



FORM 10-K405

ATS MEDICAL INC - ATSI

Exhibit:

Filed: March 30, 2000 (period: December 31, 1999)

Annual report. The Regulation S-K Item 405 box on the cover page is checked

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SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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, 1999
COMMISSION FILE NO. 0-18602

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

MINNESOTA
(State or other jurisdiction of
incorporation or organization)

41-1595629
(I.R.S. Employer
Identification No.)

3905 ANNAPOLIS LANE
MINNEAPOLIS, MINNESOTA
(Address of principal executive offices)

55447
(Zip Code)

Registrant's telephone number, including area code: (612) 553-7736

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock \$.01
par value

Indicate 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 if disclosure of delinquent filers pursuant to
Item 405 of Regulation S-K 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. (X)

The aggregate market value of voting stock held by nonaffiliates of the
registrant as of March 17, 2000, was approximately \$157,364,793.75 (based on the
last sale price of such stock as reported by the NASDAQ National Market).

The number of shares outstanding of each of the registrant's classes of
common stock as of March 17, 2000, was:

Common Stock, \$.01 par value 17,926,371 shares

DOCUMENTS INCORPORATED BY REFERENCE

Pursuant to General Instruction G, the responses to Items 5, 6, 7, and
8 of Part II of this report are incorporated by reference to certain information
contained in the Registrant's Annual Report to Shareholders for the fiscal year
ended December 31, 1999 and the responses to Items 10, 11, 12 and 13 of Part III
of this report are incorporated herein by reference to certain information
contained in the Registrant's definitive Proxy Statement for its 2000 Annual
Meeting of Shareholders to be held on May 4, 2000.

PART I

ITEM 1. BUSINESS

OVERVIEW

We manufacture and market a mechanical bileaflet heart valve with a unique open pivot design. Our valve is used to treat heart valve failure caused by the natural aging process, rheumatic heart disease, prosthetic valve failure and congenital defects. Our Chairman, Chief Executive Officer and founder, Manuel Villafana, has led ATS in the development of a valve designed to achieve a significant advancement in mechanical heart valve technology. Mechanical heart valves have been in use since the early 1960s. In 1976, Mr. Villafana founded St. Jude Medical, Inc. to develop a bileaflet mechanical heart valve that has become the world's most frequently implanted prosthetic heart valve and is currently the industry standard. The U.S. market for replacement heart valves in 1998 was estimated to be over \$325 million.

The ATS heart valve is designed to "advance the standard" among mechanical heart valves by incorporating a pivot consisting of protruding spheres upon which the leaflets of the valve pivot to open and close. This unique open pivot has been designed to eliminate the cavity associated with the pivot of other bileaflet valves and to improve the ability of the blood to flow through the valve without forming clots.

PROSTHETIC HEART VALVE MARKET

There are two types of replacement heart valves: tissue and mechanical. Tissue valves are made from animal or cadaver tissue or in some cases the patient's own tissue. Tissue valves do not present the same level of risk of blood clotting around the valve as mechanical valves. Tissue valves, however, have limited long-term durability due to calcification and deterioration. If a tissue valve fails, a new prosthetic valve must be implanted, requiring another open heart surgery. Mechanical valves are made from durable materials such as metals and carbon. In vitro testing of current pyrolytic carbon mechanical valves has yielded estimated useful lives in excess of any patient's lifetime. Current mechanical valves, however, require the use of anti-coagulants to prevent formation of blood clots; tissue valves generally do not require anti-coagulant treatment. Tissue valves are generally prescribed for patients who are less able to tolerate anti-coagulants due to conditions such as gastrointestinal ulcers or liver dysfunction, elderly patients, women in their childbearing years and very active people.

Heart surgeons choose a particular type of mechanical valve based on a number of factors. A principal factor in the choice of a valve is the potential for forming blood clots, or thrombosis, resulting from areas in the valve where the blood can stagnate. Blood clots can impair the performance of a valve and, if the clot detaches and moves through the bloodstream (a thromboembolism), result in an arterial blockage or stroke. Another principal factor in the choice of a mechanical valve is the blood flow efficiency, or hemodynamics, of the valve. A mechanical valve should allow blood to flow easily through the valve with minimal pressure required to open the valve and minimal backflow of blood when the valve closes. The valve also should not exert force on the blood that could damage the fragile blood cells. Other factors that are important in a surgeon's choice of a mechanical valve are the ease in implanting and monitoring the valve's performance, the patient's quality of life and the physician's familiarity with and confidence in the valve.

In addition to heart surgeons, administrators or business managers at hospitals and clinics have become increasingly influential in the purchase decision-making process in recent years. The increasing emphasis on medical cost containment in most world markets has elevated the decision-making power of the administrator to a level equal to or greater than that of the surgeon. The administrator tends to focus on cost-effectiveness and, in some markets, primarily on the cost of the valve.

We estimate that the total heart valve market in the U.S. in 1997 was approximately \$310 million. We estimate that approximately 75,000 heart valve replacement surgeries were conducted in the United States in 1997. Of the total number of heart valve replacement surgeries, approximately 50,000, or 67%, involved mechanical heart valves and approximately

25,000, or 33%, involved tissue heart valves. Since 1993, the total U.S. replacement heart valve market grew at a compound annual growth rate of 2.5 to 3.0%, with mechanical valves growing at an annual rate of 1.5 to 2.0%.

THE ATS OPEN PIVOT BILEAFLET VALVE

Our product is designed to advance the standard of existing mechanical heart valves by combining a proprietary open pivot design and other innovative features with the widely accepted biocompatibility and durability of pyrolytic carbon. The standard ATS heart valve is available in seven sizes ranging from 19mm to 31mm in diameter, with sewing cuffs for either aortic valve or mitral valve replacement. In 1994, we introduced the Advanced Performance series of the ATS heart valve in international markets. This valve is available in seven sizes ranging from 16mm to 28mm in diameter. Our 16mm valve is currently the world's smallest mechanical valve.

The major design features of the ATS heart valve are:

OPEN PIVOT AREAS. The proprietary open pivot areas of the ATS heart valve feature spherical protrusions from the orifice that match spherical notches in the leaflets. The pivot areas protrude into the orifice and so are exposed to the washing action of the blood flowing through the heart valve. All other currently marketed bileaflet valves contain pivot cavities in the orifice wall into which protrusions from the semi-circular leaflets extend to allow the leaflets to open and close. The open pivot design also features angled inflow and outflow pivot stops.

A THIN BUT DURABLE ORIFICE. The orifice of the ATS heart valve is manufactured using a mandrel which is coated with pyrolytic carbon. The mandrel is then removed, leaving a solid pyrolytic carbon orifice. In contrast, the industry standard valve's orifice is composed of a soft graphite substrate coated with pyrolytic carbon. By eliminating the graphite substrate, we have made the orifice wall thinner, resulting in a larger average inside diameter. The orifice is surrounded by a titanium stiffening ring and is rotatable.

LOW PROFILE DESIGN. The ATS heart valve has a low profile design. The profile of a mechanical heart valve refers to the extension of the orifice and leaflets above and below the natural tissue anulus, or location of the natural heart valve. The inflow side of the orifice of the ATS heart valve is flat, unlike the most popular cavity pivot valve which has upward protrusions on the orifice to house the cavity.

AN ADVANCED SEWING CUFF. The sewing cuff surrounding the orifice of the ATS heart valve is made of double velour polyester and includes a surgical felt ring for ease of sewing. An extended sewing cuff is used with the 31mm carbon components to create a 33mm valve for special mitral valve replacements. The Advanced Performance series offers a reconfigured sewing cuff, allowing a valve with a larger inside diameter to be used in small anulus situations.

PYROLYTIC CARBON. Pyrolytic carbon has been used in mechanical heart valves for over 25 years. The orifice of our heart valve is fabricated entirely from pyrolytic carbon, while the leaflets are fabricated by coating pyrolytic carbon on graphite substrates. Pyrolytic carbon used in other mechanical valves has been tested to function longer than any patient's lifetime. Pyrolytic carbon is believed to be superior to metal and plastics in terms of the human body's acceptance of the material, thus resulting in lower rates of thrombosis and thromboembolism than with other materials. Because of its durability and biocompatibility, pyrolytic carbon is used in virtually every mechanical heart valve in the market.

TWO LEAFLETS. Bileaflet valves are used in substantially all mechanical heart valves being marketed today. The leaflets in the ATS heart valve have tungsten impregnated in the substrate to make them visible under x-ray.

The ATS heart valve is designed to provide the following primary advances over the industry standard mechanical heart valve:

REDUCED RATES OF THROMBOEMBOLIC COMPLICATIONS. The pivot cavities found in other bileaflet heart valves are areas of blood flow stagnation and possible blood clot formation. By eliminating the cavities in the orifice and placing the pivot areas within the normal blood flow, the improved washing action in the ATS heart valve is intended to lower the likelihood of blood clot formation and the resulting incidence of thromboembolism. The open pivot design as well as the angled inflow and outflow pivot stops also result in low levels of hemolysis (damage to blood cells), which may contribute to a low rate of thromboembolic complications.

IMPROVED BLOOD FLOW EFFICIENCIES. We have made the orifice of our product both durable and thinner, thereby resulting in a larger inside diameter. The larger inside diameter of the ATS heart valve is intended to result in lower pressure gradients in our product. (The term "gradients" refers to the pressure difference between the inflow and outflow side of the valve needed to support the required blood flow through the valves.) The ATS heart valve is also designed to have less regurgitation (backflow of blood when the valve is closing and closed) due to the geometry of its angled inflow and outflow pivot stops which minimize the direct leakage paths. These design characteristics are intended to result in superior blood flow efficiencies which should reduce the workload on the heart.

EASE OF IMPLANT. Our product has been designed for ease of use by the heart surgeon. The low profile of the ATS heart valve is intended to minimize implant complications. Leaflets that extend significantly below the natural tissue annulus in the mitral position may obstruct blood outflow or interfere with the septum or other parts of the heart. Protrusions on the inflow side of the annulus in the aortic position may snag sutures used to attach the mechanical valve to the heart. In addition, because the orifice can be rotated, the surgeon can optimize valve orientation by adjusting the position of the leaflets after the ATS heart valve has been sutured in the natural anatomical position in the patient's heart. Suturing the ATS heart valve into the heart is made easier by reducing the number of layers of polyester material in the aortic and mitral cuffs and by adding the surgical felt ring in the sewing cuff, thereby easing the passage of the suture needle through the sewing cuff. The packaging and accessories of the ATS heart valve also are designed to facilitate the implant procedure by including all of the required items pre-assembled in a sterilized dual barrier container.

IMPROVED FOLLOW-UP DIAGNOSTIC CAPABILITY. Our product facilitates the follow-up diagnostic process by being more easily visible to x-rays. The titanium stiffening ring provides a clear image on x-rays when taken from any angle. The leaflets also have a higher density of tungsten impregnated in the substrate, making them more visible to x-rays.

IMPROVED PATIENT QUALITY OF LIFE THROUGH LOWER NOISE LEVELS. Patients with other implanted mechanical heart valves frequently complain of disturbances resulting from the clicking sound created as the valve closes. These disturbances range from irritability and insomnia to paranoia and depression. Spouses of patients with implanted mechanical valves also report disturbances resulting from the noise of the valve. Based on informal surveys, we believe that the ATS heart valve is quieter than our competitors' valves and below the threshold of hearing of most patients. We believe that the reduced noise level of our product further improves the quality of life of the patient.

In 1997, we introduced an aortic valved graft. The aortic valved graft consists of an ATS heart valve connected to a collagen-impregnated vascular graft. It is used in cases where the aortic valve and a portion of the ascending aorta must be replaced.

CLINICAL RESULTS AND REGULATORY STATUS

The ATS heart valve has not yet been approved for sale in the United States. On August 3, 1999, the FDA accepted for filing our PMA application for approval to sell the ATS heart valve in the United States. On February 4, 2000, we received a letter from the FDA requesting additional information regarding the ATS heart valve. To support our PMA application with the FDA, we submitted data on over 950 implants of the ATS heart valve in 17 U.S. and 3 international clinical centers. An application for marketing the ATS heart valve is also under review in Canada by Health Canada.

In May 1992, we began to sell the ATS heart valve in Switzerland, Germany, Belgium and the United Kingdom. We received ISO 9001 certification in April 1994 and European Regulatory Approval ("CE") for the ATS heart valve in March 1995. The ISO 9001 certification signifies that our procedures and manufacturing facilities comply with international standards for quality assurance. The CE mark denotes conformity with European standards for safety and allows certified devices to be sold in all European Union countries. By the end of 1995, the ATS heart valve was available in most European countries. We received approval to begin commercial sales in Japan in June 1996 and in Australia in September 1998. We have obtained regulatory approvals in other countries where required. As of December 31, 1999, the ATS heart valve was available for sale in 32 countries worldwide.

As of December 31, 1999, we estimate that over 33,500 ATS heart valves have been implanted in patients. We have received implant registration data from over 172 institutions in 26 countries which have implanted the ATS heart valve in patients.

MARKETING, SALES AND DISTRIBUTION

Our international marketing strategy combines the substantial cardiovascular sales experience of our senior officers with a network of experienced independent distributors to sell the ATS heart valve internationally. We believe that our independent distributor network has provided a rapid and cost efficient means of increasing market penetration and commercial acceptance of the ATS heart valve in key international markets. The use of an independent distributor does not involve significant expense to us. We have been able to attract experienced mechanical valve sales organizations familiar with local markets and customs to act as independent distributors.

