluder became the first approved occlusion device in Japan. Devices in

Japan must also receive reimbursement approval prior to marketing. Following receipt of reimbursement approval in April 2006, we launched our *AMPLATZER* Septal Occluder in Japan in May 2006.

AMPLATZER Duct Occluder

Our *AMPLATZER* Duct Occluder is intended for the closure of PDAs larger than 4 millimeters, which we believe represent approximately 30% of total PDA defects. Smaller PDAs are treated using drug therapy or coils. Our *AMPLATZER* Duct Occluder products are uniquely shaped to achieve consistent, effective closure of PDAs. In addition to the typical features of our *AMPLATZER* occlusion devices, the *AMPLATZER* Duct Occluder employs what we call a retention "skirt," which allows the device to be positioned properly and remain in place at the entrance to the duct. The "skirt" is the flat top portion of the device that is connected to a conical body. The body is positioned into the duct.

The *AMPLATZER* Duct Occluder was granted a CE Mark in Europe in February 1998 and FDA PMA approval in May 2003 and approval in Japan in December 2008. Devices in Japan must also receive reimbursement approval prior to marketing and reimbursement approval for our device was received in July 2009. Our *AMPLATZER* Duct Occluder and our *AMPLATZER* Septal Occluder are the only approved occlusion devices in Japan. Our second generation of *AMPLATZER* Duct Occluders, which has been granted a CE Mark in Europe, can be delivered in even smaller catheters and is appropriate for both smaller ducts and ducts with different geometries as we have eliminated the fabric, which is typically embedded in the disc, and instead rely solely on multi-layered braiding for rapid occlusion.

AMPLATZER VSD Occluders

We market and sell our *AMPLATZER* VSD Occluders to address membranous VSDs and muscular VSDs. Membranous VSDs are defects in the upper portion of the ventricular septum near the valve connecting the heart with the aorta and characterized by more flexible, membranous tissue. Muscular VSDs are defects in the middle portion of the ventricular septum, which is characterized by thicker, more muscular tissue. We also market and sell a third version of the *AMPLATZER* VSD Occluders, the *AMPLATZER* Post Infarct Muscular VSD Occluder which is designed for VSDs that are created as a result of heart attacks. The different designs of our three *AMPLATZER* VSD Occluders are characterized by the shape and sizing of the discs and the length of the waist between the discs.

Our *AMPLATZER* Membranous VSD Occluder device received a CE Mark in Europe in 1998. We have completed a safety study in the United States and are in the process of gathering data from the use of the device in Europe prior to proceeding with additional clinical studies in the United States. Our *AMPLATZER* Muscular VSD Occluder device received a CE Mark in 1998 and received PMA approval in the United States in September 2007. Our *AMPLATZER* Post Infarct Muscular VSD Occluder was approved in Europe in 2001. We filed for approval in the United States under a Humanitarian Device Exemption, or HDE, in 2007, and that application is under review by the FDA. An HDE exemption is typically granted for medical devices with a patient population of less than 4,000 patients per year. We believe the market for the *AMPLATZER* Post Infarct Muscular VSD Occluder is smaller than 4,000 patients per year, given the serious nature of the event (a tear in the ventricular septum) following a heart attack, as most potential patients do not survive long enough to have the tear in the ventricular septum repaired. The FDA has requested that we conduct additional pre-clinical testing. Specifically, the FDA requested additional testing designed to simulate (in the lab) the structural performance of the device when implanted for an extended period of time along with associated biocompatibility. This testing is routinely requested for devices designed to be implanted in the heart and associated major blood vessels. We are working to complete the additional pre-clinical testing and answer all remaining questions posed by the FDA.

AMPLATZER PFO Occluder

Our *AMPLATZER* PFO Occluder closes all types of PFOs and is shaped to achieve consistent, effective closure of PFOs. Unlike other structural heart defects that could be described as holes, PFOs are more like tunnels formed by two overlapping membranes that fail to seal closed at birth. Our *AMPLATZER* PFO Occluder is characterized by a thin waist that provides flexibility for the two discs to adjust dynamically to the unique anatomy of the patient's PFO. Our *AMPLATZER* PFO Occluder is available in four sizes of 18, 25, 30 and 35 millimeters, as measured by the diameter of the disk that is positioned on the right side of the atrium.

In Europe, we received a CE Mark in February 1998 for use in patients with PFO. From April 2002 to October 2006, we marketed the device in the United States under a HDE status granted by the FDA. On October 31, 2006, we agreed with the FDA to voluntarily withdraw the HDE designation of our *AMPLATZER* PFO Occluder. We currently can enroll patients in the United States who have had at least two strokes and do not otherwise qualify for our PFO stroke study. We can sell the device to hospitals that are approved to enroll patients in the PFO Access registry study. No more than 2,000 patients can be enrolled per year in the registry. There is a growing body of evidence that the presence of PFOs may be linked to stroke and migraine, and we are conducting two other clinical trials to support PMA approval in the United States for use of our *AMPLATZER* PFO Occluders in stroke or migraine patients with PFO.

AMPLATZER Cardiac Plug

Our *AMPLATZER* Cardiac Plug, with an initial indication for LAA Occlusion, is constructed with braided nitinol wire, similar to our structural heart defect occluders. The device is implanted through a standard femoral artery procedure and uses a specially designed delivery system and catheter that includes the standard *AMPLATZER* screw attachment to permit retrieval and repositioning prior to release from the cable. Unless the patient has an open PFO permitting access by the catheter to the left atrium, implanting an *AMPLATZER* Cardiac Plug requires the puncture of a small hole in the wall of the atrium. This procedure, sometimes referred to as a transseptal puncture, is increasingly being used by cardiologists in other interventional procedures in the heart. Following the deployment of the device and similar to other *AMPLATZER* devices, tissue will grow over the device providing a permanent seal to the left atrial appendage. We believe that our *AMPLATZER* Cardiac Plug will be particularly appealing for those patients who cannot tolerate current blood thinners used in medical management or who do not wish to be subject to long term management on blood thinners with the corresponding frequent monitoring and risks of bleeding.

We received CE Mark clearance in December 2008 and are marketing the device in Europe, Asia and South America. We also applied to the FDA in August 2008 to begin a clinical study to support U.S. approval of our *AMPLATZER* Cardiac Plug. We received a request from the FDA in August 2009 for modifications to the clinical trial design. We have had ongoing discussions with the FDA regarding these modifications and now expect to receive approval to begin our IDE study in the U.S. in the first half of 2010.

AMPLATZER Vascular Products

Our vascular products represented 7.4%, 6.0%, and 3.9% of net sales for the fiscal years ended December 31, 2009, 2008, and 2007, respectively.

AMPLATZER Vascular Plugs

Our *AMPLATZER* Vascular Plugs are expandable, cylindrical devices made from nitinol wire that reduce or eliminate blood flow to abnormal blood vessels. Vascular occlusion can be used to reroute blood away from inappropriately formed blood vessels to different blood vessels. Vascular occlusions

were previously only accomplished by surgically closing the blood vessel. More commonly, occlusions have been performed by releasing small wire coils at the point of the occlusion, causing a clot to form, blocking the flow of blood. Typically six to ten coils are required to occlude the vessel, which results in a technically challenging, time-intensive, costly procedure with the potential for adverse events if the coils migrate away from the intended location. Our *AMPLATZER* Vascular Plug can be precisely positioned in the vessel. The nitinol wire provides a cross sectional barrier that slows down the flow of the blood resulting in occlusion of the vessel. A single plug is generally sufficient even in a procedure that would have required many coils, which makes it a comparatively efficient and cost-effective alternative. Our *AMPLATZER* Vascular Plugs are designed for use in abnormal blood vessels outside the heart, below the neck and above the knee and utilize standard delivery systems commonly used by interventional radiologists and vascular surgeons in these procedures.

Each of our vascular plugs has been developed to increase the number of treatable vessels and each subsequent product does not replace the previous product. Two versions of the plug are approved for marketing in the United States and Europe, and the remaining two versions are approved for marketing in Europe only.

Vascular Plug. Our original *AMPLATZER* Vascular Plug received a CE Mark in February 2004 and FDA 510(k) clearance in September 2003. Our *AMPLATZER* Vascular Plug provides occlusion of the vessel in an average of ten minutes.

Vascular Plug II. The *AMPLATZER* Vascular Plug II received a CE Mark and FDA 510(k) clearance in August 2007. Unlike the two surface areas of the *AMPLATZER* Vascular Plug, the *AMPLATZER* Vascular Plug II is designed to have six surface areas, with each surface area progressively slowing down the blood flow leading to formation of the clot within the device. In pre-clinical studies, the *AMPLATZER* Vascular Plug II's unique multi-segmented design significantly reduced the time to occlusion for transcatheter embolization procedures by 20% to 30% in comparable vessels when compared to the *AMPLATZER* Vascular Plug in pre-clinical studies. In many blood vessels, the typical occlusion time of the vessel is approximately six minutes. The *AMPLATZER* Vascular Plug II comes in a broader range of sizes than the *AMPLATZER* Vascular Plug, including smaller and larger sizes.

Vascular Plug III. The *AMPLATZER* Vascular Plug III received a CE Mark in Europe in May 2008 and we applied for 510(K) clearance in the United States in February 2008. Based on feedback we received from the FDA regarding our application, we intend to refile our application for 510(K) clearance in the US in the second half of 2010. The combination of a denser braid and an oval shape will make the *AMPLATZER* Vascular Plug III an attractive alternative for irregularly shaped vessels requiring rapid occlusion.

Vascular Plug IV. The *AMPLATZER* Vascular Plug IV received a CE Mark in Europe in July 2009. We have applied for 510(K) clearance in the United States and hope to receive regulatory clearance in the first half of 2010. The primary benefit of this plug is that it can be delivered through a standard diagnostic catheter. The advantage of this approach is that there will be no added cost or time required to exchange from a diagnostic catheter to a therapeutic delivery catheter.

AMPLATZER Vascular Grafts

We are developing a family of *AMPLATZER* Vascular Grafts to treat aneurysms in a variety of blood vessels, including smaller arteries, such as the iliac arteries, and larger vessels, such as the thoracic and abdominal portions of the aorta. Our devices are composed of multiple layers of braided nitinol filaments woven into precise shapes and sizes. The unique design of our graft seals or excludes the aneurysm without the need for a fabric covering.

We believe our *AMPLATZER* Vascular Grafts will have the following advantages over traditional grafts:

Truly minimally invasive transcatheter procedure. Our *AMPLATZER* Vascular Grafts will be comprised of a highly flexible, multi-layer braided nitinol, eliminating the need for fabric covering the outside of the graft. Competitor devices typically use fabric coatings to reduce the size of the aneurysm. The devices that we are developing use denser and multi-layer braiding without fabric and thus can be compressed to a much smaller size and delivered in a smaller catheter through a more superficial artery, eliminating the need for an arterial cut-down.

Unique graft design. We designed our grafts with nitinol, which quickly integrates with the arterial wall, strengthening the vessel from within. In contrast, commonly used grafts never integrate with the artery because they are covered by fabric, typically polyester, presenting a continued risk of leaks, migration or clots forming along the implant.

Ability to treat aneurysms at an earlier stage. Because our devices can be introduced through a smaller catheter and have the potential to avoid many of the safety concerns related to current products, we believe that we may be able to safely treat patients at an earlier stage.

Our initial focus will be on aneurysms that occur on smaller peripheral arteries, such as the iliac arteries, as we have already designed a tubular graft with the appropriate diameter to be deployed in this artery which is smaller than the aorta. We encountered some issues with the delivery system in connection with the final engineering validation of our graft. We believe these issues will require further engineering and design work on the delivery system. We had filed for a CE Mark in Europe in June 2009, but due to these issues, we now intend to complete this work and refile for CE Mark approval in the second half of 2010. We had previously intended to apply to the FDA for an IDE in the first half of 2009 and then in the second half of 2009, but due to the issues with the delivery system described above, we now expect to apply to the FDA for an IDE in the first half of 2011.

We are also developing vascular grafts to treat thoracic aortic aneurysms, or TAAs. Our vascular graft design incorporates features not currently available in other grafts. Key elements include smaller delivery systems and the ability to provide secure positioning without the use of barbs or hooks, which could damage the aorta. We believe we will need to complete a feasibility study in Europe to support a CE Mark application. This study may be initiated in the first half of 2011. We plan to file a CE mark upon successful completion of that study. Our U.S. regulatory pathway is under review.

We are also developing vascular grafts to treat abdominal aortic aneurysms, or AAAs, which are in the product design phase.

For financial information regarding our net sales, income from operations and total assets, please refer to our financial statements, which can be found in Item 8 of this Form 10-K.

Our Strategy

We seek to remain a leader in the innovation and manufacture of occlusion devices for the treatment of structural heart defects and to leverage our core competencies into leading positions in new markets. To accomplish this objective, we intend to:

- *Grow Our Business of Structural Heart Defect Occlusion and Vascular Devices.* We have a leading market position for occlusion devices to treat ASDs, PDAs and VSDs and our vascular plug family is currently our fastest growing product segment in terms of revenue. It grew 46.0% from $10.0 million in 2008 to $14.6 million in 2009. We intend to build on our existing portfolio with a series of product line extensions that will expand our addressable market opportunity. For example, we received CE Mark in July 2009 for the *AMPLATZER* Vascular Plug IV which can be delivered through standard diagnostic catheters with the advantage of no additional cost or

time required to exchange from a diagnostic catheter to a therapeutic delivery catheter, meaningfully expanding the addressable market for our Vascular Plug family. We also filed for regulatory approval of this device in the United States and hope to receive clearance in the first half of 2010.

- *Capitalize on the PFO Market Opportunity.* We believe that the performance of our devices, the *AMPLATZER* brand name and our global distribution network position us to take advantage of the large potential PFO market opportunity. We believe that physicians prefer our *AMPLATZER* PFO Occluders over our competitors' devices because of their ease of use, highly effective closure rates and its safety record. In Europe, we have the leading market position in PFO occlusion devices. In the U.S. market, we are conducting the RESPECT study to assess the impact of our PFO closure device in reducing the occurrence of certain types of stroke. We believe that physicians outside the United States will rely on a successful outcome of the RESPECT trial, which may lead to an acceleration of international PFO sales.
- *Expand and Commercialize Our Research and Development Pipeline.* Our co-founder and former President, Dr. Kurt Amplatz, supported by a team of physicians, scientists and engineers in our research and development department, has leveraged our core competencies in nitinol braiding and transcatheter delivery systems to develop and expand our pipeline of products. We received CE Mark clearance in December 2008 for our *AMPLATZER* Cardiac Plug, an occlusion device with an initial indication to close the LAA, and are currently marketing the device in Europe, Asia and South America. We are also developing uniquely designed vascular grafts made of multiple layers of braided nitinol that are delivered through small catheters for the treatment of aneurysms. We intend to re-file for a CE Mark in Europe in the second half of 2010 and to apply for an IDE in the United States for the first of these products in the first half of 2011.
- *Continue to Strengthen Our Global Distribution.* We currently market our products in 112 countries. We have established a direct U.S. field organization of 49 representatives, 29 of whom focus on our structural heart defect occlusion devices, with the other 20 focusing on vascular products. Outside of the U.S., we have a direct field organization of approximately 60 field representatives located throughout Europe. We also believe that there are significant opportunities to capture market share in developing markets, such as China, India and Latin America through selective distributor relationships. In China, for example, we established a distributor relationship with the Abbott Vascular division of Abbott Laboratories, Inc. for the distribution of our products.

We believe we have significant opportunities to leverage our expertise and further expand our structural heart and vascular product portfolio by developing new products, product enhancements and new applications for our existing products to address:

- *Patent Foramen Ovale.* By closing the PFO with an occlusion device, we believe we may be able to reduce the incidence of certain types of stroke and migraines. We currently sell our *AMPLATZER* PFO Occluder outside the United States, representing 15.3%, 12.0% and 13.2% of our net sales for the years ended December 31, 2009, 2008 and 2007. Our largest clinical trial, the RESPECT study, is being conducted at approximately 60 U.S. sites to assess the impact of our *AMPLATZER* PFO Occluder in reducing the occurrence of certain types of stroke. Based on our statistical models, we believe 500 patients should be sufficient to support a successful outcome in the RESPECT study, and as of January 31, 2010, we had enrolled 667 patients. According to decision rules, a successful outcome in the clinical trial is achieved once a claim of superiority of PFO closure versus drug therapy is supported. A successful outcome can be achieved at any time during the study. We intend to continue to enroll up to 900 patients unless a successful outcome is achieved earlier. If we can establish a successful outcome, the next step would be to prepare the submission of our PMA to the FDA, which we would expect to do

within three to six months after achieving a successful outcome. Following receipt of a PMA application, the FDA determines whether it is sufficiently complete and, therefore, may be accepted for review. On a statutory basis, the FDA is required to complete a preliminary review of a PMA application within six months. The FDA review process of a PMA application, however, may take up to several years. Once the FDA has approved the PMA application, we would be able to begin marketing the product in the United States. We estimate that the market opportunity for PFO closure in the prevention of certain types of stroke in the United States and Europe is greater than $1 billion annually.

- *Left Atrial Appendage.* We are developing a device to occlude the Left Atrial Appendage, or LAA, which targets reducing the incidence of stroke in patients with atrial fibrillation, one of the most common cardiac abnormalities in older people. We received CE Mark clearance in Europe in December 2008 and have initiated marketing of the device in Europe Asia and South America. We also applied to the FDA to begin a clinical trial to support U.S. approval of our *AMPLATZER* Cardiac Plug, with an initial indication for LAA occlusion, in August 2008, and expect to receive approval to commence this trial in the first half of 2010. We estimate that clinical trials in the United States could take approximately two to three years, after which we would file a PMA application with the FDA. We estimate that the market opportunity for LAA closure with a transcatheter approach worldwide is greater than $1 billion annually.
- *Vascular Aneurysms.* We are developing vascular grafts made from multiple layers of braided nitinol for the transcatheter treatment of aneurysms in a variety of blood vessel sizes. Aneurysms are localized bulges of a blood vessel caused by disease or weakening of the vessel wall. Our initial focus has been on aneurysms that occur in smaller peripheral arteries, such as the iliac arteries, arteries that branch off from the aorta and lead to the legs. We intend to refile for a CE Mark in Europe and to apply to the FDA for an Investigational Device Exemption, or IDE, in the United States in the second half of 2010. We estimate that CE Mark review could take 90 to 180 days from the time of submission, and after a CE Mark is granted, we would be able to begin marketing the product in Europe. We also estimate that clinical trials in the United States could take approximately two to three years, after which we would file a PMA application with the FDA. We estimate that the market opportunity for the transcatheter treatment of aneurysms in the United States and Europe is greater than $1 billion annually.

AMPLATZER Structural Heart Defect Occluders

We believe that our *AMPLATZER* structural heart defect occlusion devices offer the following advantages over our competitors' devices and open-heart surgery:

- *Easier to Implant, Retrieve and Reposition.* We believe that our *AMPLATZER* occlusion devices are easier to implant than our competitors' devices. Our occlusion devices are delivered through relatively small catheters and incorporate a unique mechanism to attach, deliver and release the devices at the site of the defect to be closed. We believe that our occlusion devices are the only fully retrievable and repositionable occluders on the market. The ability to retrieve and reposition the devices during the same procedure eliminates the need to remove the occlusion device and the catheter, which minimizes potential trauma to the patient, potential complications with the procedure and disposal of damaged devices that could not be properly deployed.
- *Highly Effective Closure Rates.* Our devices have consistently been shown to be highly effective in closing structural heart defects. Clinical publications have reported closure rates of approximately 96% for our *AMPLATZER* ASD and PFO Occluders. Our occlusion devices have a long history of durability as evidenced by some devices having been implanted in patients for over 13 years.

- *Minimally Invasive Procedures.* All of our devices are inserted into the human body through a small catheter via the femoral artery in the patient's groin and then travel through the body's vasculature to the heart. This transcatheter approach minimizes blood loss, trauma and other surgical complications associated with invasive open-heart surgery. Most patients have the procedure done on an outpatient or overnight basis and do not have to endure the lengthy two- to three-month recovery process required following open-heart surgery.
- *Cost Efficient.* The minimally invasive nature of the procedures required to implant our *AMPLATZER* occlusion devices reduces costs by taking advantage of shorter hospital stays and reduced therapy and follow-up care requirements. The average open-heart surgery procedure costs approximately $15,000 to $30,000, while the average total procedure cost to implant one of our *AMPLATZER* occlusion devices is generally less than $12,000, including device and hospital costs.

AMPLATZER Vascular Products

We are leveraging our expertise in nitinol braiding and our proficiency in the design of transcatheter delivery systems to develop products for the treatment of vascular diseases. We believe our existing vascular products and vascular products in our pipeline address a number of conditions characterized by large patient populations and existing therapies with significant shortcomings. Our initial vascular products seek to occlude abnormal blood vessels with our family of *AMPLATZER* Vascular Plugs and treat aneurysms in small arteries, such as the iliac arteries, and larger vessels, such as the thoracic and abdominal portions of the aorta, with our family of *AMPLATZER* Vascular Grafts.

Clinical Development Programs

We support many of our new product initiatives with scientific clinical studies in order to obtain regulatory approval and provide marketing data. The goal of a clinical trial is to meet the primary endpoint, which measures the clinical effectiveness and/or safety of a device and is the basis for FDA approval. Primary endpoints for clinical trials are selected based on the intended benefit of the medical device. Although clinical trial endpoints are measurements at an individual patient level, the results are extrapolated to entire populations of patients based on clinical similarities to patients in the clinical trials.

RESPECT (U.S. Pivotal Trial for Recurrent Cryptogenic Stroke)

A number of studies have suggested a relationship between cryptogenic stroke and PFO. Cryptogenic stroke is a stroke that occurs in a patient who does not possess any of the known risk factors for stroke. A main cause of the stroke is believed to be an emboli that, ordinarily filtered out by the lungs, instead crosses the PFO and passes through the circulatory system to the brain where it blocks a blood vessel causing what is termed an ischemic stroke.

RESPECT is our U.S. and Canadian trial to evaluate the safety and efficacy of our *AMPLATZER* PFO Occluder to prevent recurrent cryptogenic stroke. RESPECT is a randomized trial, meaning patients are randomly assigned to a treatment arm, which in this trial involves treatment with our *AMPLATZER* PFO Occluder, or a control arm, which involves treatment by one of the accepted drug therapies. The objective of the study is to determine whether PFO closure is superior to drug therapy in preventing recurrent cryptogenic stroke. RESPECT will enroll approximately 500 to 900 patients, with 50% randomly selected for the treatment arm and 50% for the control arm.

We are currently enrolling patients in approximately 60 centers. As of January 31, 2010, 667 patients were enrolled in the study with 1,244 patient follow-up years. Patients must have recently experienced a cryptogenic stroke. The trial is designed as a comparison of the number of events, being either stroke or death, in each arm of the study, and is designed with a statistical method that allows it

to be stopped when one of several decision rules are achieved. If a decision rule supporting superiority is reached, that is PFO closure is more successful than drug therapy, based on a comparison of the number of events between the two arms, then the trial can be stopped immediately, and we can begin preparation of a PMA for the FDA. This design is different from many FDA approved clinical trials that require the trial to wait one or more years following enrollment of the last patient to complete an analysis of the data. A decision rule can be met at any time during the study. We will continue to enroll up to 900 patients and monitor all patients until a decision rule is achieved. There are also decision rules that stop the study if it is determined that we will not be able to demonstrate superiority when compared to medical management by drug treatment.

PC (European Clinical Trial for Recurrent Cryptogenic Stroke)

PC is our European trial to evaluate the safety and efficacy of our *AMPLATZER* PFO Occluder to prevent recurrent cryptogenic stroke. PC is also a randomized trial that will involve data from at least 450 patients, randomly selected in equal numbers to participate in the treatment and control arms. As of December 31, 2009, 414 patients were enrolled in the study at approximately 30 centers.

PFO ACCESS Registry Study

Until October 31, 2006, our *AMPLATZER* PFO Occluder was approved in the United States under a humanitarian device exemption. An HDE designation permits the sale of devices in cases in which a small population of patients—defined as less than 4,000 eligible patients annually—are thought to be able to benefit from the procedure. After discussions with the FDA, we voluntarily withdrew our HDE for our *AMPLATZER* PFO Occluder because we agreed that the eligible patient population was greater than 4,000 patients. We subsequently received approval from the FDA for a registry of up to 2,000 patients annually who experience at least two cryptogenic strokes but would not otherwise qualify for the RESPECT study. The registry is open to centers that were approved to enroll patients under the HDE by each center's Institutional Review Board, being a committee of hospital and community experts that review and approve all clinical studies. Although we will collect and monitor data from the sites on product performance and safety, the data will not be used to support a regulatory filing. The study will terminate when a PFO occluder receives regulatory approval in the United States.

PREMIUM (U.S. Pivotal Trial for Migraine with and without Aura)

Historical research has noted a possible association between PFOs and migraine headaches. In particular, prevalence of a PFO is especially high in patients who have migraine with aura, which means visual, auditory, sensory and motor abnormalities preceding a migraine attack. Data from past studies have indicated that as many as 80% of migraine sufferers who had their PFO closed for other reasons have reported a resolution or significant reduction, *i.e.*, a reduction of greater than 50% in the frequency, of migraine headaches. For example, two studies published in 2005 in the Journal of the American College of Cardiology reported elimination or a significant reduction in the frequency of migraine attacks in greater than 70% of patients one year after PFO closure.

PREMIUM is a U.S. trial to evaluate the safety and efficacy of our *AMPLATZER* PFO Occluder to treat migraine headaches in patients with a PFO. To be eligible for the study, prospective patients must have a PFO and recently experienced a number of migraine attacks per month within a specified range. The PREMIUM protocol was approved by the FDA in June 2006. At the time, the protocol specified enrolling a maximum of 470 patients, with 235 under a treatment arm and 235 under a control arm, in up to 40 centers. In April 2009, the FDA granted conditional approval to amend the protocol to modify some of the conditions for patient eligibility in the trial. The FDA also agreed to reduce the number of patients to be enrolled in the study to 230 patients, with 115 in the treatment arm and 115 in the control arm. The changes were granted based on newly published clinical literature used to develop key assumptions in migraine trials and based on our experience in enrolling patients in the study. Conditional approval allows the clinical trial to commence but requires the specified conditions to be satisfied before the completion of the clinical trial.

Patients in the treatment arm receive our *AMPLATZER* PFO Occluder to close their PFO, and patients in the control arm undergo a sham procedure whereby their PFO is not closed. Patients in each arm also continue on their approved medications. The primary efficacy endpoint for PREMIUM will be a 50% reduction in the number of migraine attacks in at least 50% of patients when compared to the control arm. The period from which the measurement will be calculated will be one year following the procedure being performed on the patient. We are currently enrolling patients in this trial and enrolled the first patient under our amended protocol in October 2009.

PRIMA (International Trial for Migraine with Aura)

PRIMA is our international trial to evaluate the safety and efficacy of our *AMPLATZER* PFO Occluder to treat migraine headaches in patients with a PFO. PRIMA is also a randomized trial that will involve data from approximately 140 patients, with 70 under a treatment arm and 70 under a control arm.

The design of PRIMA is similar to PREMIUM with the same general eligibility, except that (1) PRIMA will only enroll patients who experience migraine attacks with aura, and (2) patients in the control arm will not undergo a procedure but will only receive conventional medical management by drug treatment for their migraines. Patients in the treatment arm will receive both the implant and conventional medical management.

PRIMA is currently enrolling in approximately 15 centers in Canada, the United Kingdom and Germany.

Other Studies

We are conducting, or plan to conduct, a number of other clinical studies in the United States and Europe. We are currently conducting two post-approval studies that were required as a condition of approval by the FDA of the *AMPLATZER* Septal Occluder and the *AMPLATZER* Muscular VSD Occluder. The studies are designed to monitor patients for a period of up to five years after the procedure. The objective is to collect and report to the FDA additional data on the long-term safety and efficacy of the device. The majority of patients enrolled in these two studies were children at the time of receiving their implant. In some cases, it can be challenging to follow these patients for up to five years as they and their families move or otherwise stop seeing the physician who performed the treatment. In these cases, we have requested and received approval from the FDA to enroll new patients and follow them for up to five years to satisfy the FDA's requirements.

We have conditional approval from the FDA to conduct a clinical study in the United States to support the approval of the *AMPLATZER* Duct Occluder II. The study is approved to enroll approximately 170 patients in up to 25 centers. The study is designed as a single arm study in which all eligible patients receive the device. We commenced enrolling patients in the second half of 2008. Conditional approval allows the clinical trial to commence but requires the specified conditions to be satisfied before the completion of the clinical trial. In this particular instance, the conditions require us to conduct additional laboratory testing designed to simulate the structural performance of the product when implanted for an extended period of time along with associated biocompatibility.

We filed for approval to conduct an IDE study in the United States in August of 2008, to support approval of the *AMPLATZER* Cardiac Plug with an initial indication to close the left atrial appendage. In August 2009, we received a request from the FDA for modifications to the clinical trial design. Since August, we have had ongoing discussions with the FDA about our trial design and expect to receive approval to begin our IDE study in the U.S. in the first half of 2010.

We are also planning other clinical studies for products in our development pipeline. We plan to develop these studies and, where appropriate and required, file for approval in the United States and Europe following the completion of the required pre-clinical studies.

Marketing and Sales

We market and sell our *AMPLATZER* family of devices to hospitals and physicians, including interventional cardiologists, interventional radiologists, vascular surgeons and electrophysiologists. Procedures that use our devices are generally recommended to patients by pediatric and adult interventional cardiologists, and physician referrals and peer-to-peer selling are critical elements of our sales strategy. Physicians are, in most cases, the decision makers on whether to use our products. In certain countries where the government administers the healthcare system, a tender or bidding process is often used in product selection. Even in these cases, and given the history and performance of our devices, we believe that physicians have a significant influence on product selection. As a relatively small percentage of patients treated with our devices today are over 65, we do not rely extensively on Medicare for reimbursement on the sale of our devices. However, this may change in the future as we commercialize products in our pipeline for the treatment of structural heart defects and vascular abnormalities.

We are not dependent on any single customer, and no single customer (including distributors) accounted for more than 10% of our net sales for the years ending December 31, 2009, 2008 and 2007.

International

We market and sell our products in Europe through a direct sales force of approximately 60 field representatives. Internationally, we have agreements with approximately 80 physician specialists to train new physicians in the use of our products. We have also placed computer simulation systems in both our United Kingdom and German offices for use in customer training.

As part of our strategy to grow internationally, we may continue to selectively convert our distribution to direct sales representation in certain countries, as we did in the United Kingdom in 2006, in Spain in April 2008, in Slovakia in July 2008, and France, Italy, Portugal, Belgium, the Netherlands, Luxembourg and Canada in January 2009. We intend to also focus on expanding our presence in underserved countries, such as China, Brazil, and India where we sell through distributors.

United States

We market and sell our products in the United States through a direct sales force of 49 representatives, 29 of whom focus on our structural heart defect occlusion devices, with the other 20 focusing on vascular products. Marketing and selling of our products is largely accomplished by frequent sales calls to on-site locations, as well as our targeted marketing efforts through medical conferences, journals and various marketing materials. We use in the United States approximately 60 experienced physician specialists who are employed on a contract basis to provide training to new physicians in the use of our products.

Worldwide Operations.

For financial reporting purposes, net sales and long-lived assets attributable to significant geographic areas are presented in Note 15 to our financial statements set forth in Item 15 of this Form 10-K.

Research and Development

Our research and development efforts are led by Dr. Kurt Amplatz, our co-founder, former President and inventor of our family of *AMPLATZER* occlusion devices and *AMPLATZER* vascular plugs. Dr. Amplatz is currently a research and development consultant to our company. Dr. Amplatz retired in 1999 from the University of Minnesota after a distinguished career as the Malcolm B. Hanson Research Professor of Diagnostic Radiology. Dr. Amplatz received the Society of Interventional Radiology's Gold Medal in 1996 in recognition of his contributions to the field, and he is credited with more than 700 journal articles, books and abstracts in the field of radiology. All of our research and development efforts take advantage of our core competency in the use of braided nitinol in the design and manufacture of occlusion devices. Since our first product sales in 1996, we have launched 13 different structural heart and vascular devices worldwide and have a successful track record of receiving product approvals and regulatory clearances. Introduced in the late 1990s, our family of *AMPLATZER* occlusion devices was the first of a number of devices that successfully resulted in widespread adoption worldwide of a less invasive transcatheter approach to treat structural heart defects. Our current research and development efforts are focused on both line extensions to our existing occluders and vascular devices and the development and commercialization of new structural heart devices such as the *AMPLATZER* Cardiac Plug, with an initial indication for LAA occlusion, and our family of vascular grafts.

During the years ended December 31, 2009, 2008 and 2007, we incurred research and development expenses of $35.2 million, $32.8 million, and $26.6 million, respectively. As a result of our expected investments in enhancing the capabilities of our devices and exploring new applications and devices, we expect research and development efforts and expenses to increase in absolute dollar terms but to decrease as a percentage of net sales.

We have contractual relationships with a number of outside laboratories to conduct preclinical studies. The normal process for designing a new occlusion device involves the development and refinement of device prototypes. We then validate these designs using preclinical models at outside laboratories. This is then followed by formal preclinical trials. In parallel with these trials, the design of the device and the components used in its manufacture are formally validated by our engineering staff. Once the testing and component validation has been completed, we may file directly for approval by the FDA or by our Notified Body in Europe or, in cases where clinical trials are required, permission by the FDA or similar agencies in other countries for the design and conduct of the trial. The clinical trials are conducted by physicians following approval of the study by independent monitoring groups at each hospital called Institutional Review Boards. Once the clinical trials are completed, we submit the results of the trials and all associated testing of the device for regulatory approval.

Manufacturing

We manufacture our *AMPLATZER* occlusion devices at our corporate headquarters in Plymouth, Minnesota. The manufacturing process combines the use of advanced technology and manual labor. First, a technician uses large mechanical braiders to spin fine nitinol filaments into a braided tube, which composes the body of the occlusion devices. The tube is then secured into a metal mold and baked at a high temperature to set the shape of the occlusion device. For certain devices, the technicians then sew polyester fabric into the inside of each device. Lastly the devices are inspected, packaged, sent to a third party local subcontractor for sterilization and then returned to us ready for shipment.

We continue to invest in improvements to our manufacturing process. These investments include the automation and enhanced control of key processes, as well as the implementation of automated inspection to improve quality control. We plan to continue to invest in improvements to our manufacturing process. Many of these improvements, however, must first be approved by the FDA and

foreign regulatory bodies before they can be implemented in routine production. We believe that continued improvements to our manufacturing process are important to our objective of remaining a leader in the innovation and manufacture of occlusion devices for the treatment of structural heart defects and leveraging our core competencies into leading positions in new markets.

Our devices undergo strict quality-control measures and manufacturing protocols. We are certified under ISO 13485 and had a qualification audit in January 2006 to qualify for this standard. Our quality system is compliant with both U.S. and European standards, including ISO 13485:2003, ISO 9001:2000, and European 93/42/EEC for Medical Devices and Annex II(3). We use a combination of 100% inspection and statistical process control to ensure quality. The last stages of manufacturing of our products are completed using Class 10,000 clean rooms with sterilization for all products assured by a local subcontractor. Our quality system was audited by the FDA in July 2006 and in February 2009, when they made several findings, and no additional regulatory actions were required. In the February 2009 audit, the FDA's findings included a request to use alternate definitions when referring to certain product returns to require such returns to be characterized as complaints. We complied with this request and received a letter from the FDA in June 2009 indicating that the audit of our quality system was closed.

Our *AMPLATZER* occlusion devices, vascular plugs and vascular grafts are composed of nitinol, a metal which contains a mixture of nickel and titanium alloy. We use nitinol because its shape memory properties allow our *AMPLATZER* occlusion devices, vascular plugs and vascular grafts to be compressed into a small catheter and advanced to the site of interest and, upon deployment, to regain their original shape as the sheath is withdrawn. Most of the component parts and raw materials used in our manufacturing and assembly operations are purchased from outside suppliers and are, in some instances, manufactured on a custom basis. Also, most of these component parts and raw materials are available from more than one supplier. However, the primary component in our devices, nitinol, is provided by a single third-party supplier. We currently have no formal agreement with this supplier of nitinol. There are, however, additional suppliers of nitinol should our existing supplier fail to meet our requirements. In addition, this manufacturer has multiple facilities qualified to supply us with nitinol, and we maintain at least a year's supply of nitinol. We have never experienced supply interruptions during our ten-year relationship with our existing supplier. However, if we encounter a cessation, interruption or delay in the supply of nitinol, we may be unable to obtain nitinol through other sources, on acceptable terms, within a reasonable amount of time or at all. In addition, any change of supplier of nitinol would require FDA approval. Any such cessation, interruption or delay may impair our ability to meet scheduled product deliveries to our customers, hurt our reputation or cause customers to cancel orders.

Competition

The structural heart defect and the vascular disease and associated conditions device markets in which we compete are characterized as having relatively few competitors and high barriers to entry, including intellectual property and the clinical and regulatory processes required for product approval. Competition in these product markets is primarily based on:

- ability to treat defects and conditions safely and effectively;
- ease of use;
- predictable clinical performance;
- brand name recognition; and
- cost effectiveness.

We believe we compete favorably with respect to these factors, although there can be no assurance that we will be able to continue to do so in the future or that new products that perform better than those we offer will not be introduced. We believe that our continued success depends on our ability to:

- continue to innovate and maintain scientifically advanced technology;
- obtain and enforce patents or other protection for our products;
- obtain and maintain regulatory approvals;
- attract and retain skilled scientific and sales personnel; and
- cost effectively manufacture and successfully market our products.

While our competitors include certain multi-product companies with significantly greater financial, marketing and other resources than we have, we compete with a limited number of companies across our product lines. In the United States, our primary competitor in the ASD occluder market is W.L. Gore & Associates, or W.L. Gore; our primary competitors in the PDA occluder market are Cook, Inc., or Cook, and Boston Scientific Corporation, or Boston Scientific; our primary competitor in the VSD occluder market is NMT Medical, Inc., or NMT Medical; and our primary competitors in the vascular plug market are Cook and Boston Scientific. In Europe, our primary competitors in the ASD occluder market are W.L. Gore and Cardia, Inc., or Cardia; our primary competitors in the PDA occluder market are Cook and Boston Scientific; our primary competitor in the VSD occluder market is NMT Medical; our primary competitors in the PFO occluder market are Cardia NMT Medical; and St. Jude Medical Inc., or St. Jude Medical; and our primary competitors in the vascular plug market are Cook and Boston Scientific.

Of these U.S. and European competitors, we are the only company with Japanese approval for ASD and PDA occluders, although others have received a CE Mark in Europe. Similar to us, NMT Medical and W.L. Gore are conducting clinical trials investigating PFO closure in the treatment of certain types of stroke.

Intellectual Property

We believe that to have a competitive advantage we must develop, maintain and protect the proprietary aspects of our technologies. We rely on a combination of patent, trademark, copyright, trade secret and other intellectual property laws, nondisclosure agreements, licenses and other measures to protect our intellectual property rights. We require our employees, consultants and advisors to execute confidentiality agreements. We also require our employees, consultants and advisors who develop intellectual property for us to assign their rights to all intellectual property conceived in connection with their relationship with us. We cannot provide assurance that employees and consultants will abide by the confidentiality or assignment terms of these agreements. In addition, despite measures we take to protect our intellectual property, unauthorized parties might obtain or use information that we regard as proprietary. Any patents or other intellectual property issued to us may be challenged by third parties as being invalid.

