



FORM 10-K

ATS MEDICAL INC - ATSI

Exhibit:

Filed: March 30, 1999 (period: December 31, 1998)

Annual report which provides a comprehensive overview of the company for the past year

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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, 1998
COMMISSION FILE NO. 0-18602

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

MINNESOTA 41-1595629
(State or other jurisdiction of (I.R.S. Employer Identification No.)
incorporation or organization)

3905 ANNAPOLIS LANE
MINNEAPOLIS, MINNESOTA 55447
(Address of principal executive offices) (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. ()

The aggregate market value of voting stock held by nonaffiliates of the
registrant as of March 19, 1999 was approximately \$122,044,521 (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 19, 1999 was:

Common Stock, \$.01 par value 17,838,679 shares

DOCUMENTS INCORPORATED BY REFERENCE

Pursuant to General Instruction G(3), 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 Company's definitive proxy statement for
its 1999 Annual Meeting of Shareholders to be filed with the Securities and
Exchange Commission on or before April 30, 1999.

PART I

ITEM 1. BUSINESS

GENERAL

ATS Medical, Inc. ("ATS Medical" or the "Company") manufactures and markets a pyrolytic carbon bileaflet mechanical heart valve. The Company began selling the ATS Medical(TM) valve (the "Valve") in international markets in 1992. In December, 1996 the U.S. Food and Drug Administration ("FDA") approved the Company's Investigational Device Exemption ("IDE") allowing the Company to initiate a clinical study of the Valve with the eventual goal of regulatory approval in the United States.

THE ATS OPEN PIVOT VALVE

The ATS Open Pivot Bileaflet(TM) valve is designed to advance the standard of existing mechanical heart valves by combining a proprietary open pivot design and certain innovative features with the widely accepted biocompatibility and durability of pyrolytic carbon. The following characteristics are the primary advances of the ATS Medical valve:

POTENTIAL FOR REDUCED RATES OF THROMBOEMBOLIC COMPLICATIONS

The proprietary open pivot areas of the ATS Medical valve feature spherical protrusions from the orifice that match spherical notches in the leaflets. The pivot areas project into the normal blood flow pattern where the pivots are washed by the flowing blood.

POTENTIAL FOR IMPROVED BLOOD FLOW EFFICIENCIES

The Valve's orifice is a solid pyrolytic carbon ring. By eliminating the graphite substrate used in some valves, the Company is able to make the orifice durable and thin, thereby resulting in a larger average inside diameter. This design characteristic results in blood flow efficiencies which should reduce the workload on the heart.

POTENTIAL FOR EASE OF IMPLANT

The ATS Medical valve has a low profile design to avoid complications in the implant procedure. The orifice also is rotatable, thereby allowing the surgeon to optimize valve orientation by adjusting the position of the leaflets after the Valve has been sutured in the natural anatomical position in the patient's heart. The packaging and accessories of the Valve also are designed to facilitate the implant procedure by including all of the required items pre-assembled in a sterilized dual barrier container.

POTENTIAL FOR IMPROVED FOLLOW-UP DIAGNOSTIC CAPABILITY

The ATS Medical valve eases the follow-up diagnostic process by being highly visible to x-rays. The titanium stiffening ring provides a clear image on x-rays taken from any angle. The leaflets also have a high percentage of tungsten impregnated in the substrate, making them highly visible to x-rays. This increased visibility to x-rays assists cardiologists during follow-up examinations.

POTENTIAL FOR IMPROVED PATIENT QUALITY OF LIFE THROUGH LOWER NOISE LEVELS

Initial clinical reports and preliminary studies indicate that the ATS Medical valve is substantially quiet and below the threshold of hearing for most patients. The Company believes that the reduced noise level of the Valve further improves the quality of life of the patient.

CLINICAL DATA AND TESTING RESULTS

The Company began the development of the ATS Medical valve in November 1990. During 1991 and 1992, the Company performed in vitro and animal testing of the Valve. The in vitro testing included accelerated wear testing which subjected the Valves to repeated opening and closing at speeds and forces greatly in excess of those found in the human heart. The Company has accumulated wear data in excess of 600 million cycles or equivalent to 15 years of performance in a human. The results of these accelerated wear tests show average wear rates similar to control valves. The results of the animal testing and the other in vitro testing also show performance characteristics similar to control valves.

Beginning in May 1992, after obtaining approval from its Medical Advisory Board, the Company commenced human implants in international markets. Through January 1, 1999, the Company estimates that over 28,000 ATS Medical valves have been implanted in patients outside of the United States. The Company has received implant registration data from over 172 institutions in 26 countries which have implanted the ATS Medical valve in patients. Published reports have documented the clinical performance of the ATS Medical valve.