If we receive FDA approval of our PMA application, we intend to market the ATS heart valve in the United States through a direct sales force. We plan to focus our marketing efforts on the top 20 to 30% of the approximately 880 open heart centers and on leading cardiac surgeons at those institutions. We believe that we can effectively market and sell to these surgeons through a 25 to 30 person direct sales force divided into three to four regions. The cardiac surgeons at these centers perform a significant portion of the heart valve implant procedures in the United States and tend to adopt new technologies and devices more readily. We also believe that acceptance of our product by leading U.S. cardiac surgeons will help to generate greater demand.

At December 31, 1999, we had contracts with 24 independent distributors covering 32 countries outside the United States. Sales to distributors in Japan, France and Germany represented over 45% of our total sales for each of the past three years. The table below sets forth the sales to our top three independent distributors and the respective countries in which they operate.

	SALES AS A PERCENTAGE OF TOTAL REVENUE		
	1997	1998	1999
Japan	17.2%	19.2%	18.6%
Germany	16.7	15.1	16.2
France	11.2	16.0	14.7

Each of our independent distributors has the exclusive right to sell the ATS heart valve within a defined territory. These distributors also market other medical products, although they have agreed not to sell other mechanical heart valves. Most of our distributor agreements establish quotas for sales of the ATS heart valve in the distributor's territory. Under most of the distributor agreements, we may, at our option, terminate the agreement upon the departure of certain key employees of the distributor or a change in control of us. We sell the ATS heart valve to each distributor F.O.B. Minneapolis, Minnesota. Sales to international distributors are denominated in U.S. dollars. We allow the return of unused valves as long as the valve packaging has not been opened and the sterilization date has not expired.

Our sales, marketing and customer service personnel provide support to our independent distributors. Our marketing efforts include displaying the ATS heart valve at major international, national and regional medical meetings attended by cardiovascular surgeons and cardiologists. We also distribute product brochures and product information bulletins and conduct product training sessions.

RELATIONSHIP WITH SULZER CARBOMEDICS

Sulzer Carbomedics ("Carbomedics") developed the basic design from which the ATS heart valve evolved. Carbomedics is the largest and most experienced manufacturer of pyrolytic carbon components used in mechanical heart valves. Carbomedics has also designed and patented numerous mechanical valves. Carbomedics offered to license a patented and partially developed valve to us if we would complete the development of the valve and agree to purchase carbon components from Carbomedics. Since 1990, Carbomedics has been our sole source of the carbon components used in our valve and the licensor of certain technology upon which our product is based. We recently restructured our contractual relationships with Carbomedics to lower our cost of carbon components and to begin the technology transfer which will enable us to manufacture those components ourselves.

We have three agreements with Carbomedics: a license agreement and a long-term carbon supply agreement entered into in September 1990, and a carbon technology agreement entered into in December 1999. Under the terms of the license agreement with Carbomedics, we hold an exclusive, royalty-free, worldwide license to an open pivot, bileaflet mechanical heart valve from which the ATS heart valve was developed. The license agreement does not include the right to manufacture

the pyrolytic carbon components of the ATS heart valve, except that if Carbomedics were unable to produce the components, we would have the right and license to make the components or have them made for us. Carbomedics may terminate the license agreement or declare the license to be non-exclusive if we fail to meet the minimum purchase requirements under the supply agreement during any year prior to 2001. Upon satisfaction of these minimum purchase requirements under the supply agreement, we will have a paid-up, exclusive, royalty-free, worldwide license. After making certain design changes in the valve, we finalized the design of the ATS heart valve and filed and received an additional U.S. patent covering the design modifications. The design improvements and the U.S. patent covering the modifications are the exclusive property of ATS.

The supply agreement, as amended through December 1999, runs through the end of 2007 and requires us to purchase a minimum number of valve components each year. If we do not satisfy the minimum purchase requirements during any year prior to 2001, Carbomedics will have the right to terminate the supply agreement and the license agreement or to declare the license agreement to be non-exclusive. In addition, prior to 2001, we cannot purchase valve components from any source other than Carbomedics, unless Carbomedics is unable to deliver suitable components. We have currently satisfied all of our purchase obligations under the supply agreement. We are obligated to purchase 16.5 million heart valve components from Carbomedics in 2000. After 2000, the number of valve components and the price of each set of components that we are obligated to purchase under the supply agreement will decrease substantially as compared to prior years under the agreement, subject to a yearly price adjustment for changes in the U.S. Department of Labor Employment Cost Index.

In December 1999, we entered into a carbon technology agreement with Carbomedics under which we obtained an exclusive, worldwide right and license to use Carbomedics' pyrolytic carbon technology to manufacture components for the ATS heart valve, and a non-exclusive worldwide right and license to use the technology to produce pyrolytic carbon components for other devices and manufacturers, including, after 2008, for other heart valve manufacturers. Under the agreement Carbomedics has also agreed to assist us in designing, building, equipping, qualifying and commencing operations in a pyrolytic carbon component production facility in Minneapolis, Minnesota. In return, we have agreed to pay Carbomedics a license fee totaling \$41 million in eight installments over seven years, subject to deferral if certain milestones are not satisfied.

We are obligated under the carbon technology agreement to pay all of the costs of establishing the new carbon production facility, including hourly fees and out-of-pocket expenses of the Carbomedics employees assigned to assist us in setting up the facility. We and Carbomedics have also mutually agreed not to solicit or hire each other's employees (other than sales and marketing employees) for two years after completion of the milestone payments or termination of the agreement.

The carbon technology agreement may be terminated by either party upon a material breach of the agreement by the other party, subject to certain waiting periods during which the breaching party will have an opportunity to cure the default. In addition, Carbomedics may terminate the agreement if we cease business, make an assignment for the benefit of creditors, or enter into certain insolvency, receivership or bankruptcy proceedings. We can terminate the agreement at any time after the third anniversary if we determine to exit the mechanical heart valve business.

MANUFACTURING

We assemble the ATS heart valve in a controlled clean room environment at our facility in a suburb of Minneapolis, Minnesota. Our manufacturing operation currently consists of fabricating the sewing cuff, assembling, inspecting, testing and packaging all of the components into a finished valve, and then sterilizing the valve prior to shipment to distributors.

We will have to establish a facility for manufacturing pyrolytic carbon components under the Carbomedics technology agreement. We are currently in the process of locating a facility. Our preliminary plans call for a 19,000 square-foot building with facilities capable of producing 10,000 valve sets per year. The manufacturing operations will include substrate machining and preparation, carbon coating, coated part machining and final polishing and finishing activities. We expect to hire 7 to 10 technical and production personnel over the next twelve months. We anticipate that the facility will not be operational until 2003. The key steps required to complete the facility include:

- o outfitting the building;
- o purchasing and installing manufacturing equipment;
- o training technical and production personnel;

- o conducting pilot production runs;
- o demonstrating compliance with FDA and international good manufacturing practices and quality system regulations; and
- o scaling up production.

Under the terms of our agreement with Carbomedics, we may also elect to have Carbomedics train our personnel how to machine graphite and pyrolytic carbon parts, and teach us how to fabricate our own tooling. We have not yet determined whether we will develop these capabilities internally or contract these steps out to third party vendors. We currently have in inventory enough carbon components to satisfy our projected requirements for pyrolytic carbon components for over two years. In addition, we are obligated to continue to buy some valve components from Carbomedics under the supply agreement through 2007.

COMPETITION

The prosthetic heart valve market is highly competitive with one dominant company, St. Jude Medical, Inc. In 1999, according to industry estimates, St. Jude Medical supplied approximately 50% of the mechanical heart valves sold worldwide. Other companies that sell mechanical valves include Medtronic, Inc., Carbomedics, Baxter Edwards, Sorin Biomedica sPa and Medical Carbon Research, Inc. St. Jude Medical, Medtronic, Baxter Edwards, Sorin Biomedica and CryoLife also sell tissue valves. Many of our competitors have greater financial, manufacturing, and marketing resources than we have.

We are aware of several companies that are developing new prosthetic heart valves. Several companies are developing and testing new autologous (created from the patient's own tissue) valves, potentially more durable tissue valves and new bileaflet and trileaflet mechanical designs. Advancements also are being made in surgical procedures such as mitral valve reconstruction, whereby the natural mitral valve is repaired, delaying the need for a replacement valve. Other companies are pursuing biocompatible coatings to be applied to mechanical valves in an effort to reduce the incidence of thromboembolic events and to treat tissue valves to forestall or eliminate calcific degeneration in these valves.

Competition within the prosthetic heart valve market is based on, among other things, clinical performance record, minimalization of complications, ease of use for the surgeon, patient comfort and cost effectiveness. We believe that the most important factors in a heart surgeon's selection of a particular prosthetic valve are the perceived benefits of the valve and the heart surgeon's confidence in the valve design. As a result, valves that have developed a favorable clinical performance record have a significant marketing advantage over new valves. In addition, negative publicity resulting from isolated incidents can have a significant negative effect on a valve's overall acceptance. Our success is dependent upon the surgeon's willingness to use a new prosthetic heart valve as well as the future clinical performance of the ATS heart valve compared with the more established competition.

We believe that mechanical heart valves are currently being marketed to hospitals at prices that vary significantly from country to country due to market conditions, currency valuations, distributor mark-ups and government regulations. We believe that, after distributor mark-up, the ATS heart valve sells at or above the current price of other valves in most markets. In many markets, government agencies are imposing or proposing price controls or restrictions on medical products. We work with our independent distributors to price the ATS heart valve in each market to meet these limitations. In addition, our primary competitors have the ability, due to their internal carbon manufacturing facilities and economies of scale, to manufacture their valves at a lower cost than we can currently manufacture the ATS heart valve. The market leader has recently been using price as a method to compete in several markets.

PATENTS AND PROPRIETARY TECHNOLOGY

Our policy is to protect our proprietary position by obtaining U.S. and foreign patents to protect technology, inventions and improvements important to the development of our business. Under our agreements with Carbomedics, we have obtained a royalty-free license to the Carbomedics patent on the basic design of an open pivot bileaflet mechanical heart valve and, in December 1999, the right to manufacture pyrolytic carbon components, subject to the payment of license fees. See "Business--Relationship with Sulzer Carbomedics." The Carbomedics patent expires in 2004. We subsequently made modifications to the basic design. We were issued a U.S. patent covering our design improvements to the ATS heart valve in October 1994. We also have filed patent applications in Japan, Belgium, France, Germany, Netherlands, Spain, Switzerland

and the United Kingdom relating to the design improvements. Patents have been granted in all of these countries. We cannot be certain that any patents will not be challenged or circumvented by competitors.

We also rely on trade secrets and technical know-how in the manufacture and marketing of the ATS heart valve. We typically require our employees, consultants and contractors to execute confidentiality agreements with respect to our proprietary information.

We claim trademark protection on ATS Medical(TM) and ATS Open Pivot Bileaflet(TM).

GOVERNMENT REGULATION

Our ATS heart valve is regulated in the United States as a medical device by the FDA under the Federal Food, Drug and Cosmetic Act, or FDC Act. Under the FDC Act, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, record keeping, advertising and distribution of medical devices. The FDA classifies our ATS heart valve as a Class III device, which is subject to the highest level of controls. Noncompliance with applicable regulations can result in withdrawal of prior approvals, total or partial suspension of production, fines, injunctions, recall of products, civil penalties and criminal prosecution.

Before it can be sold in the United States, the ATS heart valve requires premarket approval by the FDA. In December 1996, we received approval of our investigational device exemption application to start limited clinical studies, and on August 3, 1999, the FDA accepted for filing our PMA application. Under the FDC Act, the FDA has 180 days to review a PMA application, although the review time usually takes longer and may require additional information. The PMA application process can be expensive, uncertain and lengthy. A number of devices for which premarket approval has been sought have never been approved for marketing and sale.

On February 4, 2000, we received a letter from the FDA relating to our PMA application. In this letter, the FDA requested additional information regarding the ATS heart valve. We expect to submit the requested information in April 2000. Upon completion of this review, the FDA could, among other things, request additional information or schedule a meeting for presentation of clinical data to a FDA advisory panel. Premarket approval to sell the ATS heart valve will be subject to the advisory panel's recommendation.

We also are subject to FDA regulations concerning manufacturing processes and reporting obligations. These regulations require that manufacturing steps be performed according to FDA standards and in accordance with documentation, control and testing standards. The FDA monitors compliance with its good manufacturing practices regulations by conducting periodic inspections. We are required to provide information to the FDA on adverse incidents as well as maintain a detailed record keeping system in accordance with FDA guidelines. We expect that our carbon fabrication processes and new manufacturing facility will be subject to domestic and international regulatory inspection and review. We will be required to perform testing and analysis on the components we manufacture before we can sell the ATS heart valve in the United States and international markets. We may be required to conduct clinical studies of the ATS heart valve incorporating the components that we manufacture.

Even if regulatory approval of a product is granted, the FDA may require testing and surveillance programs to monitor the safety and effect of the product and may prevent or limit further marketing of the product based on the results of these post-marketing programs.

The advertising of our product also will be subject to both FDA and Federal Trade Commission regulations. In addition, we will be subject to the "fraud and abuse" laws and regulations promulgated by the U.S. Department of Health and Human Services and the U.S. Health Care Finance Administration if we sell the ATS heart valve to Medicare or Medicaid patients.