Patents

Where appropriate, to protect our intellectual property rights related to our medical devices, we apply for U.S. and foreign patents. As of December 31, 2009, we had approximately 197 issued patents and a pipeline of approximately 126 pending patent applications. Our issued and pending patents cover many aspects of our devices' manufacture and usage. Our patent applications may not result in issued patents, and our patents that have been issued or might be issued may not adequately protect our intellectual property rights. The first U.S. patent owned by us expires in 2014, unless extended as may be allowed under applicable law in certain circumstances. As new patents are granted, the term for

each U.S. patent granted will be 20 years from the date the application is filed. The actual protection afforded by a foreign patent may vary from country to country, depending upon the laws of such country.

We also make royalty payments with respect to certain patents that were assigned to us by Dr. Kurt Amplatz and Mr. Curtis Amplatz.

Trademarks

We have also registered, and filed applications to register, 57 trademarks with the U.S. Patent and Trademark Office and appropriate offices in foreign countries where we do business to distinguish our products from our competitors' products. We market and sell substantially all of our devices under the *AMPLATZER* trademark, which is recognized as a global leader in structural heart defect occlusion devices. U.S. trademark registrations are for an unlimited duration, provided the marks continue to be used in commerce.

Government Regulation

Medical Device Regulation

United States. Our products and operations are subject to regulation by the Food and Drug Administration (FDA) and state authorities, as well as the comparable authorities in foreign jurisdictions which are discussed below. The FDA regulates the design, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, promotion, and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses or substantially equivalent to marketed products. Medical device manufacturers are also inspected regularly by the FDA. In addition, the FDA regulates the export of medical devices manufactured in the United States to international markets and the import of components used in the manufacture of medical devices.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulator control needed to ensure safe and effective use. Classification of a device is important because the class to which a device is assigned determines, among other things, the type of application process required for FDA review and clearance or approval to market the device. Class I includes devices with the lowest risk to the patient (and subject to the least regulatory control), while Class III includes devices that pose the greatest risk to the patient (and strictest regulatory control).

The preponderance of our business involves products in Class III. FDA generally classifies devices that are surgically implanted into the heart as Class III. In contrast, some of our devices that are marketed for peripheral vascular use are designated by the FDA as Class II devices. A couple of our devices used to size the implant are classified as Class I.

Class I devices. Class I devices are considered low-risk devices subject to the least regulatory control. In general, a company can market a Class I device without premarket review by the FDA as long as it adheres to what the FFDCA calls General Controls, which sufficiently assure the safety and efficacy of the device. General Control requirements include compliance with the applicable portions of the FDA's manufacturing Quality System Regulation (QSR), facility registration and product listing, medical device reporting of adverse events, and truthful and non-misleading labeling, advertising, and promotional materials. Most Class I devices are exempt from the premarket notification process by the FDA which is discussed below. Some Class I devices are also exempt from the QSR. Examples of our Class I devices include the sizing plate and the sizing balloon used to determine the dimensions of the cardiac or vascular implants required by patients.

Class II devices. Class II devices are medium-risk devices subject to greater regulatory control than Class I devices. In addition to complying with the General Controls listed above, Class II devices are also subject to Special Controls, which may include performance standards, postmarket surveillance, patient registries, or guidelines. Most Class II devices are also required to obtain FDA clearance under Section 510(k) of the FFDCA (known as "premarket notification") before they can be marketed. When compliance with Section 510(k) is required, the company must submit to the FDA a premarket notification submission demonstrating that the device is "substantially equivalent" to a predicate device already on the market. A predicate device is either a device that was legally marketed prior to May 28, 1976 (the date upon which the Medical Device Amendments of 1976 were enacted) or another commercially available, similar device that was subsequently cleared through the 510(k) process. Data must support the safe and effective use of the device including bench testing, performance validation, and occasionally, but now more frequently, a limited amount of human clinical safety and efficacy data.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant clearance to commercially market the device. By regulation, the FDA is required to clear a completed 510(k) premarket notification application within 90 days of submission. As a practical matter, marketing clearance often takes longer in the event additional information is requested. Most device applications must now pay user fees under the Medical Device User Fee and Modernization Act which also contains FDA performance goals for faster and more predictable device product review. If the FDA determines that the device, or its intended use, is not "substantially equivalent" to a previously cleared device or use, the FDA may place the device, or the particular use of the device, into Class III. The device sponsor must then fulfill more rigorous premarketing requirements or petition to down-classify the device to Class II under the process known as "de novo" or "risk-based classification" review. An example of a Class II device is our Vascular Plug for arterial and venous embolizations in the peripheral vasculature.

Class III devices. Class III devices are higher-risk devices such as those which support or sustain life or are used invasively in the body. Class III devices are subject to the greatest amount of regulatory control. In general, a Class III device cannot be marketed unless the FDA approves the device after submission of a premarket approval application, or PMA. The PMA process is more demanding than the 510(k) premarket notification process. A PMA application, which is intended to demonstrate that the device is safe and effective, must be supported by extensive data, including data from preclinical studies and human clinical trials. Human studies are conducted pursuant to a clinical protocol generally supervised by FDA and a patient Institutional Review Board (IRB) pursuant to an approved Investigational Device Exemption application (IDE). The PMA application must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA application, once the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will accept the application for agency review. The FDA, by statute and by regulation, has 180 days to review a PMA application, although the review of an application more often occurs over a significantly longer period of time, and can take up to several years. The user fee act referenced above also contains performance goals in exchange for the application fees paid to make device product reviews more timely and predictable. In approving a PMA application, or clearing a 510(k) application, the FDA may also require some form of post-market surveillance when necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Examples of PMA devices are our Septal Occluder for transcatheter closure of atrial septal defects and our Duct Occluder for transcatheter non-surgical closure of patent ductus arteriosus (PDA).

Class III devices may also be marketed under a Humanitarian Device Exemption (HDE) for smaller patient populations. Such a designation can eliminate the need to file a full PMA supported by

human clinical safety and efficacy trials. This is a two-step process. First one must request a Humanitarian Use Device (HUD) designation for a medical device. The applicant requests the designation for treatment of a rare disease or condition, or a medically plausible subset of a more common disease or condition. The applicant must demonstrate that that the disease or condition involves fewer that 4,000 diagnosed cases per year. Within 45 days the FDA must either approve or reject the request for designation. Once a HUD designation is approved, the sponsor must apply for the HDE. The applicant must show that the device would not be available unless the HDE were granted and that no comparable device, except another HUD, is available to treat the disease or condition. The FDA may request additional pre-clinical or other testing before approving or rejecting the application. Once the HUD device is available for marketing under an HDE, the amount charged for the device cannot exceed the costs of the device's research, development, fabrication, and distribution. We intend to seek an HDE for our device intended to treat Ventricular Septal Post Infarction.

Unlike a PMA, which is very difficult for the FDA to revoke, the HUD designation for an HDE may be revoked if circumstances change. For example, the FDA may revoke the HDE if the number of cases is shown to exceed 4,000 per year, another device becomes commercially available, or the disease or condition is no longer considered a medically plausible subset or indication. For example, we held an HDE for our PFO Occluder, that was subsequently converted into a conventional IDE, for the non-surgical closure of a PFO in patients with recurrent cryptogenic stroke due to presumed paradoxical embolism through a PFO and who have failed conventional drug therapy. This is an example of how the FDA may change its policies, adopt additional regulations, or revise existing regulations, any of which could impact our ability to market a device that was previously cleared or approved.

Medical devices can be marketed only for the indications for which they are cleared or approved. Modifications to a previously cleared or approved device that could significantly affect its safety or efficacy or that would constitute a major change in its intended use, design or manufacture require a 510(k) clearance, premarket approval supplement or new premarket approval. We cannot assure you that we will be successful in receiving approvals in the future or that the FDA will agree with our decisions not to seek approvals, supplements or clearances for particular device modifications. The FDA may require approval or clearances for past or any future modifications or new indications for our existing products. Such submissions may require the submission of additional clinical or preclinical data and may be time consuming and costly, and may not ultimately be cleared or approved by the FDA in a timely manner or at all.

Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and distribution of our products. The QSR also, among other things, requires maintenance of a device master record, device history record, and complaint files. Our manufacturing facility is subject to periodic scheduled or unscheduled inspections by the FDA. Based on internal audits and FDA inspections, we believe that our facility is in substantial compliance with the applicable QSR regulations. We are also required to report to the FDA if our products cause or contribute to a death or serious injury or malfunction in a way that would likely cause or contribute to death or serious injury were the malfunction to recur. The FDA and authorities in other countries can require the recall of products, or we can voluntary recall a product, in the event of material defects or deficiencies in design or manufacturing. The FDA can also withdraw or restrict our product approvals or clearances in the event of serious, unanticipated health or safety concerns.

The FDA has broad regulatory and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions from public warning letters, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure or recall of our products, total or partial shutdown of production,

withdrawal of approvals or clearances already granted, and criminal prosecution. The FDA can also require us to repair, replace or refund the cost of devices that we manufactured or distributed. If any of these events were to occur, it could materially adversely affect us.

Legal restrictions on the export from the United States of any medical device that is legally distributed in the United States are limited. However, there are restrictions under U.S. law on the export from the United States of medical devices that cannot be legally distributed in the United States. If a Class I or Class II device does not have 510(k) clearance, and the manufacturer reasonably believes that the device could obtain 510(k) clearance in the United States, then the device can be exported to a foreign country for commercial marketing without the submission of any type of export request or prior FDA approval, if it satisfies certain limited criteria relating primarily to specifications of the foreign purchaser and compliance with the laws of the country to which it is being exported (Importing Country Criteria). An unapproved Class III device can be exported if it complies with the criteria discussed above for a 510(k) device and the device has a marketing authorization in one of a list of countries listed in the FFDCA. If an unapproved Class II device is not cleared for marketing in one of the listed countries, a license from the FDA is required in order to export it. We believe that all of our current products which are exported to foreign countries currently comply with these restrictions.

International

In many of the foreign countries in which we market our products, we are subject to regulations essentially similar to those of the FDA. The regulation of our products in Europe falls primarily within the European Economic Area, which consists of the twenty-five member states of the European Union as well as Iceland, Liechtenstein and Norway. The legislative bodies of the European Union have adopted three directives in order to harmonize national provisions regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices: the Actives Implantables Directive, the Medical Device Directive (MDD) and the In-Vitro-Diagnostics Directive. Our devices are registered under the MDD. The member states of the European Economic Area have implemented the directives into their respective national law. Medical devices that comply with the essential requirements of the national provisions and the directives will be entitled to bear a CE Mark. Unless an exemption applies, only medical devices which bear a CE Mark may be marketed within the European Economic Area. The European Commission has adopted numerous guidelines relating to the medical devices directives to ensure their uniform application. The method of assessing conformity varies depending on the class and type of the medical device and can involve a combination of self-assessment by the manufacturer and a third-party assessment by a Notified Body, which is an independent and neutral institution appointed by the member states to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's devices. An assessment by a Notified Body in one country within the European Economic Area is generally required in order for a manufacturer to commercially distribute the product throughout the European Economic Area.

The European Standardization Committees have adopted numerous harmonized standards for specific types of medical devices. Compliance with relevant standards establishes the presumption of conformity with the essential requirements for a CE Mark. All of our products that we export or manufacture for sale in Europe bear a CE Mark.

Compliance activity is generally undertaken on a country-by-country basis under the control of the country's Competent Authority. A Competent Authority is the country's medical device regulatory agency, which is analogous to the U.S. FDA with regard to compliance matters. As discussed above, a Competent Authority has no role in facility inspection or product approval, which is done by the Notified Body. Adverse events relating to medical devices are reported to the Competent Authority under a system known as Vigilance, on a country-by-country basis. The Competent Authority also controls product recalls or any other compliance action within a country.

Third-Party Reimbursement

In the United States, as well as in foreign countries, government-funded or private insurance programs, commonly known as third-party payors, pay the cost of a significant portion of a patient's medical expenses. A uniform policy of reimbursement does not exist among these payors. Therefore, reimbursement can differ from payor to payor. These third-party payors may deny reimbursement if they determine that a device used in a procedure was not used in accordance with cost-effective treatment methods, as determined by the third-party payor. Also, third-party payors are increasingly challenging the prices charged for medical products and services. In international markets, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific product lines. There can be no assurance that our products will be considered cost-effective by third-party payors, that reimbursement will be available or, if available, that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably. Reimbursement is also generally granted according to the surgical procedure for which the device is used, and not for the device itself. There can be no assurance that reimbursement for the procedure itself is sufficient to justify the use of any device deemed to be too expensive for the reimbursement available for a particular procedure code.

Reimbursement in the United States depends on our ability to obtain FDA clearances and approvals to market these products. Reimbursement also depends on our ability to demonstrate the short-term and long-term clinical and cost-effectiveness of our products from the results we obtain from clinical experience and formal clinical trials. We present these results at major scientific and medical meetings and publish them in respected, peer-reviewed medical journals.

The United States Center for Medicare and Medicaid Services, or CMS, sets reimbursement policy for the Medicare program in the United States. CMS policies may alter coverage and payment related to our product portfolio in the future. These changes may occur as the result of National Coverage Decisions issued by CMS headquarters or as the result of local or regional coverage decisions by contractors under contract with CMS to review and make coverage and payment decisions. CMS maintains a national coverage policy, which provides for the utilization of our products in Medicare beneficiaries. Medicaid programs are funded by both federal and state governments. Medicaid programs are administered by the states and vary from state to state and from year to year. Commercial payor coverage for our products may vary across the United States.

All third-party reimbursement programs, whether government funded or insured commercially, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling healthcare costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, second opinions required prior to major surgery, careful review of bills, encouragement of healthier lifestyles and exploration of more cost-effective methods of delivering healthcare. These types of programs and legislative changes to reimbursement policies could potentially limit the amount which healthcare providers may be willing to pay for medical devices.

Fraud and Abuse

Our operations are directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the FFDCA, federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, these laws require us to screen individuals and other companies, suppliers and vendors in order to ensure that they are not "debarred" by the federal government and therefore prohibited from doing business in the healthcare industry. The association or conduct of business with a "debarred" entity could be detrimental to our operations and result in a negative impact on our business.

The U.S. Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. This statute is normally used to insure that bribes or other illegal remuneration are not paid to physicians, or others, to induce their use of drugs or medical devices. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The U.S. False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Various states have also enacted laws modeled after the federal False Claims Act.

In addition to the laws described above, the U.S. Health Insurance Portability and Accountability Act of 1996 created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Voluntary industry codes, federal guidance documents and a variety of state laws address the tracking and reporting of marketing practices relative to gifts given and other expenditures made to doctors and other healthcare professionals. In addition to impacting our marketing and educational programs, internal business processes will be affected by the numerous legal requirements and regulatory guidance at the state, federal and industry levels.

If our operations are found to be in violation of any of the laws described above or other applicable state and federal fraud and abuse laws, we, as well as our employees, may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare programs, and the curtailment or restructuring of our operations. Individual employees may need to defend such suits on behalf of us or themselves, which could lead to significant disruption in our present and future operations.

International Trade

The sale and shipment of our products and services across international borders, as well as the purchase of components and products from international sources, subject us to extensive governmental trade regulations. A variety of laws and regulations, both in the United States and in the countries in which we transact business, apply to the sale, shipment and provision of goods, services and technology across international borders. Because we are subject to extensive regulations in the countries in which we operate, we are subject to the risk that laws and regulations could change in a way that would expose us to additional costs, penalties or liabilities.

Existing laws and regulations significantly affect cross-border transactions and shipments. These laws and regulations govern, among other things, the following activities:

Importing Activities: We engage in the importation of raw materials, components and finished products into the countries in which we transact business. We act as importer of record in many

instances, but we also sell and ship goods to third parties who are themselves responsible for complying with applicable trade laws and regulations.

In our role as importer of record, we are directly responsible for complying with customs laws and regulations concerning the importation of our raw materials, components and finished products. If third parties violate FDA or customs laws and regulations when engaging in cross-border transactions involving our products, we may be subject to varying degrees of liability depending on our participation in the transaction. In addition, the activities of third parties may cause supply chain disruptions and delays in the distribution of our products that impact our business activities.

Exporting Activities: We are responsible for compliance with applicable export control and economic sanctions laws and regulations with respect to our export of goods, technology and services to customers and end-users located in countries in which we transact business. We also sell and provide goods, technology and services to agents, representatives and distributors who may export such items to customers and end-users.

If third parties violate applicable export control and economic sanctions laws and regulations when engaging in transactions involving our products, we may be subject to varying degrees of liability dependent upon our participation in the transaction. The activities of our third parties may cause disruption or delays in the distribution and sales of our products, or result in restrictions being placed upon our international distribution and sales of products may materially impact our business activities.

Many countries, including the United States, control the export and reexport of goods, technology and services for reasons including public health, national security, regional stability, antiterrorism policies and the nonproliferation of nuclear, chemical and biological weapons. In certain circumstances, approval from governmental authorities may be required before goods, technology or services are exported or reexported to certain destinations, to certain-end-users and for certain end-uses. In addition, governments, including the United States, may impose economic sanctions against certain countries, persons and entities. Because export control and economic sanctions laws and regulations are complex and constantly changing, we cannot assure you that laws and regulations may not be enacted, amended, enforced or interpreted in a manner materially impacting our ability to sell or distribute products.

Antiboycott Laws: Under U.S. laws and regulations, U.S. companies and their controlled-in-fact foreign subsidiaries and affiliates are prohibited from participating or agreeing to participate in unsanctioned foreign boycotts in connection with certain business activities, including the sale purchase, transfer, shipping or financing of goods or services within the United States or between the United States and a foreign country. Currently, the United States considers the Arab League boycott of Israel to constitute an unsanctioned foreign boycott.

We are responsible for ensuring we comply with the requirements of U.S. antiboycott laws for all transactions in which we are involved. If we or third parties violate U.S. antiboycott laws and regulations when engaging in transactions involving our products, we may be subject to varying degrees of liability dependent upon the nature of the transaction and our participation in the transaction. Penalties for any violations of antiboycott laws and regulations could include criminal penalties and civil sanctions such as fines, imprisonment, debarment from government contracts, loss of export privileges and the denial of certain tax benefits, including foreign tax credits, foreign subsidiary deferrals, Foreign Sales Corporation benefits and Interest Charge-Domestic International Sales Corporation benefits.

Antibribery laws. Many of the countries in which we transact business have domestic laws that restrict the offer or payment of anything of value to government officials or other persons with the intent of gaining business or favorable government action. Moreover, some of the transactions in which we and our officers, directors, employees and agents engage may be governed by the legal obligations and standards set forth under the U.S. Foreign Corrupt Practices Act and, at times, other laws modeled

on the OECD Convention for Combating Bribery of Foreign Public Officials in International Business Transactions. In addition to prohibiting certain bribery-related activity with foreign officials and other persons, these laws provide for recordkeeping and reporting obligations. Penalties for any violations of these anti-bribery laws could include criminal penalties and civil sanctions such as fines, imprisonment, debarment from government contracts and loss of export privileges.

Employees

As of December 31, 2009, we had approximately 500 employees. From time to time, we also employ independent contractors to support our operations. We believe that our continued success will depend on our ability to continue to attract and retain skilled scientific and sales personnel. We have never had a work stoppage, and none of our worldwide employees is represented by a labor union. We believe our relationship with our employees is satisfactory.

Executive Officers of the Registrant

Set forth below are the names and ages of current executive officers and significant employees of AGA Medical Holdings, Inc., as well as information regarding their positions with AGA, their periods of service in these capacities, and their business experiences. There are no family relationships among any of the officers named, nor is there any arrangement or understanding pursuant to which any person was selected as an officer.

Name	Age	Title
John R. Barr	53	President and Chief Executive Officer
Brigid A. Makes	54	Chief Financial Officer
Ronald E. Lund	75	General Counsel

John R. Barr—President and Chief Executive Officer

John R. Barr has served as our President and Chief Executive Officer since June 2008 and, prior to that, served as our Chief Operating Officer since September 2005. Prior to joining our company, Mr. Barr served as President and Chief Executive Officer of V.I. Technologies prior to its merger with Panacos Pharmaceuticals in 2005. Prior to joining V.I. Technologies, Mr. Barr served from June 1990 to November 1997 as President of North American Operations for Haemonetics Corporation, a leading medical device manufacturer, and from July 1981 to April 1990 in both financial and operational roles for Baxter Healthcare. Mr. Barr holds a Master's Degree in management from the J.L. Kellogg Graduate School of Management and a Bachelor of Science Degree in bioengineering from the University of Pennsylvania.

Brigid A. Makes—Chief Financial Officer

Brigid A. Makes has served as our Chief Financial Officer since October 2006. Prior to joining our company, Ms. Makes served in various management positions at Nektar Therapeutics from 1999 to 2006, including Vice President—R&D Operations, Vice President—Operations Management, Vice President—Finance and Administration and Chief Financial Officer. Prior to joining Nektar Therapeutics, Ms. Makes served from 1998 to 1999 as Chief Financial Officer of Oravax, Inc. and from 1995 to 1998 as Chief Financial Officer at Haemonetics Corporation. Prior to that, Ms. Makes held various management positions at Lotus Development Corporation and General Electric Company. Ms. Makes holds an MBA from Bentley College in Waltham, Massachusetts, and a Bachelor Degree in finance and international business from McGill University in Montreal, Quebec.

Ronald E. Lund—General Counsel

Ronald E. Lund has served as our General Counsel since July 2007. Mr. Lund has over 17 years experience in the healthcare industry. Prior to joining our company, Mr. Lund served from 1988 to 2000, and from 2004 to 2005, as Senior Vice President, General Counsel and Secretary for Medtronic, Inc. From 2000 to 2001, Mr. Lund was the General Counsel for the American Red Cross in Washington, D.C. From 2002 to 2003, Mr. Lund was a partner of Briggs & Morgan, a Minneapolis law firm and from 2004 until joining AGA, Mr. Lund was "of counsel" at the Minneapolis law firm of Fredrikson & Byron.

ITEM 1A. RISK FACTORS.

Risks Related to Our Business

If we do not successfully implement our business strategy, our business and results of operations will be adversely affected.

We may not be able to successfully implement our business strategy. Any such failure may adversely affect our business and results of operations. For example, to implement our business strategy we need to, among other things, develop and introduce new products, find new applications for our existing products, obtain regulatory approval for such new products and applications and educate physicians about the clinical and cost benefits of our products and thereby increase the number of hospitals and physicians that use our products. In addition, we are seeking to increase our international sales and will need to increase our worldwide direct sales force and enter into distribution agreements with third parties in order to do so, all of which may also result in additional or different foreign regulatory requirements, with which we may not be able to comply. Moreover, even if we successfully implement our business strategy, our operating results may not improve. We may decide to alter or discontinue aspects of our business strategy and may adopt different strategies due to business or competitive factors.

The market opportunities that we expect to develop for our products may not be as large as we expect or may not develop at all.

The growth of our business is dependent, in large part, upon the development of market opportunities for our new products, product enhancements and new applications for our existing products. The market opportunities that we expect to exist for our devices may not develop as expected, or at all. For example, clinical studies have shown linkages between the existence of PFOs and certain types of stroke and migraines. If the connection between PFO closure and the prevention or reduction of the occurrence of stroke and migraines is not as strong as we anticipate, the market opportunity for our *AMPLATZER* PFO Occluders will not develop as expected, if at all. Moreover, even if the market opportunities develop as expected, new technologies and products introduced by our competitors may significantly limit our ability to capitalize on any such market opportunity. Our failure to capitalize on our expected market opportunities would adversely effect our growth.

Our AMPLATZER Septal Occluders generate a large portion of our net sales. If sales of this family of products were to decline, our net sales and results of operations would be adversely affected.

Our lead family of products, the *AMPLATZER* Septal Occluders, represented 54.1% of our net sales for the year ended December 31, 2009, and we anticipate that this family of products will continue to account for a substantial portion of our net sales for the next few years. If sales of *AMPLATZER* Septal Occluders were to decline in any of our key markets because of decreased demand, adverse regulatory actions, patent infringement claims, failure to protect our intellectual property, manufacturing problems or delays, pricing pressures, competitive factors or any other reason,

our net sales would decrease, which would negatively affect our business, financial condition and results of operations.

If we are unable to successfully develop and market new products or product enhancements or find new applications for our existing products, we will not remain competitive.

Our future success and our ability to increase net sales and earnings depend, in part, on our ability to develop and market new products, product enhancements and new applications for our existing products. However, we may not be able to, among other things:

- successfully develop or market new products or enhance existing products;
- find new applications for our existing products;
- manufacture, market and distribute such products in a cost-effective manner; or
- obtain required regulatory clearances and approvals.

Our failure to do any of the foregoing could have a material adverse effect on our business, financial condition and results of operations. In addition, if any of our new or enhanced products contain undetected errors or design defects or if new applications that we develop for existing products do not work as planned, our ability to market these products could be substantially impeded, resulting in lost net sales, potential damage to our reputation and delays in obtaining market acceptance of these products. We cannot assure you that we will continue to successfully develop and market new or enhanced products or new applications for our existing products.

We make our regulatory status forecasts, including determining expected dates of filings with, or submissions to, relevant authorities, based on the information currently available to us. The actual timing for any of these regulatory steps may vary, and we may revise any such forecasts as new information becomes available.

Moreover, most new or enhanced products or new applications for our existing products require that their safety and efficacy be proven by clinical trials before they receive regulatory approval. Our clinical trials may not prove the safety and efficacy of our products, and in such circumstances our products would not receive regulatory approval. In addition, these clinical trials typically last several years, and during that time competing products, procedures or therapies may be introduced that are less expensive and/or more effective than our products and thus render our products obsolete. If we do not continue to expand our product portfolio on a timely basis or if those products and applications do not receive regulatory and market acceptance or become obsolete, we will not grow our business as we currently expect.

If we fail to educate and train physicians as to the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products, our sales will not grow.

Acceptance of our products depends, in large part, on our ability to (1) educate the medical community as to the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products compared to alternative products, procedures and therapies and (2) train physicians in the proper use and implementation of our devices. Certain of the structural heart defects and vascular diseases that can be treated by our devices can also be treated by surgery, drugs or other medical devices, some of which have a longer history of use and are more widely used by the medical community. Physicians may be reluctant to change their medical treatment practices for a number of reasons, including:

- lack of experience with new products;
- lack of evidence supporting additional patient benefits;

- perceived liability risks generally associated with the use of new products and procedures;
- lack of availability of adequate reimbursement within healthcare payment systems; and
- costs associated with the purchase of new products and equipment.

Convincing physicians to dedicate the time and energy necessary to properly train to use new devices is challenging, and we may not be successful in these efforts. If physicians are not properly trained, they may misuse or ineffectively use our products. Such misuse or ineffective use may result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us. Accordingly, even if our devices are superior to alternative treatments, our success will depend on our ability to gain and maintain market acceptance for our devices. If we fail to do so, our sales will not grow and our business, financial condition and results of operations will be adversely affected.

The expansion of our product portfolio is dependent upon the success of our clinical trials and receipt of regulatory approvals. If these trials are not completed on schedule or are unsuccessful, or if we fail to obtain or experience significant delays in obtaining the necessary regulatory approvals for our product pipeline, we will not be able to market the related products.

A number of our products are in the early stages of development. In the United States, before we can market a new medical device, or a new application of, claim for, or significant modification to, an existing device, we must first receive either approval of a PMA application from the FDA or clearance under section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act, or 510(k) clearance, unless an exemption applies. Clinical trials are always required to support a PMA application approval and may be required to support a 510(k) clearance. Currently, we have four studies underway designed to evaluate the safety and efficacy of our *AMPLATZER* PFO Occluder to treat migraine or recurrent stroke, as applicable, in patients with PFOs, as well as a number of post-approval studies.

Our current or future clinical trials contemplated in support of our PMA or 510(k) applications may not commence or conclude in a timely fashion, or at all, or may not produce the desired results. For example, several of our products under development do not yet have agreed-upon protocols or approved Investigational Device Exemptions, or IDEs. Agreeing on clinical trial designs and protocols may be time consuming and requires interaction with and advance approval from regulatory authorities. We cannot assure you that we will be able to agree on appropriate trial designs and protocols with the FDA and thus commence clinical trials or, if commenced, that our PMA applications will be approved or our 510(k) clearances will be granted, in a timely fashion or at all. If our trials for any reason do not commence, do not produce the intended results or are delayed or halted due to the occurrence of adverse events, or if we do not otherwise obtain FDA or other regulatory agency approval with respect to our products in a timely fashion, our future growth may be significantly hampered. Our failure to comply with the regulations relating to the PMA approval and 510(k) clearance processes could also lead to the issuance of warning letters, injunctions, consent decrees, manufacturing suspensions, loss of regulatory approvals, product recalls, and termination of distribution arrangements or product seizures. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities could be imposed.

Moreover, sales of our products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Because a significant portion of our product sales are made in international markets, any failure to comply with directives and regulatory requirements imposed in foreign jurisdictions could also have a material adverse effect on our business, financial condition and results of operations.

Further, we continually evaluate the potential financial benefits and costs of our clinical trials and the products being evaluated in them. If we determine that the costs associated with attaining regulatory approval of a product exceed the potential financial benefits of that product or if the projected development timeline is inconsistent with our investment strategy, we may choose to stop a clinical trial or the development of a particular product, enhancement or application, which could have a material adverse effect on the growth of our business and could result in a charge to our earnings.

We depend on clinical investigators and clinical sites to enroll patients in our clinical trials and on other third-party contract research organizations to manage our clinical trials and to perform related data collection and analysis, and as a result, we may face significant costs and delays that are outside of our control.

We rely on clinical investigators and clinical sites to enroll patients in our clinical trials and other third-party contract research organizations to manage our clinical trials and to perform related data collection and analysis. Our agreements with clinical investigators, clinical sites and other third parties for clinical testing place substantial responsibilities on these parties. If clinical investigators, clinical sites or other third parties do not carry out their contractual duties or fail to meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or the FDA's good clinical practice regulations, our clinical trials may be extended, delayed or terminated, we may face significant costs and we may be unable to obtain regulatory approval or clearance for, or successfully commercialize, new products, enhancements or applications, in a timely manner, or at all.

We also compete with other manufacturers of medical devices for investigators and clinical sites to conduct clinical trials. If we are unable to identify investigators and clinical sites on a timely and cost-effective basis, our ability to conduct trials of our products and, therefore, our ability to obtain required regulatory approval or clearance would be adversely affected.

We may be subject to compliance action, penalties or injunctions if we are determined to be promoting the use of our products for unapproved, or off-label, uses.

Our products are currently approved for the treatment of certain structural heart defects and vascular diseases. Pursuant to FDA regulations, we can only market our products in the United States for approved uses. Physicians may use our products for indications other than those cleared or approved by the FDA, even though we do not promote our products for such off-label uses. If the FDA, however, determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or could subject us to regulatory enforcement actions, including the issuance of warning letters, injunctions, consent decrees, seizures, civil fines or criminal penalties. Other federal, state or foreign enforcement authorities might also take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties from other statutory authorities.

We operate in a very competitive environment.

The medical device industry is characterized by strong competition. We have several competitors, including Boston Scientific Corporation, NMT Medical, Inc., W. L. Gore & Associates, Inc., St. Jude Medical Inc., Cook, Inc., Occlutech GmbH, Cardia, Inc. and Atritech, Inc. Certain of our competitors have substantially greater capital resources, larger customer bases, broader product lines, larger sales forces, greater marketing and management resources, larger research and development staffs and larger facilities than ours and have more established reputations with our target customers, as well as global distribution channels that may be more effective than ours.

Our competitors may develop and offer technologies and products that are safer or more effective, have better features, are easier to use, less expensive or more readily accepted by the marketplace than ours. Their products could make our technology and products obsolete or noncompetitive. Our competitors may also be able to achieve more efficient manufacturing and distribution operations than we may be able to and may offer lower prices than we could offer profitably. We may decide to alter or discontinue aspects of our business and may adopt different strategies due to business or competitive factors or factors currently unforeseen, such as the introduction by our competitors of new products or new medical technologies that would make our products obsolete or uncompetitive.

In addition, consolidation in the medical device industry could make the competitive environment more difficult. The industry has recently experienced some consolidation, and there is a risk that larger companies will enter our markets.

We depend on third-party distributors to market and sell our products internationally in a number of markets. Our business, financial condition and results of operations may be adversely affected by both our distributors' performance and our ability to maintain these relationships on terms that are favorable to us.

We depend, in part, on third-party distributors to sell our medical devices outside the United States. In 2009, our net sales through third-party distributors was 19.3% of our total net sales. Our international distributors operate independently of us, and we have limited control over their operations, which exposes us to significant risks. Distributors may not commit the necessary resources to market and sell our products and may also market and sell competitive products. In addition, our distributors may not comply with the laws and regulatory requirements in their local jurisdictions, which may limit their ability to market or sell our products. If current or future distributors do not perform adequately, or if we are unable to locate competent distributors in particular countries and secure their services on favorable terms, or at all, we may be unable to increase or maintain our level of net sales in these markets or enter new markets, and we may not realize our expected international growth.

The terms and effects of our Deferred Prosecution Agreement with the U.S. Department of Justice relating to potential violations of the U.S. Foreign Corrupt Practices Act may negatively affect our business, financial condition and results of operations.

On June 2, 2008, we entered into a Deferred Prosecution Agreement, or the DPA, with the Department of Justice concerning alleged improper payments that were made by our former independent distributor in China to (1) physicians in Chinese public hospitals in connection with the sale of our products and (2) an official in the Chinese patent office in connection with the approval of our patent applications, in each case, in potential violation of the Foreign Corrupt Practices Act, or the FCPA. The FCPA makes it unlawful for, among other persons, a U.S. company, acting directly or through an agent, to offer or to make improper payments to any "foreign official" in order to obtain or retain business or to induce such "foreign official" to use his or her influence with a foreign government or instrumentality thereof for such purpose.

As part of the DPA, we consented to the Department of Justice filing a two-count criminal statement of information against us in the U.S. District Court, District of Minnesota, which was filed on June 3, 2008. The two counts include a conspiracy to violate the FCPA and a substantive violation of the anti-bribery provisions of the FCPA related to the above-described activities in China. Although we did not plead guilty to that information, we accepted responsibility for the acts of our employees and agents as set forth in the DPA, and we face prosecution under that information, and possibly other charges as well, if we fail to comply with the terms of the DPA. Those terms require us to, for approximately three years, (1) continue to cooperate fully with the Department of Justice on any investigation relating to violations of the FCPA and any and all other matters relating to improper payments, (2) continue to implement a compliance and ethics program designed to detect and prevent violations of the FCPA and other applicable anti-corruption laws, (3) review existing, and if necessary, adopt new controls, policies and procedures designed to ensure that we make and keep fair and accurate books, records and accounts and maintain a rigorous anti-corruption compliance code designed to detect and deter violations of the FCPA and other applicable anti-corruption laws, and (4) retain and pay for an independent monitor to assess and oversee our compliance and ethics program with respect to the FCPA and other applicable anti-corruption laws. The DPA also required us to pay a monetary penalty of $2.0 million. In the fourth quarter of 2007, we had recorded a financial charge of $2.0 million for this expected settlement, which was paid in June 2008. The terms of the DPA will remain binding on any successor or merger partner as long as the agreement is in effect.

The effects that compliance with any of the terms of the DPA will have on us are unknown and they may have a material impact on our business, financial condition and results of operations. The activities of the government-approved independent monitor, as well as the continued implementation of a compliance and ethics program and the adoption of internal controls, policies and procedures to detect and prevent future violations of the FCPA and other applicable anti-corruption laws, may result in increased costs to us and change the way in which we operate, the outcome of which we are unable to predict. For example, implementing and monitoring such compliance procedures in the large number of foreign jurisdictions where we operate can be expensive and time-consuming. As a result of our remediation measures, we may also encounter difficulties conducting business in certain foreign countries and retaining and attracting additional business with certain customers, and we cannot predict the extent of these difficulties.

In addition, entering into the DPA in the United States may adversely affect our operations or result in legal claims against us, which may include claims of special, indirect, derivative or consequential damages.

Our failure to comply with the terms of the deferred prosecution agreement with the Department of Justice would have a negative impact on our ongoing operations.

As described above, we are subject to a three-year DPA with the Department of Justice. If we comply with the DPA, the Department of Justice has agreed not to prosecute us with respect to the above-described activities in China and, following the term of the DPA, to permanently dismiss the criminal statement of information that is currently pending against us. Accordingly, the DPA could be substantially nullified, and we could be subject to severe sanctions and resumed civil and criminal prosecution, as well as severe fines, penalties and other regulatory sanctions, in the event of any additional violation of the FCPA or any other applicable anti-corruption laws by us or any of our officers, other employees or agents in any jurisdiction or of our failure to otherwise meet any of the terms of the DPA as determined by the Department of Justice in its sole discretion. The claims alleged in the DPA with the Department of Justice only relate to our actions in China as outlined above, and do not relate to any future violations or the discovery of past violations not expressly covered by the DPA. Any breach of the terms of the DPA would also cause damage to our business and reputation, as well as impair investor confidence in our company and result in adverse consequences on our ability to obtain or continue financing for current or future projects.

In addition, although we are not currently restricted by the U.S. Department of Health and Human Services, Office of the Inspector General, from participating in federal healthcare programs, any criminal conviction of our company under the FCPA in the future would result in our mandatory exclusion from such programs, and it may lead to debarment from U.S. and foreign government contracts. Any such exclusion or debarment would have a material adverse effect on our business, financial condition and results of operations.

Our ability to comply with the terms of the DPA is dependent, among other things, on the success of our ongoing compliance and ethics program, including our ability to continue to manage our distributors and agents and supervise, train and retain competent employees, as well as the efforts of our employees to adhere to our compliance and ethics program and the FCPA and other applicable anti-corruption laws. It is possible that, despite our best efforts, additional FCPA issues, or issues under anti-corruption laws of other jurisdictions, could arise in the future. Any failure by us to adopt appropriate compliance and ethics procedures, to ensure that our officers, other employees and agents comply with the FCPA and other applicable anti-corruption laws and regulations in all jurisdictions in which we operate or to otherwise comply with any term of the DPA would have a material adverse effect on our business, financial condition and results of operations.

Fluctuations in foreign exchange rates may adversely affect our consolidated results of operations.

Our foreign operations expose us to currency fluctuations and exchange rate risks. Approximately 44.8% of our net sales for 2009 were in foreign currencies. Accordingly, our consolidated results of operations have been, and will continue to be, subject to fluctuations in foreign exchange rates. Although we have benefited from foreign currency exchange rate fluctuations in the past, we may not benefit from the effect of foreign currency exchange rate fluctuations in the future, which may adversely affect our consolidated results of operations. During a period in which the U.S. dollar appreciates against a given foreign currency, our consolidated net sales will be lower than they might otherwise have been because net sales earned in such foreign currency will translate into fewer U.S. dollars. At present, based on a foreign exchange rate exposure management policy initiated in the first quarter of 2009, we have started to engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. As we grow our international direct sales, we expect our foreign currency-denominated net sales will increase, which would increase our risks related to fluctuations in foreign exchange rates. We cannot assure you that our monitoring of our net foreign currency exchange rate exposure, our foreign currency exchange rate exposure management policy or any foreign currency hedging activity that we implement will be effective or otherwise adequately protect us against fluctuations in foreign currency exchange rates.

Our ability to operate our company effectively could be impaired if we lose members of our senior management team or scientific personnel.

We depend on the continued service of key managerial, scientific and technical personnel, as well as our ability to continue to attract and retain highly qualified personnel. We compete for such personnel with other companies, academic institutions, government entities and other organizations. Any loss or interruption of the services of our key personnel could significantly reduce our ability to effectively manage our operations and meet our strategic objectives, because we may be unable to find an appropriate replacement, if necessary. For example, Dr. Amplatz plays a key role in the early stages of our research and development programs, which are crucial to expanding our product portfolio. We have a five-year research and development contract with Dr. Amplatz that expires in December 2010, and we may not be able to renew it. The loss of Dr. Amplatz's services may negatively affect our ability to expand our product portfolio beyond our current pipeline. In addition, after termination of our contract with Dr. Amplatz, he is not allowed to compete with our company for 18 months in the United States. Any competition from Dr. Amplatz after that period or outside the United States may negatively affect our business.

Healthcare legislative or administrative changes resulting in restrictive third-party payor reimbursement practices or preferences for alternate treatment may decrease the demand for, or put downward pressure on the price of, our products.

Our products are purchased principally by hospitals, which typically receive reimbursement from various third-party payors, such as governmental programs (e.g., Medicare and Medicaid), private insurance plans and managed care plans, for the healthcare services provided to their patients. The ability of our customers to obtain appropriate reimbursement for their products and services from government and third-party payors is critical to our success. The availability of reimbursement affects which products customers purchase and the prices they are willing to pay. Reimbursement varies from country to country and can significantly impact the acceptance of new products. After we develop a promising new product, we may experience limited demand for the product unless reimbursement approval is obtained from private and governmental third-party payors.

Major third-party payors for hospital services in the United States and abroad continue to work to contain healthcare costs. The introduction of cost-containment incentives, combined with closer scrutiny of healthcare expenditures by both private health insurers and employers, has resulted in increased

discounts and contractual adjustments to hospital charges for services performed. Initiatives to limit the growth of healthcare costs, including price regulation, are also underway in several countries in which we do business. Implementation of new legislative and administrative changes in the United States and in overseas markets, such as Germany and Japan, may limit the price of, or the level at which reimbursement is provided for, our products and, as a result, may adversely affect both our pricing flexibility and demand for our products. Hospitals or physicians may respond to such cost-containment pressures by substituting lower-cost products or other treatments for our products.

Further legislative or administrative changes to the U.S. or international reimbursement systems that significantly reduce reimbursement for procedures using our medical devices or deny coverage for such procedures, or adverse decisions relating to our products by administrators of such systems in coverage or reimbursement issues, would have an adverse impact on the number of products purchased by our customers and the prices our customers are willing to pay for them. This, in turn, would adversely affect our business, financial condition and results of operations.

Our business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if we are excluded from being a supplier by a group purchasing organization or similar entity.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms have been launched by legislators, regulators and third-party payors to curb these costs. As a result, there has been a consolidation trend in the healthcare industry to create larger companies, including hospitals, with greater market power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important markets as group purchasing organizations, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions. If a group purchasing organization excludes us from being one of their suppliers, our net sales will be adversely impacted. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, which may exert further downward pressure on the prices of our products.

We conduct substantially all of our operations at our corporate headquarters, and any fire, explosion, violent weather conditions or other unanticipated events affecting our corporate headquarters could adversely affect our business, financial condition and results of operations.

We conduct all of our manufacturing and research and development activities, as well as most of our sales, warehousing and administrative activities, at our corporate headquarters in Plymouth, Minnesota. Our corporate headquarters is subject to the risk of catastrophic loss due to unanticipated events, such as fires, explosions or violent weather conditions. This facility and the manufacturing equipment that we use to produce our products would be difficult to replace or repair and could require substantial lead-time to do so. For example, if we were unable to utilize our existing manufacturing facility, the use of any new facility would need to be approved by the FDA, which would result in significant production delays. We may also in the future experience plant shutdowns or periods of reduced production as a result of regulatory issues, equipment failure or delays in deliveries. Any disruption or other unanticipated events affecting our corporate headquarters and therefore our sales, manufacturing, warehousing, research and development and administrative activities would adversely affect our business, financial condition and results of operations. We currently carry $60.0 million of insurance coverage for damage to our property and the disruption of our business. Such insurance coverage, however, may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

We rely on a single supplier for nitinol, the key raw material in all of our products, which makes us susceptible to supply shortages of this material.

We rely on a single supplier for nitinol, the key raw material in all of our products, and have no written agreement with this supplier. If we are unable to obtain nitinol from this supplier, we may be unable to obtain nitinol through other sources, on acceptable terms, within a reasonable amount of time or at all. Further, even if we are able to find an alternative source for nitinol, we may not be able to prevent an interruption of production of our products. Our business would be adversely affected if such interruption was prolonged. For example, if a raw material or component is a critical element, an element that can have a significant effect on performance and safety of the related device, such as nitinol with respect to our devices, FDA and foreign regulations may require additional testing and prior approval of such raw material or component from new suppliers prior to our use of these materials or components. As a result, if we need to establish additional or replacement suppliers for nitinol or any other critical component, our access to these components may be delayed while we qualify such suppliers and obtain any necessary FDA and foreign regulatory approvals. Any disruption in the ongoing shipment of nitinol could interrupt production of our products, which could result in a decrease of our net sales, or could cause an increase in our cost of sales if we have to pay another supplier a higher price for nitinol.

Any failure of our management information systems could harm our business and results of operations.

Our business's rapid growth may continue to place a significant strain on our managerial, operational and financial resources and systems. We depend on our recently implemented management information systems to actively manage our controlled regulatory and manufacturing documents. We also depend on our enterprise resource planning system to actively manage our invoicing, production and inventory planning, clinical trial information and quality compliance. We must continually assess the necessity for any upgrades to our information systems. The inability of our management information systems to operate as we anticipate could damage our reputation with our customers, disrupt our business or result in, among other things, decreased net sales and increased overhead costs. As a result, any such failure could harm our business, financial condition and results of operations.

Being a public company has substantially increased our legal and financial compliance costs, which could harm our business, financial condition and results of operations.

Until the fourth quarter of 2009, we operated our business as a private company. As a publicly-traded company, we are subject to rules and regulations that increase our legal and financial compliance costs, make some activities more time-consuming and costly, and divert our management's attention away from the operation of our business. We are obligated to file with the U.S. Securities and Exchange Commission annual and quarterly information and other reports that are specified in the Securities Exchange Act of 1934, or the Exchange Act, and are also subject to other reporting and corporate governance requirements, including requirements of the Nasdaq Global Market and the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated thereunder, all of which impose significant compliance and reporting obligations upon us. We may not be successful in complying with these obligations, and compliance with these obligations could be time consuming and expensive. Failure to comply with the additional reporting and corporate governance requirements could lead to fines imposed on us, suspension or delisting from the Nasdaq Global Market, deregistration under the Exchange Act and, in the most egregious cases, criminal sanctions could be imposed.

We may need to raise additional capital in the future, which may not be available to us on acceptable terms, or at all.

We may require significant additional debt and equity financing in order to implement our business strategy. In particular, our capital requirements depend on many factors, including the amount of

expenditures on research and development and intellectual property, the number of clinical trials that we conduct, new product development and the cash required to service our debt. To the extent that our existing or future capital is insufficient to meet these requirements and cover any losses, we will need to refinance all or a portion of our existing debt, raise additional funds through financings or curtail our growth, reduce our costs or sell certain of our assets. For example, we raised additional capital from affiliates of Welsh, Carson, Anderson & Stowe IX, L.P., or Welsh Carson, to finance the acquisition of the assets of our Italian distributor. We cannot assure you that such investors will agree to provide us with additional financing in the future. Our ability to raise additional capital will likely depend on, among others, our performance, our prospects, our level of indebtedness and market conditions. Any additional equity or debt financing, if available at all, may be on terms that are not favorable to us. The recent global economic crisis and related tightening of credit markets has made it more difficult and more expensive to raise additional capital. If we are unable to access additional capital on terms acceptable to us, we may not be able to fully implement our business strategy, which may limit the future growth and development of our business. In addition, equity financings could result in dilution to our stockholders, and equity or debt securities issued in future financings may have rights, preferences and privileges that are senior to those of our common stock. If our need for capital arises because of significant losses, the occurrence of these losses may make it more difficult for us to raise the necessary capital.

Product liability claims and uninsured or underinsured liabilities could have a material adverse effect on our business.

The manufacturing and marketing of medical devices involve an inherent risk of product liability claims. Our product development and production processes are extremely complex and could expose our products to defects. Any defects could harm our credibility, lead to product liability claims and litigation and decrease our products' market acceptance. Our current product liability policies provide $35.0 million of insurance coverage, with a $250,000 deductible per occurrence for new claims. We cannot assure you that such insurance will be available or adequate to satisfy future claims or that our insurers will be able to pay claims on insurance policies which they have issued to us. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, adversely affecting our financial condition and results of operations. In the event that we are held liable for a claim or for damages exceeding the limits of our insurance coverage, that claim could materially damage our reputation and business. We currently have no outstanding products liability claims. However, defending a lawsuit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, and for these reasons, any product liability claims could result in significant costs and harm to our business, financial condition and results of operations.

We may not successfully make or integrate acquisitions or enter into strategic alliances.

We may pursue selected acquisitions and strategic alliances. We compete with other medical device companies for these opportunities, and we cannot assure you that we will be able to effect acquisitions or strategic alliances on commercially reasonable terms, or at all. Even if we enter into these transactions, we may experience the following, among other things:

- difficulties in integrating any acquired companies and products into our existing business;
- inability to realize the benefits we anticipate in a timely fashion, or at all;
- attrition of key personnel from acquired businesses;
- significant costs, charges or writedowns; or

- unforeseen operating difficulties that require significant financial and managerial resources that would otherwise be available for the ongoing development and expansion of our existing operations.

Consummating these transactions could also result in the incurrence of additional debt and related interest expense, as well as unforeseen contingent liabilities, all of which could have a material adverse effect on our business, financial condition and results of operations. We may also issue additional equity in connection with these transactions which would dilute our existing stockholders.

Risks Related to Regulation

If we fail to comply with the U.S. Federal Anti-Kickback Statute and similar state and foreign laws, we could be subject to criminal and civil penalties and exclusion from Medicare, Medicaid and other governmental programs.

A provision of the U.S. Social Security Act, commonly referred to as the U.S. Federal Anti-Kickback Statute, prohibits the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for or recommending the ordering, purchasing or leasing of items or services payable by Medicare, Medicaid or any other federal healthcare program. The Federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, most of the states in which our products are sold in the United States have adopted laws similar to the Federal Anti-Kickback Statute, and some of these laws are even broader than the Federal Anti-Kickback Statute in that their prohibitions are not limited to items or services paid for by a federal healthcare program but, instead, apply regardless of the source of payment. Violations of the Federal Anti-Kickback Statute or such similar state laws may result in substantial civil or criminal penalties and exclusion from participation in federal or state healthcare programs. We derive a significant portion of our net sales from international operations, and many foreign governments have equivalent statutes with similar penalties.

All of our financial relationships with healthcare providers and others who provide products or services to federal healthcare program beneficiaries are potentially governed by the Federal Anti-Kickback Statute and similar state or foreign laws. We believe our operations are in material compliance with the Federal Anti-Kickback Statute and similar state or foreign laws. However, we cannot assure you that we will not be subject to investigations or litigation alleging violations of these laws, which could be time-consuming and costly to us, could divert management's attention from operating our business and could prevent healthcare providers from purchasing our products, all of which could have a material adverse effect on our business. In addition, if our arrangements were found to violate the Federal Anti-Kickback Statute or similar state or foreign laws, it could have a material adverse effect on our business and results of operations.

The possibility of non-compliance with manufacturing regulations raises uncertainties with respect to our ability to manufacture our products. Our failure to meet strict regulatory requirements could require us to pay fines, incur other costs or even close our facilities.

The FDA and other federal, state and foreign regulatory authorities require that our products be manufactured according to rigorous standards, including, but not limited to, Quality System Regulations, Good Manufacturing Practices and International Standards Organization, or ISO, standards. These federal, state and foreign regulatory authorities may conduct periodic audits of our facilities or our processes to monitor our compliance with applicable regulatory standards. If a regulatory authority finds that we fail to comply with the appropriate regulatory standards, it may require product validation, new processes and procedures or shutdown of our manufacturing operations. It may impose fines on us or delay or withdraw clearances or other regulatory approvals. If

a regulatory authority determines that our non-compliance is severe, it may impose other penalties including limiting our ability to secure approvals for new devices and accessories. In addition, many of the improvements we make to our manufacturing process must first be approved by the FDA and other federal, state and foreign regulatory authorities. Our failure to obtain the necessary approvals may limit our ability to improve the way in which we manufacture our products.

Our business will be harmed if we fail to obtain necessary clearances or approvals to market our medical devices.

Our products are classified as medical devices and are subject to extensive regulation in the United States by the FDA and other federal, state and local authorities. Similar regulatory review and approval processes also exist in foreign countries in which our products are marketed. These regulations relate to product design, development, testing, manufacturing, labeling, sale, promotion, distribution, import, export and shipping.

Before we can market a new medical device, or a new use of, or claim for, or significant modification to, an existing product in the United States, we must first receive either PMA approval or 510(k) clearance from the FDA unless an exemption applies. The PMA approval process, commonly used for riskier devices such as those which support or sustain life or are used invasively in the body, requires an applicant to demonstrate the safety and efficacy of the device based, in part, on data obtained in clinical trials. The PMA approval process and clinical trials can be expensive and lengthy and entail significant user fees. In the 510(k) clearance process, the FDA must determine that the proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and efficacy, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA approval pathway is much more costly and uncertain than the 510(k) clearance process. It generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. The 510(k) clearance process usually takes from three to 12 months, but it can take longer.

In many of the foreign regions in which we market our products, such as Europe, we are subject to regulations substantially similar to those of the FDA, although these foreign regulatory requirements may vary widely from country to country. In Europe, only medical devices which bear a CE Mark may be marketed. Japan has a regulatory process that generally accepts clinical data from either the United States or Europe supplemented by a small study in Japan to establish experience and confirm safety. In addition, as we selectively convert into direct sales forces in foreign regions, we will be subject to additional regulations in these markets.

Any failure to receive desired marketing clearances or approvals from the FDA or other federal, state or foreign regulatory authorities may adversely affect our ability to market our products and may have a significant adverse effect on our overall business. Moreover, the value of existing clearances or approvals can be eroded if safety or efficacy problems develop.

We may fail to comply with continuing post-market regulatory requirements of the FDA and other federal, state or foreign authorities and become subject to substantial penalties, or our products may subsequently prove to be unsafe, forcing us to recall or withdraw such products from the market.

Even after product clearance or approval, we and our contract manufacturers must comply with continuing regulation by the FDA and other federal, state or foreign authorities, including the FDA's Quality System Regulation requirements, which obligate manufacturers, including third-party contract manufacturers, to adhere to stringent design, testing, control, documentation and other quality assurance procedures during the design and manufacture of a device. We are also subject to medical device reporting regulations in the United States and abroad. For example, we are required to report to

the FDA if our products may have caused or contributed to a death or serious injury or malfunction in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. We must report corrections and removals to the FDA where the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the U.S. Food, Drug, and Cosmetic Act caused by the device that may present a risk to health, and we must maintain records of other corrections or removals. The FDA closely regulates promotion and advertising, and our promotional and advertising activities may come under scrutiny. If any medical device reports we file with the FDA regarding death, serious injuries or malfunctions indicate or suggest that one of our products presents an unacceptable risk to patients, including when used off-label by physicians, we may be forced to recall our product or withdraw it from the market.

We have had several product recalls in the past. For example, in October 2006, we recalled catheter and delivery systems after internal testing revealed the potential for a tear to develop in the packaging under extreme shipping conditions. We immediately modified our shipping method and subsequently received approval from the FDA and our Notified Body in Europe to modify the packaging to prevent tears from developing. Approximately 15,871 devices were returned and replaced by us. On February 28, 2007, we submitted a letter to the FDA formally requesting the recall to be closed, and on October 9, 2008 the FDA confirmed that the recall has been completed. During the third quarter of 2005, we voluntarily recalled 80 of our *AMPLATZER* Vascular Plug devices over concerns that our operators failed to follow internal sterilization procedures. Of the 80 devices, only two had left our possession. After testing the recalled products, none of them were found to be non-sterile. We submitted a letter to the FDA formally requesting closure of the recall, and the recall has been closed. In September 2005, we recalled our *AMPLATZER* Duct Occluder device after discovering through in-process testing during manufacturing that the device had the potential to rub against the catheter during the implant procedure. Approximately 2,800 devices were recalled, 92% of which had left our possession. We made the required changes to our *AMPLATZER* Duct Occluder, and these changes have been approved both internationally and by the FDA. We submitted letters to the FDA formally requesting closure of the recall, and the recall has been closed. Finally, on December 8, 2004, we initiated a voluntary recall of all catheters and delivery systems in the field because of non-toxic contaminated tubing produced by one of our suppliers. We received several toxicology tests that confirmed the level of contamination was negligible and posed no threat to patients. We submitted letters to the FDA formally requesting closure of the recall, and the recall has been closed.

We are currently conducting two post-approval studies that were required as a condition of approval by the FDA of the *AMPLATZER* Septal Occluder and the *AMPLATZER* Muscular VSD Occluder. The studies are designed to monitor, for a period of up to five years after the procedure, patients treated with a device in the clinical studies that supported approval of the product. The objective is to collect and report to the FDA additional data on the long-term safety and efficacy of the device. The majority of patients enrolled in these two studies were children at the time of receiving their implants. In some cases, it has been challenging to follow these patients for up to five years as they and their families move or otherwise stop seeing the physician who performed the treatment.

Any failure to comply with continuing regulation by the FDA or other federal, state or foreign authorities could result in enforcement action that may include regulatory letters requesting compliance action, suspension or withdrawal of regulatory clearances or approvals, product recall, modification or termination of product marketing, entering into a consent decree, seizure and detention of products, paying significant fines and penalties, criminal prosecution and similar actions that could limit product sales, delay product shipment and harm our profitability. Any of these actions could materially harm our business, financial condition and results of operations.

Modifications to our products may require new regulatory approvals or clearances or may require us to recall or cease marketing our modified products until approvals or clearances are obtained.

Modifications to our products may require new approvals or clearances in the United States and abroad, such as PMA approvals or 510(k) clearances in the United States and CE Marks in Europe. The FDA requires device manufacturers to initially make a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification does not significantly affect safety or efficacy or does not represent a major change in its intended use, so that no new U.S. or foreign approval or clearance is necessary. We have made modifications that we determined do not require approval or clearance. However, the FDA and foreign authorities can review a manufacturer's decision, including any of our decisions, and may disagree. If the FDA or other foreign authority disagrees and requires new approvals or clearances for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may also be subject to significant enforcement actions.

If we determine that a modification to an FDA-approved or cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then we must obtain a new PMA or PMA supplement approval or 510(k) clearance. Where we determine that modifications to our products require a new PMA or PMA supplemental approval or 510(k) clearance, we may not be able to obtain those additional approvals or clearances for the modifications or additional indications in a timely manner, or at all. For those products sold in Europe, we must notify AMTAC, our European Union Notified Body, if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Delays in obtaining required future approvals or clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Risks Related to Our Intellectual Property and Potential Litigation

We have been and may in the future become subject to claims that our products violate the patent or intellectual property rights of others, which could be costly and disruptive to us.

We operate in an industry that is susceptible to significant patent litigation, and in recent years, it has been common for companies in the medical device industry to aggressively challenge the rights of other companies to prevent the marketing of new or existing devices. As a result, we or our products may become subject to patent infringement claims or litigation or interference proceedings declared by the U.S. Patent and Trademark Office, or USPTO, or the foreign equivalents thereto to determine the priority of claims to inventions. The defense of intellectual property suits, USPTO interference proceedings or the foreign equivalents thereto, as well as related legal and administrative proceedings, are both costly and time consuming and may divert management's attention from other business concerns. An adverse determination in litigation or interference proceedings to which we may become a party could, among other things:

- subject us to significant liabilities to third parties, including treble damages;
- require disputed rights to be licensed from a third party for royalties that may be substantial;
- require us to cease using such technology; or
- prohibit us from selling certain of our products.

Any of these outcomes could have a material adverse effect on our business, financial condition and results of operations.

On March 28, 2006, we settled a patent infringement suit with NMT Medical, Inc. in which we paid NMT Medical and a second patent holder a $30.0 million one-time payment. As part of the settlement, we received a fully paid, royalty-free license for the related patents.

In addition, we may have disputes with our licensors regarding the scope of their patents. We make royalty payments with respect to certain patents that were assigned to us by Mr. Curtis Amplatz. In 2008, Mr. Curtis Amplatz inquired regarding the scope of the royalty agreements we had with him and whether they applied to additional products of ours. In response, we had discussions in which we clarified the scope of the agreements and our payments under the agreements. We believe the inquiry of Mr. Curtis Amplatz to be concluded. However, any dispute relating to the products included in a portfolio subject to a royalty agreement or license could result in us being subject to additional royalty payments, although we do not believe any such dispute to limit our right to sell or market any of our devices.

We are currently subject to claims by Medtronic that substantially all of our occluder and vascular plug products infringe certain of Medtronic's patents. If we are not successful in our defense of these claims or in our counterclaims, we may be subject to damages, ongoing royalties and other remedies which could have a material adverse effect on our business, financial condition and results of operations.

In January 2007, Medtronic, Inc. filed a patent infringement action against us in the U.S. District Court for the Northern District of California, alleging that substantially all of our *AMPLATZER* occluder and vascular plug devices, which have historically accounted for substantially all of our net sales, infringe three of Medtronic's method and apparatus patents on shape memory alloy stents (U.S. Patent Nos. 5,190,546, 6,306,141 and 5,067,957). Medtronic is seeking compensatory damages with respect to our products manufactured or sold in the United States. Medtronic asserted but later withdrew its requests for injunctive relief and for damages based on willfulness.

We have asserted defenses and counterclaims for non-infringement and challenged the validity and enforceability of Medtronic's patents. On April 28, 2009, the court granted summary judgment in our favor finding that we do not infringe Medtronic's '546 patent. Subsequently, Medtronic withdrew certain allegations with respect to the remaining two patents. The trial on the remaining issues in the case was divided into a jury trial phase and non-jury, bench trial phase. On August 5, 2009, the jury returned a verdict that the subject *AMPLATZER* occluder and vascular plug products infringed the claims at issue with respect to both of the two remaining Medtronic patents and that the Medtronic patent claims at issue had not been proven by us to be invalid. The jury verdict awarded Medtronic damages of $57.8 million representing 11% of historical sales of the occluder and vascular plug products in question during the timeframe specified for each patent. The verdict is not enforceable until the completion of the trial and entry of a final, non-appealable judgment.

Following the jury verdict, the court held the non-jury phase of the trial in early December 2009 to hear, our claim that the '141 patent is invalid based on the doctrine of double patenting, which prohibits obtaining two patents covering the same basic invention in a continuation application . Upon conclusion of the non-jury phase of the trial, the court will consider post-trial motions and enter a judgment, which we expect will take place in mid to late 2010. Additional detail regarding this litigation can be found elsewhere in this Form 10-K in Item 3 legal Proceedings under the subheading "Medtronic Litigation in the United States."

If we do not receive a favorable judgment, we expect we will appeal such judgment and expect that we will likely be required to post a bond in order to be allowed to appeal as set forth below. If any damage amount is entered as a part of the judgment, we will likely be required at that time to accrue a non-cash charge equal to the amount of such damages. Any such accrual will have an adverse effect on our results of operations for the applicable period. If we decide to appeal, such appeal may not be decided for several months and may require the posting of a bond in the face amount of up to 150% of

the judgment amount, if any. We do not expect the cash cost associated with posting such a bond to be material, but we would likely be required to secure such bond with collateral. The amount of collateral required by the provider of the bond would be determined based on several factors, such as the amount of our debt and our financial condition.

If we are required to accrue a charge relating to, or post an appeal bond in connection with, the Medtronic litigation, we may not be able to comply with the covenants contained in our senior secured credit facility in future periods. While we do not believe that accruing a charge and/or posting an appeal bond in connection with the Medtronic litigation will cause us to breach any such covenant, doing so may adversely affect our ability to comply with our maintenance covenants in our senior secured credit facility. If we breached any such covenant, we would need to seek to amend or refinance our senior secured credit facility. We believe that such an amendment could require us to pay upfront fees and an increased interest rate on our borrowings thereunder, which could materially adversely affect our financial condition and results of operations. Alternatively, we could refinance our senior secured credit facility, but we may not be able to do so on reasonable terms or at all. If we fail to obtain such an amendment or refinancing, we would suffer an event of default under such facility and the lenders thereto would have the right to accelerate the indebtedness outstanding thereunder. In addition, the lenders' obligations to extend letters of credit or make loans under our senior secured credit facility are dependent upon our ability to make our representations and warranties thereunder at the time such letters of credit are extended or such loan is made. If we are unable to make the representations and warranties in our senior secured credit facility at such time, we will be unable to borrow additional amounts under our senior secured credit facility in the future.

These proceedings are costly and time consuming, and we cannot assure you that the outcome of any of these proceedings will be favorable to us. However, because Medtronic withdrew its request for injunctive relief from the trial court, we believe that it is likely that the final judgment will not prevent the continued marketing or sale of any of our products. If we do not prevail before the trial or appellate courts in overturning the jury verdict or reducing or eliminating the damages award in the jury verdict, we will have to pay the awarded damages and may have to pay royalties on a substantial portion of our future sales, and our results of operations and financial condition may be materially adversely affected. Medtronic also could appeal from rulings adverse to it, which could result in an appellate decision with effects adverse to us on issues of liability and/or relief. In addition, Medtronic may attempt to request injunctive relief in the future, which, if granted, would have a material adverse effect on our business, financial condition and results of operations.

Notwithstanding the litigation proceedings, we have implemented changes to our business processes intended to create an alternative process that we believe does not infringe Medtronic's patents. These changes do not affect the product design, but modify the final step prior to inspection in our manufacturing processes and the instructions for use of our products by physicians. We believe this to be standard practice. These changes require that our products be cooled prior to use and therefore rely on a property of our nitinol material that makes use of temperature rather than stress for expansion. The use of temperature for expansion of nitinol was disclaimed during the prosecution of the Medtronic patents. We do not expect any of these changes to impact the future sales of our products. In addition, we are considering establishing manufacturing operations in Europe for all of our devices that are sold in international markets. In addition to providing other benefits for our business, such as mitigating the risk inherent in relying on only one manufacturing facility the manufacture of our products outside of the United States would eliminate any claims for ongoing royalty payments on future sales with respect to such products sold outside of the United States. We cannot assure you that any of these changes will avoid future litigation or will not result in a subsequent finding of infringement of Medtronic's patents and/or patents held by others. If any of our modified business processes were found to infringe any such patents, we may be required to pay additional damages and royalties. We cannot assure you that such damages and royalties would not exceed the 11% rate

applied by the Medtronic case jury for past sales. Any such royalties may not be on commercially reasonable terms and could have a material adverse effect on our results of operations and financial condition. Also, if a court grants an injunction, we may be prevented from selling some or any infringing products. While we believe we have taken reasonable steps to inform third parties who use such products of the alternative process by changing the instructions for use that are referenced in the information that accompanies each such product, such third parties may not review such information and may not adopt the alternative process even if they do review the new instructions for use. To the extent such third parties continue to use the prior process, we may be liable for such use whether or not the alternative process infringes Medtronic's patents.

We have filed and may in the future file patent litigation claims in the U.S. and foreign jurisdictions to protect our patent portfolio. If we are unsuccessful in these claims, our business, financial condition and results of operations could be adversely affected.

We may initiate litigation to assert claims of infringement, enforce our patents, protect our trade secrets or know-how, or determine the enforceability, scope and validity of the proprietary rights of others. Any lawsuits that we initiate could be expensive, time consuming and divert management's attention from other business concerns. Furthermore, litigation may provoke third parties to assert claims against us and may put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being issued.

In August 2006, we brought a patent infringement action in Germany against Occlutech GmbH, an European manufacturer of cardiac occlusion devices, and DRABO Medizintechnik, based on the German part of one of our European patents, which was granted to us in October 2005 for intravascular occlusion devices and the method of manufacturing such devices. On July 31, 2007, the District Court in Düsseldorf entered a judgment in our favor finding that Occlutech and DRABO literally infringed the German part of our European patent. Under German practice, the court required us to post a bond in the amount of €1.0 million to secure our ability to respond to damages claimed by Occlutech in the event that the decision of the District Court is reversed on appeal or our patent is held invalid in related proceedings in the German patent court. The bond amount is not a limitation on such damages. On August 6, 2007, Occlutech filed an appeal against the District Court judgment before a German Court of Appeals contending that the District Court judgment was based on an overly broad interpretation of our European patent, and in addition, it initiated invalidation proceedings against the patent. On December 22, 2008, the German Court of Appeals dismissed Occlutech's appeal and entered a judgment in our favor finding that Occlutech infringed our patent. Occlutech has filed an appeal with the German Federal Court of Justice. A final decision on the appeal with the German Federal Court of Justice and a decision on the invalidation proceedings are not expected to be reached until 2010 or later. In addition, Occlutech initiated proceedings against our corresponding patents in Italy, the Netherlands, the United Kingdom, Spain and Sweden, seeking invalidity and non-infringement declarations. On October 29, 2008, the Patent Court in the Netherlands ruled in favor of Occlutech in the non-infringement declaration. The court did not rule on the invalidity claim. On November 3, 2008, we filed an appeal with the Dutch appellate court. On July 31, 2009, a United Kingdom patent court upheld the validity of our patent, but it ruled that the Occlutech products do not infringe on our patent. We intend to appeal the decision that Occlutech did not infringe on our patent. Final decisions in these actions are also not expected to be reached until 2010 or later. We cannot assure you that the outcome in any of these proceedings will be favorable to us, and if we do not prevail in one or more jurisdictions, we face the risk of increased competition and significant damages being awarded against us.

We have also been forced to defend our patent rights in China against various entities, including Shanghai Shape Memory Alloy Company Ltd., a medical device manufacturer based in Shanghai, China, and Beijing Starway Medical Devices Ltd., a medical device manufacturer based in Beijing, both

of which in recent years have been manufacturing and exporting medical devices that we believe infringe our patent rights. We did not prevail in our lawsuits in China against these entities and two of our patents in China were invalidated as a result. Consequently, we are no longer able to assert rights under these patents within China and will need to rely primarily on foreign patents to prevent the importation of products from China into countries in which such importation would violate our local patent rights. In addition, their activities have resulted in litigation in India and could result in future and potentially costly litigation in other countries in which we have patent rights against importers and distributors of infringing products originating in China.

In addition, we may not prevail in lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

If our patents and other intellectual property rights do not adequately protect our products, we may lose market share to our competitors and be unable to operate our business profitably.

Patents and other proprietary rights are essential to our business, and our ability to compete effectively with other companies depends on the proprietary nature of our technologies. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop, maintain and strengthen our competitive position. We seek to protect these, in part, through confidentiality agreements with certain employees, consultants and other parties. We pursue a policy of generally obtaining patent protection in both the United States and key foreign countries for patentable subject matter in our proprietary devices and also attempt to review third-party patents and patent applications to the extent publicly available to develop an effective patent strategy, avoid infringement of third-party patents, identify licensing opportunities and monitor the patent claims of others. Our patent portfolio includes approximately 199 issued patents, the first of which expires in the United States in 2014 and in Europe in 2015, and approximately 110 pending patent applications. We cannot assure you that any pending or future patent applications will result in issued patents, that any current or future patents issued or licensed to us will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide a competitive advantage to us or prevent competitors from entering markets which we currently serve. Any required license may not be available to us on acceptable terms, if at all. In addition, some licenses may be non-exclusive, and therefore our competitors may have access to the same technologies as we do. Furthermore, we may have to take legal action in the future to protect our trade secrets or know-how, or to defend them against claimed infringement of the rights of others. Any legal action of that type could be costly and time-consuming to us, and we cannot assure you that such actions will be successful. The invalidation of key patents or proprietary rights which we own or unsuccessful outcomes in lawsuits to protect our intellectual property may have a material adverse effect on our business, financial condition and results of operations.

The laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. For example, foreign countries generally do not allow patents to cover methods for performing surgical procedures. If we cannot adequately protect our intellectual property rights in these foreign countries, our competitors may be able to compete more directly with us, which could adversely affect our competitive position and, as a result, our business, financial condition and results of operations.

Risks Related to Our Debt

Our substantial debt may adversely affect our financial condition and operating activities.

We have a significant amount of indebtedness. As of December 31, 2009, we have debt of $222.3 million outstanding. Based on that level of indebtedness and interest rates applicable as of

December 31, 2009, our annualized interest expense would be $7.9 million. In addition, we have $25.0 million of available borrowings under our revolving credit facility, and we have the ability to increase the aggregate amount of our Tranche B term loan under our senior secured credit facility by up to $75.0 million without the consent of any person other than the institutions agreeing to provide all or any portion of such increase. Although we believe that our current cash flow is sufficient to cover our annual interest expense for the foreseeable future, any increase in the amount of debt or any decline in the amount of cash available to make interest payments may require us to divert funds identified for other purposes for debt service and impair our liquidity position.

Our substantial level of indebtedness could have other significant consequences to our stockholders, including:

- requiring us to use a substantial portion of our cash flow from operations to pay interest and principal on our debt, thereby reducing the availability of our cash flow to fund working capital, research and development, including clinical trials, acquisitions and other general corporate purposes;
- limiting our ability to obtain additional financing in the future for working capital, research and development, including clinical trials, acquisitions and other general corporate purposes;
- subjecting us to the risk of interest rate increases on our indebtedness with variable interest rates;
- subjecting us to the possibility of an event of default under the financial and operating covenants contained in the agreements governing our indebtedness; and
- limiting our ability to adjust to rapidly changing market conditions, reducing our ability to withstand competitive pressures and making us more vulnerable to a downturn in general economic conditions than our competitors with less debt.

Our inability to generate sufficient cash flow may require us to seek additional financing.

If we are unable to generate sufficient cash flow from operations in the future to service our debt, we may be required to refinance all or a portion of our existing debt, sell assets, borrow more money or raise capital through sales of our equity securities. If these or other kinds of additional financing become necessary, we cannot assure you that we could arrange such financing on terms that are acceptable to us, or at all.

We may incur additional indebtedness from time to time to finance research and development, including clinical trials, acquisitions, investments or strategic alliances or for other purposes.

We may incur substantial additional indebtedness in the future. Although the agreements governing our senior secured credit facility contain restrictions on the incurrence of additional indebtedness, these restrictions are subject to a number of qualifications and exceptions, and the indebtedness incurred in compliance with these restrictions could be substantial. For example, we have $25.0 million of available borrowings under our revolving credit facility, and we have the ability to increase the aggregate amount of our Tranche B term loan under our senior secured credit facility by up to $75.0 million without the consent of any person other than the institutions agreeing to provide all or any portion of such increase. If we incur additional debt above the levels currently in effect, the risks associated with our leverage would increase.

We are subject to restrictive debt covenants, which may restrict our operational flexibility.

Our senior secured credit facility contains various financial and operating covenants, including, among other things, restrictions on our ability to incur additional indebtedness, pay dividends on and

redeem capital stock, make other restricted payments, make investments, sell our assets or enter into consolidations, mergers and transfers of all or substantially all of our assets. Our senior secured credit facility also requires us to maintain specified financial ratios and satisfy financial condition tests. Our ability to meet those financial ratios and tests can be affected by events beyond our control, and we cannot assure you that we will continue to meet those ratios and tests. A breach of any of these covenants, ratios, tests or restrictions could result in an event of default under our senior secured credit facility. Agreements governing any additional indebtedness we incur in the future may contain similar or more stringent covenants. Covenants in our existing or future debt agreements could limit our ability to take actions that we believe are in our best interests. If an event of default exists under our senior secured credit facility or any additional indebtedness we incur in the future, the lenders under such agreements could elect to declare all amounts outstanding thereunder to be immediately due and payable. If any such lender accelerates the payment of one of our indebtednesses, we cannot assure you that our assets would be sufficient to repay in full that indebtedness and our other indebtedness that would become due as a result of any acceleration.

Our obligations under our senior secured credit facility are secured by substantially all of our assets.

Our obligations under our senior secured credit facility are secured by liens on substantially all of our and our subsidiaries' assets. If we become insolvent or are liquidated, or if repayment under our senior secured credit facility is accelerated and we cannot repay such indebtedness, the lenders will be entitled to exercise the remedies available to a secured lender under applicable law and the applicable agreements and instruments, including the right to foreclose on all of our and our subsidiaries' assets.

Risks Related to Our Common Stock

Our controlling stockholders have substantial control over us and could influence the outcome of key transactions, including a change of control.

We are controlled by Welsh Carson, WCAS Capital Partners IV, L.P. and other individuals and entities affiliated with Welsh Carson, which we collectively refer to as the WCAS Stockholders, and Franck L. Gougeon, our director and co-founder, and other entities controlled by Mr. Gougeon, which we collectively refer to as the Gougeon Stockholders. The WCAS Stockholders and the Gougeon Stockholders beneficially own or control approximately 50.2% and 20.1%, respectively, of our common stock, and they have entered into a stockholders agreement with us in relation to their stock ownership. Accordingly, we are a "controlled company" as set forth in Rules 5605 and 5615 of the Nasdaq Global Market because more than 50% of our voting power is held by a group formed by the WCAS Stockholders and the Gougeon Stockholders. As a result, the WCAS Stockholders and the Gougeon Stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other material corporate transactions. They may also vote in a way with which minority stockholders disagree and which may be adverse to minority stockholders' interests. Any conflict of interests between the WCAS Stockholders and the Gougeon Stockholders, on the one hand, and the other holders of our common stock, on the other, may result in an actual or perceived conflict of interest on the part of our directors affiliated with the WCAS Stockholders and the Gougeon Stockholders. The existence or perception of such a conflict of interest could materially limit the ability of these directors to participate in consideration of the matter. In addition, the concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

Some provisions of Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws may deter third parties from acquiring us.

Provisions contained in our amended and restated certificate of incorporation and amended and restated bylaws and the laws of Delaware, the state in which we are incorporated, could make it more difficult for a third party to acquire us, even if doing so might be beneficial to our stockholders. Provisions of our amended and restated certificate of incorporation and bylaws impose various procedural and other requirements, which could make it more difficult for stockholders to effect certain corporate actions. For example, our amended and restated certificate of incorporation authorizes our board of directors to determine the rights, preferences, privileges and restrictions of unissued series of preferred stock, without any vote or action by our stockholders. Thus, our board of directors can authorize and issue shares of preferred stock with voting or conversion rights that could adversely affect the voting or other rights of holders of our common stock.

These anti-takeover defenses could discourage, delay or prevent a transaction involving a change in control of our company. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing and cause us to take other corporate actions that they desire.

We do not anticipate paying any cash dividends in the foreseeable future.

We currently intend to retain our future earnings, if any, for the foreseeable future, to repay indebtedness and to fund the development and growth of our business. We do not intend to pay any dividends to holders of our common stock even if permitted to do so under our senior secured credit facility. As a result, capital appreciation in the price of our common stock, if any, will be our stockholders' only source of gain on an investment in our common stock.

Even if we decide in the future to pay any dividends, AGA is a holding company with no independent operations of its own. As a result, AGA depends on its direct and indirect subsidiaries for cash to pay its obligations and make dividend payments. Deterioration in the financial conditions, earnings or cash flow of our subsidiaries for any reason could limit or impair their ability to pay cash dividends or other distributions to AGA. In addition, our ability to pay dividends in the future is dependent upon AGA's receipt of cash from its subsidiaries. Such subsidiaries may be restricted from sending cash to AGA by, among other things, existing law or certain provisions of our senior secured credit facility the documents governing our future indebtedness that restrict our ability to pay dividends or otherwise distribute cash or other assets.

Our results of operations may fluctuate significantly from period to period and cause the market price of our common stock to decline.

We have experienced significant fluctuations in our results of operations from period to period, and we cannot assure you that we will not do so in the future. Such fluctuations have occurred primarily due to non-recurring items. For example, we recorded for 2005 a $29.0 million charge related to our one-time payment in settlement of a patent infringement lawsuit and a $50.8 million charge related to in-process research and development that we determined would not reach technical feasibility or hold an alternative use. Our results of operations may fluctuate significantly in the future from period to period due to many factors, including current and potential patent infringement lawsuits and the timing of our research and development expenditures, as well as the other factors described in this section. Any such fluctuation may cause the market price of our common stock to decline.