Regulation of heart valves varies widely in foreign countries. Foreign countries vary from having no regulations to having a pre-market notice or pre-market approval process. The European Union has adopted rules which require that medical products receive the right to affix the CE mark, an international symbol that denotes conformity with European standards for safety and allows certified devices to be marketed in all European Union countries. As part of the CE compliance, manufacturers are required to comply with the ISO 9000 series of standards for quality operations. We received ISO 9001 certification in 1994 and CE mark approval in March 1995. We will continue to be subjected to various audits and tests under the European Community directives. In June 1996, we received approval to begin commercial sales in Japan through a Shonin regulatory approval obtained by our distributor, Century Medical, Inc. In September 1998, we received approval from the

Therapeutic Goods Administration for commercial sales in Australia. We are in the process of pursuing regulatory approval for the ATS heart valve in Canada.

THIRD PARTY REIMBURSEMENT

In the United States, healthcare providers that purchase medical devices, such as our product, generally rely on third-party payors, including Medicare, Medicaid, private health insurance carriers and managed care organizations, to reimburse all or part of the cost and fees associated with the procedures performed using these devices. The commercial success of the ATS heart valve will depend on the ability of health care providers to obtain adequate reimbursement from third-party payors for the surgical procedures in which our products are used. Third-party payors are increasingly challenging the pricing of medical products and procedures. Even if a procedure is eligible for reimbursement, the level of reimbursement may not be adequate. In addition, third-party payors may deny reimbursement if they determine that the device used in the treatment was not cost-effective or was used for a non-approved indication.

In international markets, market acceptance of the ATS heart valve depends in part upon the availability of reimbursement from healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country. The main types of healthcare payment systems in international markets are government sponsored healthcare and private insurance. Countries with governmental sponsored healthcare, such as the United Kingdom, have a centralized, nationalized healthcare system. New devices are brought into the system through negotiations between departments at individual hospitals at the time of budgeting. In Japan, France and Germany, the government sets an upper limit of reimbursement for various valve types. In most foreign countries, there are also private insurance systems that may offer payments for alternative devices.

We have pursued reimbursement for our ATS heart valve internationally through our independent distributors. While the healthcare financing issues in these countries are substantial, we have been able to sell the ATS heart valve to private clinics and nationalized hospitals in each of the countries served by our distributors.

PRODUCT LIABILITY AND INSURANCE

Cardiovascular device companies are subject to an inherent risk of product liability and other liability claims in the event that the use of their products results in personal injury. A mechanical heart valve is a life-sustaining device, and the failure of any mechanical heart valve usually results in the death of the patient. We have not received any reports of mechanical failure of our valves implanted to date and have not experienced any product liability claims. Any product liability claim could subject us to costly litigation, damages and adverse publicity.

We currently maintain product liability insurance policy with an annual coverage limit of \$25 million in the aggregate. A \$5 million product liability insurance policy is required by the supply agreement with Carbomedics. We are financially responsible for any uninsured claims or claims which exceed the insurance policy limits. Product liability insurance is expensive for mechanical valves. If insurance becomes completely unavailable, we must either develop a self-insurance program or sell without insurance, which would require the consent of Carbomedics. The development of a self-insurance program would require significant capital.

Carbomedics has made no warranty on our valve components. We have agreed to hold Carbomedics harmless and indemnify Carbomedics in the event claims are made or damages are assessed against Carbomedics as a result of our valve.

EMPLOYEES

As of January 1, 2000 we had 80 full-time employees, of whom 21 were engaged in regulatory affairs and quality assurance, 38 in production and 21 in administrative, purchasing and marketing activities.

ITEM 2. PROPERTIES

We lease approximately 23,912 square feet of administrative, production and engineering space in a suburb of Minneapolis, Minnesota. The lease expires on February 28, 2003. Although we believe that this facility is adequate for our current needs,

we intend to establish a new pyrolytic carbon manufacturing facility in close proximity to our principal executive offices. Also, see our discussion of a possible new manufacturing facility under Item 1, "Manufacturing."

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers are as follows:

Name	Age	Position
----	---	-----
Manuel A. Villafana	59	Chairman of the Board and Chief Executive Officer
Richard W. Kramp	54	President, Chief Operating Officer and Director
Russell W. Felkey	49	Executive Vice President of Regulatory Affairs and Secretary
John H. Jungbauer	50	Vice President, Treasurer and Chief Financial Officer
Frank R. Santiago	48	Vice President, Sales and Marketing

MANUEL A. VILLAFANA, a founder of our company, has served as Chief Executive Officer and Chairman of the Board since our inception in 1987. From 1983 to 1987, Mr. Villafana served as Chairman of GV Medical, Inc., a company co-founded by Mr. Villafana to develop, manufacture and market the LASTAC System, a laser transluminal angioplasty catheter system. From 1976 to 1982, Mr. Villafana served as President and Chairman of St. Jude Medical, Inc., a company founded by Mr. Villafana to develop, manufacture and market a prosthetic bileaflet heart valve manufactured from pyrolytic carbon. From 1972 to 1976, Mr. Villafana served as President and Chairman of Cardiac Pacemakers, Inc., a company founded by Mr. Villafana to develop, manufacture and market a new generation of lithium powered pacemakers.

RICHARD W. KRAMP has served as our President and Chief Operating Officer and a Director since March 1988. Mr. Kramp also will be responsible for overseeing the development of and managing the new pyrolytic carbon manufacturing facility. Prior to joining us, Mr. Kramp was Vice President of Sales and Marketing for St. Jude Medical, Inc., where Mr. Kramp served in a variety of sales and marketing capacities from 1978 to 1988. From 1976 through 1978, Mr. Kramp served as Illinois Sales Manager for Life Instruments, a distributor of cardiovascular products. From 1972 to 1976, Mr. Kramp was the Senior Design Engineer and then Supervisor of Electrical Design for Cardiac Pacemakers, Inc., where he designed the first lithium powered demand pacemaker for which he received a U.S. patent. Mr. Kramp also is a director of MedAmicus, Inc., a medical products company.

RUSSELL W. FELKEY has served as our Executive Vice President of Regulatory Affairs since April 1991 and as Secretary since October 1995. From 1989 to 1991, Mr. Felkey was Vice President of Regulatory Affairs and Quality Assurance at Cardiovascular Imaging Systems, Inc., a company involved in the development of peripheral and coronary ultrasound catheters. From 1984 to 1989, Mr. Felkey was Vice President of Regulatory Affairs at GV Medical, Inc.

JOHN H. JUNGBAUER has served as Vice President since April 1995 and as Treasurer and Chief Financial Officer since October 1990. From 1988 to 1990, Mr. Jungbauer was Executive Vice President of Titan Medical, Inc., a medical products company. During 1987, Mr. Jungbauer served as a consultant to Titan Medical, Inc. From 1981 to 1987, Mr. Jungbauer was Vice President of Finance at St. Jude Medical, Inc.

FRANK R. SANTIAGO has served as our Vice President, Sales and Marketing since June 1998 and as Director of Sales and Marketing since June 1997. From March 1985 to March 1997, Mr. Santiago owned and operated Hemotech Systems, a cardiovascular products and services company providing services such as ambulatory recording of electrocardiograms and

blood pressure. Prior to 1987, Mr. Santiago was a cardiovascular specialist at American Edwards/Baxter, a regional training manager in various sales and marketing divisions of Johnson and Johnson and a product specialist at Ayerst Laboratories/American Home Products.

MEDICAL ADVISORY BOARD

The Company has a Medical Advisory Board that meets periodically to review and guide the design and testing of the valve as well as to provide assessments of potential new cardiovascular products. The members of the Medical Advisory Board are as follows:

DR. DEMETRE M. NICOLOFF is a world-renowned cardiac surgeon practicing with Cardiac Surgical Associates in association with the Minneapolis Heart Institute and St. Paul Heart and Lung Center. Previously, Dr. Nicoloff was an Associate Professor of Surgery at the University of Minnesota and taught in the Department of Surgery at the University of Minnesota for over 15 years. Dr. Nicoloff participated in the first human implant of the ATS Medical valve in May 1992. Dr. Nicoloff also participated in the design of the first general of bileaflet valves and performed the first human implant of the most frequently implanted mechanical bileaflet valve. Dr. Nicoloff previously was a member of the Scientific Advisory Board of St. Jude Medical, Inc. Dr. Nicoloff received his medical degree from Ohio State University.

DR. H. DAVID FRIEDBERG is a Clinical Professor of Medicine and Cardiology at the University of South Florida. Dr. Friedberg is certified in cardiac pacing and electrophysiology. He is a Fellow of the American College of Cardiology, American College of Chest Physicians and the Council of Clinical Cardiology of the American Heart Association. Dr. Friedberg participated in the first implant of the ATS Medical valve in May 1992. Dr. Friedberg previously was a member of the Scientific Advisory Board of St. Jude Medical, Inc. Dr. Friedberg obtained his medical degree in South Africa and performed his internal medicine studies and residencies in London, England.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED SHAREHOLDER MATTERS

The information contained under the heading "Common Stock Information" on page 10 of the Company's Annual Report to Shareholder's for the year ended December 31, 1999 (the "Annual Report to Shareholders") is incorporated herein by reference.

ITEM 6. SELECTED FINANCIAL DATA

The information contained under the heading "Financial Highlights" on the inside cover of the Annual Report to Shareholders is incorporated herein by reference.

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

The information contained under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" on pages 6 to 10 of the Annual Report to Shareholders is incorporated herein by reference.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The information contained under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations--Liquidity and Capital Resources" on page 8 of the Annual Report to Shareholders is incorporated herein by reference.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information contained under the headings "Consolidated Statements of Financial Position," "Consolidated Statements of Income," "Consolidated Statement of Changes in Shareholders' Equity," "Consolidated Statements of Cash Flows," and "Notes to Consolidated Financial Statements" on pages 12 to 20 of the Annual Report to Shareholders is incorporated herein by reference.

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

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

See Part I of this Report. Pursuant to General Instruction G(3), reference is made to information contained under the heading "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" in the Company's definitive proxy statement for its 2000 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission on or before April 30, 2000, which information is incorporated herein.

ITEM 11. EXECUTIVE COMPENSATION

Pursuant to General Instruction G(3), reference is made to information contained under the heading "Executive Compensation" and "Compensation of Directors" in the Company's definitive proxy statement for its 2000 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission on or before April 30, 2000, which information is incorporated herein, excluding the "Report of the Compensation Committee Concerning Executive Compensation."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Pursuant to General Instruction G(3), reference is made to information contained under the heading "Security Ownership of Certain Beneficial Owners and Management" and "Election of Directors" in the Company's definitive proxy statement for its 2000 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission on or before April 30, 2000, which information is incorporated herein.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Pursuant to General Instruction G(3), reference is made to information contained under the heading "Election of Directors" and "Executive Compensation" in the Company's definitive proxy statement for its 2000 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission on or before April 30, 2000, which information is incorporated herein, excluding the "Report of the Compensation Committee Concerning Executive Compensation."

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) 1. FINANCIAL STATEMENTS

The financial statements of the Company are incorporated by reference from the Company's Annual Report to Shareholders.

(a) 2. FINANCIAL STATEMENT SCHEDULES

The financial statement schedule is incorporated by reference from the Company's Annual Report to Shareholders.

All other schedules have been omitted because of absence of conditions under which they are required or because the required information is included in the financial statements or notes thereto.

(a) 3. LISTING OF EXHIBITS

EXHIBIT NUMBER	DESCRIPTION
3.1	Restated Articles of Incorporation, as amended to date (Incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1993 (the "1993 Form 10-K")).
3.2	Bylaws of the Company, as amended to date (Incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 1996 (the "1996 Form 10-K")).
4.1	Specimen certificate for shares of Common Stock of the Company (Incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1997 (the "1997 Form 10-K")).
4.2	Form of Warrant issued in 1993 Private Placement (Incorporated by reference to Exhibit 4.4 to the 1993 Form 10-K).
10.1**	1987 Stock Option and Stock Award Plan, as restated and amended to date (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997).
10.2**	Agreement between the Company and Manuel A. Villafana dated April 20, 1998 (Incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q for the quarter ended June 30, 1998).
10.3	Lease Agreement between the Company and Crow Plymouth Land Limited Partnership dated December 22, 1987 (Incorporated by reference to Exhibit 10(d) to the Company's Registration Statement on Form S-18, File No. 33-34785-C (the "Form S-18")).
10.4	Amendment No. 1 to Lease Agreement between the Company and Crow Plymouth Land Limited Partnership, dated January 5, 1989 (Incorporated by reference to Exhibit 10(e) to the Form S-18).
10.5	Amendment No. 2 to Lease Agreement between the Company and Crow Plymouth Land Limited Partnership, dated January 1989 (Incorporated by reference to Exhibit 10(f) to the Form S-18).
10.6	Amendment No. 3 to Lease Agreement between the Company and Crow Plymouth Land Limited Partnership, dated June 14, 1989 (Incorporated by reference to Exhibit 10(g) to the Form S-18).
10.7	Amendment No. 4 to Lease Agreement between the Company and Plymouth Business Center Limited Partnership, dated February 10, 1992 (Incorporated by reference to Exhibit 10.8 to the 1996 Form 10-K).

- 10.8 Development Agreement dated September 24, 1990, with CarboMedics, Inc. (confidential treatment granted)* (Incorporated by reference to Exhibit 10.9 to the 1996 Form 10-K).
- 10.9 O.E.M. Supply Contract dated September 24, 1990, with CarboMedics, Inc. (confidential treatment granted)* (Incorporated by reference to Exhibit 10.10 to the 1996 Form 10-K).
- 10.10 License Agreement dated September 24, 1990, with CarboMedics, Inc. (confidential treatment granted)* (Incorporated by reference to Exhibit 10.11 to the 1996 Form 10-K).
- 10.11 Option Agreement dated September 24, 1990, with CarboMedics, Inc. (confidential treatment granted)* (Incorporated by reference to Exhibit 10.12 to the 1996 Form 10-K).
- 10.12 Helix BioCore, Inc. Self-Insurance Trust Agreement dated February 28, 1991 (Incorporated by reference to Exhibit 10.13 to the 1996 Form 10-K).
- 10.13 Amendment 1 to License Agreement dated December 16, 1993, with CarboMedics, Inc. (Incorporated by reference to Exhibit 10.17 to the 1993 Form 10-K).
- 10.14 Amendment 4 to O.E.M. Supply Contract dated December 16, 1993, with CarboMedics, Inc. (confidential treatment granted)* (Incorporated by reference to Exhibit 10.18 to the 1993 Form 10-K).
- 10.15 Amendment 5 to O.E.M. Supply Contract dated September 1, 1994, with CarboMedics, Inc. (confidential treatment granted)* (Incorporated by reference to Exhibit 10.19 to the 1994 Form 10-K).
- 10.16 Amendment 1 to Option Agreement dated December 16, 1993, with CarboMedics, Inc. (confidential treatment granted)* (Incorporated by reference to Exhibit 10.19 to the 1993 Form 10-K).
- 10.17 Line of Credit dated August 11, 1994, between the Company and First Bank National Association (Incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q for the quarter ended September 30, 1994).
- 10.18 Form of Distributor Agreement. (Incorporated by reference to Exhibit 10.22 to the 1994 Form 10-K).
- 10.19** Form of Agreement between ATS Medical, Inc. and each officer dated June 30, 1995, concerning severance benefits upon a change in control (Incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the year ended December 31, 1995 (the "1995 Form 10-K")).
- 10.20 ATS Medical, Inc. Change in Control Severance Pay Plan (Incorporated by reference to Exhibit 10.24 to the 1995 Form 10-K).
- 10.21 Amendment No. 5 to Lease Agreement between the Company and St. Paul Properties, Inc., dated May 30, 1996 (Incorporated by reference to Exhibit 10.22 to the 1996 Form 10-K).
- 10.22 Stock Purchase Agreement dated February 3, 1997 between ITOCHU Corporation and the Company (Incorporated by reference to Exhibit 1 to Schedule 13D filed with respect to the Company by ITOCHU Corporation on February 18, 1997).
- 10.23 Amendment No. 6 to Lease Agreement between the Company and St. Paul Properties, Inc., dated November 25, 1997 (Incorporated by reference to Exhibit 10.23 to the 1997 Form 10-K).
- 10.24 1998 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 4 to the Company's Registration Statement on Form S-8, File No. 333-57527).
- 10.25** 1998 Management Incentive Compensation Plan (Incorporated by reference to Exhibit 10.25 to the 1998 Form 10-K).

10.26*	Carbon Agreement by and between Sulzer Carbomedics, Inc. and ATS Medical, Inc., dated December 29, 1999 (Incorporated by reference to Exhibit 99.1 to the Company's Registration Statement on Form S-8, January 13, 2000, File No. 000-18602).
10.27*	Amendment 7 to OEM Supply Contract by and between Sulzer Carbomedics, Inc. and ATS Medical, Inc., dated December 29, 1999 (Incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8, January 13, 2000, File No. 000-18602).
10.28	Amendment 2 to License Agreement by and between Sulzer Carbomedics, Inc. and ATS Medical, Inc., dated December 29, 1999 (Incorporated by reference to Exhibit 99.3 to the Company's Registration Statement on Form S-8, January 13, 2000, File No. 000-18602).
13	1999 Annual Report to Shareholders
23	Consent of Ernst & Young LLP.
24	Power of Attorney.
27	Financial Data Schedule.
99	Cautionary Statements.

*Pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended,
confidential portions of this exhibit have been redacted.

**Represents a management contract or compensatory plan or arrangement required
to be filed as an exhibit pursuant to Item 14(c) of Form 10-K.

(b) Reports on Form 8-K

None.

(c) Exhibits

See Exhibit Index and Exhibits attached as a separate section of this report.

(d) Financial Statement Schedule

See Financial Statement Schedule attached on a separate section of this report.

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 to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 28, 2000

ATS MEDICAL, INC.

By /s/ John H. Jungbauer

John H. Jungbauer
Chief Financial Officer

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 date indicated.

SIGNATURE

TITLE

Manuel A. Villafana*	Chairman, Chief Executive) Officer, and Director (principal executive officer))))
Richard W. Kramp*	President, Chief Operating Officer and Director))
John H. Jungbauer*	Vice President, Treasurer and Chief Financial Officer (principal financial and accounting officer)))))
Charles F. Cuddihy, Jr.*	Director)
David L. Boehnen*	Director)
A. Jay Graf*	Director)

By: /s/ John H. Jungbauer

John H. Jungbauer
Pro se and
Attorney-in-fact

Dated: March 28, 2000

*By Power of Attorney filed with this report as Exhibit 24 hereto.

ATS MEDICAL, INC.
ANNUAL REPORT ON FORM 10-K
YEAR ENDED DECEMBER 31, 1999

ITEM 8 AND ITEM 14(a) (1) AND (2) AND (d)
FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULE
COMMISSION FILE NUMBER 0-18602

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ATS MEDICAL, INC.

FORM 10-K ITEM 8 AND ITEM 14(a) (1) and (2) and (d)

LIST OF FINANCIAL STATEMENTS AND STATEMENT SCHEDULE

The following financial statements of ATS Medical, Inc. are incorporated in Part II, Item 8 and Part IV, Item 14(a)(1) of this Annual Report on Form 10-K by this reference:

Report of Independent Auditors.

Consolidated Statements of Financial Position at December 31, 1999 and 1998.

Consolidated Statements of Income for the years ended December 31, 1999, 1998 and 1997.

Consolidated Statement of Changes in Shareholders' Equity for the years ended December 31, 1999, 1998 and 1997.

Consolidated Statements of Cash Flows for the years ended December 31, 1999, 1998 and 1997.

Notes to Consolidated Financial Statements.

The following financial statement schedule of ATS Medical, Inc. is incorporated in Part IV, Item 14(a)(2) and (d) of this Annual Report on Form 10-K by this reference:

Schedule II - Valuation and Qualifying Accounts and Reserves

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ATS MEDICAL, INC.

SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

COL. A	COL. B	COL. C		COL. D	COL. E
Description	Balance at Beginning of Year	Additions		Deductions- Describe	Balance at End of Year
		(1) Charged to Costs and Expenses	(2) Charged to Other Accounts- Describe		
Allowance for Doubtful Accounts -----					
Year ended December 31, 1999:					
Deducted from asset accounts:					
Allowance for doubtful accounts	\$185,000	\$ 20,000	--	--	\$205,000
Totals	\$185,000	\$ 20,000	\$ 0	\$ 0	\$205,000
Year ended December 31, 1998:					
Deducted from asset accounts:					
Allowance for doubtful accounts	\$260,000	\$ 20,000	--	\$ 95,000 (1)	\$185,000
Totals	\$260,000	\$ 20,000	\$ 0	\$ 95,000	\$185,000
Year ended December 31, 1997:					
Deducted from asset accounts:					
Allowance for doubtful accounts	\$200,000	\$ 60,000	--	--	\$260,000
Totals	\$200,000	\$ 60,000	\$ 0	\$ 0	\$260,000
Reserve for Obsolete Inventory -----					
Year ended December 31, 1999:					
Deducted from asset accounts:					
Reserve for Obsolete Inventory	\$200,000	\$ 38,045	--	\$ 38,045 (2)	\$200,000
Totals	\$200,000	\$ 38,045	\$ 0	\$ 38,045	\$200,000
Year ended December 31, 1998:					
Deducted from asset accounts:					
Reserve for Obsolete Inventory	\$ 0	\$200,000	--	--	\$200,000
Totals	\$ 0	\$200,000	\$ 0	\$ 0	\$200,000

(1) Uncollectible accounts written off due to a single customer going bankrupt.

(2) Obsolete part written off that is no longer in use.

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION
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- 13 1999 Annual Report to Shareholders.

23	Consent of Ernst & Young LLP.
24	Power of Attorney.
27	Financial Data Schedule.
99	Cautionary Statements.

*Pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, confidential portions of this exhibit have been redacted.

**Represents a management contract or compensatory plan or arrangement required to be filed as an exhibit pursuant to Item 14(c) of Form 10-K.

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ATS MEDICAL

1999 ANNUAL REPORT

[PHOTO]
ADVANCING THE STANDARD

FINANCIAL HIGHLIGHTS

YEAR ENDED DECEMBER 31,

	1999	1998	1997	1996	1995
Net sales	\$17,461,964	\$17,960,483	\$14,515,915	\$11,859,765	\$9,300,540
Operating income for the year	1,766,243	1,555,296	689,150	702,727	21,756
Net income for the year	2,637,911	2,838,943	2,102,667	1,321,602	714,524
Net income per share--diluted	0.14	0.16	0.12	0.08	0.05
Total assets	61,116,685	58,431,376	54,386,031	33,320,300	31,329,128
Long-term debt	0	0	0	0	0
Total shareholders' equity	58,841,598	55,819,575	53,522,739	31,926,739	29,059,421

[BAR CHARTS OMITTED]

FDA Disclaimer

This annual report to shareholders is for communication with shareholders and potential shareholders of ATS Medical, Inc. The ATS Medical, Inc. heart valve is being studied according to a protocol which is part of the INVESTIGATIONAL DEVICE EXEMPTION issued by the U.S. FOOD AND DRUG ADMINISTRATION (FDA) and as such is available for use only at participating clinical centers in the United States. None of the information contained in this annual report is intended for use by physicians or patients in the United States for determining the appropriateness of the ATS Medical, Inc. heart valve in the care of heart valve patients in the United States.

[PHOTO]
Mr. Shinmura of Century Medical, Inc.
meets with Dr. Murata.

INTERNATIONAL
SALES

We have been selling the ATS heart valve since 1992 through independent distributors in most major international markets, including Europe, Japan and Australia. At December 31, 1999 we had contracts with 24 independent distributors covering 32 countries. We estimate that over 35,000 ATS heart valves have been implanted in patients since 1992.

Our international marketing strategy combines the substantial cardiovascular sales experience of our senior officers with a network of experienced independent distributors to sell the ATS heart valve internationally. We believe that our independent distributor network has provided a rapid and cost effective means of increasing market penetration and commercial acceptance of the ATS heart valve in key international markets. The use of an independent distributor does not involve significant expense to us. We have been able to attract experienced mechanical valve sales organizations familiar with local markets and customs to act as independent distributors.

Each of our independent distributors has the exclusive right to sell the ATS heart valve within a defined territory. These distributors also market other medical products, although they have agreed not to sell other mechanical heart valves. Most of our distributor agreements establish quotas for the sales of the ATS heart valve in the distributor's territory. Sales to international distributors are denominated in United States dollars. Sales to distributors in Japan, France and Germany represented over 45% of our total sales for each of the past three years.

Our sales, marketing and customer service personnel provide support to our independent distributors. Our marketing efforts include displaying the ATS heart valve at major international, national and regional medical meetings attended by cardiovascular surgeons and cardiologists. We distribute product brochures and product information bulletins and conduct product training sessions.

PAGE 1 [LOGO]

TO OUR
SHAREHOLDERS

Dear Shareholders and Friends,

When we started this project ten years ago, we knew that we faced many challenges in bringing to the hands of the physicians a new generation heart valve capable of reducing valve-related complications which continue to occur with currently available heart valves.

Additionally, we knew that we faced a difficult regulatory path and would need to market against financially stronger competitors. We also knew that we would be working with supply conditions that would make it difficult for us to compete on the basis of price and that we would have to rely entirely on the talents and skills of our employees and our distribution network, coupled with the fine product we intended to develop.

Ten years have passed. We entered the new millennium with a tremendous track record, still facing difficult challenges, but encouraged by the fact that we now have over 35,000 implants throughout the world without a single post-operative structural failure and with credible data being received which supports our belief that we have, in fact, developed the finest valve in the world.

[SIDEBAR]

"However, due to strong fiscal controls as well as improvements in productivity, we were able to remain profitable."

Manny A. Villafana
CHAIRMAN/CEO

On the regulatory side, in 1995, we completed a rigorous clinical study at five international institutions which demonstrated the safety and efficacy of our valve to the satisfaction of the European Community resulting in the issuance of our CE Mark. Similarly, we successfully completed a thorough study in Japan resulting in the issuance of the Shonin. In 1997, we began a clinical study of our valve in the United States, and during 1999, we submitted to the FDA our clinical data with over 1,300 patient years of data. These data were accepted for review in September of 1999. In early February, 2000 we received a letter from the FDA requesting additional information regarding our valve. We expect to be able to respond to these questions soon and continue the approval process.

During 1999, our valve units sold continued to grow but, due to the strong U.S. dollar and the decline of the exchange value of the Euro in particular, we had to make price concessions to remain competitive resulting in a 2.6% decrease in revenues. However, due to strong fiscal controls as well as improvements in productivity, we were able to remain profitable. We are one of very few medical device companies that do not have FDA approval but still achieve profitability from business overseas.

Mission Statement

The mission of ATS Medical is to continuously "Advance the Standard" of cardiovascular products worldwide through a dedicated organization working together to improve the quality of life for patients and our community profitably.