We qualify as a controlled company within the meaning of the Nasdaq Global Market rules and, as a result, rely and expect to continue to rely on exemptions from certain corporate governance requirements.

We are a "controlled company" as set forth in Rules 5605 and 5615 of the Nasdaq Global Market, because more than 50% of our voting power is held by a group formed by the WCAS Stockholders and the Gougeon Stockholders. Under the Nasdaq Global Market rules, a "controlled company" may elect not to comply with certain Nasdaq Global Market corporate governance requirements, including the requirement that a majority of the board of directors consist of independent directors and the requirement that directors nominations and executive compensation must be approved by a majority of independent directors or a nominating or compensation committee, as applicable, comprised solely of independent directors. Accordingly, stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq Global Market corporate governance requirements.

ITEM 2. PROPERTIES.

Our corporate headquarters and center of domestic operations in Plymouth, Minnesota, was purchased by us in 2003. In 2006, we refurbished the facility and consolidated all of our U.S. activities, including our sales, manufacturing, warehousing, research and development and administrative activities, into that location. The facility consists of approximately 205,000 square feet, of which manufacturing and distribution occupies approximately 24,000 square feet. Outside the United States, we lease a sales and distribution office in Birmingham, United Kingdom of approximately 5,800 square feet, a sales office in Frankfurt, Germany of approximately 5,000 square feet, a sales office in Madrid, Spain of approximately 5,700 square feet, a sales office in Paris, France of approximately 6,700 square feet, and a sales and distribution office in Milan, Italy of approximately 8,300 square feet. We believe our facilities are suitable for our current needs.

ITEM 3. LEGAL PROCEEDINGS.

We are from time to time subject to, and are presently involved in, litigation or other legal proceedings in the ordinary course of business.

We believe that there are no pending lawsuits or claims, other than the Medtronic litigation discussed below, that, individually or in the aggregate, are likely to have a material adverse effect on our business, financial position or results of operations.

Foreign Corrupt Practices Act Settlement

On June 2, 2008, we entered into a Deferred Prosecution Agreement, or the DPA, with the Department of Justice concerning alleged improper payments that were made by our former independent distributor in China to (1) physicians in Chinese public hospitals in connection with the sale of our products and (2) an official in the Chinese patent office in connection with the approval of our patent applications, in each case, in potential violation of the Foreign Corrupt Practices Act, or the FCPA. The FCPA makes it unlawful for, among other persons, a U.S. company, acting directly or through an agent, to offer or to make improper payments to any "foreign official" in order to obtain or retain business or to induce such "foreign official" to use his or her influence with a foreign government or instrumentality thereof for such purpose.

We initiated the investigation that ultimately resulted in the DPA and initially disclosed such investigation to the Department of Justice in July 2005. Our investigation revealed that between December 1997 and February 2005, certain of our current and former employees were aware of and approved our former distributor's payment of kickbacks to physicians employed by government-owned hospitals in China in order to induce them to use our products. These physicians are deemed to be "foreign officials" under the FCPA, which would cause such kickbacks to be considered improper payments in violation of the FCPA. The investigation also revealed that in March 2001, our former distributor indicated to certain of our current and former employees that it would be necessary to "sponsor" a Chinese patent official in order to get approval for patent applications filed by us in China in a timely manner, and we agreed to cover the fee. Subsequently, our former distributor informed us that it had paid $20,000 to a Chinese patent official to help obtain approval of patents for our products. Our investigation included a review of our activities and those of our other foreign distributors, and this review revealed no other violations of the FCPA. During the period in question, our sales from China were approximately $13.5 million.

In July 2006, we voluntarily disclosed in writing to the Department of Justice the results of our internal investigation. Between July 2006 and March 2008, the Department of Justice conducted confirmatory interviews with certain of our employees and third parties, and we produced relevant documents to the Department of Justice obtained through our internal investigation and as requested by the Department of Justice. The Department of Justice has not filed individual charges against any of

our officers or other employees, nor is there any indication that it will commence any investigation of any of our officers or other employees with respect to the conduct covered by the DPA.

As part of the DPA, we consented to the Department of Justice filing a two-count criminal statement of information against us in the U.S. District Court, District of Minnesota, which was filed on June 3, 2008. The two counts include a conspiracy to violate the FCPA and a substantive violation of the anti-bribery provisions of the FCPA related to the above-described activities in China. Although we did not plead guilty to that information, we accepted responsibility for the acts of our employees and agents as set forth in the DPA, and we face prosecution under that information, and possibly other charges as well, if we fail to comply with the terms of the DPA. Those terms require us to, for approximately three years, (1) continue to cooperate fully with the Department of Justice on any investigation relating to violations of the FCPA and any and all other matters relating to improper payments, (2) continue to implement a compliance and ethics program designed to detect and prevent violations of the FCPA and other applicable anti-corruption laws, (3) review existing and, if necessary, adopt new controls, policies and procedures designed to ensure that we make and keep fair and accurate books, records and accounts and maintain a rigorous anti-corruption compliance code designed to detect and deter violations of the FCPA and other applicable anti-corruption laws, and (4) retain and pay for an independent monitor to assess and oversee our compliance and ethics program with respect to the FCPA and other applicable anti-corruption laws. The DPA also required us to pay a monetary penalty of $2.0 million. In the fourth quarter of 2007, we had recorded a financial charge of $2.0 million for the potential settlement. The terms of the DPA will remain binding on any successor or merger partner as long as the agreement is in effect.

If we comply with the DPA, the Department of Justice has agreed not to prosecute us with respect to the activities in China that were disclosed, as described above, and, following the term of the DPA, to permanently dismiss the criminal statement of information that is currently pending against us. Furthermore, since July 2005, we have taken a number of steps to reinforce our commitment to conduct our business in compliance with all applicable anti-corruption laws by enhancing our compliance and ethics program, including (1) requiring the execution of revised contracts with foreign distributors containing comprehensive FCPA and other applicable anti-corruption provisions, (2) retaining an independent third party to perform background checks on all new foreign distributors and compliance audits for existing foreign distributors, (3) implementing FCPA and other applicable anti-corruption training for all foreign distributors and our employees, (4) establishing and appointing the position of Chief Compliance Officer, (5) establishing a compliance committee, consisting of our entire executive management team, which must approve all requests to make any payments to foreign officials, healthcare providers and charities, (6) implementing an appropriate process for documenting and approving such payments, (7) establishing an audit committee of the board of directors with oversight over our compliance and ethics program, and (8) retaining an internal auditor to audit the compliance program against the terms of the DPA.

A criminal conviction of our company under the FCPA would lead to our mandatory exclusion from participation in federal healthcare programs, and it may lead to debarment from U.S. and foreign government contracts. We have discussed the DPA with the U.S. Department of Health and Human Services, Office of Inspector General, or the HHS/OIG, and the HHS/OIG confirmed to us in writing that the DPA and the activities related thereto will not result in exclusion from participation in federal healthcare programs.

Medtronic Litigation in the United States

In January 2007, Medtronic, Inc. filed a patent infringement action against us in the U.S. District Court for the Northern District of California, alleging that substantially all of our *AMPLATZER* occluder and vascular plug devices, which have historically accounted for substantially all of our net sales, infringe three of Medtronic's method and apparatus patents on shape memory alloy stents (U.S.

Patent Nos. 5, 190,546, 6,306,141 and 5,067,957). Medtronic is seeking compensatory damages with respect to our products manufactured or sold in the United States. Medtronic asserted but later withdrew its requests for injunctive relief and for damages based on willfulness.

We have asserted defenses and counterclaims for non-infringement and challenged the validity and enforceability of Medtronic's patents. On April 28, 2009, the court granted summary judgment in our favor finding that we do not infringe Medtronic's '546 patent. Subsequently, Medtronic withdrew certain allegations with respect to the remaining two patents. The trial on the remaining issues in the case was divided into a jury trial phase and non-jury, bench trial phase.

The issues of infringement and certain issues of validity based on obviousness and anticipation of the asserted claims in the two remaining patents were the subject of a jury trial before the U.S. District Court for the Northern District of California that began on July 6, 2009. On August 5, 2009, the jury returned a verdict that the subject *AMPLATZER* occluder and vascular plug products infringed the claims at issue with respect to both of the two remaining Medtronic patents and that the Medtronic patent claims at issue had not been proven by us to be invalid. The jury verdict awarded Medtronic damages of $57.8 million. This amount is equal to 11% of historical sales of the occluder and vascular plug products in question during the timeframe specified for each patent. Any infringement of the '141 apparatus patent after March 31, 2009 to the date of a final, non-appealable judgment will be considered in calculating the final amount of damages, if any, to be paid. The '957 patent expired in May 2004. Because the issue was not before it, the jury made no determination regarding the payment of royalties on future sales of the company's products after the date of a final, non-appealable judgment. The verdict is not enforceable until the completion of the trial and entry of a final, non-appealable judgment. If we do not receive a favorable judgment, we expect we will appeal such judgment and expect that we will likely be required to post a bond in order to be allowed to appeal as set forth below. The verdict is not enforceable because a judgment has not yet been entered, and as a matter of law only judgments are enforceable for purposes of execution against the non-prevailing party. A judgment has not yet been entered because all claims have not yet been adjudicated between the parties and the court has not yet ordered a judgment be entered. In addition, on August 5, 2009, Medtronic's counsel agreed with the judge on the record that a judgment would not be entered until after the non-jury trial phase is completed. Furthermore, upon approval of an appeal bond, the execution of any appealed judgment is stayed during the appeal.

On August 19, 2009, the United States Court of Appeal for the Federal Circuit, sitting en banc, issued a decision in Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc. In Cardiac Pacemakers, the Federal Circuit established a new rule of law and held as a matter of law that the practice of a method claim of a patent outside of the United States cannot infringe a United States method patent. When a controlling new rule of law is announced that affects the parties to a patent litigation, the court will ordinarily apply the supervening change in law retroactively to a pending case. In our litigation with Medtronic, a portion of the jury's damage award was based on a finding of infringement of Medtronic's '957 method patent for sales of our products outside of the United States, and we believe it is therefore directly contrary to the holding as stated in the Cardiac Pacemakers decision. Applying the rate of damages established by the jury, 11% of historical sales, to the total sales of our products outside of the United States during the period for which we believe damages were awarded for infringement of the '957 patent would result in a reduction of approximately $14 million. Such $14 million of damages relates only to periods of time before the '141 patent was enforceable against us. As a result, we believe it is likely that the trial court in our case will reduce the jury's damage award by approximately such amount to reflect this recent decision, although there can be no assurance that the damage award will be reduced by this or any other amount. On September 8, 2009, we filed a motion seeking, at Medtronic's choice, either a new trial or the above-mentioned reduction of $14 million, which motion is publicly available. We do not expect a ruling on this motion until the conclusion of the non-jury phase of the trial in early 2010.

Following the jury verdict, the court held the non-jury phase of the trial in early December 2009, to hear our claim that the '141 patent is invalid based on the doctrine of double patenting, which prohibits obtaining two patents covering the same basic invention in a continuation application. In the event the judge finds in our favor in the non-jury phase of the trial, she can decide that the '141 patent is invalid and eliminate the damages awarded by the jury against us on the '141 patent. Upon conclusion of its decision of the non-jury phase of the trial, the court will consider post-trial motions and enter a judgment, which we expect will take place in mid to late 2010. As part of its decision, the trial court could order a new trial on some or all of the issues in the case or amend or reaffirm the jury verdict based on one or more issues regarding infringement, validity, enforceability and damages. We also expect the trial court to decide whether any royalty payments relating to the '141 patent, which does not expire until 2018, are due for future periods and, if so, at what rate. Any such royalties may not be on commercially reasonable terms, and may exceed the 11% rate of damages applied by the jury. If any damage amount is entered as a part of the judgment, we will likely be required at that time to accrue a non-cash charge equal to the amount of such damages. Any such accrual will have an adverse effect on our results of operations for the applicable period.

Thereafter, the judgment will be subject to appeal which could result in the judgment being affirmed or amended, or in an order for a new trial on one or more of the same issues raised before the trial court. If we decide to appeal, such appeal may not be decided for several months and may require the posting of a bond in the face amount of up to 150% of the judgment amount, if any. We do not expect the cash cost associated with posting such a bond to be material, but we would likely be required to secure such bond with collateral. The amount of collateral required by the provider of the bond would be determined based on several factors, such as the amount of our debt and our financial condition.

Occlutech Litigation in Europe

In August 2006, we brought a patent infringement action in Germany against Occlutech GmbH, a European manufacturer of cardiac occlusion devices, and DRABO Medizintechnik based on the German part (DE No. 695 34 505) of one of our European patents (EP No. 08080 138), granted to us in October 2005, for intravascular occlusion devices and the method of manufacturing such devices.

On July 31, 2007, the District Court in Düsseldorf entered a judgment in our favor finding that Occlutech and DRABO literally infringed the German part of our European patent. The three-judge panel granted us the right to enforce an order prohibiting the defendants from possessing, manufacturing or selling the infringing products. The judgment also entitled us to enforce the immediate destruction of all infringing products in Occlutech's inventory. Consequently, Occlutech has destroyed over 2,300 occluders before a notary public and is currently prohibited from manufacturing or selling the infringing products in Germany. Under German practice, the District Court required us to post a bond in the amount of €1 million to secure our ability to respond to damages claimed by Occlutech in the event that the decision of the District Court is reversed on appeal or our patent is held invalid in related proceedings in the German patent court. The bond amount is not a limitation on damages.

On August 6, 2007, Occlutech filed an appeal against the District Court judgment before a German Court of Appeals, contending that the District Court judgment was based on an overly broad interpretation of our European patent, and, in addition, initiated invalidation proceedings against the patent. On January 6, 2009, the German Court of Appeals dismissed Occlutech's appeal and entered a judgment in favor of finding that Occlutech infringed our patent. Occlutech has filed an appeal with the German Federal Court of Justice. The German Federal Court of Justice has twice denied Occlutech's motions to stay enforcement of the judgment. A final decision on the appeal with the German Federal Court of Justice and a decision on the invalidation proceedings are not expected to be reached until 2010 or later. In the meantime, we expect to seek damages and other remedies in the

enforcement proceedings based on the German Court of Appeals' decision. Neither the pending appeal nor the invalidation proceedings affect our ability to continue to enforce the District Court's judgment. On October 29, 2009, the German Regional Court in Düsseldorf, Germany granted a preliminary injunction against the manufacture, possession and sale of the Figulla® Flex occluders manufactured by Occlutech and determined that Occlutech's product infringed our German patent.

In addition, Occlutech initiated proceedings against our corresponding patents in Italy, the Netherlands, the United Kingdom, Spain and Sweden, seeking invalidity and/or non-infringement declarations. On October 29, 2008, the Patent Court in the Netherlands ruled in favor of Occlutech in the non-infringement declaration. The court did not rule on the invalidity claim. On November 3, 2008, we filed an appeal on the Dutch appellate court. On July 31, 2009, a United Kingdom patent court upheld the validity of our patent, but it ruled that the Occlutech products do not infringe on our patent. We intend to appeal the decision that Occlutech did not infringe upon our patent. Final decisions in these actions are not expected to be reached until 2010 or later. We intend to vigorously defend our patents and believe that we have a good basis for prevailing in both the appeals before the German and Dutch appellate courts, in the planned appeal before the United Kingdom appellate court and against Occlutech's various invalidation proceedings. However, the outcome in any of these proceedings may not be favorable to us.

University of Minnesota Litigation in the United States

On November 30, 2007, the University of Minnesota filed a patent infringement action against us in the United States District Court for Minnesota, alleging that our *AMPLATZER* occlusion devices infringe the University's method and apparatus patents on septal occlusion devices (U.S. Patent Nos. 6,077,291, or the '291 patent, and 6,077,281). The University is seeking injunctive relief as well as damages, including damages for alleged willful infringement, although no damage amount has been specified in the complaint. We have filed an answer and counterclaims seeking a declaration of non-infringement, invalidity, unenforceability, equitable estoppel, laches, and expiration of the '291 patent, among others. The litigation is currently in the discovery process. On April 18, 2008, the Court granted our motion for partial summary judgment declaring that the '291 patent expired for failure to pay the maintenance fees and has been unenforceable from and after June 21, 2004. Subsequently, the U.S. Patent and Trademark Office repeatedly rejected the University's petition to reinstate the '291 patent, which is, therefore, no longer enforceable. A trial date has not been set in the litigation. Although we presently believe that the lawsuit lacks merit, we cannot guarantee that the outcome of this litigation will be favorable to us or that material damages will not be awarded against us.

Subject to the Medtronic litigation disclosed above, we believe that there are no pending lawsuits or claims, including those noted above, that, individually or in the aggregate, are likely to have a material adverse effect on our business, financial position or results of operations.

ITEM 4. REMOVED AND RESERVED

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Holders

Our common stock began trading on October 21, 2009 on the Nasdaq Global Select Stock Market under the symbol "AGAM" in connection with our initial public offering. Prior to that time there was no public market for our stock. The following table sets forth, for the fourth quarter, the high and low last sale prices of our common stock beginning on October 21, 2009.

	High	Low
Fiscal 2009		
Fourth Quarter (from October 21, 2009)	$15.00	$11.91

Dividends

We did not pay dividends to holders of our common stock during the fiscal year ended December 31, 2009. AGA currently intends to retain our future earnings, if any, for the foreseeable future, to repay indebtedness and to fund the development and growth of our business. AGA does not intend to pay any dividends to holders of our common stock.

Securities Authorized for Issuance under Equity Compensation Plans

For information on our equity compensation plans, refer to Item 12, "Principal Stockholders and Management Stockholdings" and "Equity Compensation Plan Information."

Purchases of Equity Securities by the Company

None.

Recent Sales of Unregistered Securities

None.

Use of Proceeds

The effective date of our registration statement filed on Form S-1 under the Securities Act of 1933 (File No. 333-151822) relating to our initial public offering of shares of common stock, $0.01 par value was October 20, 2009. A total of 15,812,500 shares of our common stock were registered and 13,750,000 were sold, including 6,509,000 shares of common stock sold by us and 7,241,000 shares of common stock sold by the selling stockholders. The option we granted to the underwriters to purchase up to 2,062,500 additional shares of our common stock expired without being exercised. Merrill Lynch, Pierce, Fenner & Smith Incorporated, Citigroup Global Markets Inc., Deutsche Bank Securities Inc., Leerink Swann LLC and Wells Fargo Securities, LLC acted as joint book-running managers of the offering.

The aggregate offering price of securities registered was $229,281,250 and the aggregate amount sold was $199,375,000. The aggregate underwriting discount was $12,959,375, none of which was paid to our affiliates. We incurred approximately $5.0 million of other expenses in connection with the offering. Net proceeds we received from this offering totaled approximately $82.2 million. We used $25.0 million of the net proceeds from our initial public offering to fully repay principal and accrued and unpaid interest under our revolving credit facility. We used $50.0 million of the net proceeds from our initial

public offering to prepay the principal amount of our 10% senior subordinated notes due 2012 that were issued in 2005, or the 2005 notes. In addition, we used approximately $5.0 million of the net proceeds from our initial public offering to pay accrued and unpaid interest on the 2005 notes and the 10% senior subordinated notes due 2012 that were issued in 2009. We have used and intend to continue to use remaining proceeds from our initial public offering for working capital and general corporate purposes.

ITEM 6. SELECTED FINANCIAL DATA.

The data given below as of and for each the periods indicated, has been derived from our audited consolidated financial statements. In order to understand the effect of accounting policies and material uncertainties that could affect our presentation of financial information, such data should be read in conjunction with our consolidated financial statements and notes thereto included under Item 8 of this Form 10-K and in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operation included under Item 7 to this Form 10-K.

On July 28, 2005, the stockholders of AGA Medical contributed all of the outstanding shares of AGA Medical to AGA in exchange for shares of AGA. As a result of that, AGA Medical became a wholly owned subsidiary of AGA. All periods prior to July 28, 2005 are referred to as "Predecessor", and all periods on or after such date are referred to as "Successor." The data for Predecessor periods represents consolidated financial information of AGA Medical and its consolidated subsidiaries and the selected financial information for all Successor periods represents financial information of AGA and its consolidated subsidiaries. The financial statements for all Successor periods are not comparable to those of Predecessor periods.

	Successor					Predecessor
	Year ended December 31,				Period From July 28, to December 31,	Period From January 1, to July 27,
(in thousands, except per share data)	2009	2008	2007	2006	2005	2005
Statement of Operations Data:						
Net sales	$198,710	$166,896	$147,255	$127,529	$ 39,917	$58,206
Cost of goods sold	31,240	26,635	22,819	24,985	8,967	11,580
Gross profit	167,470	140,261	124,436	102,544	30,950	46,626
Operating expenses:						
Selling, general and administrative	98,908	65,669	50,190	37,515	15,035	14,145
Research and development	35,197	32,760	26,556	12,096	3,084	4,012
Amortization of intangible assets	20,115	15,540	15,233	12,682	5,099	—
Change in purchase consideration	(1,149)	—	—	—	—	—
Litigation settlement	—	—	—	—	29,000	—
FCPA settlement	—	—	2,000	—	—	—
In-process research and development	—	—	—	—	50,800	—
Loss (gain) on disposal of property and equipment	63	68	(3)	709	26	—
Total operating expenses	153,134	114,037	93,976	63,002	103,044	18,157
Operating income (loss)	14,336	26,224	30,460	39,542	(72,094)	28,469
Investment income (loss)	(2,352)	(1,202)	(751)	754	193	(166)
Interest income	92	230	426	1,174	423	777
Interest income—related party	—	—	6	—	—	394
Interest expense	(17,219)	(16,492)	(21,213)	(22,893)	(6,418)	—
Other income, (expense), net	3,220	722	994	957	(91)	340

(in thousands, except per share data)	Successor					Predecessor
	Year ended December 31,				Period From July 28, to December 31, 2005	Period From January 1, to July 27, 2005
	2009	2008	2007	2006		
Income (loss) before income taxes	(1,923)	9,482	9,922	19,534	(77,987)	29,814
Income tax (benefit) expense	(828)	386	3,844	6,909	9,926	10,565
Net income (loss)	(1,095)	9,096	6,078	12,625	(68,061)	19,249
Less Series A and Series B preferred stock and Class A common stock dividends	(14,282)	(17,067)	(15,372)	(59,410)	(6,271)	—
Net income (loss) applicable to common stockholders	$(15,377)	$ (7,971)	$ (9,294)	$(46,785)	$(74,332)	$19,249
Net income (loss) per common share—basic and diluted	$ (0.57)	$ (0.37)	$ (0.41)	$ (2.00)	$ (3.18)	
Cash dividends per Class A common stock	$ 0.00	$ 0.00	$ 0.00	$ 2.15	$ 0.00	
Cash dividends per share of common stock	$ 0.00	$ 0.00	$ 0.00	$ 2.15	$ 0.72	
Weighted average shares—basic and diluted	27,069	21,482	22,550	23,356	23,356	

(in thousands)	Successor				
	As of December 31,				
	2009	2008	2007	2006	2005
Balance Sheet Data:					
Cash and cash equivalents	$ 24,470	$ 22,867	$ 13,854	$ 8,190	$ 17,707
Working capital	50,444	30,546	16,454	27,080	27,061
Total assets	340,580	272,328	256,015	258,794	282,372
Long-term debt, less current portion	219,962	253,442	242,600	242,589	140,151
Redeemable convertible Series A and Series B preferred stock and Class A common stock		174,571	158,701	158,425	154,795
Total stockholders' equity (deficit)	36,457	(226,458)	(217,769)	(210,568)	(121,140)

Presentation gives effect to the 1.00 for 7.15 reverse stock split of our common stock that occurred immediately prior to the Company's initial public offering for Successor periods.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing under Item 8 of this Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and expected financial results, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" under Item 1A for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a leading innovator and manufacturer of medical devices for the minimally invasive treatment of structural heart defects and vascular diseases, which we market under the *AMPLATZER* brand. We were founded in 1995 to capitalize on the attributes of nitinol to make occlusion devices for the transcatheter treatment of structural heart defects, and our *AMPLATZER* occlusion devices initially focused on the treatment of these defects. We received a CE Mark in Europe for our occlusion devices and related delivery systems in 1998. In 2001, we received U.S. regulatory approval to commercialize our *AMPLATZER* Septal Occluder, which addresses one of the largest treatment areas of the structural heart defect market. We received U.S. regulatory approval to commercialize our *AMPLATZER* Duct Occluder device in 2003 and our *AMPLATZER* Muscular VSD Occluder device in 2007.

Our *AMPLATZER* occlusion devices utilize our expertise in braiding nitinol and designing transcatheter delivery systems. Historically, the majority of our sales were to interventional cardiologists to treat a range of structural heart defects. We have recently leveraged our core competencies in braiding nitinol and designing transcatheter delivery systems to develop products for the treatment of certain vascular diseases. Our vascular products are sold through a separate sales force targeted at interventional radiologists and vascular surgeons. Our first products in this area, which we launched in the United States in September 2003 and in Europe in January 2004, are vascular plugs for the closure of abnormal blood vessels that develop outside the heart. A second version of our vascular plug was approved and launched in the United States and Europe in August 2007, and a third version is under review by the regulatory authorities in the United States and Europe.

We are also focused on capitalizing on the growing body of evidence that links the presence of PFOs to certain types of stroke and migraines. Since 2001, we have initiated four PFO clinical trials, two focused on strokes and two focused on migraines. These clinical trials have significantly increased our research and development expenses.

Our other products in development include a new version of our *AMPLATZER* Duct Occluder, which received a CE Mark in February 2008 and will require a clinical trial to support U.S. approval, additional versions of our *AMPLATZER* Vascular Plugs, an occlusion device to close the Left Atrial Appendage, or LAA, and to prevent strokes, which device received a CE Mark in February 2008, and vascular grafts to treat aneurysms. Our *AMPLATZER* Vascular Plug III received a CE Mark in Europe in May 2008, and we applied for FDA approval in the United States in February 2008. The FDA has requested additional non-clinical testing of the device, and we are in the process of completing that testing and answering all remaining questions from the FDA. Our *AMPLATZER* Vascular Plug IV received a CE Mark in Europe in July 2009. We have applied to the FDA for U.S. approval to conduct a clinical trial for the new version of our *AMPLATZER* Duct Occluder and expect to apply to the FDA for approval to begin new clinical trials to support U.S. approval of other products in 2009. We believe that our new products for prevention of strokes related to the LAA and our family of vascular grafts will likely require clinical trials in order to receive U.S. regulatory approval.

On July 28, 2005, we implemented a corporate reorganization, which we refer to as our July 2005 reorganization. As part of our July 2005 reorganization, AGA Medical purchased and redeemed all of the outstanding shares of common stock owned by one of its two then existing stockholders. To finance our July 2005 reorganization, AGA Medical (1) issued an aggregate principal amount of $50.0 million of the 2005 notes, which were purchased by one of the WCAS Stockholders at a discount, (2) issued 128,524 shares of Series A preferred stock to the WCAS Stockholders at a purchase price of $1,000 per share and (3) borrowed $107.0 million under a $122.0 million senior credit facility, consisting of a $107.0 million senior term loan and a $15.0 million revolving credit facility. The remaining stockholder and new investors subsequently contributed all of their outstanding shares in AGA Medical to AGA in exchange for shares of AGA.

On April 28, 2006, we completed a $240.0 million recapitalization, which we refer to as our April 2006 recapitalization. As part of our April 2006 recapitalization, we entered into an amended and restated senior secured credit facility consisting of a $215.0 million seven-year Tranche B term loan facility and a $25.0 million revolving credit facility, which we refer to collectively as our senior secured credit facility. The Tranche B term loan was drawn in full in April 2006, and the proceeds were used to pay off existing senior debt, accrued dividends of $11.0 million to the Series A preferred and Class A common stockholders, a $0.30 per share dividend to all Series A preferred, Class A common and other common stockholders, and transaction-related expenses, as well as to fund general working capital needs. On October 5, 2008, Lehman Commercial Paper Inc. ("LCPI") filed for protection under Chapter 11 of the Federal Bankruptcy Code. LCPI had committed to provide $9.5 million under the $25 million revolving credit facility. In March 2009, Bank of America, N.A. assumed the commitment under our revolving credit facility previously held by LCPI.

In January 2007, Medtronic, Inc. filed a patent infringement action against us in the U.S. District Court for the Northern District of California, alleging that substantially all of our *AMPLATZER* occluder and vascular plug devices, which have historically accounted for substantially all of our net sales, infringe three of Medtronic's method and apparatus patents on shape memory alloy stents (U.S. Patent Nos. 5, 190,546, 6,306,141 and 5,067,957). Medtronic is seeking compensatory damages with respect to our products manufactured or sold in the United States. Medtronic asserted but later withdrew its requests for injunctive relief and for damages based on willfulness.

For additional detail regarding the Medtronic litigation and its potential impact on our results of operations, please refer to Item 3 Legal Proceedings of this Form 10-K under the subheading "Medtronic Litigation in the United States." We have not recorded an expense related to damages in connection with this litigation matter because any potential loss is currently neither probable nor reasonably estimatable under ASC Topic 450 Contingencies (ASC 450).

Recent Acquisitions

Effective January 1, 2009, we purchased the distribution rights, inventory and intangible assets from our distributors in Canada, Portugal, France, Belgium and the Netherlands and began direct distribution in these countries. The aggregate purchase price of these acquisitions totaled $10.8 million, consisting of cash payments of $6.1 million, the discounted value of $1.4 million in additional guaranteed payments and the discounted value of up to $3.3 million in additional contingent payments if certain revenue goals are achieved. Effective January 1, 2009, we began direct distribution in Italy as a result of our purchase on January 8, 2009 of certain distribution rights, inventory, equipment, intangible assets and goodwill from our former Italian distributor. The aggregate purchase price was $41.0 million, consisting of cash payments of $26.6 million, the discounted value of $9.2 million in additional guaranteed payments and the discounted value of up to $5.2 million in additional contingent payments if certain revenue goals are achieved during the first three years following completion of the acquisition.

Components of Results of Operations

Net Sales

Our net sales are derived primarily from the sales of our *AMPLATZER* occlusion devices for the repair of structural heart defects and, more recently, our *AMPLATZER* Vascular Plugs for the repair of abnormal blood vessels. In addition, we also sell accessories, such as delivery systems, sizing balloons and guidewires. Other components of net sales include freight revenue, restocking fees and net adjustments to sales return reserves. Since 2006, the geographic distribution of our net sales between U.S. and international net sales has remained relatively stable with U.S. net sales constituting approximately 40% of our net sales.

From 2006 to 2009, our net sales have presented a compound annual growth rate of 15.9%. Our net sales have grown during that time primarily due to:

- the increasing awareness, acceptance and use of non-invasive devices for treatment of structural heart defects and vascular diseases;
- selected conversion of our international distributors to direct sales and the expansion of our U.S. direct sales force beginning in 2007;
- higher average selling prices, primarily in the United States;
- the expansion of our product portfolio; and
- our geographic expansion into additional international markets.

A majority of our net sales are generated by our direct sales efforts for products that are shipped and billed to hospitals throughout the world. In countries where we do not have a direct sales force, sales are generated by shipments to distributors who, in turn, sell to hospitals. We have agreements in place with each of our distributors that provide them exclusive rights to sell our products in their specified territories. Substantially all of our net sales to our distributors are denominated in U.S. dollars, while international direct sales are typically denominated in the local currency.

Cost of Goods Sold

We manufacture a substantial majority of the products that we sell. Our cost of goods sold consists primarily of our costs associated with direct labor, raw materials and components, manufacturing overhead, salaries, other personnel-related expenses for our management team, quality control, royalties, freight, service warranty, insurance and depreciation.

Our cost of goods sold has decreased as a percentage of net sales over the past three years primarily as a result of higher average selling prices of our devices, lower net royalty costs as a percent of sales and improved manufacturing efficiencies. As we manufacture substantially all of our products at our headquarters in Plymouth, Minnesota, substantially all of our costs of goods sold are in U.S. dollars. We are evaluating manufacturing operations in Europe for all of our devices that are sold in international markets within 12 to 18 months.

Our management reviews and analyzes the components of cost of goods sold and utilizes cost of goods sold as a percentage of net sales as an indicator of our efficiency in manufacturing our products.

Selling, General and Administrative

Our selling and marketing expenses consist primarily of salaries, commissions and other personnel-related expenses for employees engaged in sales, marketing and support of our products, trade shows, promotions and physician training. General and administrative expenses consist of expenses for our

executive, finance, legal, compliance, administrative, information technology and human resource departments.

Our selling, general and administrative expenses have increased as a percentage of net sales over the past three years primarily as a result of establishing and expanding our U.S. and European direct sales forces, increasing legal costs, and increased headcount associated with enhancing our management team and corporate infrastructure to support the growth of the business. Except for the costs associated with our European direct sales force and facilities, our selling, general and administrative expenses are primarily in U.S. dollars.

We expect our sales and marketing expenses to increase in absolute terms as we continue to expand our direct sales force, both in the United States and internationally to support the growth of the business and new products launches. We expect that our general and administrative expenses will increase in dollar amounts will decline as a percentage of sales over the longer term as a result of the growth of the business. We believe the combination of our investments in our corporate infrastructure, having an established sales force infrastructure in place in Europe and the US, and with the successful completion of clinical trials, will allow us to leverage the investments we have made in support of a larger business.

Our management reviews and analyzes selling, general and administrative expenses in absolute terms and as a percentage of net sales as an indicator of our ability to manage our business to our annual operating plans.

Research and Development

Our research and development expenses consist primarily of those (1) associated with the development, design and testing of new products, product enhancements and new applications for our existing products, and (2) incurred to operate our clinical trials, including trial design, clinical-site reimbursement, data management and associated travel expenses. These expenses include engineering, pre-clinical studies, clinical trials and clinical personnel costs, cost of materials, supplies, services and an allocation of facility overhead costs. We expense all of our research and development costs as incurred.

Our research and development expenses have increased over the past three years primarily as a result of increased clinical trial and research and development spending as a result of focusing on commercializing our pipeline of new products, product enhancements and new applications for our existing products.

We expect to continue to invest in the development of new products and technologies. We, therefore, expect our total research and development expenses to increase in absolute terms but do not expect them to significantly increase as a percentage of net sales. We also expect period-to-period increases to be driven by research and development expenses related to clinical trials as these expenses are subject to periodic variation based on various factors, such as the number of clinical trials underway at any given time, the number of patients in each trial and the pace of enrollment. We expect research and development to decrease as a percentage of net sales over the longer term.

Amortization of Intangible Assets

We amortize intangible assets, such as developed technology, royalty rights, patents and customer relationships over their useful life, typically periods ranging from five to ten years. Our amortization of intangible assets has increased over the past three years primarily as a result of our:

- *July 2005 reorganization.* As a result of our July 2005 reorganization, we recorded goodwill and intangibles in the amount of $178.0 million, resulting in amortization of intangible assets of $12.2 million in each of the three years ended December 31, 2009, 2008 and 2007, respectively.

- *2007 purchase of patent rights.* Effective January 2007, we purchased certain patent rights relating to our products for a $14.5 million payment which resulted in the creation of an intangible asset to be amortized over 7.5 years. We recorded amortization expense of $1.9 million in each of the three years ended December 31, 2009, 2008 and 2007, related to this purchase of patent rights. The purchase reduced our cost of goods sold by approximately 2% per year. The royalty payments associated with these patents would have continued until 2014 and 2015 for U.S. and international sales, respectively, had the purchase not taken place.
- *Distributor to direct conversions.* As a result of our distributor to direct conversions, we recorded goodwill and intangibles in the amount of $72.3 million, resulting in amortization of intangible assets of $5.7 million, $1.2 million, and $0.9 million in each of the three years ended December 31, 2009, 2008 and 2007, respectively.

Change in purchase consideration

Change in purchase consideration represents changes in the fair value of contingent payment obligations in accordance with ASC Topic 805 accounting for business combinations. See "—Recent Accounting Pronouncements." For the year ended December 31, 2009, we recorded as a reduction to operating expenses $1.1 million for a change in purchase consideration derived from a reduction in the fair value of contingent payment obligations resulting from the acquisitions of distribution rights from former distributors in Canada, Italy, the Netherlands and Portugal based on actual and forecasted revenue assumptions for 2009, and for Italy revenue assumption for 2010 and 2011.

Foreign Corrupt Practices Act Settlement

On June 2, 2008, we entered into a Deferred Prosecution Agreement, or the DPA, with the U.S. Department of Justice concerning alleged improper payments that were made by our former independent distributor in China. As part of the DPA, we were required, among other things, to pay a monetary penalty of $2.0 million. In anticipation of the settlement, we recorded in 2007 a charge of $2.0 million.

Loss on disposal of property and equipment

Loss on disposal of property and equipment represents the remaining net book value of these assets at the time of their disposal.

Investment Income (Loss)

Investment income (loss) includes the difference between the proceeds received from the sale of an investment and its carrying value. In addition, investment income (loss) includes our portion of losses under the equity method of accounting that we recognize in connection with our investment in a private early-stage structural heart medical device company.

Interest Income

Interest income is comprised of interest income earned on our cash and cash equivalents and short-term investments, consisting primarily of certain investments that have contractual maturities no greater than three months at the time of purchase.

Interest Expense

Interest expense consists primarily of interest and debt discounts on borrowings under our senior secured credit facility entered into in connection with our July 2005 reorganization and amended and

restated in connection with our April 2006 recapitalization, as well as the 2005 notes entered into in connection with our July 2005 reorganization.

Other Income (Expense), Net

Other income (expense), net primarily includes royalty income and foreign exchange gains and losses net of certain other expenses.

Income Taxes

Income taxes are comprised of federal, state, local and foreign taxes based on income.

Net Income

During the past three years, our net income has declined despite our significantly increased net sales and higher gross margins. These higher gross margins have been offset by increases in investments we have made in our business, such as increased expenses associated with selective conversion of our distributors to a direct sales force, research and development expenses, including increased clinical trial expenses related to the expansion of our product pipeline, increased selling, general and administrative expenses, including legal fees related to defending our intellectual property and expenses related to strengthening our corporate infrastructure, and increased interest and amortization expense resulting primarily from our distributor to direct conversions.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, net sales and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates including those related to product returns, bad debts, inventories, income taxes, long-lived assets and intangibles. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

The accounting policies we believe to be most critical to understanding our financial results and condition and that require complex and subjective management judgments are discussed below.

Revenue Recognition

In the United States and certain European countries, where we primarily sell our products directly to hospitals, we recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sales price is fixed or determinable; and the collectibility is reasonably assured. These criteria are typically met at the time of shipment when the risk of loss and title passes to the customer.

In other international markets, we sell our products to international distributors who subsequently resell the products to hospitals. Sales to distributors are recognized at the time of shipment, provided that we have received an order, the sales price is fixed or determinable, collection of the resulting receivable is reasonably assured and we can reasonably estimate returns. In cases where our products are held on consignment at a customer's location, we recognize net sales at the time the product is used in the procedure rather than at shipment.

Product Returns Policy

We warrant that our products are free from manufacturing defects at the time of shipment. We allow for product returns in certain circumstances, such as damaged or faulty products or products that are incorrectly sized and subsequently unused during a procedure. Allowances are provided for estimated product returns at the time of sale based on historical returns experience and recorded as a reduction of sales. Allowances are provided for estimated warranty costs at the time of shipment. We reserve approximately 1% to 5% of sales for these various return categories.

In July 2006, we established a change to our product returns policy, effective January 1, 2007, whereby we would no longer accept the return of expired products from our customers. As a result of this change in policy, we recorded reductions to our product returns reserve balances of $1.3 million for the year ended December 31, 2007 and none for the years ended December 31, 2008 and 2009. These recorded reductions had the effect of increasing net sales in 2007.