PAGE 2 [LOGO]

[PHOTO]
Manuel A. Villafana

[PHOTO]
Richard W. Kramp

For the past several years, we have faced the challenge of increasing component costs due to the terms of our multi-year supply agreement with Sulzer Carbomedics. At the same time the market price for mechanical heart valves has been declining due to currency fluctuations and price-cutting by competitors. Recognizing that pyrolytic carbon components, which make up the major part of our valve, represented over 80% of the cost of our final product, we decided to investigate the possibility of making our own pyrolytic carbon. That investigation led us to modify our contracts with Carbomedics, in a manner which allows us to reduce the purchases that we were previously required to make, reduce our component costs, and secure all the technical know-how to make our own pyrolytic carbon parts. Furthermore, a new agreement with Carbomedics allows us to eventually become an OEM manufacturer of pyrolytic material for other medical companies. We were able to structure this agreement in such a way that the cost of the technology license (\$41 million) would be paid over a period of seven years. Further, Carbomedics agreed that it would not manufacture components for the ATS valve for anyone (other than ATS) even after our patent has expired. It will give us, once and for all, the much needed technology to be a fully integrated, stand-alone company. We now feel that we are further on our way to accomplishing one of the goals that we set in 1990, and that is, being No. 1 in the heart valve industry.

We indicated in 1998 that 1999 would be a transitional year, it truly was. We will continue the transition through 2000. We have been blessed with a staff of competent, loyal employees who have enthusiastically pursued this goal. As we get closer to U.S. approval, we will be meeting new challenges including that of establishing a first class sales and marketing force in the United States to complement the excellent distribution network that we have overseas. We will be making significant investments to meet the costs of setting up this sales force, to fund our obligations to Carbomedics, and to fund the establishment of the new carbon manufacturing facility. By the time you read this we should have closed on a \$9.9 million private equity sale. While this transaction will carry us through 2000, we may need to raise additional capital to fund our plans for 2001 and beyond.

Again, we thank you for being patient with us. We all knew that to "Advance the Standard" would be a difficult challenge as well as a worthy goal. We thank you for your continued support and we ask that you join us in a most exciting adventure as we go into the new millennium.

Respectfully submitted for the Board of Directors,

March 2000

/s/ Manuel A. Villafana
Manuel A. Villafana
CHAIRMAN/CEO

/s/ Richard W. Kramp
Richard W. Kramp
PRESIDENT/COO

PAGE 3 [LOGO]

[PHOTO]

Rich Kramp, our president and chief operating officer, has assumed full responsibility for this important project.

CARBON

The basic design from which the ATS heart valve evolved was developed by Sulzer Carbomedics, Inc. Carbomedics is the largest and most experienced manufacturer of the pyrolytic carbon components used in mechanical valves. Since 1990, Carbomedics has been the sole source of the carbon components used in our valve and the licensor of certain technology upon which our product is based. Since 1990, most of the major mechanical heart valve manufacturers have acquired or established their own carbon manufacturing capability. Competition in the heart valve market has intensified since 1990 leading to price cutting in some markets. Manufacturers with control of their component costs are usually in a better position to use price to gain market share, especially in lesser developed countries where price is a critical factor.

Late in 1999, we restructured our contractual relationships with Carbomedics to lower our cost of carbon components and to begin the technology transfer which will enable us to manufacture those components ourselves.

First, our supply agreement with Carbomedics was revised. Under the 1990 contract we were obligated to buy certain minimum quantities of heart valve components through the year 2000. We were also obligated to replace each unit we sold during each year from 2001 through 2007. The price of components was set under formulas from 1990, which escalated the price each year according to changes in the U.S. Department of Labor, Employment Cost Index, but also allowed for volume discounts. In the revised supply agreement, we agreed to declining minimum quantities of valve components for 2001 through 2007. We feel these minimums are well below the quantities we would have been required to buy under the old agreement. We also reset the base price for these Carbomedics purchases to a level approximately 20% lower than our 1999 cost. These prices will escalate under the same formula tied to the U.S. Department of Labor, Employment Cost Index.

Under the 1990 agreements, there was no plan for component supply after 2007. Therefore in December 1999, we entered into a carbon technology agreement with Carbomedics under which we obtained an exclusive, worldwide right and license to use Carbomedics' pyrolytic carbon technology to manufacture components for the ATS heart valve. We also received a non-exclusive worldwide right and license to use the technology to produce pyrolytic carbon components for other devices and manufacturers, including, after 2008, for other heart valve manufacturers. Under the agreement Carbomedics has also agreed to assist us in designing, building, equipping, qualifying and commencing operations in a pyrolytic carbon component manufacturing facility in Minneapolis, Minnesota. In return, we have agreed to pay Carbomedics a license fee totaling \$41 million in eight installments over seven years, subject to deferral if certain milestones are not satisfied. We are obligated under the carbon technology agreement to pay all of the costs of establishing the new carbon production facility, including hourly fees and out-of-pocket expenses of the Carbomedics employees assigned to assist us in setting up the facility.

We are currently in the process of locating a facility. Our preliminary plans call for a 19,000 square foot building for facilities capable of producing approximately 10,000 valve sets per year. The manufacturing operations will include substrate machining and preparation, carbon coating, coated part machining and final polishing and finishing activities. We expect to hire 7 to 10 technical and production personnel over the next 12 months. We anticipate that the facility will not be operational until 2003. The key steps required to complete the facility include:

- o Outfitting the building
- o Purchasing and installing manufacturing equipment
- o Conducting pilot production, qualification and validation runs
- o Demonstrating compliance with FDA and international good manufacturing practices and quality system regulations; conducting human clinical testing, if required; and
- o Scaling up production.

Under the terms of the agreement with Carbomedics, we may also elect to have Carbomedics train our personnel how to machine graphite and pyrolytic carbon parts and teach us how to fabricate our own production tooling. We have not determined whether we will develop these capabilities internally or contract these steps out to third party vendors. We currently have in our inventory enough carbon components to satisfy our projected requirements for pyrolytic carbon components for over two years. In addition, we are obligated to continue to buy some valve components from Carbomedics under the supply agreement through 2007.

This is an important strategic step for our Company. We look forward to sharing its progress with you.

ATS Medical, Inc.

Consolidated Financial Statements

YEARS ENDED DECEMBER 31, 1999, 1998 AND 1997

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Management's Discussion and Analysis of
Financial Condition and Results of Operations

OVERVIEW

We manufacture and market a mechanical bileaflet heart valve with a unique pivot design. Our heart valve is used to treat heart valve failure caused by the natural aging process, rheumatic heart disease and congenital defects. We have received regulatory approvals to market the ATS heart valve in several international markets, principally Europe, Japan and Australia. On August 3, 1999, the FDA accepted for filing our PMA application to sell the ATS heart valve in the United States. On February 3, 2000, the FDA sent us a letter requesting additional information about our valve.

We commenced selling the ATS heart valve in international markets in 1992. We sell the valve to independent distributors with assigned territories (generally a specific country or region) who in turn sell the valve to hospitals or clinics. Sales to our European distributors represented approximately 60% of our net sales in 1997, 1998 and 1999. Sales to our international distributors are denominated in U.S. dollars so currency risk is borne by the distributor; however, as the dollar increases in value against the distributor's local currency, the cost of the valve increases for the distributor even though ATS does not change the selling price. We expect that substantially all of our revenue will be derived from sales to international distributors, unless we receive FDA approval to market the ATS heart valve in the United States. Assuming we receive FDA approval, we plan to sell the ATS heart valve in the United States with a direct sales force.

We currently purchase all of the pyrolytic carbon components for the ATS heart valve from Sulzer Carbomedics, Inc. pursuant to a multi-year supply agreement. The cost of the pyrolytic carbon components represents approximately 80% of the total cost of the ATS heart valve. Under the supply agreement, the cost of the pyrolytic carbon components has varied according to annual volume purchases and is adjusted annually by reference to increases in the U.S. Department of Labor Employment Cost Index. In December 1999, we renegotiated the supply agreement with Carbomedics. The supply agreement, as amended, provides for significant reductions in our minimum purchase requirements and unit costs beginning in 2001. We are obligated to purchase pyrolytic carbon components from Carbomedics through 2007. In addition, under a new carbon agreement, Carbomedics has granted us an exclusive right to use its carbon coating technology to manufacture pyrolytic carbon components for the ATS heart valve. Carbomedics also has agreed to assist us in establishing our own pyrolytic carbon component manufacturing facility. In return, we have agreed to pay a license fee totaling \$41 million over seven years.

Results of Operations

YEAR ENDED DECEMBER 31, 1999 COMPARED TO 1998

Net sales for the year ended December 31, 1999 decreased 3% to \$17,461,964 compared to \$17,960,483 for the year ended December 31, 1998. Unit sales increased 2% in 1999 compared to 1998. The decline in net sales was primarily due to a decrease in the average selling price for the valve. The exchange rate for most of the currencies in the countries where our customers are located declined significantly from 1998 to 1999 which effectively increased the price of our valve to our distributors. The average selling price for the valve decreased 4% on a worldwide basis, and over 5% in Europe, from 1998 to 1999, due to price concessions granted by us to our distributors. We felt these concessions were necessary as our competitors lowered their prices and as the Euro declined in value by nearly 15%. We do not have direct control over the price the distributor charges the hospital or clinic. Given the current strength of the U.S. dollar and the pricing strategies of our competitors we do not expect to be able to raise prices in 2000.

The other significant component of the revenue decline for the year ended December 31, 1999 compared to 1998 was a decline in sales in the United States. Prior to January 1997, all sales of valves were to customers outside of the United States. In 1997, we commenced a clinical study of the valve at seventeen hospitals in the United States. During the study, valves were being provided to the hospitals at prices designed to recover some of the costs of the clinical study. As we reached the desired number of implants in our U.S. clinical study of the valve, the rate of sales in the United States declined because surgeons were not eager to voluntarily fill out the additional paperwork and perform the additional tests required by the clinical protocol.

Cost of sales totaled \$10,986,114 and \$11,328,647 for 1999 and 1998, respectively, or 63% of sales for each of those years. The price of the carbon components contained in the valves sold in 1999 increased 3% as compared to the price of carbon components contained in the valves sold in 1998. Based upon the Company's internal sales projections, the price of the carbon contained in valves sold in 2000 is expected to be 1% lower than in 1999. The Company uses the first-in first-out ("FIFO")

method of accounting for inventory. Approximately 71% of the valves sold in 1999 were made with carbon purchased in 1997 (under FIFO) and the remainder with carbon purchased in 1996. The cost of carbon components, after giving effect to volume discounts and inflationary adjustments, rose 3.3% in 1995 (the third contract year), decreased 7% in 1996, rose 3% in 1997, decreased 4.5% in 1998 and rose 3.8% in 1999 (the seventh contract year). We expect to pay 6% less for carbon components in 2000 than in 1999.

Gross profit totaled \$6,475,850 or 37% of sales for year ended December 31, 1999, compared to gross profit of \$6,631,836 for the year ended December 31, 1998 or 37% of sales.

Research, development and engineering expenses totaled \$1,306,531 for the year ended December 31, 1999 versus \$1,484,989 for the year ended December 31, 1998. The decrease in research, development and engineering expenses in 1999 was primarily due to the winding down of our U.S. clinical study during that year. Approximately 31% and 27% of our research and development expenses for 1999 and 1998, respectively, were for testing and outside consulting services related to the valve.

We began human implants in the United States under an Investigational Device Exemption ("IDE") in January 1997. We sold the valves to the hospitals involved in the U.S. clinical study and the cost of the valve is eligible for reimbursement by Medicare and most private pay insurance companies. We are responsible for reimbursing the hospital for certain additional tests and procedures required by the clinical protocol. The estimated total cost of follow-up is accrued at the time of the sale as research and development expense.

Selling, general and administrative expenses totaled \$3,403,076 for the year ended December 31, 1999, a decrease from the \$3,591,551 reported for the year ended December 31, 1998. We accrued a significantly smaller amount of money for management bonuses in 1999 compared to 1998. Management bonuses are determined by a formula that takes into account growth in sales and operating income. We had 86 employees at December 31, 1999 compared to 78 employees at December 31, 1998.

Interest income totaled \$927,552 for the year ended December 31, 1999 compared to \$1,355,647 for the year ended December 31, 1998. The decrease in interest income in 1999 was primarily due to lower average cash balances caused by using cash to meet our obligations under the Carbomedics supply agreement.

Net income totaled \$2,637,911 for the year ended December 31, 1999 compared to \$2,838,943 for the year ended December 31, 1998. The \$428,095 decrease in interest income in 1999 as compared to 1998 was the primary factor in the decrease in net income.

We have accumulated net operating loss carryforwards for U.S. tax purposes. Section 382 of the Internal Revenue Code of 1986, as amended, provides, in part, that if an "ownership change" occurs with respect to any corporation with net operating loss carryforwards, such as our Company, the net operating loss carryforwards can be used to offset future income only to the extent of the annual "Section 382 limitation." An ownership change generally occurs if there has been more than a 50 percent change in the stock ownership of a corporation over a three-year period. The Section 382 limitation is an amount determined by multiplying the value of the corporation's stock on the date of an ownership change by the federal long-term tax-exempt rate in effect for the month of the ownership change. As a result of Section 382, utilization of all or a portion of a corporation's net operating loss carryforwards may be limited. We believe that as a result of our registered direct equity offering in early 1995 and the sale of 1,568,940 shares of common stock in 1997, we experienced an ownership change, and our ability to fully utilize \$15 million of our existing net operating loss carryforwards will be restricted to approximately \$3 million per year. Due to the application of the annual Section 382 limitation and the other provisions of Section 382, some of our net operating loss carryforwards may expire before we can use them to reduce our federal income tax liabilities.