Accounts Receivable and Allowance for Doubtful Accounts

We have receivables from a diversified customer base. The creditworthiness of customers is analyzed and monitored before sales are approved. We record an allowance for doubtful accounts based on past history, current economic conditions and the composition of our accounts receivable aging, and in some cases, we make allowances for specific customers based on several factors, such as the creditworthiness of those customers, payment history and disputes with customers. We historically have not had any material issues with respect to allowance for doubtful accounts as a result of collection.

Inventory Reserves

We calculate inventory reserves for estimated obsolescence or excess inventory based on historical turnover and assumptions about future demand for our products and market conditions. Our industry is characterized by regular new product development, and as such, our inventory is at risk of obsolescence following the introduction and development of new or enhanced products. Our estimates and assumptions for excess and obsolete inventory are reviewed and updated on a quarterly basis. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our sales forecasts. Future product introductions and related inventories may require additional reserves based upon changes in market demand or introduction of competing technologies. Increases in the reserve for excess and obsolete inventory result in a corresponding expense in cost of goods sold. Our reserve for excess and obsolete inventory was $1.9 million as of December 31, 2009 and $1.8 million as of December 31, 2008.

Goodwill and Indefinite Lived Intangibles

We periodically evaluate whether events and circumstances have occurred that may affect the estimated useful life or the recoverability of the remaining balance of our goodwill and indefinite lived intangible assets. If such events or circumstances were to indicate that the carrying amount of those assets would not be recoverable, we would estimate the future cash flows expected to result from the use of the assets and their eventual disposition. The process of evaluating the potential impairment is subjective and requires management to exercise judgment in making assumptions related to future cash flows and discount rates. If the sum of the expected future cash flows (undiscounted and without interest charges) were less than the carrying amount of goodwill and indefinite lived intangibles, we would recognize an impairment loss. Goodwill and indefinite lived intangibles is tested for impairment during the fourth quarter of each year or if events otherwise require. As of December 31, 2009, 2008 and 2007, we concluded that there was no impairment. Since December 31, 2009, there has been no

event or adverse business trend that would suggest that goodwill or our indefinite lived intangibles have been impaired or that an interim test should be performed.

Contingent Consideration

Contingent consideration is recorded at the acquisition-date estimated fair value of the contingent milestone for all acquisitions subsequent to January 1, 2009. The fair value of the contingent milestone consideration is remeasured at the estimated fair value at each reporting period with the change in fair value included in our consolidated statements of operations.

Long-Lived Assets

We periodically review and evaluate long-lived assets, primarily property, plant and equipment and intangible assets with finite lives, when events and circumstances indicate that the carrying amount of these assets may not be recoverable. For long-lived assets, this evaluation is based on the expected future undiscounted operating cash flows of the related assets. Should such evaluation result in us concluding that the carrying amount of long-lived assets has been impaired, an appropriate write-down to their fair value is recorded.

Income Taxes

We account for income taxes in accordance with ASC Topic 740, *Income Taxes* (ASC 740). Under this method, we determine tax assets and liabilities based upon the differences between the financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. The tax consequences of most events recognized in the current year's financial statements are included in determining income taxes currently payable. However, because tax laws and financial accounting standards differ in their recognition and measurement of assets, liabilities and equity, revenues, expenses, gains and losses, differences arise between the amount of taxable income and pretax financial income for a year and between the tax basis of assets or liabilities and their reported amounts in the financial statements. Because we assume that the reported amounts of assets and liabilities will be recovered and settled, respectively, a difference between the tax basis of an asset or liability and its reported amount in the balance sheet will result in a taxable or a deductible amount in some future years when the related liabilities are settled or the reported amounts of the assets are recovered, giving rise to a deferred tax asset or liability.

Effective January 1, 2007, we adopted ASC Topic 740-10, accounting for uncertainty in income taxes (ASC 740-10), which prescribes detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in an enterprise's financial statements in accordance with ASC 740. The interpretation prescribes a recognition threshold and measurement attribute for a tax position taken or expected to be taken in a tax return and also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. Tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized upon the adoption of ASC 740-10 and in subsequent periods.

At December 31, 2009, 2008 and 2007, the Company has capital loss carryforwards of $5.6 million, $1.6 million, and $1.6 million respectively, which expire at various times beginning in 2010 through 2014. The Company has established a valuation allowance against these capital loss carryforwards, as it does not believe they will be realizable before the expiration.

As of December 31, 2009 the Company's valuation allowance was $2.7 million compared to $0.9 million at December 31, 2008 The net increase in the Company's valuation allowance during the year is due to an increase in the federal capital loss carry forward as a result of the disposition of an investment in Ample Medical (net of the expiration for prior year capital losses) and valuation

allowances recorded on net operating losses expected in the Company's foreign subsidiaries. Management believes that it is not more likely than not that the Company will generate enough capital gains to absorb the additional capital losses generated during the year. The valuation allowances in place for foreign subsidiaries are due to lack of sufficient positive evidence to realize the deferred tax assets associated with the net operating losses in each country.

Stock-Based Compensation

We follow ASC Topic 718, *Compensation—Stock Compensation* (ASC 718), in accounting for our stock-based awards. ASC 718 establishes accounting for stock-based awards exchanged for employee services. Accordingly, stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the life of the grant. We calculate the fair value of the stock option grants using the Black-Scholes option pricing model. In addition, we use the straight-line (single option) method for expense attribution over the related vesting period, according to which we estimate forfeitures and only recognize expense for those shares expected to vest.

We account for equity instruments issued to non-employees in accordance with ASC 718, which requires that these equity instruments be recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest. As a result, the non-cash charge to operations for non-employee options with vesting criteria is affected each reporting period by changes in the fair value of our common stock.

The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions used for grants:

	Year Ended December 31,		
	2009	2008	2007
Risk-free interest rate	1.83% - 3.30%	1.87% - 3.57%	5.01% - 5.04%
Expected term	4.5 - 6.5 years	6.5 years	6.5 years
Estimated volatility	54% - 57%	53% - 58%	45% - 64%
Expected dividend yield	0%	0%	0%

(1) Rates for options granted during this time period varied within this range.

We do not have information available which is indicative of future exercise and post-vesting behavior to estimate the expected term. As a result, we adopted the simplified method of estimating the expected term of a stock option, as permitted by ASC 718. Under this method, the expected term is presumed to be the mid-point between the vesting date and the contractual end of the term.

As a newly-public entity, historic volatility is not available for our shares. As a result, we estimated volatility based on a peer group of companies, which collectively provides a reasonable basis for estimating volatility. We intend to continue to consistently use the same group of publicly traded peer companies to determine volatility in the future until sufficient information regarding volatility of our share price becomes available or the selected companies are no longer suitable for this purpose.

The risk-free interest rate is based on the implied yield available on U.S. Treasury zero-coupon issues with a remaining term approximately equal to the expected life of our stock options. The estimated pre-vesting forfeiture rate is based on our historical experience.

We recorded non-cash stock-based compensation expense for employee and non-employee stock option grants of $3.7 million, $2.6 million and $1.9 million during the years ended December 31, 2009, 2008, and 2007, respectively. Based on stock options outstanding as of December 31, 2009, we had unrecognized stock-based compensation of $8.7 million. We expect to continue to grant stock options in the future, and to the extent that we do, our actual stock-based compensation expense recognized in future periods will likely increase.

As of December 31, 2009, after giving effect to the for 1.00 for 7.15 reverse stock split of our common stock, we had outstanding vested options to purchase 1,577,043 shares of our common stock and unvested options to purchase 1,403,453 shares of our common stock with an intrinsic value of approximately $10.4 million and $5.0 million, respectively, based on the fair market value determined at the time of grant.

Significant Factors Used in Determining Fair Value of Our Common Stock

The fair value of the shares of common stock that underlie the stock options we have granted has historically been determined by our board of directors based upon information available to it at the time of grant. Because, prior to our initial public offering, there had been no public market for our common stock, our board of directors had determined the fair value of our common stock by utilizing, among other things, contemporaneous valuation studies conducted as of April 30, 2006 and June 30, 2007. The findings of these valuation studies were based on our business and general economic, market and other conditions that could be reasonably evaluated at that time. The analyses of the valuation studies incorporated extensive due diligence that included a review of our company, including its financial results, business agreements, intellectual property and capital structure. The valuation studies also included a thorough review of the conditions of the industry in which we operate and the markets that we serve. The methodologies of the valuation studies included an analysis of the fair market value of our company using three widely accepted valuation methodologies: (1) market multiple, (2) comparable transactions, and (3) discounted cash flow. These valuation methodologies were based on a number of assumptions, including our future revenues and industry, general economic, market and other conditions that could reasonably be evaluated at the time of the valuation.

The market multiple methodology involved the multiplication of revenues by risk-adjusted multiples. Multiples were determined through an analysis of certain publicly traded companies, which were selected on the basis of operational and economic similarity with our principal business operations. Revenue and cash flow multiples, when applicable, were calculated for the comparable companies based upon daily trading prices. A comparative risk analysis between our and the public companies formed the basis for the selection of appropriate risk-adjusted multiples for our company. The risk analysis incorporated factors that relate to, among other things, the nature of the industry in which we and other comparable companies are engaged. The comparable transaction methodology also involved multiples of earnings and cash flow. Multiples used in this approach were determined through an analysis of transactions involving controlling interests in companies with operations similar to our principal business operations. The discounted cash flow methodology involved estimating the present value of the projected cash flows to be generated from the business and theoretically available to the capital providers of our company. A discount rate was applied to the projected future cash flows to reflect all risks of ownership and the associated risks of realizing the stream of projected cash flows. Since the cash flows were projected over a limited number of years, a terminal value was computed as of the end of the last period of projected cash flows. The terminal value was an estimate of the value of the enterprise on a going concern basis as of that future point in time. Discounting each of the projected future cash flows and the terminal value back to the present and summing the results yielded an indication of value for the enterprise. Our board of directors took these three approaches into consideration when establishing the fair value of our common stock.

In addition, we received input from the underwriters of our initial public offering in October 2007 with respect to valuation of our company. Based on the foregoing factors, our board of directors determined on October 22, 2007 to increase the fair value of our common stock to $2.75 (without giving effect to the 1.00 for 7.15 reverse stock split that occurred in conjunction with completion of our initial public stock offering, or $19.66 after giving effect to such reverse stock split). The valuation carried out by our board of directors in October 2007, which, as mentioned above, already took into consideration input from the underwriters, was based not only on our results for the nine months

ended September 30, 2007 but also on our expected growth rates for certain periods of time, including for the fourth quarter of that year and for 2008. Results for the fourth quarter of 2007 and, subsequently, for the first quarter of 2008, reflected growth rates lower than the ones projected and used in the valuation carried out in October 2007. As a result, even though revenues increased in 2007 when compared to 2006, our board of directors determined that this increase was not sufficient to cause a change in the estimated fair market value of our common stock. Our valuation also did not increase, in part, due to the general decline in prices for public companies during this time period. In addition, until June 2, 2008, we were subject to an FCPA investigation that impaired our future prospects, both as a result of potential criminal charges and monetary fines and as a result of potential significant limitations on our business. Once the FCPA investigation was concluded as a result of the Deferred Prosecution Agreement we entered into with the Department of Justice, these potential impediments to the growth of our business were resolved. In addition, shortly thereafter, we became aware that our second-quarter results would achieve higher growth rates. Based on the foregoing factors, our board of directors determined to proceed with filing of the Registration Statement on June 20, 2008. In addition, our board of directors then determined that all commitments to grant stock options entered into between June 21, 2008 and December 31, 2008, would contain an exercise price equal to the actual initial public offering price, unless the initial public offering was not consummated by December 31, 2008, in which case the options would be granted on that date and would contain an exercise price that was based on the fair market value of our common stock determined by our board of directors for such date. The exercise price for all stock option grants was determined as of December 31, 2008, the date of grant, based on the estimated fair value of our common stock on that date, and not during the period in which we had solely a contractual commitment to grant such options upon occurrence of a pre-determined event that established the price. Accordingly, as of December 31, 2008, our board of directors confirmed that the fair market value of our common stock on that date remained at $2.75 (without giving effect to the 1.00 for 7.15 reverse stock split that occurred in conjunction with completion of our initial public stock offering, or $19.66 after giving effect to such reverse stock split), based on the methodologies previously used by the board and additional informal input received from the underwriters of our initial public offering with respect to their views of industry, general economic, market and other conditions. Even though we experienced an increase in revenue and other positive developments, such as receiving CE Mark clearance for the *AMPLATZER* Cardiac Plug in December 2008 and approval in Japan for the *AMPLATZER* Duct Occluder in December 2008, the recent economic recession and related substantial decrease in equity valuations of public companies in the United States offset these positive developments in our business and operations. For these reasons, our board of directors determined the fair market value of our common stock had not changed. Stock options that have been granted from December 31, 2008 to completion of the Company's initial public stock offering in October 2009 have the same exercise price. Stock options granted after completion of the Company's initial public stock offering are granted with an exercise price equal to market price of the Company's stock at the date of grant.

Common Stock Valuation Information on stock options granted is summarized as follows:

Date of Issuance	Number of Options Granted	Exercise Price	Grant Date Fair Value
April 27, 2006	1,615,801	$7.15	$7.15
May 19, 2006 to May 29, 2007	697,190	$7.15	$7.15
May 30, 2007 to October 22, 2007	292,302	$14.30	$14.23
October 23, 2007 to October 25, 2009	705,577	$19.66	$19.66
October 26, 2009 to December 31, 2009	113,045	$13.45 to $14.50	$13.45 to $14.50

Results of Operations

The following table sets forth, for the periods indicated, our results of operations expressed as a percentage of net sales.

(% of net sales)	Year Ended December 31, 2009	2008	2007
Net sales	100.0%	100.0%	100.0%
Cost of goods sold	15.7	16.0	15.5
Gross profit	84.3	84.0	84.5
Operating expenses:			
Selling, general and administrative	49.8	39.3	34.1
Research and development	17.7	19.6	18.0
Amortization of intangible assets	10.1	9.3	10.3
Change in purchase consideration	(0.5)	—	—
FCPA settlement	—	—	1.4
Operating income	7.2	15.8	20.7
Investment loss	(1.2)	(0.7)	(0.5)
Interest income	—	0.1	0.3
Interest expense	(8.6)	(9.9)	(14.4)
Other income, net	1.6	0.4	0.6
Income (loss) before income taxes	(1.0)	5.7	6.7
Income tax (benefit) expense	(0.4)	0.2	2.6
Net income (loss)	(0.6)	5.5	4.1
Less Series A and Series B preferred stock and Class A common stock dividends	(7.1)	(10.2)	(10.4)
Net loss applicable to common stockholders	(7.7)%	(4.7)%	(6.3)%

Year Ended December 31, 2009 Compared to Year Ended December 31, 2008

Net sales. Net sales for the year ended December 31, 2009 increased 19.1% to $198.7 million from $166.9 million for the same period in 2008. Our family of *AMPLATZER* Septal Occluder devices represented 54.1% of net sales for the year ended December 31, 2009 and 58.5% of net sales for the year ended December 31, 2008, *AMPLATZER* PFO Occluder devices represented 15.3% and 12.1% of net sales for the year ended December 31, 2009 and 2008, respectively. Vascular devices represented 7.4% of net sales for the year ended December 31, 2009 and 6.0% of net sales for the year ended December 31, 2008. All other devices represented 11.4% and 12.0% of net sales for the year ended December 31, 2009 and 2008, respectively. Accessories, including delivery systems, represented 11.8% and 11.4% of net sales for the year ended December 31, 2009 and 2008, respectively. Of the total $31.8 million increase in net sales, $25.7 million was derived from international product sales which represented an increase of 26.0% compared to international product sales for the same period in 2008 and $6.1 million was derived from increased U.S. product sales, which represented an increase of 8.9% compared to U.S. product sales for the same period in 2008. These increases were offset in part by decreases in freight revenue, restocking fees and adjustments to sales return reserves. The $31.8 million increase in international and U.S. product sales were primarily due to $27.6 million derived from higher average selling prices, mainly as a result of the previously-mentioned conversion of distribution rights in January 2009, which allowed us to sell directly to our customers and therefore increase our average selling prices, an increase of $7.3 million derived from higher sales volume of device and accessories units, which included an increase of $3.1 million derived from the launch of new products, and due to changes in product and geographic mix. These increases were partially offset by the effects of the

appreciation of the U.S. dollar against foreign currencies on our international product sales. U.S. net sales and international net sales represented 37.3% and 62.7%, respectively, of our total net sales for the year ended December 31, 2009, compared to 40.8% and 59.2%, respectively, for the same period in 2008. The increase in international net sales as a percentage of total net sales was mainly attributable to higher average selling prices internationally due to the acquisitions of distribution rights from former distributors in January 2009. International direct net sales represented 69.2% and 41.1% of total international net sales for the years ended December 31, 2009 and 2008, respectively. This increased percentage of direct international sales was also mainly attributable to the January 2009 conversion of certain former distributors in Europe to direct operations.

Cost of goods sold. Cost of goods sold for the year ended December 31, 2009 increased 17.3% to $31.2 million from $26.6 million for the same period in 2008. This increase in cost of goods sold was partly attributable to $3.7 million of costs associated with the repurchase of inventory from former distributors whose distribution rights were acquired in January 2009. This represented an increase of $1.9 million from $1.8 million for a similar charge recorded in 2008. Additionally, $2.7 million of higher cost of goods was derived from higher volume of units sold. Excluding the $3.7 million and $1.8 million attributable to higher cost of repurchased inventory for 2009 and 2008 respectively, cost of goods sold as a percentage of net sales for the year ended December 31, 2009 would have been 13.8% compared to 14.9% for the same period in 2008. Gross margins increased to 84.3% for the year ended December 31, 2009 from 84.0% for the year ended December 31, 2008. Excluding the $3.7 million and $1.8 million of repurchased inventory charges in 2009 and 2008 respectively, gross margins for the year ended December 31, 2009 improved to 86.2% from 85.1% during the same period in 2008. In addition, a stronger dollar during the year ended December 31, 2009 impacted gross margins versus the same period in 2008. Excluding the impact of currency and holding everything else constant, gross margins would have been 84.5% for the year ended December 31, 2009 versus 84.0% for the same period in 2008.

Selling, general and administrative. Selling, general and administrative expenses for the year ended December 31, 2009 increased 50.6% to $98.9 million from $65.7 million for the same period in 2008. This increase was primarily due to a $18.3 million increase in costs related to expanding our direct sales force in several European countries, a $8.4 million increase in ongoing investments in domestic and international corporate infrastructure and a $6.6 million increase in legal expenses associated with litigation and patent defense costs. Our investment in corporate infrastructure includes customer service, finance, information systems, human resources, regulatory and legal. As we continue to grow, we will be required to invest in corporate infrastructure to support our business. We have increased our international direct sales force over the past three years, which naturally caused an increase in the number of employees and infrastructure required to support our operations. In addition, we have added similar infrastructure at our U.S. headquarters to support larger U.S. and international operations. As a percentage of net sales, our selling, general and administrative expenses for the year ended December 31, 2009 increased to 49.8% compared to 39.3% for the same period in 2008.

Research and development. Research and development expenses for the year ended December 31, 2009 increased 7.4% to $35.2 million from $32.8 million for the same period in 2008. This increase was primarily attributable to a $2.1 million increase in payroll and related costs derived from an increase in headcount to support both our pre-clinical and development efforts, and clinical trials. As a percentage of net sales, our research and development expenses for the year ended December 31, 2009 decreased to 17.7% from 19.6% for the same period in 2008.

Amortization of intangible assets. Amortization expenses for the year ended December 31, 2009 increased 29.4% to $20.1 million compared to $15.5 million for the same period in 2008. As a percentage of net sales, amortization of intangible assets for the year ended December 31, 2009 increased to 10.1% from 9.3% for the same period in 2008. The increase is attributable to the

intangible assets purchased as part of expanding our direct sales force in several European countries, primarily associated with Italy.

Change in purchase consideration. Change in purchase consideration for the year ended December 31, 2009 included a benefit of $1.1 million derived from a reduction in the fair value of contingent payment obligations resulting from the acquisition of distribution rights from former distributors in Canada, Italy and the Netherlands based on actual and forecasted revenue assumptions for 2009.

Investment income (loss). Investment (loss) for the year ended December 31, 2009 increased to $(2.4) million from $(1.2) million for the same period in 2008, reflecting our write-off in March 2009 of our investment in a privately held early stage company that is focused on pre-clinical studies relating to the development of minimally invasive devices to treat structural heart defects.

Interest income. Interest income for the year ended December 31, 2009 decreased to $0.1 million from $0.2 million for the same period in 2008, mainly as a result of reduced levels of cash, short-term investment balances, and lower interest rates.

Interest expense. Interest expense for the year ended December 31, 2009 increased 4.4% to $17.2 million from $16.5 million for the same period in 2008. The $17.2 million includes $2.7 million for write-off of the unamortized debt discount on the $50.0 million subordinated debt paid with the proceeds from the public offering in October 2009. Excluding the write-off of the unaccreted discount on the $50.0 million of subordinated debt, interest expense for the year was $14.5 million, a decrease of 11.8% over the same period in 2008. The decrease in interest expense reflects our lower average interest rate for the year ended December 31, 2009, which was partially offset by additional borrowings under our revolving credit agreement and the issuance of the 2009 notes, as well as the addition of accreted interest charges on future guaranteed obligations payable to the distributors acquired in January 2009 as part of expanding our direct sales force in several European countries.

Other income, net. Other income, net for the year ended December 31, 2009 increased to $3.2 million from $0.7 million for the same period in 2008, mainly as a result of a fourth quarter benefit of $1.9 million as a payment received as restitution for damages suffered by the company in the shareholder dispute that was settled in 2005. We also had an increase in foreign exchange gains of $0.6 million.

Income taxes. Income tax expense (benefit) for the year ended December 31, 2009 reflected a benefit of $0.8 million as compared to a $0.4 million expense for the same period in 2008, based on lower pre-tax income, purchase accounting related to the January 2009 acquisitions of distribution rights from former distributors, and the write-off in 2009 of our investment in a privately held early stage company that is focused on pre-clinical studies relating to the development of minimally invasive devices to treat structural heart defects.

Net income (loss). Net (loss) for the year ended December 31, 2009 was $(1.1) million as compared to net income of $9.1 million for the same period in 2008.

Year Ended December 31, 2008 Compared to Year Ended December 31, 2007

Net sales. Net sales for 2008 increased 13.3% to $166.9 million from $147.3 million for 2007. Excluding the favorable effect to net sales in 2007 of $1.3 million in reductions to our product returns reserve resulting from a change in our product returns policy, net sales would have increased $20.9 million, or 14.3%. Our family of *AMPLATZER* Septal Occluder devices represented 58.7% and 61.7% of net sales for 2008 and 2007, respectively, *AMPLATZER* PFO Occluder devices represented 12.0% and 13.2% of net sales for 2008 and 2007, respectively, all other devices represented 17.9% and 14.5% of net sales for 2008 and 2007, respectively, and accessories, including delivery systems,

represented 11.4% and 10.6% of net sales for 2008 and 2007, respectively. Of the total $20.9 million increase in net sales (after excluding the effect to net sales resulting from our change in product returns policy), $14.0 million derived from increased international product sales in 2008, which represented an increase of 16.5% over 2007, and $6.9 million derived from increased U.S. product sales, which represented an increase of 11.4%, offset in part by decreases in freight revenue, restocking fees and adjustments to sales return reserves. The increases in international and U.S. product sales were primarily due to an increase of $13.3 million derived from higher sales volume of device and accessories units, which include an increase of $2.6 million derived from the launch of new products and an additional increase of $7.1 million derived from higher average selling prices (including as a result of changes to product mix). U.S. net sales and international net sales represented 40.8% and 59.2%, respectively, of our net sales for 2008, compared to 42.1% and 57.9%, respectively, for 2007. International direct net sales represented 40.8% and 38.2% of total international net sales for 2008 and 2007, respectively, while international distributor net sales represented 59.2% and 61.8%, respectively, of total international net sales.

Cost of goods sold. Cost of goods sold for 2008 increased 16.7% to $26.6 million from $22.8 million for 2007. This increase in cost of goods sold was attributable primarily to an increase of $3.0 million derived from higher volume of units sold and an increase of $1.8 million derived from higher purchased inventory values as a result of the April and July 2008 acquisitions of the distribution rights from our former Spanish and Polish distributors, which were partially offset by a $1.1 million decrease due to increased manufacturing efficiencies. As a percentage of net sales, cost of goods sold in 2008 increased to 16.0% from 15.5% for 2007. As a result, gross margins decreased to 84.0% in 2008 from 84.5% for 2007.

Selling, general and administrative. Selling, general and administrative expenses for 2008 increased 30.8% to $65.7 million from $50.2 million for 2007. This increase was primarily due to a $4.9 million increase in costs related to expanding our direct sales force in several European countries, a $2.6 million increase in ongoing investments in corporate infrastructure and a $5.8 million increase in legal expenses associated with litigation, patent defense costs and the FCPA investigation. As a percentage of net sales, our selling, general and administrative expenses for 2008 increased to 39.3% compared to 34.1% for 2007.

Research and development. Research and development expenses for 2008 increased 23.4% to $32.8 million from $26.6 million for 2007. This increase was primarily attributable to a $3.7 million increase in payroll and related costs derived from an increase in headcount to support both our pre-clinical and development efforts and a $2.7 million increase derived from higher clinical trial expenses. As a percentage of net sales, our research and development expenses for 2008 increased to 19.6% from 18.0% for 2007.

Amortization of intangible assets. Amortization expenses for 2008 increased 2.0% to $15.5 million compared to $15.2 million for 2007. As a percentage of net sales, amortization of intangible assets for 2008 decreased slightly to 9.3% from 10.3% for 2007.

Investment income (loss). Investment (loss) for 2008 increased to $(1.2) million from $(0.8) million for 2007, reflecting our prorated share of the losses incurred in our investment in a privately held early stage company that is focused on pre-clinical studies relating to the development of minimally invasive devices to treat structural heart defects.

Interest income. Interest income for 2008 decreased to $0.2 million from $0.4 million for 2007, mainly as a result of reduced levels of cash and short-term investment balances.

Interest expense. Interest expense for 2008 decreased 22.3% to $16.5 million from $21.2 million for 2007. This decrease in interest expense reflects lower weighted-average effective interest rates on

our Tranche B term loan facility for 2008 of 5.1% as compared to 7.4% for 2007. The decrease in the effective weighted-average interest rate is due to the decrease in LIBOR.

Other income net. Other income, net for 2008 decreased to $0.7 million from $1.0 million for 2007, mainly as a result of a decrease of foreign exchange gains.

Income taxes. Income tax expense for 2008 decreased to $0.4 million from $3.8 million for 2007. This decrease is primarily the result of a $2.4 million reduction in our income tax contingency accrual as a result of the expiration of the applicable statutes of limitations, lower pre-tax income, and a decrease in the effective tax rate to 29.4% in 2008 from 38.7% in 2007, prior to this reduction in our income tax contingency accrual. See note 7 to our consolidated financial statements.

Net income. Net income for 2008 increased 49.7% to $9.1 million from $6.1 million for 2007.

Liquidity and Capital Resources

Our principal sources of liquidity are existing cash, including cash generated from our initial public offering to the extent it was not used to repay our indebtedness, internally generated cash flow and borrowings under our senior secured credit facility. We believe that these sources will provide sufficient liquidity for us to meet our liquidity requirements for the next 12 months. Our principal liquidity requirements are to service our debt and to meet our working capital, research and development, including clinical trials, and capital expenditure needs. We may, however, require additional liquidity as we continue to execute our business strategy. We anticipate that to the extent that we require additional liquidity, it will be funded through the incurrence of indebtedness, additional equity financings or a combination of these potential sources of liquidity. We cannot assure you that we will be able to obtain this additional liquidity on reasonable terms, or at all. Additionally, our liquidity and our ability to fund our capital requirements are also dependent on our future financial performance, which is subject to general economic, financial and other factors that are beyond our control, including those described in Item 1A Risk Factors and Item 3 Legal Proceedings of this Form 10-K. Accordingly, we cannot assure you that our business will generate sufficient cash flow from operations or that future borrowings will be available under our senior secured credit facility or otherwise to meet our liquidity needs.

Cash Flows

Cash Flows Provided By Operating Activities

Net cash provided by operating activities for 2009 decreased to $10.9 million from $18.8 million for 2008. This decrease compared to the prior period was primarily attributable to the following changes in cash flows for 2009 compared to 2008: a $10.2 million decrease in net income, a $14.4 million increase in accounts receivable (mainly attributable to our acquisitions of distribution rights from former distributors in Italy, France, Portugal, Poland, Canada and the Netherlands in January 2009), a $3.7 million decrease in accrued expenses, a $1.1 million benefit in change in purchase consideration (resulting from a reduction in the fair value of contingent payment obligations derived from the acquisition of distribution rights from former distributors in Canada, Italy and Portugal), a $1.9 million decrease in trade accounts payable and a $2.8 million increase in income tax receivable, which were partially offset by a $5.8 million increase in depreciation and amortization (resulting from increases in intangible assets resulting from our acquisitions of distribution rights from former distributors in Europe in January 2009), a $1.3 million increase in accretion of debt discount and loan origination fees, a $2.7 million write-off of unamortized discount on long-term debt in October 2009, a $1.1 million increase in losses on our equity investment in a privately held early-stage company that is focused on pre-clinical studies relating to the development of minimally invasive devices to treat structural heart defects (primarily the result of the impairment and write-off of this investment during March 2009), a

$0.3 million increase in reserves for customer returns, a $1.2 million increase in stock-based compensation relating to issuances of stock options, a $2.7 million decrease in inventory, a $5.6 million increase in current, accrued and deferred income taxes payable, a $3.5 million decrease in prepaid and other expenses, and a $2.0 million payment in connection with the FCPA settlement during 2008.

Net cash provided by operating activities for 2008 decreased to $18.8 million from $32.9 million for 2007. This decrease compared to the prior period was attributable mainly to the following changes in cash flows for 2008 compared to 2007: a $4.0 million decrease in FCPA settlement, a $0.4 million decrease in deferred income taxes, a $1.2 million increase in inventory, a $9.2 million increase in accounts receivable (mainly as a result of increased sales volumes and our conversions to direct sales in Spain and Poland in mid-year 2008) and a $0.9 million increase in reserves for customer returns (primarily as a result of higher sales volumes, including an increase of $13.3 million in net sales derived from higher sales volumes of device and accessories units), which were partially offset by a $3.0 million increase in net income a $1.0 million increase in trade accounts payable, a $0.8 million increase in depreciation and amortization and a $0.7 million increase in stock-based compensation relating to issuances of stock option grants.

Cash Flows Used In Investing Activities

Net cash used in investing activities for 2009 increased to $46.3 million from $16.7 million for 2008. This increase compared to the prior period was primarily attributable to the following changes in cash flows 2009 compared to 2008: $29.5 million used in acquisitions of distribution rights from former distributors and $1.0 million increase in purchases of property and equipment, which was partially offset by a $1.2 million incremental investment in the same period in 2008 in a privately held early-stage company that is focused on pre-clinical studies relating to the development of minimally invasive devices to treat structural heart defects and a $0.3 million increase in restricted cash.

Net cash used in investing activities for 2008 increased to $16.7 million from $11.3 million for 2007. This increase compared to the prior period was primarily attributable to the following changes in cash flows for 2008 compared to 2007: a $20.0 million decrease in net proceeds from the sale of short-term investments, $5.0 million used in connection with our April 2008 purchase of distribution rights from a former Spanish distributor, a $2.8 million increase in purchases of property and equipment, $1.1 million used in connection with our July 2008 purchase of distribution rights from a former Slovak Republic distributor and a $1.2 million incremental investment in a privately held early-stage company that is focused on pre-clinical studies relating to the development of minimally invasive devices to treat structural heart defects, which was partially offset by $14.5 million used to purchase patent rights in 2007.

Cash Flows Provided By (Used In) Financing Activities

Net cash provided by financing activities increased to $35.9 million for 2009 from $6.4 million for 2008. This increase compared to the prior period was primarily attributable to the following changes in cash flows for 2009 compared to the same period in 2008: $82.2 million resulting from the sale of common stock, $15.0 million resulting from the issuance of the 2009 notes and a $2.5 million decrease in dividends paid, which was partially offset by a $50.0 million payment of long-term debt, a $9.9 million net payment on the revolving line of credit, and a $1.6 million payment of deferred financing fees.

Net cash provided by financing activities increased to $6.4 million for 2008 from net cash used in financing activities of $16.2 million for 2007. This increase compared to the prior period was primarily attributable to the following changes in cash flows for 2008 compared to 2007: $9.9 million of proceeds from our line of credit and a redemption of 1.9 million shares of Class A common stock (after giving effect to the 1.00 for 7.15 reverse stock split of our common stock effected immediately prior to completion of our initial public offering) in July 2007, which resulted in a $15.1 million payment by us to one of our stockholders. This increase was partially offset by $2.5 million of dividends paid to our stockholders in April 2008.

Cash Position and Indebtedness

On July 28, 2005, in connection with our July 2005 reorganization, our wholly-owned subsidiary AGA Medical issued $50.0 million aggregate principal amount of the 2005 notes to one of the WCAS Stockholders. The 2005 notes required semiannual interest payments, were unsecured obligations of AGA Medical and were subordinated in right of payment to our senior secured credit facility. As part of the transaction agreement, AGA Medical issued 6,524 shares of Series A preferred stock valued at $6.5 million to the WCAS Stockholders, which shares were converted to 912,447 shares of our common stock immediately prior to completion of our initial public offering. As a result, the discounted issue value of the 2005 note was $43.5 million. The $6.5 million of discount from the face value was accreted on our balance sheet to the 2005 note repayment amount utilizing the effective interest rate. The original issue discount has been recognized as interest expense of $3.4 million, $0.9 million, and $0.9 million for the years ended December 31, 2009, 2008 and 2007, respectively. In compliance with the terms of the securities purchase agreement governing the 2005 notes, we used a portion of our net proceeds from our initial public offering to prepay these notes at a price equal to 100% of their face principal amount plus accrued and unpaid interest. The interest expense for the year of $3.4 million includes $2.7 million write-off of the unamortized debt discount that remained upon extinguishment.

On April 28, 2006, we completed a $240.0 million recapitalization, in connection with which we entered into our senior secured credit facility, which consists of a $215.0 million seven-year Tranche B term loan facility and a $25.0 million revolving credit facility. The revolving credit facility matures on July 28, 2011, and the Tranche B term loan facility matures on April 28, 2013. As of December 31, 2009, we had no outstanding borrowings under our revolving credit facility and $197.0 million outstanding under our Tranche B term loan facility. We currently have $25.0 million availability under our revolving credit facility. On October 5, 2008, Lehman Commercial Paper Inc. ("LCPI") filed for protection under Chapter 11 of the Federal Bankruptcy Code. LCPI had committed to provide $9.5 million under the $25.0 million revolving credit facility. In March 2009 Bank of America, N.A. assumed the participation of this credit agreement previously held by LCI.

On January 5, 2009, in order to finance, in part, the acquisition of the assets of our former Italian distributor, AGA Medical issued to one of the WCAS Stockholders for an aggregate purchase price of $15.0 million (1) $15.0 million in aggregate principal amount of the 2009 notes, and (2) 1,879 shares of Series B preferred stock valued at $1.9 million, which shares were converted to 95,562 shares of our common stock immediately prior to completion of our initial public offering. The 2009 notes are fully and unconditionally guaranteed by Amplatzer Medical Sales Corporation, our wholly-owned subsidiary. The discounted issue value of the subordinated note is $13.1 million. The $1.9 million of discount from the face value is being accreted on our balance sheet to the 2009 note repayment amount utilizing the effective interest rate. The original issue discount has been recognized as interest expense of $0.5 million for year ended December 31, 2009. As of December 31, 2009, the accreted value of our outstanding 2009 notes on our balance sheet was $13.6 million. Interest on the senior subordinated note is payable on a semiannual basis in arrears on January 1 and July 1 of each year. The effective interest rate of the 2009 notes at December 31, 2009 was 14.7%, compounded semiannually.

On October 26, 2009, we completed our initial public offering of 13,750,000 shares of common stock for cash consideration of $13.5575 per share (net of underwriting discounts) to a syndicate of underwriters led by Merrill Lynch, Pierce, Fenner & Smith Incorporated, Citigroup Global Markets Inc., Deutsche Bank Securities Inc., Leerink Swann LLC and Wells Fargo Securities, LLC as the joint book-running managers for the offering. The other underwriter in the syndicate was Natixis Bleichroeder Inc. We issued and sold 6,509,000 shares of our common stock in the offering and received net proceeds of approximately $82.2 million. For a description of the use of proceeds from our initial public offering, refer to Item 5 Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities under the subheading "Use of Proceeds."

Our total indebtedness was $222.3 million at December 31, 2009, $253.4 million at December 31, 2008, and $243.6 million at December 31, 2007.

The following table sets forth the amounts outstanding under our Tranche B term loan facility and our revolving credit facility, the effective interest rates on such outstanding amounts and amounts available for additional borrowing thereunder as of December 31, 2009.

Senior Secured Credit Facility	Effective Interest Rate	Amount Outstanding	Amount Available for Additional Borrowing
		(dollars in millions)	
Revolving Credit Facility	2.50%	$ —	$25.0
Tranche B Term Loan Facility	2.28%	197.0	—
Total		$197.0	$25.0

Following the end of each fiscal year, our Tranche B term loan facility requires us to make an annual prepayment of the term loan facility equal to 50% of any excess cash flow for any fiscal year for which the leverage ratio at the end of such fiscal year is greater than 4.50 to 1.00, 25% of excess cash flow for any fiscal year for which the leverage ratio at the end of such fiscal year is less than or equal to 4.50 to 1.00 and greater than 4.00 to 1.00, and none of excess cash flow for any fiscal year for which the leverage ratio at the end of such fiscal year is less than or equal to 4.00 to 1.00. The leverage ratio is defined as the ratio of total indebtedness on such date to Consolidated EBITDA (as defined in the credit agreement) for the four most recent consecutive fiscal quarters ended prior to such date. Consolidated EBITDA is defined under our senior secured credit facility as EBITDA further adjusted to give effect to unusual non-recurring items, non-cash items and certain other adjustments. These adjustments include items such as patent litigation defense costs and settlements, FCPA-related costs and product recalls.

Our senior secured credit facility also places certain restrictions on us, including restrictions on our ability to incur indebtedness, grant liens, pay dividends, sell all of our assets or any subsidiary, use funds for capital expenditures, make investments, make optional payments or modify debt instruments, or enter into sale and leaseback transactions. Our senior secured credit facility also requires us to maintain compliance with specified financial covenants. As of December 31, 2009, we were in compliance with all of our financial covenants specified in our senior secured credit facility. If we are required to accrue a charge relating to, or post an appeal bond in connection with, the Medtronic litigation, we may not be able to comply with the covenants contained in our senior secured credit facility in future periods. While we do not believe that accruing a charge and/or posting an appeal bond in connection with the Medtronic litigation will cause us to breach any such covenant, doing so may adversely affect our ability to comply with our maintenance covenants in our senior secured credit facility. If we breached any such covenant, we would need to seek to amend or refinance our senior secured credit facility. We believe that such an amendment could require us to pay upfront fees and an increased interest rate on our borrowings thereunder, which could materially adversely affect our financial condition and results of operations. Alternatively, we could refinance our senior secured credit facility, but we may not be able to do so on reasonable terms or at all. If we fail to obtain such an amendment or refinancing, we would suffer an event of default under such facility and the lenders thereto would have the right to accelerate the indebtedness outstanding thereunder. In addition, the lenders' obligations to extend letters of credit or make loans under our senior secured credit facility are dependent upon our ability to make our representations and warranties thereunder at the time such letters of credit are extended or such loan is made. If we are unable to make the representations and warranties in our senior secured credit facility at such time, we will be unable to borrow additional amounts under our senior secured credit facility in the future.

The indebtedness under our senior secured credit facility is secured by a perfected first priority security interest in all of our tangible and intangible assets (including, without limitation, intellectual property, owned real property and all of our capital stock and each direct and indirect subsidiaries, provided that no assets of any foreign subsidiary is included as collateral and no more than 65% of the voting stock of any first-tier foreign subsidiary is required to be pledged).

Contractual Obligation and Commitments

The following table summarizes our outstanding contractual obligations as of December 31, 2009:

		Payments Due by Year			
(in millions)	Total	2010	2011-2012	2013-2014	2015 and Thereafter
Tranche B Term Loan Facility	$197.0	$ —	$ —	$197.0	$ —
Revolving Credit Facility	—	—	—	—	—
Operating leases	5.6	1.7	1.8	1.2	0.9
Royalty obligations(1)	2.3	2.3	—	—	—
Former France Distributor Obligations(2)	1.5	1.5	—	—	—
Former Portugal Distributor Obligations(3)	0.8	0.8	—	—	—
Former Netherlands Distributor Obligations(4)	0.3	0.3	—	—	—
Former Canada Distributor Obligations(5)	0.8	0.8	—	—	—
Former Italy Distributor Obligations(6)	13.8	4.4	9.4	—	—
Senior Subordinated Notes	15.0	—	15.0	—	—
Total contract obligation and commitments	$237.1	$11.8	$26.2	$198.2	$0.9

(1) We have made and expect to continue making royalty payments under two royalty agreements relating to patented technology assigned to us, namely: (1) a royalty-bearing research-related agreement with Dr. Kurt Amplatz, our founder, under which we pay Dr. Amplatz a fixed percentage of royalties on products of ours that incorporate current and future patented technology developed by Dr. Amplatz and assigned to us under the agreement; and (2) royalty-payment agreements with Curtis Amplatz, Dr. Amplatz's son, under which we pay Curtis Amplatz a fixed percentage of royalties throughout the life of certain of our patents for which Curtis Amplatz is the named inventor. These agreements obligate us to pay royalties on specific product sales and are payable throughout the life of the patents. These payments will be variable because they depend on future product sales.

(2) As of December 31, 2009, we had a $1.5 million discounted contingent obligation due January 2010 to our former France distributor related to achievement of certain revenue goals.

(3) As of December 31, 2009, we had a $0.8 million discounted contingent obligation due January 2010 to our former Portugal distributor related to achievement of certain revenue goals

(4) As of December 31, 2009, we had a $0.3 million discounted contingent obligation due January 2010 to our former Netherlands distributor related to achievement of certain revenue goals.

(5) As of December 31, 2009, we had a $0.8 million discounted contingent obligation due January 2010 to our former Canada distributor related to achievement of certain revenue goals.

(6) As of December 31, 2009, we had a $3.1 million obligation due January 2010, and a $1.3 million discounted contingent obligation due January 2010, in each case, to our former Italy distributor related to achievement of certain revenue goals. In addition, we had $6.7 million in obligations ($7.2 million without giving effect to the discount) due in each of 2011 and 2012, and $2.7 million

in discounted contingent obligations ($3.3 million without giving effect to the discount) due in each of 2011 and 2012 if certain revenue goals are achieved.

In addition, we have agreements with clinical sites and contract research organizations for the conduct of our clinical trials. We make payments to these sites and organizations based upon the number of patients enrolled and the period of follow-up in the trials.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Seasonality

While our results of operations are not materially affected by seasonality, our net sales are affected by holiday and vacation periods, especially in the third quarter in Europe.

Information Regarding Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. Such "forward-looking" information is included in this Form 10-K, including this Item 7, as well as in other materials filed or to be filed by us with the Securities and Exchange Commission (as well as information included in oral statements or other written statements made or to be made by the Company).

This Form 10-K contains forward-looking statements that involve risks and uncertainties. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve known and unknown risks, uncertainties and other factors that may cause our results or our industry's actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Forward-looking statements are only predictions and are not guarantees of performance. These statements are based on our management's beliefs and assumptions, which in turn are based on currently available information. Our forward-looking statements in this Form 10-K generally relate to the following:

- our belief with respect to our competitive position in our industry and our ability to leverage that position and our experience to expand our business;
- our estimates with respect to market opportunities, including addressable patient populations, for the devices we manufacture and sell and those we intend to develop;
- our expectations, plans and assumptions with respect to our clinical trials and regulatory submissions;
- our expectations with respect to the outcome of material litigation and our potential responses to such outcome;
- our beliefs with respect to the competitive advantages of our products;
- our intentions with respect to growing our business through product line extensions and the development of new products;
- our plans and beliefs with respect to international growth opportunities;

- our plans regarding converting our distribution to direct sales representation;
- our plans and expectations with respect to continued investment in research and development and manufacturing;
- our intention to establish manufacturing operations in Europe;
- our expectations with respect to future sales and marketing and research and development expenses; and
- our beliefs with respect to the adequacy of our cash flow

Forward-looking statements are only predictions and are not guarantees of performance. These statements are based on our management's beliefs and assumptions, which in turn are based on currently available information. Important assumptions relating to the forward-looking statements include, among others, assumptions regarding demand for our products, the expansion of product offerings geographically, the timing and cost of planned capital expenditures, competitive conditions and general economic conditions. These assumptions could prove inaccurate. Forward-looking statements also involve known and unknown risks and uncertainties, which could cause actual results that differ materially from those contained in any forward-looking statement. Many of these factors are beyond our ability to control or predict. Such factors include, but are not limited to, the following:

- our ability to continue to innovate and maintain scientifically advanced technology;
- our ability to obtain and maintain regulatory approvals;
- our ability to attract and retain skilled scientific and sales personnel;
- our ability to obtain and enforce intellectual property protection;
- the outcome of pending material litigation and any future material litigation;
- our ability to cost effectively manufacture and successfully market our products; and
- other factors discussed under "Risk Factors" or elsewhere in this Form 10-K.

These important factors include those that we discuss under Item 1A "Risk Factors." You should read these risk factors and the other cautionary statements made in this Form 10-K as being applicable to all related forward-looking statements wherever they appear in this Form 10-K. We cannot assure you that the forward-looking statements in this Form 10-K will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, if at all. Other than as required by law, we undertake no obligation to update these forward-looking statements, even though our situation may change in the future.

Recent Accounting Pronouncements

In September 2009, the Company adopted the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") Topic 105 as the single official source of authoritative, nongovernmental generally accepted accounting principles in the United States. On the effective date, all the then-existing non-SEC accounting literature and reporting standards were superseded and deemed nonauthoritative. The adoption of this pronouncement did not have a material impact on the Company's consolidated financial statements; however, the ASC affected the way the Company references authoritative guidance in its consolidated financial statements.

In 2009, the Company adopted the provisions of ASC Topic 855, *Subsequent Events* ("ASC 855"), which was effective for interim and annual periods after June 15, 2009 and amended on February 24,

2010. This Statement incorporates guidance into accounting literature that was previously addressed only in auditing standards. The statement refers to subsequent events that provide additional evidence about conditions that existed at the balance-sheet date as "recognized subsequent events." Subsequent events which provide evidence about conditions that arose after an issuer's most recent balance-sheet date but prior to the issuance of its most recent financial statements are referred to as "non-recognized subsequent events." It also requires companies to evaluate subsequent events through the date the financial statements were issued.

In April 2009, the FASB issued additional guidance, ASC Topic 825 (ASC 825) under which disclosures about fair value of financial instruments are required for interim reporting periods of publicly traded companies as well as in annual financial statements. The guidance requires disclosures in summarized financial information at interim reporting periods and is effective for interim and annual reporting periods ending after June 15, 2009. The Company adopted ASC Topic 825 during the three months ended June 30, 2009. The implementation of ASC Topic 825 did not have a material impact on the Company's consolidated financial statements.

In March 2008, the FASB issued additional guidance on derivative instruments and hedging activities disclosure in ASC Topic 815 (ASC 815). ASC Topic 815 applies to all derivative instruments and non-derivative instruments that are designated and qualify as hedging instruments and related hedged items. The provisions of ASC Topic 815 requires entities to provide greater transparency through additional disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS 133 and its related interpretations and (c) how derivative instruments and related hedged items affect an entity's financial position, results of operations and cash flows. The Company adopted ACS Topic 815 effective January 1, 2009. The adoption of this statement did not have a material effect on the Company's consolidated financial statements.

In December 2007, the FASB issued additional guidance on business combinations contained in ASC Topic 805 (ASC 805) and additional guidance on noncontrolling interests in consolidated financial statements contained in ASC Topic 810, which are effective for fiscal years beginning after December 15, 2008. These new standards represent the completion of the FASB's first major joint project with the International Accounting Standards Board and are intended to improve, simplify and converge internationally the accounting for business combinations and the reporting of noncontrolling interests (formerly minority interests) in consolidated financial statements.

ASC Topic 805 changes the method for applying the acquisition method in a number of significant respects, including the requirement to expense transaction fees and expected restructuring costs as incurred, rather than including these amounts in the allocated purchase price; the requirement to recognize the fair value of contingent consideration at the acquisition date, rather than the expected amount when the contingency is resolved; the requirement to recognize the fair value of acquired in-process research and development assets at the acquisition date, rather than immediately expensing; and the requirement to recognize a gain in relation to a bargain purchase price, rather than reducing the allocated basis of long-lived assets. The Company adopted these standards effective January 1, 2009. The new presentation and disclosure requirements for pre-existing non-controlling interests are retroactively applied to all prior period financial information presented. See note 14 ("Fair Value Measurements") for further discussion of the impact the adoption of ASC Topic 805 had on the Company's results of operations and financial conditions as a result of its acquisitions in the first quarter 2009.

In September 2006, the FASB issued ASC Topic 820 (ASC 820), which defines fair value, establishes a framework for the measurement of fair value and enhances disclosure about fair value measurement. The statement does not require any new fair value measures. ASC Topic 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly

transaction between market participants at the measurement date (exit price). The provisions under ASC Topic 820 are effective for all financial assets and liabilities and for nonfinancial assets and liabilities recognized or disclosed at fair value in the Company's consolidated financial statements on a recurring basis beginning January 1, 2008 and are expected to be applied prospectively. The Company adopted the provisions of ASC Topic 820 for financial assets and liabilities that are measured at fair value for its fiscal year beginning January 1, 2008. For all other nonfinancial assets and liabilities, the Company adopted ASC Topic 820 effective beginning January 1, 2009. The adoption of this statement did not have a material effect on the Company's consolidated financial statements.

In June 2009, the FASB issued ASC Topic 860 (ASC 860) which defines accounting standards for transfers and servicing of financial assets and extinguishments of liabilities. This standard eliminates the concept of a qualifying special-purpose entity, changes the requirements for derecognizing financial assets, and requires additional disclosures. The standard will become effective in the first quarter of 2010. The Company does not expect that the adoption of this standard will have a material impact on the Company's consolidated financial statements.

In June 2009, the FASB issued ASC Topic 810 (ASC 810) which defines accounting standards on variable interest entities to address the elimination of the concept of a qualifying special purpose entity. This standard also replaces the quantitative-based risks and rewards calculation for determining which enterprise has a controlling financial interest in a variable interest entity with an approach focused on identifying which enterprise has the power to direct the activities of a variable interest entity and the obligation to absorb losses of the entity or the right to receive benefits from the entity. Additionally, it provides more timely and useful information about an enterprise's involvement with a variable interest entity. The standard will become effective in the first quarter of 2010. The Company does not expect that adoption of this standard will have a material impact on the Company's consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Foreign Exchange Risk Management

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies could adversely affect our financial results. In 2009 and in 2008, approximately $89.1 million or 44.8% and $40.6 million, or 24.3% of our net sales were denominated in foreign currencies. For sales not denominated in U.S. dollars, if there is an increase in the rate at which a foreign currency is exchanged for U.S. dollars, it will require more of the foreign currency to equal a specified amount of U.S. dollars than before the rate increase. In such cases and if we price our products in the foreign currency, we will receive less in U.S. dollars than we did before the rate increase went into effect. If we price our products in U.S. dollars and competitors price their products in local currency, an increase in the relative strength of the U.S. dollar could result in our price not being competitive in a market where business is transacted in the local currency. Based on our 2009 operations, a 10% change in foreign exchange rates would cause an increase or decrease to income before income taxes of approximately $5.0 million on an annual basis.

In the first quarter of 2009, we initiated a foreign currency hedging program. The objectives of the program are to reduce earnings volatility due to movements in foreign currency markets, limit loss in foreign currency-denominated cash flows, and preserve the operating margins of our foreign subsidiaries. We generally use foreign currency forward contracts to hedge transactions related to known inter-company sales and inter-company trades payables or notes receivable. We also may hedge firm commitments. These contracts generally relate to our European operations and are denominated primarily in euros and sterling. All of our foreign exchange contracts are recognized on the balance sheet at their fair value. We do not enter into foreign exchange contracts for speculative purposes. Amounts on our balance sheet at December 31, 2009 are immaterial.

Interest Rate Risk

We are exposed to interest rate risk in connection with our Tranche B term loan facility and any borrowings under our revolving credit facility, which bear interest at floating rates based on Eurodollar or the greater of prime rate or the federal funds rate plus an applicable borrowing margin. For variable rate debt, interest rate changes generally do not affect the fair value of the debt instrument, but do impact future earnings and cash flows, assuming other factors are held constant. We do not currently hedge our interest rate exposure and do not enter into financials instruments for trading and speculative purposes.

Based on the amount currently outstanding under our Tranche B term loan facility and our revolving credit facility, a change of one percentage point in the applicable interest rate would cause an increase or decrease in interest expense of approximately $2.0 million on an annual basis.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our financial statements and notes there to appear beginning at page 97 of this report.

Quarterly Financial Data (Unaudited)

2009	Quarter ended March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
Net sales	$ 44,420	$49,962	$50,158	$54,170
Gross profit	35,612	41,766	43,559	46,533
Net income (loss)	(6,364)	2,167	2,187	914
Series A preferred stock and Class A common stock dividends	(4,234)	(4,236)	(4,570)	(1,242)
Net income (loss) applicable to common stockholders	(10,598)	(2,069)	(2,383)	(328)
Net income (loss) per common share-basic	$ (0.49)	$ (0.10)	$ (0.11)	$ (0.01)
Net income (loss) per common share-diluted	$ (0.49)	$ (0.10)	$ (0.11)	$ (0.01)

2008	Quarter ended March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
Net sales	$36,813	$44,032	$43,638	$42,413
Gross profit	31,326	37,062	36,976	34,897
Net income	501	1,852	5,875	868
Series A preferred stock and Class A common stock dividends	(3,809)	(5,006)	(4,063)	(4,190)
Net income (loss) applicable to common stockholders	(3,308)	(3,154)	1,812	(3,322)
Net income (loss) per common share-basic	$ (0.15)	$ (0.15)	$ 0.05	$ (0.15)
Net income (loss) per common share-diluted	$ (0.15)	$ (0.15)	$ 0.04	$ (0.15)

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A(T). CONTROLS AND PROCEDURES.

Disclosure Controls

Our Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, are responsible for establishing and maintaining our disclosure controls and procedures. The Certifying Officers have reviewed and evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 240.13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934) as of December 31, 2009. Based on that review and evaluation, which included inquiries made to certain other employees of the Company, the Certifying Officers have concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures, as designed and implemented, are effective in ensuring that information relating to the Company required to be disclosed in the reports that the Company files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, including ensuring that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Limitations on Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. In addition, the design of any system of controls is based in part on certain assumptions about the likelihood of future events, and controls may become inadequate if conditions change. There can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Changes in Internal Controls

There were no changes in our internal controls over financial reporting during the fourth quarter of fiscal year 2009 that may have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Other than the information included in this Form 10-K under the heading "Executive Officers of the Registrant," which is set forth at the end of Part I, the information required by Item 10 is incorporated by reference to the sections labeled "Election of Directors," "Governance of AGA" and "Outstanding Shares and Voting Rights—Share Ownership Information," all of which appear in our definitive proxy statement for our 2010 Annual Meeting to be filed within 120 days after the end of the Company's fiscal year.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by Item 11 is incorporated herein by reference to the sections entitled "Executive Compensation," "2008 Director Compensation," and "Executive Compensation-Role of the Compensation Committee," all of which appear in our definitive proxy statement for our 2010 Annual Meeting.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

Other than as set forth below, information required by Item 12 is incorporated herein by reference to the sections entitled "Outstanding Shares and Voting Rights—Share Ownership Information" which appear in our definitive proxy statement for our 2010 Annual Meeting.

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	3,226,596	10.74	1,574,736
Equity compensation plans not approved by security holders	-0-	-0-	-0-
Total	3,226,596	10.74	1,574,736

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by Item 13 is incorporated herein by reference to the sections entitled "Governance of AGA—Independence" and "Governance of AGA—Certain Relationships and Related Transactions," which appear in our definitive proxy statement for our 2010 Annual Meeting.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by Item 14 is incorporated herein by reference to the section entitled "Report of the Audit Committee—Audit and Non-Audit Fees," which appears in our definitive proxy statement for our 2010 Annual Meeting.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a) The following exhibits and financial statements are file as part of, or are incorporated by reference into, this report:

(1) Financial Statements

The consolidated financial statements required by this item are submitted in a separate section beginning on page 97:

Report of Independent Registered Public Accounting Firm dated March 4, 2010

- Consolidated Balance Sheets as of December 31, 2009 and December 31, 2008
- Consolidated Statements of Operations for the Fiscal Years Ended December 31, 2009, December 31, 2008, and December 31, 2007
- Consolidated Statements of Stockholders' Equity for the Fiscal Years Ended December 31, 2009, December 31, 2008, and December 31, 2007
- Consolidated Statements of Cash Flows for the Fiscal Years Ended December 31, 2009, December 31, 2008, and December 31, 2007
- Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

The following financial statement schedule is filed with this Annual Report and can be found following the Notes to Consolidated Financial Statements:

- Schedule II—Valuation and Qualifying Accounts.

All other schedules have been omitted because the information required to be shown in the schedules is not applicable or is included elsewhere in the financial statements and notes thereto.

(3) Exhibits

See "Exhibit Index" following the signature page of this Form 10-K for a description of the documents that are filed as Exhibits to this report on Form 10-K or incorporated by reference herein.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 4, 2010

AGA MEDICAL HOLDINGS, INC.

By	/s/ JOHN R. BARR	By	/s/ BRIGID A. MAKES
	President and Chief Executive Officer		*Senior Vice President and Chief Financial Officer*

POWER OF ATTORNEY

Each person whose signature appears below constitutes JOHN R. BARR and BRIGID A. MAKES his true and lawful attorneys-in-fact and agents, each acting alone, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any or all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all said attorneys-in-fact and agents, each acting alone, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof. Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	Title	
/s/ JOHN R. BARR	Chief Executive Officer, President (principal executive officer)	March 4, 2010
/s/ BRIGID A. MAKES	Chief Financial Officer (principal financial and accounting officer)	March 4, 2010
/s/ TOMMY G. THOMPSON	Chairman	March 4, 2010
/s/ FRANCK L. GOUGEON	Director	March 4, 2010

Signatures	Title	
/s/ JACK P. HELMS	Director	March 4, 2010
/s/ DANIEL A. PELAK	Director	March 4, 2010
/s/ PAUL B. QUEALLY	Director	March 4, 2010
/s/ TERRY ALLISON RAPPUHN	Director	March 4, 2010
/s/ DARRELL J. TAMOSUINAS	Director	March 4, 2010
/s/ SEAN M. TRAYNOR	Director	March 4, 2010

EXHIBIT INDEX
AGA MEDCIAL HOLDINGS, INC.
FORM 10-K

Exhibit No.	Description
2.1	Sale and Purchase Agreement, dated December 9, 2008, between AB Medica S.p.A., AGA Medical Italia S.r.l. and AGA Medical Corporation—incorporated by reference to Exhibit 2.1 to our Form S-1/A dated August 31, 2009
3.1	Form of Amended and Restated Certificate of Incorporation of AGA Medical Holdings, Inc.—incorporated by reference to Exhibit 3.1 to our Form S-1/A dated October 20, 2009
3.2	Form of Amended and Restated Bylaws of AGA Medical Holdings, Inc.—incorporated by reference to Exhibit 3.2 to our Form S-1/A dated October 1, 2009
4.1	Second Amendment to Amended and Restated Stockholders Agreement, dated as of January 5, 2009, by and among AGA Medical Holdings, Inc., Welsh, Carson, Anderson & Stowe IX, L.P., Franck L. Gougeon, Gougeon Shares, LLC and The Franck L. Gougeon Revocable Trust Under Agreement dated June 28, 2006—incorporated by reference to Exhibit 4.4 to our Form S-1/A dated July 20, 2009
4.2	Second Amended and Restated Stockholders Agreement, dated as of October 2, 2009, by and among AGA Medical Holdings, Inc., Welsh, Carson, Anderson & Stowe IX, L.P., WCAS Capital Partners IV, L.P., the WCAS Stockholders as defined therein, Franck L. Gougeon, Gougeon Shares, LLC and The Franck L. Gougeon Revocable Trust Under Agreement Dated June 28, 2006—incorporated by reference to Exhibit 4.1 to our Form S-1/A dated October 5, 2009
4.3	Third Amended and Restated Stockholders Agreement, dated as of October 20, 2009, by and among AGA Medical Holdings, Inc., Welsh, Carson, Anderson & Stowe IX, L.P., WCAS Capital Partners IV, L.P., the WCAS Stockholders as defined therein, Franck L. Gougeon, Gougeon Shares, LLC and The Franck L. Gougeon Revocable Trust Under Agreement Dated June 28, 2006—incorporated by reference to Exhibit 4.1 to our Form S-1/A dated October 20, 2009
4.4	Securities Purchase Agreement, dated as of July 28, 2005, between AGA Medical Corporation and WCAS Capital Partners IV, L.P.—incorporated by reference to Exhibit 4.4 to our Form S-1/A dated August 8, 2008
4.5	Amendment No. 1 to Securities Purchase Agreement, dated as of April 28, 2006, by and among AGA Medical Corporation and WCAS Capital Partners IV, L.P.—incorporated by reference to Exhibit 4.5 to our Form S-1/A dated August 8, 2008
4.6	Amended and Restated Stock Purchase Agreement, dated as of July 28, 2005, by and among AGA Medical Corporation, Franck L. Gougeon and Welsh, Carson, Anderson & Stowe IX, L.P. and its co-investors listed therein—incorporated by reference to Exhibit 4.5 to our Form S-1/A dated July 20, 2009
4.7	Amendment No. 2 to Amended and Restated Stock Purchase Agreement, dated as of June 20, 2008, by and among AGA Medical Corporation, Welsh, Carson, Anderson & Stowe IX, L.P. and its co-investors therein and Franck L. Gougeon.—incorporated by reference to Exhibit 4.8 to our Form S-1/A dated August 8, 2008

Exhibit No.	Description
4.8	Amended and Restated Registration Rights Agreement, dated as of April 21, 2008, by and among AGA Medical Holdings, Inc., Welsh, Carson, Anderson & Stowe IX, L.P., WCAS Capital Partners IV, L.P., the WCAS Investors as defined therein, Franck L. Gougeon, Gougeon Shares, LLC and The Franck L. Gougeon Revocable Trust Under Agreement Dated June 28, 2006—incorporated by reference to Exhibit 4.8 to our Form S-1/A dated November 24, 2008
4.9	First Amendment to Amended and Restated Registration Rights Agreement, dated as of January 5, 2009, by and between AGA Medical Holdings, Inc. and Welsh, Carson, Anderson & Stowe IX, L.P.—incorporated by reference to Exhibit 4.9 to our Form S-1/A dated June 5, 2009
4.10	AGA Medical Holdings, Inc. 2008 Employee Stock Purchase Plan—incorporated by reference to Exhibit 4.11 to our Form S-8 dated October 26, 2009
10.1	Amended and Restated Credit Agreement among AGA Medical Corporation, as borrower, AGA Medical Holdings, Inc., Lehman Commercial Paper Inc., Lehman Commercial Bank, Bank of America, N.A., Citicorp USA, Inc. and Wachovia Bank, National Association as lenders, Lehman Brothers Inc. and Citigroup Global Markets Inc, as joint lead arrangers and joint bookrunners, Citigroup Global Markets Inc, as syndication agent and Lehman Commercial Paper Inc., as administrative agent, dated April 28, 2006—incorporated by reference to Exhibit 10.1 to our Form S-1/A dated July 20, 2009
10.2*	AGA Medical Holdings, Inc. 2006 Equity Incentive Plan.—incorporated by reference to Exhibit 10.2 to our Form S-1/A dated August 8, 2008
10.3*	AGA Medical Holdings, Inc. 2008 Equity Incentive Plan—incorporated by reference to Exhibit 10.3 to our Form S-1/A dated September 22, 2009
10.4*	Form of Incentive Stock Option Agreement under 2006 Equity Incentive Plan (filed herewith)
10.5*	Form of Non-Qualified Stock Option Agreement under 2006 Equity Incentive Plan (filed herewith)
10.6*	Form of Stock Option Award Agreement under 2008 Equity Incentive Plan (filed herewith)
10.7*	Form of Restricted Stock Option Award Agreement under 2008 Equity Incentive Plan (filed herewith)
10.8	Deferred Prosecution Agreement, dated June 2, 2008, between AGA Medical Corporation and the U.S. Department of Justice—incorporated by reference to Exhibit 10.4 to our Form S-1/A dated August 8, 2008
10.9*	Consulting Agreement of Franck L. Gougeon, dated June 20, 2008—incorporated by reference to Exhibit 10.5 to our Form S-1/A dated August 8, 2008
10.10*	Transition Agreement dated as of June 20, 2008, between AGA Medical Corporation and Franck L, Gougeon—incorporated by reference to Exhibit 10.6 to our Form S-1/A dated August 8, 2008
10.11*	Amended and Restated Employment Agreement of Franck L. Gougeon, dated April 21, 2008—incorporated by reference to Exhibit 10.7 to our Form S-1/A dated August 8, 2008
10.12*	Engagement Letter of Franck L. Gougeon, dated June 20, 2008—incorporated by reference to Exhibit 10.8 to our Form S-1/A dated August 8, 2008
10.13*	Engagement Letter of Terry Allison Rappuhn, dated May 25, 2006—incorporated by reference to Exhibit 10.9 to our Form S-1/A dated August 8, 2008

Exhibit No.	Description
10.14*	Engagement Letter of Daniel A. Pelak, dated June 1, 2006—incorporated by reference to Exhibit 10.10 to our Form S-1/A dated August 8, 2008
10.15*	Engagement Letter of Darrell J. Tamosuinas, dated May 6, 2006—incorporated by reference to Exhibit 10.11 to our Form S-1/A dated August 8, 2008
10.16*	Memorandum of Understanding dated May 7, 2008 between Secretary Tommy Thompson and AGA Medical Corporation, relating to Proposed Terms of Employment dated July 28, 2005—incorporated by reference to Exhibit 10.12 to our Form S-1/A dated August 8, 2008
10.17*	Summary of Proposed Terms of Employment between Secretary Tommy Thompson and AGA Medical Corporation, dated July 28, 2005—incorporated by reference to Exhibit 10.13 to our Form S-1/A dated August 8, 2008
10.18*	Employment Agreement of John R. Barr, dated September 19, 2005—incorporated by reference to Exhibit 10.14 to our Form S-1/A dated August 8, 2008
10.19*	Employment Agreement of Brigid A. Makes, dated October 2, 2006—incorporated by reference to Exhibit 10.15 to our Form S-1/A dated August 8, 2008
10.20*	Independent Contractor Agreement of Ronald E. Lund and Ronald E. Lund, LLC, dated June 1, 2007—incorporated by reference to Exhibit 10.16 to our Form S-1/A dated August 8, 2008
10.21*	Employment Agreement of Ronald Lund, dated July 1, 2008—incorporated by reference to Exhibit 10.17 to our Form S-1/A dated August 8, 2008
10.22*	Research Agreement with Dr. Kurt Amplatz, dated December 23, 2005—incorporated by reference to Exhibit 10.18 to our Form S-1/A dated October 10, 2008
10.23	Royalty Agreement with Mr. Curtis Amplatz and Frank Kotula, dated April 22, 1996—incorporated by reference to Exhibit 10.19 to our Form S-1/A dated September 10, 2008
10.24	Royalty Agreement with Mr. Curtis Amplatz, dated as of November 1, 2000—incorporated by reference to Exhibit 10.20 to our Form S-1/A dated September 10, 2008
10.25	Consent to Assignment of Royalty Agreements with Mr. Curtis Amplatz, dated January 5, 2007—incorporated by reference to Exhibit 10.21 to our Form S-1/A dated September 10, 2008
10.26	Quit Claim Assignment from Mr. Curtis Amplatz, dated November 11, 2000—incorporated by reference to Exhibit 10.23 to our Form S-1/A dated November 24, 2008
10.27	Securities Purchase Agreement, dated as of January 5, 2009, among AGA Medical Corporation, AGA Medical Holdings, Inc., WCAS Capital Partners IV, L.P. and Amplatzer Medical Sales Corporation—incorporated by reference to Exhibit 10.25 to our Form S-1/A dated June 5, 2009
10.28*	Reformation Agreement, dated as of December 30, 2008, between AGA Medical Corporation and Ronald Lund—incorporated by reference to Exhibit 10.26 to our Form S-1/A dated June 5, 2009
10.29	Waiver and Consent under Securities Purchase Agreement by WCAS Capital Partners IV, L.P., dated as of October 20, 2009, to the Securities Purchase Agreement, dated as of January 5, 2009, among AGA Medical Corporation, AGA Medical Holdings, Inc., WCAS Capital Partners IV, L.P. and Amplatzer Medical Sales Corporation—incorporated by reference to Exhibit 10.26 to our Form S-1/A dated October 20, 2009

Exhibit No.	Description
21.1	Subsidiaries of AGA Medical Holdings, Inc.—(filed herewith)
23.1	Consent of Ernst & Young LLP (filed herewith)
24.1	Power of Attorney (included on the "Signatures" page of this Form 10-K)
31.1	Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
31.2	Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
32	Certification by Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith)

* Indicates a management contract or compensatory plan or arrangement required to be filed as an exhibit to this Form 10-K.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
AGA Medical Holdings, Inc.

We have audited the accompanying consolidated balance sheets of AGA Medical Holdings, Inc. and subsidiaries as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of three years in the period ended December 31, 2009. Our audits also included the financial statement schedule listed in Item 15(a)2. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of AGA Medical Holdings, Inc. and subsidiaries at December 31, 2009 and 2008, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth herein.

/s/ Ernst & Young LLP

March 4, 2010
Minneapolis, Minnesota

AGA Medical Holdings, Inc.

Consolidated Balance Sheets

(in thousands, except per share amounts)

	December 31, 2009	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 24,470	$ 22,867
Accounts receivable, less allowance for doubtful accounts of $481 and $933 and discounts of $395 and none at December 31, 2009, and 2008, respectively	48,730	26,851
Inventory	12,408	10,680
Prepaid expenses	1,408	1,019
Income tax receivable	2,762	—
Other tax receivable	799	—
Deferred tax assets, net	8,339	8,282
Total current assets	98,916	69,699
Property and equipment, net	38,669	35,103
Goodwill	85,381	63,009
Intangible assets, net	111,655	95,128
Other assets, net	3,683	7,735
Deferred financing costs, net	2,276	1,654
Total assets	$340,580	$272,328
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Reserve for customer returns	$ 9,335	$ 8,025
Trade accounts payable	8,643	9,693
Accrued royalties	2,299	1,933
Accrued interest	1,462	3,132
Accrued wages	10,549	7,373
Short-term obligations to former distributors, less discount	7,880	1,500
Accrued expenses	5,391	6,642
Income taxes payable	2,913	855
Total current liabilities	48,472	39,153
Long-term debt, less current portion	196,963	206,883
Senior subordinated note payable, less discount of $1,383 and $3,441 at December 31, 2009, and 2008, respectively	13,617	46,559
Long-term obligations to former distributors, less discount	9,382	—
Deferred tax liabilities	32,984	28,432
Accrued income taxes	2,705	3,188
Series A preferred stock, $0.001 par value:		
Authorized shares—149		
Issued and outstanding shares—none at December 31, 2009 and 129 at December 31, 2008	—	166,044
Series B preferred stock, $0.001 par value:		
Authorized shares—2		
Issued and outstanding shares—none at December 31, 2009 and 2008	—	—
Class A common stock, $0.01 par value:		
Authorized shares—20,000		
Issued and outstanding shares—none at December 31, 2009 and 6,600 at December 31, 2008	—	8,527
Stockholders' (deficit) equity:		
Common stock, $0.01 par value:		
Authorized shares—400,000		
Issued and outstanding shares—50,094 at December 31, 2009 and 20,559 at December 31, 2008	501	206
Class B common stock, $0.01 par value:		
Authorized shares—35,000		
Issued and outstanding shares—none at December 31, 2009 and 37 at December 31, 2008	—	—
Additional paid-in capital	273,309	—
Excess purchase price over Predecessor basis	(63,500)	(63,500)
Accumulated other comprehensive income	(489)	(1,646)
Accumulated deficit	(173,364)	(161,518)
Total stockholders' (deficit) equity	36,457	(226,458)
Total liabilities and stockholders' (deficit) equity	$340,580	$272,328

The accompanying notes are an integral part of these consolidated financial statements.

AGA Medical Holdings, Inc.

Consolidated Statements of Operations

(in thousands, except per share amounts)

	Year Ended December 31,		
	2009	2008	2007
Net sales	$198,710	$166,896	$147,255
Cost of goods sold	31,240	26,635	22,819
Gross profit	167,470	140,261	124,436
Operating expenses:			
Selling, general, and administrative	98,908	65,669	50,190
Research and development	35,197	32,760	26,556
Amortization of intangible assets	20,115	15,540	15,233
FCPA settlement	—	—	2,000
Change in purchase consideration	(1,149)	—	—
Loss (gain) on disposal of property and equipment	63	68	(3)
Total operating expenses	153,134	114,037	93,976
Operating income	14,336	26,224	30,460
Investment income (loss)	(2,352)	(1,202)	(751)
Interest income	92	230	426
Interest income—related party	—	—	6
Interest expense	(17,219)	(16,492)	(21,213)
Other income, net	3,220	722	994
Income (loss) before income taxes	(1,923)	9,482	9,922
Income tax (benefit) expense	(828)	386	3,844
Net income (loss)	(1,095)	9,096	6,078
Less Series A and B preferred stock and Class A common stock dividends	(14,282)	(17,067)	(15,372)
Net loss applicable to common stockholders	$(15,377)	$ (7,971)	$ (9,294)
Net loss per common share—basic and diluted	$ (0.57)	$ (0.37)	$ (0.41)
Weighted average common shares—basic and diluted	27,069	21,482	22,550

The accompanying notes are an integral part of these consolidated financial statements.

AGA Medical Holdings, Inc

Consolidated Statements of Stockholders' (Deficit) Equity

(in thousands)

	Common Stock		Class B Common Stock		Additional Paid-In Capital	Excess Purchase Price Over Predecessor Basis	Accumulated Other Comprehensive Income (Loss)	Accumulated Earnings (Deficit)	Total
	Shares	Stock	Shares	Stock					
Balance at December 31, 2006	20,560	$206	—	$—	$ —	$(63,500)	$ 171	$(147,445)	$(210,568)
Series A preferred stock dividends	—	—	—	—	(1,648)	—	—	(12,209)	(13,857)
Class A common stock dividends	—	—	—	—	(193)	—	—	(1,322)	(1,515)
Issuance of Class B common stock	—	—	7	1	50	—	—	—	51
Purchase of Class B common stock	—	—	(7)	(1)	(130)	—	—	—	(131)
Tax benefit related to purchase of shares	—	—	—	—	30	—	—	—	30
Compensation expense related to stock option plan	—	—	—	—	1,891	—	—	—	1,891
Other comprehensive income:									
Unrealized gain on short-term investments, net of tax of $4	—	—	—	—	—	—	7		7
Translation adjustment, net of tax of $243	—	—	—	—	—	—	245	—	245
Net income for the year ended December 31, 2007	—	—	—	—	—	—	—	6,078	6,078
Total comprehensive income									6,330
Balance at December 31, 2007	20,560	206	—	—	—	(63,500)	423	(154,898)	(217,769)
Dividend paid to Series A preferred stockholders	—	—	—	—	(62)	—	—	(1,077)	(1,139)
Dividend paid to Class A common stockholders	—	—	—	—	(3)	—	—	(56)	(59)
Dividend paid to common stockholders	—	—	—	—	(71)	—	—	(1,232)	(1,303)
Series A preferred stock dividends	—	—	—	—	(2,396)	—	—	(12,699)	(15,095)
Class A common stock dividends	—	—	—	—	(123)	—	—	(652)	(775)
Issuance of Class B common stock	—	—	6	—	47	—	—	—	47
Purchase of Class B common stock	—	—	(1)	—	(27)	—	—	—	(27)
Compensation expense related to stock option plan	—	—	—	—	2,635	—	—	—	2,635
Other comprehensive income:									
Translation adjustment, net of tax of $(389)	—	—	—	—	—	—	(2,069)	—	(2,069)
Net income for the year ended December 31, 2008	—	—	—	—	—	—	—	9,096	9,096
Total comprehensive income									7,027
Balance at December 31, 2008	20,560	206	5	—	—	(63,500)	(1,646)	(161,518)	(226,458)
Series A preferred stock dividends	—	—	—	—	(3,322)	—	—	(10,116)	(13,438)
Series B preferred stock dividends	—	—	—	—	(38)	—	—	(116)	(154)
Class A common stock dividends	—	—	—	—	(171)	—	—	(519)	(690)
Issuance of Common stock related to initial public offering	6,509	65	—	—	82,178	—	—	—	82,243
Issuance of Common stock related to exercise of options	68	—	—	—	490	—	—	—	490
Conversion of Series A preferred stock to Common stock	17,975	180	—	—	128,344	—	—	—	128,524
Conversion of Series B preferred stock to Common stock	96	1	—	—	1,879	—	—	—	1,880
Conversion of Class A common to Common stock	923	9	—	—	6,591	—	—	—	6,600
Conversion of Series A preferred dividends to Common stock	3,759	38	—	—	50,920	—	—	—	50,958
Conversion of Series B preferred dividends to Common stock	11	—	—	—	154	—	—	—	154
Conversion of Class A common dividends to Common stock	193	2	—	—	2,615	—	—	—	2,617
Issuance of Class B common stock	—	—	12	1	83	—	—	—	84
Purchase of Class B common stock	—	—	(17)	(1)	(332)	—	—	—	(333)
Compensation expense related to stock option plan	—	—	—	—	3,794	—	—	—	3,794
Tax benefit related to purchase of shares	—	—	—	—	124	—	—	—	124
Other comprehensive income (loss):									
Translation adjustment	—	—	—	—	—	—	1,157	—	1,157
Net income (loss) for the year ended December 31, 2009	—	—	—	—	—	—	—	(1,095)	(1,095)
Total comprehensive income									62
Balance at December 31, 2009	50,094	$501	—	$—	$273,309	$(63,500)	$ (489)	$(173,364)	$ 36,457

The accompanying notes are an integral part of these consolidated financial statements.