Income taxes for years ended December 31, 1999 and 1998 are mostly due to alternative minimum tax on earnings. The alternative minimum tax can be used as a credit against future regular tax liabilities, however, we have provided 100% valuation allowances against this credit and all of its other tax attributes. We will recognize the benefit of our tax attributes when it is more likely than not that these benefits will be realized.

YEAR ENDED DECEMBER 31, 1998 COMPARED TO 1997

Net sales for the year ended December 31, 1998 increased 24% to \$17,960,483 compared to \$14,515,915 for the year ended December 31, 1997. Unit sales increased 22% in 1998 compared to 1997 which was more than four times the rate of unit growth in the overall heart valve market. The two largest revenue increases in 1998 over 1997 were in France and Japan. Combined, these two markets represented 59% of the

Management's Discussion and Analysis of
Financial Condition and Results of Operations
(CONTINUED)

total revenue increase. For 1998 the sales growth over the corresponding period was achieved in spite of significant price competition from other valve manufacturers and the increased strength of the U.S. dollar relative to almost all foreign currencies. During 1998 and 1997 we were selling valves in most developed countries and several lesser developed countries, or LDCs, so sales growth came primarily from increased usage in existing markets. In 1996 and each of the previous years, a portion of the sales increase came from opening new markets as well as increased usage within existing markets. The average selling price of the valve increased 3% from 1997 to 1998.

Cost of sales for 1998 totaled \$11,328,647, or 63% of sales, compared to \$9,428,959 or 65% of sales for 1997. The price of the carbon components contained in the valves sold in 1998 decreased 4% as compared to the cost of carbon components contained in the valves sold in 1997. Based upon our internal sales projections, the price of the carbon contained in valves sold in 1999 is expected to be 3% higher than in 1998.

Gross profit totaled \$6,631,836 for the year ended December 31, 1998, or 37% of sales, compared to gross profit of \$5,086,956, or 35% of sales, for year ended December 31, 1997. The increase in average selling price accounted for most of the gross profit increase. This improvement, along with the 4% decrease in carbon component prices and operating efficiencies accounts for the gross profit increase.

Research, development and engineering expenses totaled \$1,484,989 for the year ended December 31, 1998 versus \$1,058,318 for the year ended December 31, 1997. The majority of the increase is related to the costs associated with our U.S. clinical study. Approximately 27% and 42% of research and development expenses for the years ended December 31, 1998 and 1997, respectively, were for testing and outside consulting services related to the valve. During the year ended December 31, 1997 a significant component of the development expense was for work on our aortic valved graft. The aortic valved graft is a standard replacement aortic heart valve sutured at the end of a collagen-impregnated dacron tube. This product extension is used in surgeries where the patient's aorta and aortic valve are damaged or degenerated. Most other valve manufacturers provide a similar product. This development project was completed in 1997 and there was not a similar project expense in 1998.

Selling, general and administrative expenses totaled \$3,591,551 for the year ended December 31, 1998, an increase from the \$3,339,488 reported for the year ended December 31, 1997. The year ended December 31, 1997 included \$225,000 related to the shutdown of our subsidiary in Glasgow, Scotland. Separation pay totalling \$153,921 and the loss on the disposal of fixtures and equipment were the major portion of this expense. The increase in selling, general and administrative expenses for the year ended December 31, 1998 compared to 1997 is in part because salaries and benefits increased 14% in 1998. We had 78 employees at December 31, 1998 compared to 65 employees at December 31, 1997.

Interest income totaled \$1,355,647 for the year ended December 31, 1998 compared to \$1,427,363 for the year ended December 31, 1997. The decrease in interest income in 1998 was the result of lower average investable cash balances during 1998 and lower interest rates. Cash on hand at December 31, 1998 was less than the amount on hand at December 31, 1997.

Income taxes for years ended December 31, 1998 and 1997 are mostly due to alternative minimum tax on earnings. The alternative minimum tax can be used as a credit against future regular tax liabilities, however, we have provided 100% valuation allowances against this credit and all of its other tax attributes.

Net income totaled \$2,838,943 for the year ended December 31, 1998 compared to \$2,102,667 for the year ended December 31, 1997. The \$866,146 increase in operating income in 1998 as compared to 1997 was the primary factor in the increase in net income.

LIQUIDITY AND CAPITAL RESOURCES

Cash, cash equivalents and marketable securities decreased by \$10,916,959 from \$20,606,962 at December 31, 1998 to \$9,690,003 at December 31, 1999. Inventory purchases and the \$5 million first payment under our new carbon agreement with Carbomedics, caused us to have negative cash flow from operations.

During 1999 we purchased \$15.3 million of heart valve components in accordance with the terms of our long-term supply agreement with Carbomedics. During 2000 we are obligated to purchase approximately \$16.5 million of carbon components under the supply agreement. The minimum purchases under the supply agreement are not tied to sales of our valve and we do not expect sales of the valve to exceed the minimum purchase requirements under the supply agreement unless the valve is approved for sale in the United States.

In December 1999, we renegotiated our supply agreement with Carbomedics. The supply agreement, as amended, provides for significant reductions in our minimum purchase requirements and unit costs for the years 2001 through 2007. We estimate that our minimum purchase requirements under the supply agreement from 2001 through 2007 will total approximately \$39 million. Under the new carbon agreement entered into in December 1999, we have agreed to pay Carbomedics a license fee of \$41 million in installments over the next seven years. In addition to granting us an exclusive worldwide right and license to use its carbon coating technology to manufacture pyrolytic carbon components for the valve under this agreement, Carbomedics has agreed to assist us in designing, building and commencing operations in our own pyrolytic carbon production facility in Minneapolis, Minnesota.

Accounts receivable increased from \$5,820,699 at December 31, 1998 to \$6,159,624 at December 31, 1999. Most of our sales have been to customers in international markets. We have standard 60 day terms for receivables, however, competitive pressures and local economic situations have caused us to selectively extend the terms for payment. At December 31, 1999, the account balance for our five largest European distributors totaled 69% of outstanding receivables. We have done business with these customers since 1992 and the size of the receivables, while substantial, is consistent with the growth of business in these markets and in line with the size of these customers' overall business.

Current liabilities decreased from \$2,611,801 at December 31, 1998 to \$2,275,087 at December 31, 1999. The decrease reflects primarily a decrease in accounts payable related to the amount owing to Carbomedics under the supply agreement.

Based upon our current rate of sales, our anticipated purchase obligations under the supply agreement, the license fee payments under the carbon agreement, the expenses associated with establishing a direct sales force in the United States and other expected expenses, we anticipate that we will need substantial additional capital during 2000. Depending on the amount of capital raised in 2000, the timing of FDA approval for sales of our valve in the United States and the rate of increase in worldwide valve sales, we may need to raise additional capital in the future.

On March 22, 2000, the Company accepted a subscription agreement for the private sale of 1,100,000 shares of our common stock. The stock is priced at \$9.00 per share and after expenses we expect to realize \$9.75 million. This transaction is expected to close in April 2000. This capital should be sufficient to meet our needs through March 2001. We will need additional capital after that date. We cannot be certain that additional capital will be available or that, if available, it will be on terms favorable to the Company.

We do not use derivatives and therefore do not face market risk from currency or interest rate changes on these types of instruments. If we are required to finance future operations with debt we would have exposure to increases in interest rates on borrowings. Assuming that we did use borrowing to meet our cash needs during 2000, and that interest rates increased by 10%, we estimate that we could incur an additional \$25,000 in interest expense.

THE SINGLE EUROPEAN CURRENCY

A significant portion of our sales occurs in Europe. Effective January 1, 1999 various European countries began utilizing a single currency, the "Euro." From January 1999 through December 2001, merchants will be encouraged to discontinue using local country currencies and begin using the Euro to transact business. Beginning in 2002, it will be required that business in the European community be conducted using the Euro. We sell to all of our customers in U.S. dollars and do not expect to have accounting system issues relative to currency translation. Our selling prices are similar to most of our European distributors and therefore should not cause significant disruption whether in dollars or Euros. From its introduction in January 1999, the rate of exchange for the Euro versus the U.S. dollar declined by as much as 15%. Several of the our European distributors were unable to increase their local currency selling price for the valve. These distributors complained to us that their profits were being squeezed. Our European revenue declined 5% in 1999 compared to 1998. We did offer volume price discounts to some distributors who met or exceeded quota. The decline in the Euro offset the potential positive effect of these discounts, and units sold in Europe only increased 1.4% in 1999 compared to 1998. Europe is a very important market for us. Disruption or loss of a portion of our European business could have a material and adverse impact on our financial position.

CAUTIONARY STATEMENT PURSUANT TO THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

The Private Securities Litigation Reform Act of 1995 (the "Act") provides a "safe harbor" for forward-looking statements to encourage companies to provide prospective information about their business, so long as those statements are identified as forward-looking and are accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those discussed in the statement. ATS Medical, Inc. desires to take advantage of the safe harbor provisions with respect to any

forward-looking statements it may make

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Management's Discussion and Analysis of
Financial Condition and Results of Operations
(CONTINUED)

in this filing, other filings with the Securities and Exchange Commission and any public oral statements or written releases. The words or phrases "will likely," "is expected," "will continue," "is anticipated," "estimate," "projected," "forecast," or similar expressions are intended to identify forward-looking statements within the meaning of the Act. Such statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those projected. The Company cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date made.

In accordance with the Act, the Company identifies the following important general factors which if altered from the current status could cause the Company's actual results to differ from those described in any forward-looking statements: the continued acceptance of the Company's mechanical heart valve in international markets, the acceptance by the U.S. FDA of the Company's regulatory submissions, the continued performance of the Company's mechanical heart valve without structural failure, the actions of the Company's competitors including pricing changes and new product introductions, the continued performance of the Company's independent distributors in selling the valve, the risk of product returns in connection with distributor terminations, the actions of the Company's supplier of pyrolytic carbon components for the valve and difficulties we may encounter in establishing and operating our own pyrolytic carbon manufacturing capability. This list is not exhaustive, and the Company may supplement this list in any future filing or in connection with the making of any specific forward-looking statement.

Common Stock Information

The Company's common stock (the "Common Stock") is traded on the Nasdaq National Market(R) under the symbol "ATSI." The following table sets forth the high and low sale prices since January 1, 1998. Prices represent transactions between dealers and do not reflect retail markups, markdowns or commissions.

1999	High	Low	1998	High	Low
First Quarter	\$ 8.87	\$6.50	First Quarter	\$8.18	\$4.75
Second Quarter	8.13	6.00	Second Quarter	8.37	6.37
Third Quarter	11.38	7.69	Third Quarter	8.00	5.00
Fourth Quarter	14.94	8.88	Fourth Quarter	7.69	4.31

As of December 31, 1999 there were 509 record holders of the Common Stock. The Company has not paid cash dividends and has no present intentions of paying cash dividends on its Common Stock.

MARKET MAKERS

During 1999, the following securities firms were the most significant market makers of the Company's Common Stock:

Piper Jaffray Companies Inc.	Knight Securities L.P.
A.G. Edwards & Sons, Inc.	Mayer & Schweitzer Inc.
Raymond James & Associates	Herzog, Heine, Geduld, Inc.
PaineWebber, Inc.	John G. Kinnard & Co., Inc.
Spear, Leeds & Kellogg	

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ATSI

NASDAQ
LISTED

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Report of Independent Auditors

Board of Directors and Shareholders
ATS Medical, Inc.

We have audited the accompanying consolidated statements of financial position of ATS Medical, Inc. and subsidiary as of December 31, 1999 and 1998, and the related consolidated statements of income, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 1999. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as 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 ATS Medical, Inc. and subsidiary at December 31, 1999 and 1998, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 1999, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

March 23, 2000

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ATS Medical, Inc.

Consolidated Statements of Financial Position

	DECEMBER 31	
	1999	1998

ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,030,641	\$ 7,754,077
Short-term investments	5,659,362	12,852,885
	-----	-----
Accounts receivable, less allowance of \$205,000 in 1999 and \$185,000 in 1998	9,690,003	20,606,962
Inventories	6,159,624	5,820,699
Prepaid expenses	38,634,589	29,954,718
	-----	-----
Total current assets	427,834	458,663
Furniture and equipment, net	54,912,050	56,841,042
Technology license	801,443	1,202,784
Other assets	5,000,000	--
	-----	-----
Total assets	403,192	387,550
	-----	-----
	\$61,116,685	\$58,431,376
	=====	=====
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,022,302	\$ 2,355,443
Accrued payroll and expenses	252,785	256,358
	-----	-----
Total current liabilities	2,275,087	2,611,801
Shareholders' equity:		
Common Stock, \$.01 par value:		
Authorized shares--40,000,000		
Issued and outstanding shares--17,909,010 in 1999 and 17,824,137 in 1998	179,090	178,241
Additional paid-in capital	71,633,414	71,249,846
Accumulated other comprehensive income	43,494	43,799
Accumulated deficit	(13,014,400)	(15,652,311)
	-----	-----
Total shareholders' equity	58,841,598	55,819,575
	-----	-----
Total liabilities and shareholders' equity	\$61,116,685	\$58,431,376
	=====	=====

SEE ACCOMPANYING NOTES.