AGA Medical Holdings, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,		
	2009	2008	2007
Operating activities:			
Net income (loss)	$ (1,095)	$ 9,096	$ 6,078
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	25,262	19,429	18,662
Debt discount accretion and deferred financing cost amortization	2,619	1,312	1,291
Write-off of unamortized discount on long-term debt	2,676	—	—
Reserve for FCPA settlement	—	(2,000)	2,000
Stock-based compensation	3,794	2,635	1,891
Loss on equity investment	2,352	1,202	751
Foreign currency transaction gain/loss	—	93	—
Change in deferred taxes	(3,875)	(6,498)	(6,087)
Change in purchase accounting consideration	(1,149)	—	—
Loss (gain) on disposal of property and equipment	63	68	(3)
Changes in operating assets and liabilities, net of acquisition:			
Accounts receivable	(22,404)	(8,033)	1,180
Inventory	2,414	(312)	914
Prepaid expenses and other assets	1,416	(2,079)	(887)
Income tax receivable	(2,767)	—	507
Reserve for customer returns	1,213	957	87
Reserve for product recall	—	—	(1,160)
Trade accounts payable	(988)	864	(131)
Income tax payable	2,058	641	389
Accrued income taxes	(482)	(2,088)	5,275
Accrued expenses	(184)	3,505	2,162
Net cash provided by operating activities	10,923	18,792	32,919
Investing activities:			
Acquisitions	(36,630)	(7,138)	(1,000)
Purchases of property and equipment	(8,761)	(7,782)	(4,942)
Purchases of short-term investments	—	—	(9,025)
Equity investment	—	(1,200)	(700)
Purchase of patent rights	—	—	(14,500)
Increase in restricted cash	(914)	(621)	(1,100)
Proceeds from sale of short-term investments	—	—	19,954
Net cash used in investing activities	(46,305)	(16,741)	(11,313)
Financing activities:			
Proceeds from long-term debt	$ 15,000	$ —	$ —
Proceeds from revolving line of credit	15,080	9,920	—
Payments on revolving line of credit	(25,000)	—	—
Payments on long-term debt	(50,000)	(1,000)	(1,000)
Payment of deferred financing fees	(1,625)	(58)	—
Redemption of Class A common stock	—	—	(13,400)
Proceeds from sale of Common stock	82,243	—	—
Proceeds from exercise of stock options	574	47	50
Purchase of Class B common stock	(333)	(27)	(131)
Dividends paid	—	(2,501)	(1,696)
Net cash provided by (used in) financing activities	35,939	6,381	(16,177)
Effect of exchange rate changes on cash	1,046	581	235
Net change in cash and cash equivalents	1,603	9,013	5,664
Cash and cash equivalents at beginning of period	22,867	13,854	8,190
Cash and cash equivalents at end of period	$ 24,470	$ 22,867	$ 13,854
Supplemental disclosures of cash flow information:			
Interest paid	$ 13,478	$ 15,363	$ 21,289
Taxes paid	$ 4,759	$ 8,426	$ 5,976

The accompanying notes are an integral part of these consolidated financial statements.

1. Description of Business

AGA Medical Holdings, Inc. (AGA or the Company), is a leading manufacturer of minimally invasive devices to treat structural heart defects and vascular diseases, which the Company markets under the *AMPLATZER* brand. The Company develops, manufactures, and markets a complete line of minimally invasive, transcatheter treatments to occlude, or close holes, relating to seven different types of structural heart defects, as well as, to occlude abnormal blood vessels outside of the heart. AGA products are sold in 112 countries through a combination of direct sales and the use of distributors. The Company is investing in clinical trials to confirm new indications for existing devices and the development of both line extensions to existing devices and new devices to treat new therapeutic indications. All research and development programs take advantage of AGA's core competencies in braiding fine wires using an alloy, nitinol. The Company has a portfolio of patents to protect its intellectual property rights.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Basis of Presentation

The Company's common stock, basic and diluted net income (loss) per common share and basic and diluted weighted average shares give effect for all periods to the 7.15 for 1.00 reverse stock split of the Company's common stock which occurred immediately prior to the Company's October 21, 2009 initial public offering of stock.

Reclassification

The cash flow statement, inventory disclosure, and property and equipment disclosure reflect the reclassification of certain prior period amounts to conform to the current year presentation.

Recently Issued Accounting Standards

In September 2009, the Company adopted the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") Topic 105 as the single official source of authoritative, nongovernmental generally accepted accounting principles in the United States. On the effective date, all the then-existing non-SEC accounting literature and reporting standards were superseded and deemed nonauthoritative. The adoption of this pronouncement did not have a material impact on the Company's consolidated financial statements; however, the ASC affected the way the Company references authoritative guidance in its consolidated financial statements.

In 2009, the Company adopted the provisions of ASC Topic 855, *Subsequent Events* ("ASC 855"), which was effective for interim and annual periods after June 15, 2009 and amended on February 24, 2010. This Statement incorporates guidance into accounting literature that was previously addressed only in auditing standards. The statement refers to subsequent events that provide additional evidence about conditions that existed at the balance-sheet date as "recognized subsequent events." Subsequent events which provide evidence about conditions that arose after an issuer's most recent balance-sheet date but prior to the issuance of its most recent financial statements are referred to as "non-recognized

2. Summary of Significant Accounting Policies (Continued)

subsequent events." It also requires companies to evaluate subsequent events through the date the financial statements were issued.

In April 2009, the FASB issued additional guidance, ASC Topic 825 (ASC 825) under which disclosures about fair value of financial instruments are required for interim reporting periods of publicly traded companies as well as in annual financial statements. The guidance requires disclosures in summarized financial information at interim reporting periods and is effective for interim and annual reporting periods ending after June 15, 2009. The Company adopted ASC Topic 825 during the three months ended June 30, 2009. The implementation of ASC Topic 825 did not have a material impact on the Company's consolidated financial statements.

In March 2008, the FASB issued additional guidance on derivative instruments and hedging activities disclosure in ASC Topic 815 (ASC 815). ASC Topic 815 applies to all derivative instruments and non-derivative instruments that are designated and qualify as hedging instruments and related hedged items. The provisions of ASC Topic 815 requires entities to provide greater transparency through additional disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS 133 and its related interpretations and (c) how derivative instruments and related hedged items affect an entity's financial position, results of operations and cash flows. The Company adopted ACS Topic 815 effective January 1, 2009. The adoption of this statement did not have a material effect on the Company's consolidated financial statements.

In December 2007, the FASB issued additional guidance on business combinations contained in ASC Topic 805 (ASC 805) and additional guidance on noncontrolling interests in consolidated financial statements contained in ASC Topic 810, which are effective for fiscal years beginning after December 15, 2008. These new standards represent the completion of the FASB's first major joint project with the International Accounting Standards Board and are intended to improve, simplify and converge internationally the accounting for business combinations and the reporting of noncontrolling interests (formerly minority interests) in consolidated financial statements.

ASC Topic 805 changes the method for applying the acquisition method in a number of significant respects, including the requirement to expense transaction fees and expected restructuring costs as incurred, rather than including these amounts in the allocated purchase price; the requirement to recognize the fair value of contingent consideration at the acquisition date, rather than the expected amount when the contingency is resolved; the requirement to recognize the fair value of acquired in-process research and development assets at the acquisition date, rather than immediately expensing; and the requirement to recognize a gain in relation to a bargain purchase price, rather than reducing the allocated basis of long-lived assets. The Company adopted these standards effective January 1, 2009. The new presentation and disclosure requirements for pre-existing non-controlling interests are retroactively applied to all prior period financial information presented. See note 12 ("Fair Value Measurements") for further discussion of the impact the adoption of ASC Topic 805 had on the Company's results of operations and financial conditions as a result of its acquisitions in the first quarter 2009.

In September 2006, the FASB issued ASC Topic 820 (ASC 820), which defines fair value, establishes a framework for the measurement of fair value and enhances disclosure about fair value measurement. The statement does not require any new fair value measures. ASC Topic 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly

2. Summary of Significant Accounting Policies (Continued)

transaction between market participants at the measurement date (exit price). The provisions under ASC Topic 820 are effective for all financial assets and liabilities and for nonfinancial assets and liabilities recognized or disclosed at fair value in the Company's consolidated financial statements on a recurring basis beginning January 1, 2008 and are expected to be applied prospectively. The Company adopted the provisions of ASC Topic 820 for financial assets and liabilities that are measured at fair value for its fiscal year beginning January 1, 2008. For all other nonfinancial assets and liabilities, the Company adopted ASC Topic 820 effective beginning January 1, 2009. The adoption of this statement did not have a material effect on the Company's consolidated financial statements.

In June 2009, the FASB issued ASC Topic 860 (ASC 860) which defines accounting standards for transfers and servicing of financial assets and extinguishments of liabilities. This standard eliminates the concept of a qualifying special-purpose entity, changes the requirements for derecognizing financial assets, and requires additional disclosures. The standard will become effective in the first quarter of 2010. The Company does not expect that the adoption of this standard will have a material impact on the Company's consolidated financial statements.

In June 2009, the FASB issued ASC Topic 810 (ASC 810) which defines accounting standards on variable interest entities to address the elimination of the concept of a qualifying special purpose entity. This standard also replaces the quantitative-based risks and rewards calculation for determining which enterprise has a controlling financial interest in a variable interest entity with an approach focused on identifying which enterprise has the power to direct the activities of a variable interest entity and the obligation to absorb losses of the entity or the right to receive benefits from the entity. Additionally, it provides more timely and useful information about an enterprise's involvement with a variable interest entity. The standard will become effective in the first quarter of 2010. The Company does not expect that adoption of this standard will have a material impact on the Company's consolidated financial statements.

Cash Equivalents

The Company considers all highly liquid investments with contractual maturities of three months or less when purchased to be cash equivalents.

Accounts Receivable and Allowance for Doubtful Accounts

The Company has receivables from a diversified customer base. The creditworthiness of customers is monitored before sales are approved. The Company records an allowance for doubtful accounts based on past history, current economic conditions, and the composition of its accounts receivable aging and, in some cases, makes allowances for specific customers based on several factors, such as the creditworthiness of those customers and payment history.

2. Summary of Significant Accounting Policies (Continued)

Inventory

Inventory is valued at the lower of cost or market with cost determined using the first-in, first-out method. Inventory consists of the following:

(in thousands)	December 31, 2009	2008
Raw materials	$ 7,030	$ 5,468
Work-in-process	360	647
Finished goods-warehouses	5,614	5,697
Finished goods-consignment	1,306	685
Inventory reserve	(1,902)	(1,817)
	$12,408	$10,680

The Company makes adjustments to the value of inventory based on estimates of potentially excess and obsolete inventory after considering forecasted demand and forecasted average selling prices.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Additions and improvements that extend the lives of assets are capitalized, while expenditures for repairs and maintenance are expensed as incurred. Depreciation is provided using the straight-line method over the estimated useful lives of the individual assets and ranges from 3 to 40 years. Manufacturing equipment are depreciated over 5 years, office furniture and equipment are depreciated over 3 to 5 years, computer hardware and software are depreciated over 3 to 5 years, building costs are depreciated over 40 years, leasehold improvements are depreciated over the estimated lives of the related assets or the life of the lease, whichever is shorter, and building and land improvements are depreciated over 10 years. Assets not in service is not depreciated until the related asset is put into use. Property and equipment consist of the following:

(in thousands)	December 31, 2009	2008
Manufacturing equipment	$ 5,566	$ 4,006
Land	5,103	5,103
Office furniture and equipment	4,762	4,040
Computer hardware and software	12,891	6,619
Building	16,123	16,123
Building improvements	1,651	597
Leasehold improvements	3,951	2,466
Land improvements	1,493	1,478
Assets not in service	1,490	4,212
	53,030	44,644
Accumulated depreciation	(14,361)	(9,541)
	$ 38,669	$35,103

2. Summary of Significant Accounting Policies (Continued)

Total depreciation expense of property and equipment was $5.1 million, $4.0 million, and $3.3 million for the years ended December 31, 2009, 2008 and 2007 respectively.

Goodwill and Intangible Assets

ASC Topic 350, *Intangibles—Goodwill and Other* (ASC 350), requires that goodwill and other intangible assets with indefinite useful lives be evaluated for impairment on an annual basis or more frequently if certain events occur or circumstances exist. The Company completed its annual impairment tests of goodwill and indefinite lived intangible assets during the fourth quarters of 2008 and 2009 and identified no impairment associated with the carrying values of the indefinite lived intangibles or goodwill.

The Company evaluates goodwill for impairment based on a two-step process. The first step compares the fair value of a reporting unit with its carrying amount, including goodwill. The second step compares the implied fair value of reporting unit goodwill with the carrying amount of that goodwill. The measurement of possible impairment is based upon the comparison of the fair value of each reporting unit with the book value of its assets. The Company has one consolidated reporting unit. In reviewing intangible assets with indefinite useful lives for impairment, the Company compares the carrying amount of such asset to its fair value. The Company estimates the fair value using discounted cash flows expected from the use of the asset. When the estimated fair value is less than its carrying amount, an impairment loss is recognized equal to the difference between the asset's fair value and its carrying amount. In addition, intangible assets with indefinite useful lives are reviewed for impairment whenever events such as product discontinuance or other changes in circumstances indicate that the carrying amount may not be recoverable.

The performance of the goodwill and intangible asset impairment tests are subject to significant judgment in determining the estimation of future cash flows, the estimation of discount rates, and other assumptions. Changes in these estimates and assumptions could have a significant impact on the fair value and impairment of goodwill and intangible assets.

Impairment of Long-Lived Assets

Long-lived assets, primarily property, plant, and equipment and intangible assets with finite lives, are periodically reviewed and evaluated by the Company when events and circumstances indicate that the carrying amount of these assets may not be recoverable. For long-lived assets, this evaluation is based on the expected future undiscounted operating cash flows of the related assets. Should such evaluation result in the Company concluding that the carrying amount of long-lived assets has been impaired, an appropriate write-down to their fair value is recorded.

Revenue Recognition

In the United States and certain countries, the Company sells its products directly to hospitals and clinics. The Company recognizes revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred to a third-party shipper; the sales price is fixed or determinable; and collectibility is reasonably assured. These criteria are met at the time of shipment when the risk of loss and title passes to the customer.

2. Summary of Significant Accounting Policies (Continued)

In other international markets, the Company sells its products to international distributors, which subsequently resell the products to hospitals. Sales to distributors are recognized at the time of shipment, provided that the Company has received an order, the price is fixed or determinable, collectibility of the resulting receivable is reasonably assured, and the Company can reasonably estimate returns. In cases where the Company's products are held in consignment at a customer's location, the Company recognizes net sales at the time the product is used in the procedure rather than at shipment.

The Company allows for product returns in certain circumstances, such as damaged or faulty products, products that are past their sterility dates, and physician mis-sizing. Allowances are provided for estimated product returns at the time of sale based on historical returns experience and recorded as a reduction of revenue. During 2006, the Company amended its product return policy to no longer accept returns for product past its sterility date after March 31, 2007. As a result, the Company reduced the required reserve by $1.3 million ($0.8 million, net of tax) in 2007.

The Company warrants that its products are free from manufacturing defects at the time of shipment. Allowances are provided for estimated warranty costs at the time of shipment. To date, warranty costs have been insignificant.

Shipping Costs

Shipping costs are classified as cost of goods sold.

Other income, net

Gains and losses on foreign currency transactions are included in other income, net. In 2009 the Company recorded a one time benefit of $1.9 million as a payment received as restitution for damages suffered by the Company in the shareholder dispute that was settled in 2005.

Income Taxes

Income taxes are accounted for under the liability method. Deferred income taxes are provided for temporary differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Research and Development

Research and development costs are charged to expense as incurred.

Advertising

The Company expenses advertising costs as incurred. Advertising costs for the years ended December 31, 2009, 2008 and 2007, were $0.7 million, $0.6 million and $0.9 million, respectively.

Accounting for Stock-Based Compensation

At December 31, 2009, 2008, and 2007, the Company had a stock- based employee compensation plan which is more fully described in Note 11. The Company follows provisions of ASC Topic 718, *Compensation—Stock Compensation*, in accounting for its stock-based compensation.

2. Summary of Significant Accounting Policies (Continued)

Net Income (Loss) Per Share

Basic net income or loss per share is calculated in accordance with ASC Topic 260, *Earnings Per Share*. Basic earnings per share ("EPS") is calculated using the weighted-average common shares outstanding in each period under the two-class method. The two class method requires that the Company include in its basic EPS calculation when dilutive, the effect of the Company's convertible preferred stock as if that stock were converted into common shares. The convertible preferred shares are not included in the Company's basic EPS calculation when the effect of inclusion would be antidilutive.

Diluted EPS assumes the conversion, exercise or issuance of all potential common stock equivalents, unless the effect of inclusion would result in the reduction of a loss or the increase in income per share. For purposes of this calculation, the Company's stock options are considered to be potential common shares and are only included in the calculation of diluted EPS when the effect is dilutive. The shares used to calculate basic and diluted EPS represent the weighted-average common shares outstanding. The Company's preferred stockholders have the right to participate with common stockholders in the dividends and unallocated income. Net losses are not allocated to the preferred stockholders. Therefore, when applicable, basic and diluted EPS are calculated using the two-class method as the Company's convertible preferred stockholders have the right to participate, or share in the undistributed earnings with common stockholders. Diluted net loss per common share is the same as basic net loss per share for the years ended December 31, 2009, 2008 and 2007, since the effect of any potentially dilutive securities was excluded as they were anti-dilutive due to the net loss attributable to common stockholders.

The effect of the Company's participating convertible Series A and Series B preferred stock is excluded in basic EPS, under the two-class method in accordance with ASC Topic 260, *Earnings Per Share* because the effect is anti-dilutive as a result of the net loss attributable to common stockholders.

(in thousands, except per share amounts)	Year Ended December 31, 2009	2008	2007
Numerator:			
Net income (loss)	$ (1,095)	$ 9,096	$ 6,078
Series A and Series B preferred stock and Class A common stock dividends	(14,282)	(17,067)	(15,372)
Net loss applicable to common stockholders	$(15,377)	$ (7,971)	$ (9,294)
Denominator:			
Weighted average common shares outstanding	27,069	20,559	20,559
Weighted average effect of the assumed conversion of Class A common stock from the date of issuance	0	923	1,991
Weighted average shares of common stock outstanding—basic and diluted	27,069	21,482	22,550
Net loss per share—basic and diluted	$ (0.57)	$ (0.37)	$ (0.41)

2. Summary of Significant Accounting Policies (Continued)

Foreign Currency Translation and Transaction Gains and Losses

The financial statements for operations outside the United States are maintained in their local currency. All assets and liabilities are translated to United States dollars at period-end exchange rates, while the statements of operations are translated at average exchange rates in effect during the year. Translation adjustments arising from the use of differing exchange rates are included in accumulated other comprehensive income in stockholders' deficit. Gains and losses on foreign currency transactions are included in other income, net.

Sales originating in the United States denominated in a currency other than the U.S. dollar are generally fixed in terms of the amount of foreign currency that will be received or paid. A change in exchange rates between the U.S. dollar and the currency in which a transaction is denominated increases or decreases the expected amount of functional currency cash flows upon settlement of the transaction. That increase or decrease in expected functional currency cash flows is a foreign currency transaction gain or loss and is included in determining net income for the period in which the exchange rate changes. In the first quarter of 2009, we initiated a foreign currency hedging program. The objectives of the program are to reduce earnings volatility due to movements in foreign currency markets, limit loss in foreign currency-denominated cash flows, and preserve the operating margins of our foreign subsidiaries. We generally use foreign currency forward contracts to hedge transactions related to known inter-company sales and inter-company debt. We also may hedge firm commitments. These contracts generally relate to our European operations and are denominated primarily in euros and sterling. All of our foreign exchange contracts are recognized on the balance sheet at their fair value. We do not enter into foreign exchange contracts for speculative purposes. For the year ended December 31, 2009 derivative exposures were immaterial and were not designated as hedges.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Contingent Consideration

Contingent consideration is recorded at the acquisition-date estimated fair value of the contingent milestone for all acquisitions subsequent to January 1, 2009. The fair value of the contingent milestone consideration is remeasured at the estimated fair value at each reporting period with the change in fair value included in our consolidated statements of operations.

Deferred Financing Costs

Debt financing costs are deferred and amortized to interest expense using the effective interest method over the term of the related debt instrument. In December 2008 and January 2009, the Company arranged for debt financing resulting in $0.1 million and $1.9 million of deferred financing costs, respectively. These costs are amortized using the effective interest method over the 3.5 year term of the related debt.

2. Summary of Significant Accounting Policies (Continued)

Comprehensive Income

Other comprehensive income consists of net income, the effects of foreign currency translation, and unrealized gains (losses) on short-term investments.

Legal Proceedings

The Company is involved in a number of legal actions involving both product liability and intellectual property disputes. The outcomes of these legal actions are not within the Company's complete control and may not be known for prolonged periods of time. In some actions, the claimants seek damages, as well as other relief, that could require significant expenditures. In accordance with ASC Topic 450, *Contingencies* (ASC 450) the Company records a liability in its consolidated financial statements for these actions when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is possible, but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed in the notes to the consolidated financial statements. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded. The Company's significant legal proceedings are discussed in Note 10 to the consolidated financial statements. While it is not possible to predict the outcome for most of the matters discussed in Note 10 to the consolidated financial statements, the Company believes it is possible that costs associated with them could have a material adverse effect on the Company's consolidated earnings, financial position or cash flows.

3. Acquisitions

On August 18, 2006, the Company purchased the distribution rights, inventory, equipment, intangible assets and goodwill from its distributor located in the United Kingdom, which under ASC Topic 805, *Business Combinations* (ASC 805) constitutes an acquired business. The Company established a wholly owned subsidiary in the United Kingdom called Amplatzer Medical UK Limited. The results of Amplatzer Medical UK's operations have been included in the financial statements since the date it was established. The results of sales to the distributor were included in the financial statements prior to the purchase date. The aggregate purchase price was $8.1 million.

3. Acquisitions (Continued)

The excess purchase price over the fair value of underlying assets acquired and liabilities assumed was allocated to goodwill. Goodwill was not deductible for tax purposes. The following tables summarize the consideration paid and the estimated fair value of the assets acquired at the date of acquisition.

(in thousands)	
Consideration:	
Cash payment	$5,451
Accounts receivable forgiven	774
Discounted note	1,788
Liabilities incurred	104
Total consideration paid	$8,117
Purchase price allocation:	
Inventory	$1,414
Intangible assets, amortizable	6,485
Property and equipment	19
Goodwill	199
Total purchase price allocation	$8,117

The agreement called for two additional payments of $1.0 million each, which were paid 30 days after the first and second anniversaries of the agreement. The required contractual payments were recorded on a discounted basis using a discount rate of 7.7%, the Company's effective borrowing rate.

In addition, the Company agreed to pay the former owners up to $3.5 million if certain revenue goals are achieved during the first three years of the agreement. The achievements are defined as follows:

Year 1—$1.0 million if gross revenues of Amplatzer Medical UK exceed 4.6 million pounds sterling

Year 2—$1.0 million if gross revenues of Amplatzer Medical UK exceed 5.0 million pounds sterling

Year 3—$1.5 million if gross revenues of Amplatzer Medical UK exceed 5.3 million pounds sterling

In September 2007, the Company paid the Year 1 contingent payment of $1.0 million. In September 2008, the Company paid the Year 2 contingent payment of $1.0 million. The Company did not accrue any of these contingent amounts as of December 31, 2006 or 2007. As of December 2008, the Company accrued $1.5 million related to contingent payments. In September 2009, the Company paid the Year 3 contingent payment of $1.5 million.

The acquired intangible assets, all of which are being amortized, have a weighted average useful life of approximately eight years. The intangible assets include a customer list valued at $5.3 million and a noncompete agreement valued at $1.2 million. The fair value of the identifiable intangible assets, inventory, and property and equipment were determined by management. The excess of the purchase price over the fair value of the assets acquired was recorded as goodwill.

3. Acquisitions (Continued)

On April 1, 2008, the Company purchased the distribution rights, inventory and intangible assets from its distributor located in Spain. The Company established a wholly owned subsidiary in Spain called Amplatzer Medical Espana, S.L. The results of Amplatzer Medical Spain's operations have been included in the financial statements since the date it was established. The results of sales to the distributor were included in the financial statements prior to the purchase date. The aggregate purchase price was $6.2 million.

The following tables summarize the consideration paid and the estimated fair value of the assets acquired at the date of acquisition.

(in thousands)	
Consideration:	
Cash payment	$3,528
Accounts receivable forgiven	434
Settlement payable	761
Accrued payable	1,521
Total consideration	$6,244
Purchase price allocation:	
Inventory	$2,328
Intangible assets, amortizable	3,916
Total purchase price allocation	$6,244

During July 2008, the Company paid the $0.8 million settlement payable. In addition, the Company paid the former owners $1.5 million, in October 2008 and January 2009, based upon the achievement of certain revenue goals.

The acquired intangible assets, all of which are being amortized, have a weighted average useful life of approximately eight years. The intangible assets include a customer list valued at $3.8 million and a noncompete agreement valued at $0.1 million. The fair value of the identifiable intangible assets and inventory were determined by management.

On July 1, 2008, the Company purchased assets from its distributor located in Poland, consisting of distribution rights, inventory and intangible assets. The Company established a wholly owned subsidiary in Poland called AGA Medical Polska SP z.o.o. The results of AGA Medical Poland's operations have been included in the financial statements after the date it was established. The results of sales to the distributor were included in the financial statements prior to the purchase date. The $1.5 million aggregate purchase price included a $1.0 million payment made in July 2008 and a payment of $0.5 million to repurchase inventory. In addition, the Company paid the former distributor $0.5 million in 2009 based upon the achievement of certain revenue goals.

The acquired intangible assets, all of which are being amortized, have a weighted average useful life of approximately eight years. The intangible assets include a customer list valued at $1.0 million. The fair value of the identifiable intangible assets and inventory were determined by management.

Effective January 1, 2009, the Company purchased the distribution rights, inventory and intangible assets from its distributor in France. The Company established a wholly owned subsidiary in France called Amplatzer Medical France SAS. The results of Amplatzer Medical France SAS's operations have

3. Acquisitions (Continued)

been included in the financial statements since the date it was established. The results of sales to the distributor were included in the financial statements prior to the purchase date. The $3.5 million aggregate purchase price includes a payment on April 1, 2009 which as of the acquisition date had a net present value of $1.4 million, $0.8 million for inventory, and a contingent payment in April 2010 which as of the acquisition date had a net present value of $1.3 million payable if certain revenue goals are achieved during this period. On April 1, 2009, the Company made a payment in the amount of $1.4 million.

The acquired intangible assets, all of which are being amortized, have a weighted average useful life of approximately eight years. The intangible assets include a customer list valued at $2.7 million. The fair value of the identifiable intangible assets and inventory were determined by management.

On January 1, 2009, the Company purchased the distribution rights, inventory and intangible assets from its two distributors in Portugal. The Company established a wholly owned subsidiary in Portugal called Amplatzer Medical Portugal, Unipessoal LDA. The results of Amplatzer Medical Portugal, Unipessoal LDA's operations have been included in the financial statements since the date it was established. The results of sales to the distributors were included in the financial statements prior to the purchase date. The $3.5 million aggregate purchase price includes payments of $2.5 million in January 2009, $0.2 million for inventory, and a contingent payment in January 2010 which as of the acquisition date had a net present value of $0.8 million payable if certain revenue goals are achieved during this period.

The acquired intangible assets, all of which are being amortized, have a weighted average useful life of approximately eight years. The intangible assets include a customer list valued at $3.3 million. The fair value of the identifiable intangible assets and inventory were determined by management.

On January 1, 2009, the Company purchased the distribution rights, inventory and intangible assets from its distributor in the Netherlands. The results of operations have been included in the financial statements since this date. The results of sales to the distributor were included in the financial statements prior to the purchase date. The $1.0 million aggregate purchase price includes payments of $0.4 million in January 2009, $0.3 million for inventory, and a contingent payment in January 2010 which as of the acquisition date had a net present value of $0.3 million payable if certain revenue goals are achieved during this period.

The acquired intangible assets, all of which are being amortized, have a weighted average useful life of approximately eight years. The intangible assets include a customer list valued at $0.7 million. The fair value of the identifiable intangible assets and inventory were determined by management.

On January 1, 2009, the Company purchased the structural heart product distribution rights, inventory and intangible assets from its distributor in Canada. The Company established a wholly owned subsidiary in Canada called AGA Medical Canada Inc. The results of AGA Medical Canada Inc.'s operations have been included in the financial statements since the date it was established. The results of sales to the distributor were included in the financial statements prior to the purchase date. The $2.8 million aggregate purchase price includes payments of $1.1 million in January 2009, $0.8 million for inventory, and a contingent payment in January 2010 which as of the acquisition date had a net present value of $0.9 million payable if certain revenue goals are achieved during this period.

3. Acquisitions (Continued)

The acquired intangible assets, all of which are being amortized, have a weighted average useful life of approximately eight years. The intangible assets include a customer list valued at $2.0 million. The fair value of the identifiable intangible assets and inventory were determined by management.

On January 8, 2009 (and effective as of January 1, 2009), the Company purchased the distribution rights, inventory, equipment, intangible assets and goodwill from its distributor located in Italy, which under ASC Topic 805 constitutes an acquired business. The Company established a wholly owned subsidiary in Italy called AGA Medical Italia S.R.L. The results of AGA Medical Italia S.R.L.'s operations have been included in the financial statements since the date it was established. The results of sales to the distributor were included in the financial statements prior to the purchase date. The aggregate purchase price was $41.0 million.

The excess purchase price over the fair value of underlying assets acquired and liabilities assumed was allocated to goodwill. The goodwill recorded as a result of the acquisition is not deductible for income tax purposes. The goodwill represents the strategic benefit of growing our business and the expected revenue growth from increased market penetration from future products and customers. The following tables summarize the consideration paid and the estimated fair value of the assets acquired at the date of acquisition.

(in thousands)	
Consideration:	
Cash payment	$26,600
Discounted guaranteed and contingent debt obligations	14,400
Total consideration	$41,000
Purchase Price Allocation:	
Inventory	$ 1,900
Goodwill	21,606
Other intangible assets	26,398
Total assets acquired	49,904
Current liabilities	615
Deferred income taxes, net	8,289
Net assets acquired	$41,000

In addition, the Company has agreed to pay the former owners up to $6.7 million if certain revenue goals are achieved during the first three years following the date of the agreement. The achievements are defined as follows:

Year 2009—$3.1 million guaranteed payment
$2.5 million contingent payment if gross revenues of AB Medica-AGA Division S.R.L. exceed 20.0 million Euro

Year 2010—$3.4 million guaranteed payment
$2.2 million contingent payment if gross revenues of AB Medica-AGA Division S.R.L. exceed 22.0 million Euro

3. Acquisitions (Continued)

Year 2011—$3.7 million guaranteed payment
$2.0 million contingent payment if gross revenues of AB Medica-AGA Division S.R.L. exceed 24.0 million Euro

On April 1, 2009, the Company made a $2.0 million contingent payment as a result of certain revenue goals that were achieved.

The acquired intangible assets, all of which are being amortized, have a weighted average useful life of approximately eight years. The intangible assets include a customer list valued at $24.8 million and a noncompete agreement valued at $1.6 million. The fair value of the identifiable intangible assets and inventory were determined by management.

Pro Forma Operating Results (Unaudited)

The consolidated financial statements include the operating results of each business acquired from the date of acquisition. The following unaudited pro forma condensed results of operations for 2008 and 2007 have been prepared as if the Company's purchase of distribution rights, inventory, equipment, intangible assets and goodwill from its distributor located in Italy, which under ASC Topic 805 constitutes an acquired business had occurred on January 1, 2007 (in thousands except per share data):

	2008	2007
	(in thousands, except per share data)	
Net sales	$183,325	$161,559
Operating income	30,704	35,955
Net income	10,912	7,925
Less dividends	(17,067)	(15,372)
Net income (loss) applicable to common stockholders	(6,155)	(7,447)
Net income (loss) per common share-basic and diluted	$ (0.29)	$ (0.33)

This pro forma financial information does not purport to represent results that would actually have been obtained if the transaction had been in effect on January 1, 2007 and January 1, 2008 or any future results that may be realized.

4. Goodwill and Intangible Assets

The following table provides a reconciliation of goodwill:

(in thousands)	
Balance as of December 31, 2007	$61,111
Goodwill acquired—U.K. distributor payment	2,500
Currency translation effect	(602)
Balance as of December 31, 2008	63,009
Goodwill acquired—Italy distributor	21,606
Currency translation effect	766
Balance as of December 31, 2009	$85,381

4. Goodwill and Intangible Assets (Continued)

Intangible assets consist of the following:

(in thousands)	Weighted Average Useful Life (in Years)	As of December 31, 2009			As of December 31, 2008		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Trade name	Indefinite	$ 10,650	$ —	$ 10,650	$ 10,650	$ —	$10,650
Developed technology	6.0	86,650	(43,817)	42,833	86,650	(33,897)	52,753
Customer relationships	4.9	64,694	(17,431)	47,263	29,429	(9,497)	19,932
Patent rights	7.5	14,500	(5,800)	8,700	14,500	(3,867)	10,633
Licensed patent	2.3	1,000	(763)	237	1,000	(559)	441
Noncompete agreement	11.8	2,710	(738)	1,972	992	(273)	719
		$180,204	$(68,549)	$111,655	$143,221	$(48,093)	$95,128

Intangible assets are amortized using methods that approximate the benefit provided by the utilization of the assets. Total amortization expense of intangible assets was $20.1 million, $15.5 million, $15.2 million for the years ended December 31, 2009, 2008 and 2007, respectively. Based on the intangibles in service as of December 31, 2009, estimated annual amortization expense is $20.4 million for 2010, $20.3 million for 2011, $17.4 million for 2012, $13.5 million for 2013 and $10.8 million for 2014.

In February 2007, the Company entered into an agreement to purchase the patent rights of an existing agreement with the Company. The purchase assigned the rights to receive royalties, the rights to certain inventions, and the rights for certain patent related filings to the Company. The agreement required the Company to make a onetime payment of $14.5 million. These patent rights are being amortized over 7.5 years.

5. Debt

On April 28, 2006, the Company entered into a $215.0 million term loan facility and a $25.0 million revolving credit facility. Proceeds were used to pay off existing senior debt; pay accrued dividends of $11.0 million to the Series A preferred and Class A common stockholders; pay a $0.30 per share dividend to all Series A preferred, Class A common, and common stockholders; pay transaction related expenses; and fund general working capital needs.

The term loan facility bears interest at either an alternate base rate, defined as the greater of the prime rate or the federal funds effective rate plus 0.50%, or the Eurodollar rate, plus an applicable spread based on the Company's leverage ratio. The interest rate in effect at December 31, 2009, 2008, and 2007, was 2.28%, 3.72%, and 7.25%, respectively. The Company is required to make payments on the term loan facility quarterly through the facility's termination date of April 28, 2013. Borrowings under our revolving credit facility bear interest at the alternate base rate or the Eurodollar rate, as defined above. On October 5, 2008, Lehman Commercial Paper Inc. ("LCP") filed for protection under Chapter 11 of the Federal Bankruptcy Code. LCP had committed to provide $9.5 million under the $25.0 million revolving credit facility. In March 2009 Bank of America, N.A. assumed the participation of this credit agreement previously held by LCP. At December 31, 2008, there was a borrowing of $9.9 million under our revolving credit facility, with subsequent borrowing on January 2, 2009 of

5. Debt (Continued)

$5.6 million, and March 20, 2009 of $9.5 million. On October 26, 2009, the $25.0 million borrowings under the revolving credit facility was repaid from the proceeds of the Company's initial public offering. The revolving credit facility expires on July 28, 2011.

The Company has the ability to make prepayments on the outstanding borrowings at any time. In addition, the Company is required to make additional repayments on term loan borrowings of up to 75% of the excess cash flow, as defined in the agreement, in any fiscal year. The Company made a voluntary prepayment of $17.5 million which satisfied future scheduled principal payments through March 31, 2013; therefore, no additional principal payments were due at December 31, 2008, or 2009, and accordingly, all of its senior debt is classified as long term. All of the Company's assets are pledged as collateral under this facility.

The financial covenants for these facilities include various restrictions with respect to the Company. In addition, there are restrictions on indebtedness, liens, guarantees, redemptions, mergers, acquisitions, and sale of assets over certain amounts. In addition, the covenants include maximum interest expense coverage, debt and leverage ratios, and restrictive covenants, including limitations on new debt, advances to subsidiaries and employees, capital expenditures, and transactions with stockholders and affiliates. The Company was in compliance with all covenants at December 31, 2009 and 2008, respectively.

On July 28, 2005, AGA Medical entered into a $50.0 million, 10% senior subordinated note agreement with a stockholder. As part of the agreement, AGA Medical issued 6,524 shares of Series A preferred stock valued at $6.5 million. The discounted issue value of the subordinated note was $43.5 million. Interest on the senior subordinated note is payable on a semiannual basis in arrears on January 1 and July 1 of each year. On October 26, 2009, the $50.0 million senior subordinated note was repaid from the proceeds of the Company's initial public offering. In conjunction with the repayment of the notes, the Company recorded a non-cash charge of $2.7 million representing the unamortized debt discount.

The senior subordinated note had financial and restrictive covenants similar to the term loan facility covenants. The subordinated note agreement was to mature on July 28, 2012. The $6.5 million of value assigned to the Series A preferred stock represented a discount from the face value of the note, which was accreted to its repayment amount utilizing the effective interest method. The original issue discount has been recognized as interest expense of $0.9 million for the years ended December 31, 2007 and 2008 and $3.4 million for the year ended December 31, 2009.

On January 5, 2009, the Company entered into a $15.0 million, 10% senior subordinated note agreement with a stockholder. As part of the agreement, the Company issued 1,879 shares of Series B preferred stock valued at $1.9 million to the stockholder. The discounted issue value of the subordinated note is $13.1 million. Interest on the senior subordinated note is payable on a semiannual basis in arrears on January 1 and July 1 of each year.

5. Debt (Continued)

Contractual payments due on the term loan facility, senior subordinated note, and borrowings under the revolving credit facility during each of the five years subsequent to December 31, 2009, are as follows:

(in thousands)	
2010	$ —
2011	—
2012	15,000
2013	196,963
	$211,963

The senior subordinated note executed January 2009, has financial and restrictive covenants similar to the term loan facility covenants. The subordinated note agreement matures on July 28, 2012. The $1.9 million of value assigned to the Series B preferred stock represents a discount from the face value of the note, which will be accreted to its repayment amount utilizing the effective interest method. The accreted value of notes payable as of December 31 of the following years is:

(in thousands)	
2010	$14,139
2011	14,681
2012	15,000

6. Capital Stock

Series A and B Preferred Stock

The shares of Series A and Series B preferred stock are convertible at any time, at the option of the holder, into shares of the Company's common stock at the then-applicable conversion prices ($1.00 for Series A preferred stock and $2.75 for the series B preferred stock). The conversion price for each of the Series A and B preferred stock is subject to adjustment in the event of certain events, such as dilutive issuance of additional securities.

In the event of the Company's liquidation, the holders of the Series A and Series B preferred stock will receive any distribution of corporate assets before and distributions to a junior class of equity. The amount to be distributed to the holder of Series A and Series B preferred will be the greater of (i) the Series A and Series B Preferred Accrued Value on such date and (ii) the amount that would be payable in connection with such liquidation event on the number of shares of common stock into which a share of Series A and Series B preferred stock was converted on such date.

Under the terms of the Series A and Series B preferred stock, the holders are entitled to receive cumulative dividends on each share of preferred stock at the rate of 10% per annum which shall accrue daily and, to the extent not paid, shall accumulate annually in arrears. Accrued dividends in arrears are $22.4 million, and $37.5 million at December 31, 2007 and 2008, respectively. On October 26, 2009, and in conjunction with the Company's initial public offering, all accrued dividends totaling $51.1 million were converted into 3,770,058 shares of the Company's common stock. Additionally, all shares of Series A and B preferred were converted into 18,070,946 shares of the Company's common stock.

6. Capital Stock (Continued)

Common Stock

The holders of shares of our common stock are each entitled to one vote for each share held with respect to all matters submitted to the stockholders of the Company for a vote or action by written consent.

On October 26, 2009, the Company completed its initial public of offering of 13.8 million shares of common stock and included in the issuance and sale of 6.6 million shares by the Company and 7.2 million shares by affiliates of Franck L. Gougeon, one of the controlling shareholders. As a result, the Company received approximately $82.2 million in net proceeds and issued 6.6 million shares of common stock at $14.50 per share.

Class A Common Stock

The holders of Class A common stock are each entitled to one vote for each share held with respect to all matters submitted to the stockholders of the Company for a vote or action by written consent.

Under the terms of the Class A common stock, the holders are entitled to receive cumulative dividends on each share of Class A common stock at the rate of 10% per annum which shall accrue daily and, to the extent not paid, shall accumulate annually in arrears. Accrued dividends in arrears are $1.1 million, and $1.9 million at December 31, 2007 and 2008, respectively.

On October 26, 2009, and in conjunction with the Company's initial public offering, all accrued dividends totaling $2.6 million were converted into 193,016 shares of the Company's common stock at the public offering price less the underwriting discount. Additionally, all shares of Class A common were converted into 923,076 shares of the Company's common stock.

Class B Common Stock

The holders of shares of Class B common stock are not entitled to vote on any matters submitted to the stockholders of the Company for a vote or by written consent.

Immediately prior to the Company's initial public offereing, each share of Class B common stock converted into one share of common stock.

7. Income Taxes

The provision for income taxes is based on earnings before income taxes reported for financial statement purposes. The components of earnings before income taxes are as follows:

	December 31,		
(in thousands)	2009	2008	2007
United States	$(5,229)	$4,712	$7,294
International	3,306	4,770	2,628
Total	$(1,923)	$9,482	$9,922

7. Income Taxes (Continued)

Significant components of the (benefit) provision for income taxes for the following periods are as follows:

(in thousands)	Year Ended December 31, 2009	2008	2007
Current:			
Federal	$ 2,039	$ 7,030	$ 7,849
State	250	547	576
Foreign	2,254	1,301	619
Deferred:			
Federal	(5,521)	(8,072)	(5,128)
State	(185)	(701)	(446)
Foreign	(1,527)	—	—
Valuation allowance against deferred tax assets	1,862	281	374
Total	$ (828)	$ 386	$ 3,844

A reconciliation of the federal statutory income taxable to the effective tax rate is as follows:

	Year Ended December 31, 2009	2008	2007
Federal tax statutory rate	35.0%	35.0%	35.0%
State tax (net of federal benefit)	4.7	1.5	2.1
FCPA resolution	—	—	7.0
Other permanent differences	1.1	(1.3)	(2.9)
Stock-based compensation expense	(26.6)	4.5	2.3
Research and development credit	76.4	(15.8)	(10.0)
Tax reserves	24.8	(20.1)	4.3
Valuation allowance against deferred tax assets	(96.8)	3.0	3.7
Change in contingent consideration under ASC 805	21.0	—	—
Meals and entertainment	(5.2)	1.0	1.0
Permanent reinvestment assertion in foreign subsidiaries	11.5	—	—
Federal and state provision to return true-up	11.5	—	—
Deferred rate change	(5.5)	—	—
Foreign permanently non-deductible	(20.3)	—	—
Expiring capital loss	(8.5)	—	—
Foreign rate differential	7.2	—	—
Domestic manufacturing deduction	12.7	(3.7)	(3.8)
Effective income tax rate	43.0%	4.1%	38.7%

7. Income Taxes (Continued)

Significant components of deferred tax assets and liabilities are as follows:

(in thousands)	December 31, 2009	December 31, 2008
Deferred tax assets:		
Capital losses (including unrealized losses)	$ 2,084	$ 592
Allowance for doubtful accounts	139	353
Sales returns reserve	2,790	2,728
Inventory reserves	1,821	668
ASC 718—nonqualified option expense	2,146	1,385
Foreign subsidiary profits	—	—
Other	3,589	4,533
Less valuation allowance	(2,753)	(866)
Total deferred tax assets	9,816	9,393
Deferred tax liabilities:		
Depreciation	(3,058)	(1,809)
Intangibles	(31,403)	(28,455)
Other	—	721
Total deferred tax liabilities	(34,461)	(29,543)
Net deferred tax liability	$(24,645)	$(20,150)

The Company has recorded no U.S. deferred taxes related to the undistributed earnings of its non-U.S. subsidiaries' as of December 31, 2009. Such amounts are intended to be reinvested outside of the United States indefinitely. The amount of unrecorded tax liability related to investments in foreign subsidiaries as of December 31, 2009 is approximately $0.4 million.

At December 31, 2009, 2008 and 2007, the Company has capital loss carry forwards of $5.6 million, $1.6 million, and $1.6 million respectively, which expire at various times beginning in 2010 through 2014. The Company has established a valuation allowance against these capital loss carry forwards, as it does not believe they will be realizable before the expiration.

The net increase in the Company's valuation allowance during the year is due to an increase in the federal capital loss carry forward as a result of the disposition of an investment in Ample Medical (net of the expiration for prior year capital losses) and valuation allowances recorded on net operating losses expected in the Company's foreign subsidiaries. Management believes that it is not more likely than not that the Company will generate enough capital gains to absorb the additional capital losses generated during the year. The valuation allowances in place for foreign subsidiaries are due to lack of sufficient positive evidence to realize the deferred tax assets associated with the net operating losses in each country.

7. Income Taxes (Continued)

The Company records all income tax contingency accruals in accordance with ASC Topic 740, *Income Taxes*. At December 31, 2009, 2008 and 2007 the Company had $1.8 million, $2.3 million and $4.4 million of unrecognized tax benefits, including interest and penalties, that, if recognized would result in a reduction of the Company's effective tax rate. As of December 31, 2009, 2008 and 2007, the Company had approximately $1.2 million, $1.2 million and $1.4 million accrued for interest and penalties. Over the next 12 months, the Company does not expect its recorded liability for income tax contingency accruals to be reduced. The Company recognizes interest and penalties related to income tax matters in income tax expense and reports the liability in current or long-term income taxes payable, as appropriate.

The following table summarizes the activity related to the Company's unrecognized tax benefits:

	December 31,	
(in thousands)	2009	2008
Balance at beginning of period	$1,987	$ 3,865
Increases—tax positions taken in current period	153	
Expiration of the statute of limitations for the assessment of taxes	(620)	(1,878)
Balance at end of period	$1,520	$ 1,987

The Company's federal income tax returns are subject to examination for 2006 and subsequent years. The Company's 2007 federal income tax return is currently under examination. State and foreign income tax returns are generally subject to examination for a period of three to four years after filing of the respective return. The state impact of any federal changes remains subject to examination by various states for a period up to one year after formal notification to the states.

8. Commitments

The Company leases various pieces of equipment and offices under operating lease agreements. Future minimum operating lease obligations as of December 31, 2009, are as follows:

(in thousands)	
2010	$1,687
2011	1,005
2012	769
2013	630
2014	630
Total	$4,721

Total rent expense under the operating leases for the years ended December 31, 2009, 2008 and 2007, was $2.2 million, $1.1 million, and $0.8 million, respectively. One of the Company's operating lease agreements is non-cancellable and renewable with an expiration date in the year 2012.

The Company has various royalty agreements with certain individuals which obligate the Company to pay royalties on net sales of certain products. These royalties are payable throughout the commercial life of the products. Royalties payable at December 31, 2009 and 2008, totaled $2.3 million, and

8. Commitments (Continued)

$1.9 million, respectively. Royalty expense for the years ended December 31, 2009, 2008 and 2007, was $6.9 million, $6.0 million, and $5.3 million, respectively.

9. Benefit Plan

The Company has a defined contribution salary deferral plan (the 401(k) Plan) covering substantially all employees under Section 401(k) of the Internal Revenue Code. Eligible employees may contribute a percentage of their annual compensation, subject to IRS limitations, with the Company matching a portion of the employees' contributions. Compensation expense of $1.3 million, $0.9 million, and $0.2 million, was recognized in the years ended December 31, 2009, 2008, and 2007, respectively. The Company may also contribute a discretionary Safe Harbor amount under Plan. The contribution for 2007 was 3% of qualifying wages paid during the year. The Company paid discretionary a contribution of $0.7 million for the year ended December 31, 2007. The Company did not make a Safe Harbor contribution for the years ended December 31, 2009 and 2008.

10. Litigation

On July 25, 2006, the Company commenced the voluntary disclosure process to the Department of Justice under the Foreign Corrupt Practices Act for potentially impermissible payments by the Company's unaffiliated distributor in the People's Republic of China. As part of its process, the Company engaged in a comprehensive review of all of its international distributors and the Company's own internal practices. On June 2, 2008, the Company entered into a Deferred Prosecution Agreement with the Department of Justice concerning alleged improper payments that were made by the Company's former independent distributor in China. In accordance with the terms of the agreement, the Company paid a monetary penalty of $2.0 million in June 2008. In the fourth quarter of 2007, the Company had recorded a charge of $2.0 million for the potential settlement of this matter.

On January 29, 2007, Medtronic, Inc. filed a patent infringement action against the Company in the U.S. District Court for the Northern District of California, alleging that substantially all of the Company's *AMPLATZER* occluder and vascular plug devices, which have historically accounted for substantially all of the Company's net sales, infringe three of Medtronic's method and apparatus patents on shape memory alloy stents (U.S. Patent Nos. 5, 190,546, 6,306,141 and 5,067,957). Medtronic is seeking compensatory damages with respect to the Company's products manufactured or sold in the United States. Medtronic asserted but later withdrew its requests for injunctive relief and for damages based on willfulness.

The Company has asserted defenses and counterclaims for non-infringement and challenged the validity and enforceability of Medtronic's patents. On April 28, 2009, the court granted summary judgment in the Company's favor finding that the Company does not infringe Medtronic's '546 patent. Subsequently, Medtronic withdrew certain allegations with respect to the remaining two patents. The trial on the remaining issues in the case was divided into a jury trial phase and non-jury, bench trial phase.

The issues of infringement and certain issues of validity based on obviousness and anticipation of the asserted claims in the two remaining patents were the subject of a jury trial before the U.S. District Court for the Northern District of California that began on July 6, 2009. On August 5, 2009, the jury returned a verdict that the subject *AMPLATZER* occluder and vascular plug products infringed the claims at issue with respect to both of the two remaining Medtronic patents and that the Medtronic

10. Litigation (Continued)

patent claims at issue had not been proven by the Company to be invalid. The jury verdict awarded Medtronic damages of $57.8 million. This amount is equal to 11% of historical sales of the occluder and vascular plug products in question during the timeframe specified for each patent. Any infringement of the '141 apparatus patent after March 31, 2009 to the date of a final, non-appealable judgment will be considered in calculating the final amount of damages, if any, to be paid. The '957 patent expired in May 2004. Because the issue was not before it, the jury made no determination regarding the payment of royalties on future sales of the Company's products after the date of a final, non-appealable judgment. The verdict is not enforceable until the completion of the trial and entry of a final, non-appealable judgment. If the Company does not receive a favorable judgment, the Company expects it will appeal such judgment and expects that it will likely be required to post a bond in order to be allowed to appeal as set forth below. The verdict is not enforceable because a judgment has not yet been entered, and as a matter of law only judgments are enforceable for purposes of execution against the non-prevailing party. A judgment has not yet been entered because all claims have not yet been adjudicated between the parties and the court has not yet ordered a judgment be entered. In addition, on August 5, 2009, Medtronic's counsel agreed with the judge on the record that a judgment would not be entered until after the non-jury trial phase is completed. Furthermore, upon approval of an appeal bond, the execution of any appealed judgment is stayed during the appeal.

On August 19, 2009, the United States Court of Appeal for the Federal Circuit, sitting en banc, issued a decision in *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.* In *Cardiac Pacemakers*, the Federal Circuit established a new rule of law and held as a matter of law that the practice of a method claim of a patent outside of the United States cannot infringe a United States method patent. When a controlling new rule of law is announced that affects the parties to a patent litigation, the court will ordinarily apply the supervening change in law retroactively to a pending case. In the Company's litigation with Medtronic, a portion of the jury's damage award was based on a finding of infringement of Medtronic's '957 method patent for sale of the Company's products outside of the United States, and the Company believes it is therefore directly contrary to the holding as stated in the *Cardiac Pacemakers* decision. Applying the rate of damages established by the jury, 11% of historical sales, to the total sales of our products outside of the United States during the period for which the Company believes damages were awarded for infringement of the '957 patent would result in a reduction of approximately $14 million. Such $14 million of damages relates only to periods of time before the '141 patent was enforceable against the Company. As a result, the Company believes it is likely that the trial court in the Company's case will reduce the jury's damage award by approximately such amount to reflect this recent decision, although there can be no assurance that the damage award will be reduced by this or any other amount. On September 8, 2009, the Company filed a motion seeking, at Medtronic's choice, either a new trial or the above-mentioned reduction of $14 million, which motion is publicly available. The Company does not expect a ruling on this motion until the conclusion of the non-jury phase of the trial in early 2010.

Following the jury verdict, the court held the non-jury phase of the trial in early December 2009, to hear the Company's claim that the '141 patent is invalid based on the doctrine of double patenting, which prohibits obtaining two patents covering the same basic invention in a continuation application. In the event the judge finds in the Company's favor in the non-jury phase of the trial, she can decide that the '141 patent is invalid and eliminate the damages awarded by the jury against the Company on the '141 patent. Upon conclusion of its decision on the non-jury phase of the trial, the court will consider post-trial motions and enter a judgment, which the Company expects will take place in mid to

10. Litigation (Continued)

late 2010. As part of its decision, the trial court could order a new trial on some or all of the issues in the case or amend or reaffirm the jury verdict based on one or more issues regarding infringement, validity, enforceability and damages. The Company also expects the trial court to decide whether any royalty payments relating to the '141 patent, which does not expire until 2018, are due for future periods and, if so, at what rate. Any such royalties may not be on commercially reasonable terms, and may exceed the 11% rate of damages applied by the jury. If any damage amount is entered as a part of the judgment, the Company will likely be required at that time to accrue a non-cash charge equal to the amount of such damages. Any such accrual will have an adverse effect on the Company's results of operations for the applicable period.

Thereafter, the judgment will be subject to appeal which could result in the judgment being affirmed or amended, or in an order for a new trial on one or more of the same issues raised before the trial court. Medtronic also could appeal from rulings adverse to it, which could result in an appellate decision with effects adverse to the Company on issues of liability and/or relief. If the Company decides to appeal, such appeal may not be decided for several months and may require the posting of a bond in the face amount of up to 150% of the judgment amount, if any. The Company does not expect the cash cost associated with posting such a bond to be material, but the Company would likely be required to secure such bond with collateral. The amount of collateral required by the provider of the bond would be determined based on several factors, such as the amount of the Company's debt and the Company's financial condition.

The Company has not recorded an expense related to damages in connection with this litigation matter because any potential loss is currently neither probable nor reasonably estimable under ASC Topic 450, *Contingencies* (ASC 450).

On November 30, 2007, the University of Minnesota filed a patent infringement action alleging that the Company's *AMPLATZER* occlusion devices infringe their method and apparatus patents on septal devices. One of the two patents expired in 2004. The Company believes that it has significant defenses to the litigation, including unenforceability, invalidity and non-infringement. The Company believes this claim is without merit and will continue to vigorously defend its position. As the outcome is uncertain, the Company has not accrued any costs resulting from the claim at December 31, 2008 or 2009.

On January 15, 2008, Dr. Paul Teirstein filed a patent infringement action against the Company in the United States District Court for Minnesota, alleging that the Company's *AMPLATZER®* occlusion devices infringe Teirstein's patent for body passageway closure apparatus and method of use (U.S. Patent No. 5,499,995). On September 23, 2009, the Company entered into a settlement agreement with Teirstein in which the parties agreed to the dismissal of all claims and counterclaims with prejudice in exchange for Teirstein's grant to the Company of a covenant not to sue on the '995 patent on all of the Company's existing and future products, and the lump-sum payment by the Company to Teirstein in the amount of $0.4 million.

The Company is subject to other various litigation claims in the normal course of business. Management does not believe that any of these claims will have a material impact on the financial statements.

11. Equity Incentive Plans

In 2006, the Company adopted an Equity Incentive Plan (the Plan) pursuant to which the Company's Board of Directors may grant up to 2.8 million stock options to directors, officers, and key employees. Under the 2008 Equity Incentive Plan, the Company's Board of Directors made available 2.1 million equity awards including stock options and restricted stock units.

At December 31, 2009 and 2008, there were 1.6 million and 2.1 million shares remaining available for the Company to grant under the Plan, respectively.

Stock Options

Options granted under the Plan vest over a range of three to five years and are generally exercisable for a range of seven to ten years after the date of grant.

The fair value of each option award is estimated using the Black-Scholes option-pricing model that used the weighted average assumptions in the following table. Prior to the Company's initial pubic offering of stock, the exercise price of the options granted under the Plan was not less than 100% of the fair market value on the date of grant. Following the initial public offering, the option awards are granted with an exercise price equal to the market price of the Company's stock at the date of grant. The Company uses the simplified method for estimating expected term because it does not have sufficient historical data as a publicly traded company to estimate expected term. Expected volatility is based on the historical volatilities of peer companies as the Company has insufficient historical data as a newly publicly traded company to calculate its own volatility. The risk-free interest rate is based on U.S. Treasury yields in effect on the date of grant whose maturity period equals or approximates the option's expected term.

	Year Ended December 31,		
	2009	2008	2007
Valuation assumptions:			
Expected dividend yield . .	—%	—%	—%
Expected volatility	54% - 57%	53% - 58%	45% - 64%
Expected term (years) . . .	4.5 - 6.5	6.50	6.50
Risk-free interest rate . . .	1.83% - 3.30%	1.87% - 3.57%	5.01% - 5.04%

The weighted average fair value of options granted was $9.92 per share in 2009, $10.82 in 2008, and $8.61 in 2007, respectively. The Company uses the straight-line (single option) method for expense attribution over the related vesting period according to which the Company estimates forfeitures and only recognizes expense for those shares expected to vest. The Company recognized compensation expense related to its stock option plan of $3.7 million, $2.6 million and $1.9 million for the years ended December 31, 2009, 2008 and 2007, respectively. The future income tax benefit to be realized by the Company related to this compensation expense is $0.8 million, $0.5 million, and $0.5 million, for the years ended December 31, 2009, 2008, and 2007, respectively.

11. Equity Incentive Plans (Continued)

A summary of stock option activity is as follows:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Term	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2006	2,147,958	$ 7.15	9.1 years	—
Granted	542,649	13.10		
Exercised	(6,992)	7.15		$ 49
Cancelled and Forfeited	(128,109)	7.15		
Balance at December 31, 2007	2,555,506	$ 8.41	8.4 years	$28,748
Granted	270,624	19.66		
Exercised	(6,571)	7.15		$ 82
Cancelled and Forfeited	(67,551)	7.37		
Balance at December 31, 2008	2,752,008	$ 9.55	7.6 years	$27,836
Granted	457,090	18.30		
Exercised	(80,209)	7.15		$ 590
Cancelled and Forfeited	(148,393)	16.83		
Balance at December 31, 2009	2,980,496	$10.59	6.8 years	$15,424
Options exercisable at December 31, 2007	619,718	$ 7.15	7.9 years	$ 7,755
Options exercisable at December 31, 2008	1,122,298	$ 7.81	7.1 years	$13,295
Options exercisable at December 31, 2009	1,577,043	$ 8.47	6.3 years	$10,396

The aggregate intrinsic value in the table above represents the difference between the estimated fair value of common stock and the exercise price, multiplied by the number of in-the-money options that would have been received by the option holders had all option holders exercised their options on December 31, 2009, 2008 and 2007, respectively.

The schedule below reflects the number and weighted average exercise price of outstanding and exercisable options segregated by exercise price ranges:

	December 31, 2009			December 31, 2008		
	Options Outstanding		Options Exercisable	Options Outstanding		Options Exercisable
Exercise Prices	Number of Options	Average Remaining Term	Number of Options	Number of Options	Average Remaining Term	Number of Options
$7.15	1,999,222	6.1 years	1,356,465	2,100,271	7.1 years	1,032,798
$13.45 - 14.50	373,599	7.4 years	127,265	290,205	8.6 years	69,224
$19.66	607,675	8.8 years	93,313	361,532	9.3 years	20,276
	2,980,496	6.8 years	1,577,043	2,752,008	7.6 years	1,122,298

11. Equity Incentive Plans (Continued)

Stock option activity for non-vested shares under the Plan is as follows:

	Options	Weighted Average Grant-Date Fair Value
Balance at December 31, 2007	1,935,788	$ 5.12
Granted	270,624	10.66
Vested	(517,541)	4.98
Cancelled and Forfeited	(59,161)	4.00
Balance December 31, 2008	1,629,710	$ 6.12
Granted	457,090	9.72
Vested	(563,343)	5.52
Cancelled and Forfeited	(120,004)	10.73
Balance December 31, 2009	1,403,453	$ 7.14

As of December 31, 2009, 2008 and 2007, there was $8.7 million, $7.4 million, and $8.5 million of unrecognized compensation cost related to non-vested, share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted average period of 2.2 years.

Restricted Stock Units

The Company grants restricted stock units to officers and key employees under the 2008 Equity Incentive Plan. Restricted stock units are not considered issued or outstanding common stock of the Company. The Company grants restricted stock units that typically cliff vest over a two to three year period and expenses the restricted stock units over the vesting period.

Restricted stock unit activity in 2009 is as follows:

	Restricted Stock Units	Weighted Average Grant Price	Weighted Average Remaining Term
Balance at December 31, 2008	—	—	—
Granted	246,100	12.48	6.9 years
Vested	—	—	—
Cancelled and Forfeited	—	—	—
Balance at December 31, 2009	246,100	$12.48	6.9 years
Exercisable at December 31, 2009	—	—	
Nonvested at December 31, 2009	246,100	12.48	

As of December 31, 2009 there was $2.7 million of unrecognized compensation cost related to non-vested restricted stock unit compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted average period of 2.9 years. The Company recognized compensation expense related to restricted units of $0.1 million for the year ended December 31, 2009.

11. Equity Incentive Plans (Continued)

Employee Stock Purchase Plan

The 2008 Employee Stock Purchase Plan, adopted by the Board of Directors and ratified by the Company's stockholders on October 2, 2009, allows employees to purchase shares of the Company's common stock at a discount through payroll deductions. The maximum number of shares which may be issued under the plan is 4 million shares. With respect to the first offering, eligible employees electing to participate entered a subscription equal to 2% of their base pay. Except as provided in connection with the first offering, an eligible employee's subscription shall authorize payroll deductions up to 10% of base pay on each payday that the subscription is in effect. The purchase price per share of stock under each offering shall be the lower of 85% of the fair market value of the stock on the offering commencement date or 85% of the fair market value of the stock on the purchase date. The initial purchase period extends from October 21, 2009 to June 30, 2010. As of December 31, 2009, plan participants have had approximately $0.1 million withheld to purchase the Company's common stock on June 30, 2010. As of December 31, 2009 the Company has recognized an immaterial amount of expense related to the Company's Employee Stock Purchase Plan.

Significant Factors Used in Determining Fair Value of the Company's Common Stock

The fair value of the shares of common stock that underlie the stock options the Company has granted has historically been determined by the board of directors of the Company based upon information available to it at the time of grant. Because there has been no public market for the common stock, the board of directors of the Company has determined the fair value of the common stock by utilizing, among other things, contemporaneous valuation studies conducted as of April 30, 2006 and June 30, 2007. The findings of these valuation studies were based on the Company's business and general economic, market and other conditions that could be reasonably evaluated at that time. The analyses of the valuation studies incorporated extensive due diligence that included a review of the Company, including its financial results, business agreements, intellectual property and capital structure. The valuation studies also included a thorough review of the conditions of the industry in which the Company operates and the markets that it serves. The methodologies of the valuation studies included an analysis of the fair market value of the Company using three widely accepted valuation methodologies: (1) market multiple, (2) comparable transactions, and (3) discounted cash flow. The board of directors of the Company took these three approaches into consideration when establishing the fair value of the common stock of the Company. In addition, the Company received input from the underwriters of the Company's initial public offering in October 2007 with respect to valuation of the Company. Based on the foregoing factors, the Company's board of directors increased the fair value of the Company's common stock to $2.75 at October 22, 2007 and the value remained unchanged throughout 2008 and until completion of the Company's initial offering of Stock in October 2009. Following the Company's initial public offering, the option awards are granted with an exercise price equal to the market price of the Company's stock at the date of grant.

12. Fair Value Measurements

The fair value of assets and liabilities is determined on the exchange prices which would be received for an asset of paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants. The determination of fair value is based upon a three-tier value hierarchy, which prioritizes the inputs used

12. Fair Value Measurements (Continued)

in fair value measurements. The three-tier hierarchy for inputs used in measuring fair value is as follows:

- Level 1—Unadjusted quoted prices in active markets for identical assets or liability
- Level 2—Unadjusted quoted price in active market for similar assets or liabilities, or unadjusted quoted prices for identical or similar assets
- Level 3—Unobservable inputs for the asset or liability for which there is little to no market data which requires the entity to develop its own assumption.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The carrying value of cash and cash equivalents approximates fair value at December 31, 2009 and 2008. Cash and cash equivalents are classified as Level 1 in the fair value hierarchy.

The Company measures the fair value of contingent consideration at each reporting period using Level 3 inputs. The Company has recorded the acquisition date estimated fair value of the contingent payment milestones as a component of consideration transferred using Level 3 inputs. The acquisition date fair values were measured based on the probability and adjusted present value of amounts expected to be paid. The probability adjusted contingent considerations were discounted at the weighted average cost of capital for each acquisition. See note 3 ("Acquisitions") and the following paragraphs for specific amounts recorded for each acquisition.

In conjunction with the January 1, 2009 purchase of distribution rights, inventory and intangible assets from the Company's former distributor in France, a contingent payment payable on April 1, 2010, which as of the acquisition date had a net present value of $1.3 million payable if certain revenue goals are achieved during this period was recorded. The Company recorded operating expense of approximately $0.2 million representing the increase in fair value of the contingent obligation for the period ended December 31, 2009. As of December 31, 2009, the balance of the contingent obligation recorded was $1.5 million.

In conjunction with the January 1, 2009 purchase of distribution rights, inventory and intangible assets from its two former distributors in Portugal, contingent payments payable in January 2010, which as of the acquisition date had a net present value of $0.8 million payable if certain revenue goals are achieved during this period was recorded. The Company recorded as a reduction to operating expense an immaterial decrease representing the decrease in fair value of the contingent obligation for the period ended December 31, 2009. As of December 31, 2009, the balance of the contingent obligation recorded was $0.8 million.

In conjunction with the January 1, 2009 purchase of distribution rights, inventory and intangible assets from its former distributor in the Netherlands, a contingent payment payable in January 2010, which as of the acquisition date had a net present value of $0.3 million payable if certain revenue goals are achieved during this period was recorded. The Company recorded as a reduction to operating expense an immaterial decrease representing the increase in fair value of the contingent obligation for the period ended December 31, 2009. As of December 31, 2009, the balance of the contingent obligation recorded was $0.3 million.

In conjunction with the January 1, 2009 purchase of distribution rights, inventory and intangible assets from its distributor in Canada, a contingent payment payable in January 2010, which as of the

12. Fair Value Measurements (Continued)

acquisition date had a net present value of $0.9 million payable if certain revenue goals are achieved during this period was recorded. The Company recorded as a reduction to operating expense approximately $0.1 million representing the decrease in fair value of the contingent obligation for the period ended December 31, 2009. As of December 31, 2009, the balance of the contingent obligation recorded was $0.8 million.

On January 8, 2009 (and effective as of January 1, 2009), the Company purchased the distribution rights, inventory, equipment, intangible assets and goodwill from its distributor located in Italy, which under ASC Topic 805 constitutes an acquired business. The Company has agreed to pay the former owners up to $6.7 million if certain revenue goals are achieved during the first three years following the date of the agreement. The achievements are defined as follows:

Year 2009—$3.1 million guaranteed payment to be paid in January 2010. $2.5 million contingent payment if gross revenues of AB Medica-AGA Division S.R.L. exceed 20.0 million Euro

Year 2010—$3.4 million guaranteed payment. $2.2 million contingent payment if gross revenues of AB Medica-AGA Division S.R.L. exceed 22.0 million Euro

Year 2011—$3.7 million guaranteed payment. $2.0 million contingent payment if gross revenues of AB Medica-AGA Division S.R.L. exceed 24.0 million Euro

On April 1, 2009, the Company made a $2.0 million contingent payment as a result of certain revenue goals that were achieved.

The Company recorded as a reduction to operating expense approximately $1.3 million representing the decrease in fair value of the contingent obligation for the period ended December 31, 2009. As of December 31, 2009, the balance of the contingent obligation recorded was $4.0 million.

The following table represents a summary of the contingent consideration liability and activity (in thousands) for the periods presented:

	December 31,	
	2009	2008
Contingent Consideration:		
Balance at Beginning of Period	$ 0	$ 0
Purchase price contingent consideration	10,558	—
Payments	(2,044)	—
Change in fair value of contingent consideration (included in the statement of operations)	(1,149)	—
Currency translation effect	92	—
Balance at End of Period	$ 7,457	$ 0

Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

During the twelve month period ending December 31, 2009, we had no significant fair value measurements of assets or liabilities at fair value subsequent to their initial recognition, except as disclosed in our equity method investment footnote.

12. Fair Value Measurements (Continued)

Fair Value of Financial Instruments

The carrying value of the Company's debt instruments approximates fair value for all periods presented.

13. Equity Method Investment

The Company held an investment in common stock in Ample Medical Inc., a privately held Company that is focused on the development of minimally invasive medical devices to treat structural heart diseases, of $0.0 million and $2.3 million as of December 31, 2009 and 2008, respectively. The balance is included in the other assets, net line item on the balance sheet. The Company held an approximately 0.0% and 35.6% ownership interest at each date. During the first quarter of fiscal year 2009, the Company determined that its equity method investment in Ample Medical, inc. was other-than-temporarily impaired and wrote off the remaining investment balance to its fair value of $0.0 million. The loss on impairment of $2.3 million is recorded in the investment income (loss) line item on the consolidated statement of operations.

The Company made an initial investment of $2.5 million during fiscal year 2006 and made an additional $1.9 million equity investment during fiscal year 2008 which included the conversion of a $0.7 million promissory note based upon achievement of a significant milestone. The Company also entered into an amended and restated stock purchase agreement, whereby the Company would have the option to make additional investments that will be available based on the achievement of certain milestone objectives. Losses on this investment of $0.0 million, $1.2 million, and $0.8 million were recorded based upon its prorated share of estimated losses during the years ended December 31, 2009, 2008, and 2007, respectively.

14. Other Comprehensive Income (loss)

Accumulated other comprehensive income (loss) has no impact on our net income (loss) but is reflected in our balance sheet through adjustments to stockholders' (deficit) equity. Accumulated other comprehensive income (loss) derives from foreign currency translation adjustments and unrealized gains (losses) on short-term investments. We specifically identify the amount of unrealized gain (loss) recognized in other comprehensive income for each short-term investment. When a short-term investment is sold we remove the investment's cumulative unrealized gain (loss), net of tax, from accumulated other comprehensive (income) loss. The components of accumulated other comprehensive income (loss) are:

(in thousands)	Foreign Currency Translation Adjustment	Unrealized Gain (Loss) On Investments, Net	Total
Balance, December 31, 2006	$ 178	$(7)	$ 171
Unrealized gain on short-term investments	—	7	7
Translation gain	245	—	245
Balance, December 31, 2007	423	—	423
Translation loss	(2,069)	—	(2,069)
Balance, December 31, 2008	(1,646)	—	(1,646)
Translation gain	1,157	—	1,157
Balance, December 31, 2009	$ (489)	$—	$ (489)

15. Segment Information

We review our operations and manage our business as one reportable segment where we develop, manufacture and market our products which are sold in 112 countries through a combination of direct sales and the use of our distributors. Factors used to identify our single operating segment include the financial information available for evaluation by our chief operating decision maker in making decisions about how to allocate resources and assess performance.

15. Segment Information (Continued)

Geographic Information

International sales to external customers were 62.7%, 59.2%, and 57.9% of revenues for 2009, 2008, and 2007 respectively. Net sales to external customers and long-lived assets by geography are as follows:

	Year Ended December 31,		
(in thousands)	2009	2008	2007
Net sales:			
United States	$ 74,115	$ 68,048	$ 61,859
International:			
Italy	24,387	9,665	8,589
Europe (exclusive of Italy)	62,753	54,363	49,573
Other	37,455	34,820	27,234
Total International	124,595	98,848	85,396
Total net sales	$198,710	$166,896	$147,255

	December 31,	
(in thousands)	2009	2008
Long-lived assets:		
United States	$172,328	$189,552
Italy	45,394	—
International	23,942	13,077
Total long-lived assets	$241,664	$202,629

A single customer's account balance of none and $2.7 million represented approximately 10.0% of the Company's consolidated accounts receivable balances at December 31, 2009 and 2008, respectively. We are not dependent on any single customer, and no single customer (including distributors) accounted for more than 10% of our net sales for the years ending December 31, 2009, 2008, and 2007.

16. Subsequent Events

On January 1, 2010, the Company purchased the vascular product distribution rights, inventory, and intangible assets from its distributor in Canada. The $0.3 million aggregate purchase price includes payments of $0.1 million in January 2010, $0.1 for inventory, and a contingent payment in January 2011 which as of the acquisition date had a net present value of $0.1 million payable if certain revenue goals are achieved during this period. The acquired intangible assets, as of which are being amortized, have a weighted average useful life of approximately eight years. The intangible assets include a customer list valued at $0.2 million. The fair value of the identifiable intangible assets and inventory were determined by management.

AGA Medical Holdings, Inc.

Schedule II
Valuation and Qualifying Accounts
Years Ended December 31, 2009, 2008 and 2007
(in thousands)

Description	Balance at Beginning of Period	Additions	Deletions	Balance at End of Period
Year Ended December 31, 2009:				
Allowance for doubtful accounts	$ 933	$ 584	$(1,036)	$ 481
Reserve for inventory	1,817	929	(844)	1,902
Reserve for sales returns	8,025	7,721	(6,411)	9,335
Total	10,775	9,234	(8,291)	11,718
Year Ended December 31, 2008:				
Allowance for doubtful accounts	992	18	(77)	933
Reserve for inventory	1,883	1,265	(1,331)	1,817
Reserve for sales returns	7,226	1,312	(513)	8,025
Total	10,101	2,595	(1,921)	10,775
Year Ended December 31, 2007:				
Allowance for doubtful accounts	588	754	(350)	992
Reserve for inventory	2,421	408	(946)	1,883
Reserve for sales returns	7,140	7,215	(7,129)	7,226
Total	$10,149	$8,377	$(8,425)	$10,101

Exhibit 31.1

CERTIFICATION

I, John R. Barr, certify that:

1. I have reviewed this report on Form 10-K of AGA MEDICAL HOLDINGS, INC.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 4, 2010

/s/ JOHN R. BARR

John R. Barr
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Brigid A. Makes, certify that:

1. I have reviewed this report on Form 10-K of AGA MEDICAL HOLDINGS, INC.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 4, 2010

/s/ BRIGID A. MAKES

Brigid A. Makes
Senior Vice President and Chief Financial Officer

Exhibit 32

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of AGA MEDICAL HOLDINGS, INC. on Form 10-K for the period ended December 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), John R. Barr, President and Chief Executive Officer and Brigid A. Makes, Senior Vice President and Chief Financial Officer, in each case, of AGA Medical Holdings, Inc., each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of AGA Medical Holdings, Inc.

Date: March 4, 2010

/s/ JOHN R. BARR

John R. Barr
President and Chief Executive Officer

/s/ BRIGID A. MAKES

Brigid A. Makes
Senior Vice President and Chief Financial Officer

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Corporate Information

Global Headquarters
AGA Medical Corporation
5050 Nathan Lane North
Plymouth, Minnesota 55442
763.513.9227
www.amplatzer.com

Common Stock
The company's common stock trades on the NASDAQ Global Select Market under the ticker symbol AGAM.

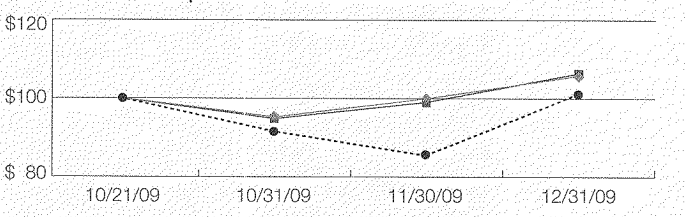
Transfer Agent and Registrar
American Stock Transfer & Trust Company, LLC
59 Maiden Lane
Plaza Level
New York, New York 10038
Toll Free: 800.937.5449
Direct: 718.921.8200

Independent Accountants
Ernst & Young, LLP
Minneapolis, Minnesota

Annual Meeting
The annual meeting of the shareholders of AGA Medical Corporation will be held on June 7, 2010, at 9:00 am at the Radisson Hotel and Conference Center in Plymouth, Minnesota.

Stock Performance Graph
The graph below compares the total stockholder return of an investment of $100 on October 21, 2009 (the first day of trading of our common stock on the Nasdaq Stock Exchange) through December 31, 2009 and the reinvestment of all dividends for (i) our common stock (ii) The Nasdaq Composite Index and (iii) The Nasdaq Medical Equipment Index.

Comparison of Cumulative Total Return



- AGA Medical Holdings, Inc.
- NASDAQ Composite
- NASDAQ Medical Equipment

Reconciliation of EBITDA to Net Income
The following is a reconciliation of EBITDA to net income for the periods presented on the front inside cover of this annual report.

	Twelve Months Ended December 31			
(in thousands)	**2009**	2008	2007	2006
Net Income (loss)	**$ (1,095)**	$ 9,096	$ 6,078	$12,625
Interest Income	**(92)**	(230)	(432)	(1,174)
Interest Expense	**17,219**	16,492	21,213	22,893
Depreciation/Amortization	**25,263**	19,429	18,661	14,567
Income Taxes	**(828)**	386	3,844	6,909
EBITDA	**$40,467**	$45,173	$49,364	$55,820

Forward-Looking Statements
This annual report and any attachments may include "forward-looking statements," within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The forward-looking statements in this annual report include, statements relating to earnings guidance, product development, sales and distribution expectations, sustainability efforts, clinical trials, and any statements about the Company's plans, strategies, prospects, market opportunities and growth. These statements reflect the Company's views with respect to future events as of the date the statements are made, are not guarantees of future performance and involve risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. These factors include, among other things, those detailed in the Company's Form 10-K for the fiscal year ended December 31, 2009, under the headings "Risk Factors" and "Information Regarding Forward-Looking Statements," as well as those identified in other periodic reports filed with the Securities and Exchange Commission. You should not put undue reliance on any forward-looking statements. Except as required by law, the Company does not undertake any obligation to update or revise forward-looking statements to reflect new information or events or circumstances that occur after the date the statements are made or to reflect the occurrence of unanticipated events or otherwise. Readers are advised to review the Company's filings with the Securities and Exchange Commission (which are available from the SEC's EDGAR database at www.sec.gov, at various SEC reference facilities in the United States and via the Company's website at www.amplatzer.com).

Statement Regarding Non-GAAP Financial Measures
To supplement the Company's summary of financial results presented in accordance with accounting principles generally accepted in the United States, or GAAP, the Company has disclosed EBITDA, which is a non-GAAP measure. EBITDA represents net income (loss) before interest income, interest expense, provision (benefit) for income tax, and depreciation and amortization. The Company presents EBITDA because it believes this measure is a useful indicator of its operating performance. While the Company believes that this financial measure is useful in evaluating the Company's business, this information should be considered as supplemental in nature and is not meant to be considered in isolation or as a substitute for the related financial information prepared in accordance with GAAP. In addition, this non-GAAP financial measure may not be the same as similarly entitled measures reported by other companies.

AGA MEDICAL CORPORATION
HOME OF AMPLATZER® PRODUCTS

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