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ATS Medical, Inc.
Consolidated Statements of Income

	YEAR ENDED DECEMBER 31		
	1999	1998	1997
Net sales	\$17,461,964	\$17,960,483	\$14,515,915
Cost of goods sold	10,986,114	11,328,647	9,428,959
Gross profit	6,475,850	6,631,836	5,086,956
Expenses:			
Research, development and engineering	1,306,531	1,484,989	1,058,318
Selling, general and administrative	3,403,076	3,591,551	3,339,488
	4,709,607	5,076,540	4,397,806
Operating income	1,766,243	1,555,296	689,150
Interest income	927,552	1,355,647	1,427,363
Income before income taxes	2,693,795	2,910,943	2,116,513
Income tax expense	55,884	72,000	13,846
Net income	\$ 2,637,911	\$ 2,838,943	\$ 2,102,667
Net income per share:			
Basic	\$.15	\$.16	\$.12
Diluted	\$.14	\$.16	\$.12
Weighted average number of shares outstanding:			
Basic	17,858,310	17,737,887	17,284,784
Diluted	18,370,964	18,130,540	17,872,989

SEE ACCOMPANYING NOTES.

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ATS Medical, Inc.

Consolidated Statement of Changes in Shareholders' Equity

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 1996	15,288,042	\$152,880	\$52,313,315	\$54,465	\$(20,593,921)	\$31,926,739
Common stock issued in a private placement, net of selling expenses of \$27,627	1,568,940	15,690	14,706,682	--	--	14,722,372
Stock options exercised	26,327	263	41,451	--	--	41,714
Stock warrants exercised	705,749	7,058	4,736,348	--	--	4,743,406
Change in unrealized loss on short-term investments, net of tax	--	--	--	(5,591)	--	(5,591)
Change in foreign currency translation	--	--	--	(8,568)	--	(8,568)
Net income for the year	--	--	--	--	2,102,667	2,102,667
Comprehensive income						2,088,508
Balance at December 31, 1997	17,589,058	175,891	71,797,796	40,306	(18,491,254)	53,522,739
Common stock issued under the Employee Stock Purchase Plan	7,934	79	42,020	--	--	42,099
Stock options exercised	227,145	2,271	(589,970)	--	--	(587,699)
Change in foreign currency translation	--	--	--	3,493	--	3,493
Net income for the year	--	--	--	--	2,838,943	2,838,943
Comprehensive income						2,842,436
Balance at December 31, 1998	17,824,137	178,241	71,249,846	43,799	(15,652,311)	55,819,575
Common stock issued under the Employee Stock Purchase Plan	17,792	178	108,960	--	--	109,138
Stock options exercised	67,081	671	274,608	--	--	275,279
Change in foreign currency translation	--	--	--	(305)	--	(305)
Net income for the year	--	--	--	--	2,637,911	2,637,911
Comprehensive income						2,637,606
Balance at December 31, 1999	17,909,010	\$179,090	\$71,633,414	\$43,494	\$(13,014,400)	\$58,841,598

SEE ACCOMPANYING NOTES.

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ATS Medical, Inc.

Consolidated Statements of Cash Flows

	YEAR ENDED DECEMBER 31		
	1999	1998	1997

OPERATING ACTIVITIES			
Net income	\$ 2,637,911	\$ 2,838,943	\$ 2,102,667
Adjustments to reconcile net income to net cash used in operating activities:			
Depreciation	290,070	267,187	246,140
Loss on disposal of equipment	209,872	1,965	50,985
Changes in operating assets and liabilities:			
Accounts receivable	(338,925)	(1,373,865)	(1,307,275)
Prepaid expenses	30,829	96,907	(87,322)
Other assets	(5,015,642)	(16,891)	17,574
Inventories	(8,679,871)	(7,268,445)	(4,444,207)
Accounts payable and accrued expenses	(227,607)	1,748,509	(530,269)
	-----	-----	-----
Net cash used in operating activities	(11,093,363)	(3,705,690)	(3,951,707)
INVESTING ACTIVITIES			
Purchases of short-term investments	(11,398,525)	(20,103,048)	(29,435,865)
Maturities of short-term investments	18,592,048	28,232,339	16,315,717
Purchases of furniture and equipment	(207,708)	(695,749)	(178,748)
	-----	-----	-----
Net cash (used in) provided by investing activities	6,985,815	7,433,542	(13,298,896)
FINANCING ACTIVITIES			
Net proceeds (payments) from issuance (redemption) of common stock	384,417	(545,600)	19,507,493
	-----	-----	-----
Net cash provided by (used in) financing activities	384,417	(545,600)	19,507,493
Effect of exchange rate changes on cash	(305)	3,493	(8,568)
	-----	-----	-----
Increase (decrease) in cash and cash equivalents	(3,723,436)	3,185,745	2,248,322
Cash and cash equivalents at beginning of year	7,754,077	4,568,332	2,320,010
	-----	-----	-----
Cash and cash equivalents at end of year	\$ 4,030,641	\$ 7,754,077	\$ 4,568,332
	=====	=====	=====

SEE ACCOMPANYING NOTES.

ATS Medical, Inc.

Notes to Consolidated Financial Statements
DECEMBER 31, 1999

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

BUSINESS ACTIVITY

ATS Medical, Inc. (the "Company") manufactures and sells a bileaflet mechanical heart valve. The principal markets for the Company's mechanical heart valve include Europe, Asia, Australia, South Africa and South America. The Company is sponsoring clinical trials of the valve in Canada and the United States in order to demonstrate safety and effectiveness and to be allowed to market the valve in these countries.

PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, ATS Medical, Ltd., after elimination of significant intercompany accounts and transactions.

CASH EQUIVALENTS

The Company considers all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents are carried at cost which approximates market value.

SHORT-TERM INVESTMENTS

Short-term investments are composed of debt securities and are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported as a part of comprehensive income in shareholders' equity. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale securities are included in other income.

INVENTORIES

Inventories are carried at the lower of cost (first-in, first-out basis) or market. The majority of the inventories consists of purchased components. The Company has recorded a valuation reserve against inventories of \$200,000 as of December 31, 1999 and 1998.

OTHER ASSETS

Prior to obtaining directors' and officers' liability insurance, the Company had placed monies into a self-insurance trust to provide coverage for potential issues. At December 31, 1999 and 1998, the deposits within the trust amounted to \$403,192 and \$387,550, respectively.

FURNITURE AND EQUIPMENT

Furniture and equipment are stated at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets as follows:

Furniture and fixtures	7 years
Equipment	5 to 7 years

Leasehold improvements are amortized over the related lease term or estimated useful life, whichever is shorter (approximately 3 years).

TECHNOLOGY LICENSE

The Company has a commitment to purchase an exclusive, worldwide right and license to use Sulzer Carbomedics, Inc. ("Carbomedics") pyrolytic carbon technology (see Note 9 - Commitments). As the specific criteria are met that obligate the Company to make payments under the commitment, the payment amount will be capitalized as part of the technology license with amortization commencing upon the Company's utilization of the technology in their own manufacturing facility.

IMPAIRMENT OF LONG-LIVED ASSETS

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to undiscounted future net cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets.

REVENUE RECOGNITION

The Company recognizes revenue at the time of shipment and invoicing of the product.

USE OF ESTIMATES

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

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.

STOCK-BASED COMPENSATION

The Company follows Accounting Principles Board Opinion No. 25, ACCOUNTING FOR STOCK ISSUED TO EMPLOYEES ("APB 25"), and related interpretations in accounting for its stock options. Under APB 25, when the exercise price of stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized.

NET INCOME PER SHARE

Basic earnings per share is computed by dividing net income by the weighted average shares outstanding and excludes any dilutive effects of options, warrants, and convertible securities. Diluted earnings per share gives effect to all dilutive potential common shares outstanding during the year.

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2. SHORT-TERM INVESTMENTS

As of December 31, 1999 and 1998, the cost of short-term investments held by the Company, which have maturity dates of one year or less, approximated their fair market value of \$5,659,362 and \$12,852,885, respectively. As a result no unrealized gains or losses were recognized at December 31, 1999 and 1998.

3. FURNITURE AND EQUIPMENT, NET

Furniture and equipment consists of the following:

	DECEMBER 31	
	1999	1998
Furniture and fixtures	\$ 190,325	\$ 181,947
Equipment	1,639,836	1,506,627
Leasehold improvements	593,819	588,830
Construction in progress	54,307	318,907
	-----	-----
	2,478,287	2,596,311
Less accumulated depreciation	1,676,844	1,393,527
	-----	-----
	\$ 801,443	\$1,202,784
	=====	=====

In fiscal 1999, the Company took delivery on customized measuring equipment. The equipment was expected to improve processing time needed to inspect the Company's products. Vendor personnel installed the machine and attempted to correct operating deficiencies of the equipment and related software. Unable to get the equipment to perform up to specification, the Company disposed of the equipment and recognized an expense of \$186,000 associated with the write-off of the equipment.

4. FINANCING ARRANGEMENT

The Company has a \$5 million revolving line of credit with a bank which accrues interest at a rate .5% below the bank's reference rate (8.0% at December 31, 1999) and is secured by a portion of the Company's short-term investments. The Company must repay any amounts owed under the line of credit by June 30, 2000. Interest on the line of credit is payable monthly. The Company had no borrowing against this facility at December 31, 1999.

5. EMPLOYEE STOCK PURCHASE PLAN

In May 1998, the Company implemented the 1998 ATS Medical, Inc. 423 Employee Stock Purchase Plan. Under the terms of the plan, employees are eligible to purchase common stock of the Company on a quarterly basis. Employees can purchase common stock at 85% of the lesser of the market price of the common stock on the first day of the quarter or the last day of the quarter. During 1999 and 1998, shares of common stock totaling 17,792 and 7,934 were purchased under the plan at prices ranging from \$4.78 to \$7.86 and \$4.68 to \$5.95 per share, respectively.

6. STOCK OPTIONS

The Company has a Stock Option and Stock Award Plan (the "Plan") under which options to purchase Common Stock of the Company may be awarded to employees and non-employees of the Company. The options may be granted under the Plan as incentive stock options (ISO) or as non-qualified stock options (non-ISO).

The following table summarizes the options to purchase shares of the Company's Common Stock under the Plan:

	Shares Reserved for Grant	Stock Options Outstanding Under the Plan		Weighted Average Exercise Price Per Share
		ISO	Non-ISO	
Balance December 31, 1996	113,129	654,670	650,375	\$4.37
Additional shares reserved	1,000,000	--	--	--
Options granted	(374,600)	284,928	89,672	5.51
Options exercised	--	(7,500)	(18,827)	1.59
Options canceled	151,250	(123,125)	(28,125)	9.15
	-----	-----	-----	
Balance December 31, 1997	889,779	808,973	693,095	4.23
Options granted	(47,500)	25,000	22,500	6.45
Options exercised	--	(90,271)	(271,173)	.95
Options canceled	43,100	(18,100)	(25,000)	6.86
	-----	-----	-----	
Balance December 31, 1998	885,379	725,602	419,422	5.27
Options granted	(333,000)	155,218	177,782	7.75

Options exercised	--	(57,638)	(10,000)	4.15
Options canceled	14,300	(14,300)	--	6.39

Balance December 31, 1999	566,679	808,882	587,204	\$5.90
	=====			

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ATS Medical, Inc.

Notes to Consolidated Financial Statements
 DECEMBER 31, 1999
 (CONTINUED)

The following table summarizes information about stock options outstanding including non-plan options to purchase 25,000 shares at December 31, 1999:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$1.00 - \$ 3.63	465,607	2.91 years	\$3.31	465,607	\$3.31
5.06 - 8.25	742,979	7.60 years	6.40	355,629	6.44
9.00 - 10.13	212,500	8.26 years	9.56	194,125	9.54
\$1.00 - \$10.13	1,421,086	6.16 years	\$5.86	1,015,361	\$5.60

The weighted average fair value of options granted during the years ended December 31, 1999, 1998 and 1997 was \$7.75, \$6.45 and \$5.51, respectively.

Non-Plan options to purchase 25,000 shares exercisable at \$3.63 per share were outstanding at December 31, 1999 and 1998.

At December 31, 1999, 1998 and 1997, Plan and non-Plan options for 1,015,361, 804,274 and 984,218 shares of common stock, respectively, were exercisable at a weighted average price of \$5.60, \$4.67 and \$3.06 per share, respectively. Options can be exercised by tendering shares previously acquired.

The Company has elected to follow Accounting Principles Board Opinion No. 25, ACCOUNTING FOR STOCK ISSUED TO EMPLOYEES ("APB 25"), and related interpretations in accounting for its employee stock options because, as discussed below, the alternative fair value accounting provided for under FASB Statement No. 123, ACCOUNTING FOR STOCK-BASED COMPENSATION ("Statement 123"), requires use of option valuation models that were not developed for use in valuing employee stock options.

Pro forma information regarding net income and earnings per share is required by Statement 123, and has been determined as if the Company had accounted for its employee stock options under the fair value method of Statement 123. The fair value of these options was estimated at the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions for 1999, 1998 and 1997: risk-free interest rate of 5.30%, 4.65% and 5.20%, respectively; dividend yield of 0%; volatility factor of the expected market price of the Company's common stock of .73, .79 and .80 and a weighted average expected life of the option of 7, 6 and 5 years, respectively.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. The Company's pro forma information is as follows:

	1999	1998	1997
Pro forma net income	\$888,867	\$2,053,588	\$1,634,401
Pro forma net income per share:			
Basic	\$.05	\$.12	\$.09
Diluted	\$.05	\$.11	\$.09

The pro forma effect on net income is not representative of the pro forma effect on net income in future years because it does not take into consideration pro forma compensation expense related to grants made prior to 1995.

The Company has 1,962,765 shares of Common Stock reserved for issuance under various option plans.

7. LEASES

The Company has an operating lease for its facilities in Plymouth, Minnesota. The lease has a remaining life of 38 months and expires February 28, 2003. Future minimum lease payments under the agreement are as follows:

2000	\$227,799
2001	245,453
2002	248,553
2003	41,425

	\$763,230
	=====

The rent expense was \$206,717, \$198,408 and \$159,096 for 1999, 1998 and 1997, respectively.

8. INCOME TAXES

At December 31, 1999, the Company had net operating loss carryforwards of approximately \$12,329,000 plus credits for increasing research and development costs of approximately \$616,000 and a credit of approximately \$89,000 from alternative minimum tax, which are available to offset future taxable income or reduce taxes payable through 2012. The Company paid income taxes of \$55,884, \$72,000 and \$13,846 in 1999, 1998 and 1997, respectively.

Components of deferred tax assets and liabilities are as follows:

	DECEMBER 31	
	1999	1998

Deferred tax assets:		
Net operating loss carryforwards	\$4,932,000	\$6,008,000
Research and development credits	616,000	616,000
AMT credit	89,000	69,000
Accrued compensation	229,000	237,000
Other accrued expenses	206,000	61,000
	-----	-----
	6,072,000	6,991,000
Deferred tax liabilities:		
Depreciation	(501,000)	(557,000)
	-----	-----
Net deferred tax assets before valuation allowance	5,571,000	6,434,000
Less valuation allowance	(5,571,000)	(6,434,000)
	-----	-----
Net deferred tax assets	\$ --	\$ --
	=====	=====

The Company's ability to utilize its net operating loss carryforwards to offset future taxable income is subject to certain limitations under Section 382 of the Internal Revenue Code due to changes in the equity ownership of the Company.

Income tax expense consists of:

	1999	1998	1997

Current:			
Federal	\$47,884	\$52,000	\$ 3,846
State	8,000	20,000	10,000
	-----	-----	-----
	\$55,884	\$72,000	\$13,846
	=====	=====	=====

Reconciliation of the statutory federal income tax rate to the Company's effective tax rate is as follows:

	1999	1998	1997

Tax at statutory rate	34.0%	34.0%	34.0%
State income taxes	6.0	6.0	6.0
Impact of net operating loss carryforwards	(39.0)	(39.0)	(39.0)
	-----	-----	-----
	1.0%	1.0%	1.0%
	=====	=====	=====

9. COMMITMENTS

In 1990, the Company entered into various agreements with Carbomedics giving the Company the exclusive worldwide license to sell a bileaflet mechanical heart valve under patents held by Carbomedics. As part of the agreements, the Company entered into a 15-year supply contract that was amended several times.

In December 1999, the Company and Carbomedics entered into an agreement which entitles the Company to an exclusive, worldwide right and license to use Carbomedics' pyrolytic carbon technology to manufacture components for the Company's mechanical heart valve. This agreement further provides that Carbomedics will assist the Company in various aspects to enable the Company's completion of a manufacturing facility in Minneapolis, Minnesota to produce its own pyrolytic carbon components. The purchase price for the technology license totals \$41 million payable in eight installments contingent upon the attainment of specified milestones. The first installment of \$5 million was paid in December 1999 and has been included in the statement of financial position at December 31, 1999.

The Company also amended the various other agreements with Carbomedics including changes to the supply agreement, which requires the Company to purchase approximately \$17 million of components in 2000 and specified minimums of components for the years 2001-2007, which will approximate \$40 million. Payments to Carbomedics were \$15,301,784, \$14,454,642 and \$12,478,323 in 1999, 1998 and 1997, respectively. The amounts payable to Carbomedics were \$1,266,452 and \$826,383 at December 31, 1999 and 1998, respectively.

At December 31, 1999, the Company's inventory is in excess of its current requirements based on the recent level of sales. Management believes that excess quantities will be utilized upon United States Food and Drug Administration ("FDA") approval of its technology and believes no loss will be incurred on its disposition. As of December 31, 1999, management cannot estimate a range of amounts of loss that could occur if FDA approval is not granted. Management is unable to make a meaningful estimate of inventory usage for the next twelve months and, accordingly, inventory is classified as a current asset as of December 31, 1999.

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ATS Medical, Inc.

Notes to Consolidated Financial Statements
DECEMBER 31, 1999
(CONTINUED)

10. BENEFIT PLAN

The Company has a defined contribution salary deferral plan covering substantially all employees under Section 401(k) of the Internal Revenue Code. The plan allows eligible employees to contribute up to 12% of their annual compensation with the Company contributing an amount equal to 25% of each employee's contribution. The Company recognized expense for contributions to the plan of \$51,302, \$47,946 and \$40,920 during 1999, 1998 and 1997, respectively.

11. SIGNIFICANT CUSTOMERS AND CONCENTRATION OF CREDIT RISK

The Company operates in one segment, the sale of a bileaflet mechanical heart valve. As a result, the information disclosed herein materially represents all of the financial information related to the Company's principal operating segment. The Company derived the following percentages of its net sales from its distributors in the following geographic markets where net sales exceeded 10% of the consolidated total:

	YEAR ENDED DECEMBER 31		
	1999	1998	1997
Japan	18.6%	19.2%	17.2%
France	14.7	16.0	11.2
Germany	16.2	15.1	16.7

The Company had a balance owing by one distributor which represented 19% and 26% of its outstanding accounts receivable at December 31, 1999 and 1998, respectively.

12. SUBSEQUENT EVENT

On March 22, 2000, the Company accepted a subscription agreement for the private sale of 1,100,000 shares of ATS Medical, Inc. common stock. The stock is priced at \$9.00 per share and after expenses the Company expects to realize \$9.75 million. The transaction is expected to close April 2000. This capital should be sufficient to meet the Company's needs through March 2001. The Company will need additional capital after that date. There is no guarantee that additional capital will be available or that, if available, it will be on terms favorable to the Company.

13. NET INCOME PER SHARE

The following table sets forth the reconciliation of the denominator for the calculation of basic and diluted net income per share:

	1999	1998	1997
Denominator for basic net income per share-weighted-average shares	17,858,310	17,737,887	17,284,784
Effect of dilutive securities:			
Stock options	512,654	392,653	585,908
Warrants	--	--	2,297
Denominator for diluted net income per share-adjusted weighted-average shares	18,370,964	18,130,540	17,872,989

14. QUARTERLY FINANCIAL DATA (UNAUDITED)

Quarterly data for 1999 and 1998 was as follows:

	Quarter			
	First	Second	Third	Fourth
Year ended December 31, 1999				
Net sales	\$4,190,296	\$4,721,854	\$4,258,127	\$4,291,687
Gross profit	1,643,384	1,783,887	1,618,877	1,429,702
Net income	688,012	779,518	655,716	514,665
Earnings per share:				
Basic	\$.04	\$.04	\$.04	\$.03
Diluted	\$.04	\$.04	\$.04	\$.03

Year ended December 31, 1998				
Net sales	\$4,248,720	\$4,565,601	\$4,138,721	\$5,007,441
Gross profit	1,608,745	1,750,626	1,545,562	1,726,903
Net income	694,617	799,558	707,239	637,529
Earnings per share:				
Basic	\$.04	\$.04	\$.04	\$.04
Diluted	\$.04	\$.04	\$.04	\$.04

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Investor Information

ANNUAL MEETING

The annual meeting of the Shareholders will be held at 3:30 p.m. Thursday, May 4, 2000 at the Minneapolis Club, 729 Second Avenue South, Minneapolis, Minnesota.

INDEPENDENT AUDITORS

Ernst & Young LLP
Minneapolis, Minnesota

LEGAL COUNSEL

Dorsey & Whitney LLP
Minneapolis, Minnesota

PATENT COUNSEL

Haugen Law Firm PLLP
Minneapolis, Minnesota

TRANSFER AGENT AND REGISTRAR

Norwest Bank Minnesota, N.A.
161 N. Concord Exchange
South St. Paul, Minnesota 55075

FORM 10-K

A copy of the Company's annual report to the Securities and Exchange Commission will be provided without charge to any shareholder upon written request to the Corporate Secretary at the corporate headquarters.

ATS MEDICAL, INC.

3905 Annapolis Lane
Minneapolis, Minnesota 55447 USA
Phone (763) 553-7736 FAX (763) 553-1492

BOARD OF DIRECTORS

Manuel A. Villafana
CHAIRMAN AND CHIEF EXECUTIVE OFFICER
ATS MEDICAL, INC.

Richard W. Kramp

PRESIDENT AND CHIEF OPERATING OFFICER
ATS MEDICAL, INC.

Charles F. Cuddihy

RETIRED, FORMER EXECUTIVE VICE PRESIDENT
MEDTRONIC, INC.

David L. Boehnen

EXECUTIVE VICE PRESIDENT
SUPERVALU, INC.

A. Jay Graf

GROUP CHAIRMAN
GUIDANT CORPORATION

OFFICERS

Manuel A. Villafana
CHAIRMAN AND CHIEF EXECUTIVE OFFICER

Richard W. Kramp

PRESIDENT AND CHIEF OPERATING OFFICER

Russell W. Felkey

EXECUTIVE VICE PRESIDENT OF REGULATORY AFFAIRS

John H. Jungbauer

VICE PRESIDENT OF FINANCE AND CHIEF FINANCIAL OFFICER

Frank R. Santiago

VICE PRESIDENT OF SALES AND MARKETING

ATS Medical(TM) and ATS Open Pivot(TM) are Trademarks of ATS Medical, Inc.

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Consent of Independent Auditors

We consent to the incorporation by reference in this Annual Report (Form 10-K) of ATS Medical, Inc. of our report dated March 23, 2000, included in the 1999 Annual Report to Shareholders of ATS Medical, Inc.

Our audit also included the financial statement schedule of ATS Medical, Inc. listed in Item 14(a). This schedule is the responsibility of the Company's management. Our responsibility is to express an opinion based on our audits. In our opinion, the financial statement schedule referred to above, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We consent to the incorporation by reference in the Registration Statements on Form S-8 No. 333-49985 pertaining to the 1998 Employee Stock Purchase Plan, Form S-3 No.333-33017 pertaining to the registration of 1,568,940 shares of ATS Medical, Inc. common stock, Form S-8 Nos. 33-44940 and 333-49985 pertaining to the 1987 Stock Option and Stock Award Plan of ATS Medical, Inc. (formerly Helix BioCore, Inc.), Form S-3 No. 33-60104 pertaining to the registration of 3,710,676 shares of ATS Medical, Inc. common stock, and Post-Effective Amendment No. 1 to Form S-3 No. 33-89070 pertaining to the registration of 900,000 shares of ATS Medical, Inc. common stock, of our report dated March 23, 2000, with respect to the consolidated financial statements incorporated herein by reference, and our report included in the preceding paragraph with respect to the financial statement schedule included in the Annual Report (Form 10-K) of ATS Medical, Inc.

Ernst & Young LLP

Minneapolis, Minnesota
March 27, 2000

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POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS that each person whose signature appears below hereby constitutes and appoints Manuel A. Villafana and John H. Jungbauer, and each of them, his attorney-in-fact, with full power of substitution, for the purpose of signing on his behalf, in any and all capacities, the Annual Report on Form 10-K of ATS Medical, Inc. pursuant to Section 13 of the Securities and Exchange Act of 1934, as amended, for the fiscal year ended December 31, 1999 (the "10-K Report") and of signing any and all amendments to the 10-K Report and to deliver the 10-K Report and any and all amendments thereto as each thereof is so signed for filing with the Securities and Exchange Commission.

/s/ Manuel A. Villafana

Manuel A. Villafana

Dated: February 11, 2000

/s/ Richard W. Kramp

Richard W. Kramp

Dated: February 11, 2000

/s/ John H. Jungbauer

John H. Jungbauer

Dated: February 11, 2000

/s/ Charles F. Cuddihy, Jr.

Charles F. Cuddihy, Jr.

Dated: February 11, 2000

/s/ David L. Boehnen

David L. Boehnen

Dated: February 11, 2000

/s/ A. Jay Graf

A. Jay Graf

Dated: February 11, 2000

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Cautionary Statements

The Private Securities Litigation Reform Act of 1995 (the "Act") provides a "safe harbor" for forward-looking statements to encourage companies to provide prospective information about their business, so long as those statements are identified as forward-looking and are accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those discussed in the statement. ATS Medical, Inc. desires to take advantage of the safe harbor provisions with respect to any forward-looking statements it may make in this filing, other filings with the Securities and Exchange Commission and any public oral statements or written releases. The words or phrases "will likely," "is expected," "will continue," "is anticipated," "estimate," "projected," "forecast," or similar expressions are intended to identify forward-looking statements within the meaning of the Act. Such statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those projected. The Company cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date made.

In accordance with the Act, the Company identifies the following important general factors which if altered from the current status could cause the Company's actual results to differ from those described in any forward-looking statements:

- * The continued acceptance of the mechanical heart valve in international markets
- * The acceptance by the U.S. FDA of regulatory submissions
- * The continued performance of the mechanical heart valve without structural failure
- * The actions of competitors including pricing changes and new product introductions
- * The continued performance of independent distributors in selling the mechanical heart valve
- * The risk of product returns in connection with distributor terminations
- * The actions of the supplier of pyrolytic carbon components for the mechanical heart valve
- * Difficulties in establishing and operating our own pyrolytic carbon manufacturing capability
- * The continued contractual relationship with Carbomedics
- * Reimbursement of costs by third-party payors
- * Potential liability claims
- * Protection of our intellectual property rights
- * Volatility of Common Stock

This list is not exhaustive, and the Company may supplement this list in any future filing or in connection with the making of any specific forward-looking statement.

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