PROSTHETIC HEART VALVE MARKET

Prosthetic heart valves have been in general use since the 1960's and represent an estimated \$600 million worldwide market. The worldwide prosthetic heart valve market has grown at a rate of 3 to 4 percent annually over the last 6 years, principally due to the expansion of cardiovascular surgery facilities into the developing markets.

The worldwide prosthetic heart valve market is projected to continue to increase at annual rates of 3 to 5 percent due to the aging of the population and the expansion of cardiovascular surgery in international markets. One of the principal causes of valve replacement is the deterioration of natural valves through the aging process, with the average age of valve replacement patients in excess of 50 years. As this segment of the population increases, the market for prosthetic heart valves is expected to increase. In addition, rheumatic heart disease is a principal cause of valve replacement, particularly in areas where penicillin has been unavailable until relatively recently. As

cardiovascular surgery facilities expand in developing markets, the number of prosthetic heart valve implants is expected to increase.

Replacement heart valves are categorized as one of two types: mechanical or tissue. Mechanical valves are made from materials such as metals, ceramics, carbon or plastics. Tissue valves are made from animal or cadaver tissue or in some cases the patient's own tissue. A majority of the prosthetic heart valves implanted worldwide are mechanical valves. As life expectancies increase, cardiac surgeons have been less likely to use tissue valves in older patients and thereby subject the patient to the risks of a possible re-operation. Mechanical valves are also used in many instances to replace degenerative prosthetic tissue valves. In 1997, however, two of the largest competitors in the industry introduced new tissue valves. The impact of these new tissue valves on the relative number of mechanical and tissue valves implanted remains to be seen.

MARKETING AND SALES

The Company's marketing strategy is to combine the substantial cardiovascular sales experience of its senior officers with a network of experienced independent distributors to sell the Valve internationally while pursuing regulatory approval in the United States.

Manuel A. Villafana and Richard W. Kramp, the Company's Chief Executive Officer and Chief Operating Officer, respectively, previously recruited, selected and managed the independent distributor network of St. Jude Medical, Inc. ("St. Jude"). St. Jude was founded in 1976 by Mr. Villafana 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. Mr. Kramp headed St. Jude's worldwide sales and marketing efforts for almost 10 years.

Since 1992, the Company has contracted with independent distributors in most of the developed international markets. The Company believes that this independent distributor network provides a rapid and cost efficient means of expanding the acceptance of the Valve in a wide range of international markets through an experienced sales force. The selection of an independent distributor does not involve significant expense to the Company and does not expose the Company to currency fluctuation risk because the distributor purchases Valves directly from the Company in United States dollars. The Company has been able to attract experienced mechanical valve sales organizations familiar with local markets and customs to act as distributors.

The Company has a standard distributor agreement with variations for certain distributors. Most of the distributor agreements establish quotas for sales of the Valve in the distributor's territory. Most of the distributor agreements also provide for termination at the option of the Company upon the departure of certain key employees of the distributor or the change in control of ATS Medical.

At December 31, 1998, the Company had contracts with 30 distributors covering 37 countries outside the United States. Sales to four of these distributors represented over 50% of total sales for each of the past three years. The table below outlines the sales of our top four distributors in the respective countries in which they operate:

Sales as a Percentage of Total Revenue

| | 1998 ---- | 1997 ---- | 1996 ---- |
|---------|--------------|--------------|--------------|
| Japan | 19.2% | 17.2% | 14.0% |
| France | 16.0 | 11.2 | 9.2 |
| Germany | 15.1 | 16.7 | 24.0 |
| Spain | 8.1 | 9.4 | 11.3 |

In 1998 the Company increased its sales management team by promoting Mr. Frank Santiago to the position of Vice President of Sales and Marketing. Mr. Santiago's strong background in cardiovascular products, distributor negotiations and his knowledge of the USA market will further strengthen our international sales effort and allow us to begin planning our entrance into the domestic valve market upon approval of our products by the FDA.

The Company sells the Valves to each distributor F.O.B. Minneapolis. The Company allows the return of unused Valves as long as the Valve has not been opened and the sterilization date has not expired.

The loss of any one distributor or group of distributors could cause a disruption in sales and have an adverse impact on the Company's reported financial results. Management attempts to foster good working relationships with its distributors and believes that there would be alternative distributors available to represent the Valve in most markets should it become necessary to replace one or more of the distributors.

The Company supports its independent distributors through the Company's sales, marketing and customer service personnel. The Company displays the Valve at major international, national and regional medical meetings attended by cardiovascular surgeons and cardiologists. The Company also develops and distributes product brochures and product information bulletins and conducts product training sessions. When feasible, the Company also responds to special requests from physicians for supporting accessories and custom devices.

During 1998 the exchange rate for the U.S. Dollar remained strong relative to many international currencies. Currencies in the Far East were particularly weakened and since the Company sells in U.S. Dollars these currency changes were, in effect, price increases. In markets where the currency change was particularly dramatic such as Korea, sales actually declined because the Company could not reduce prices enough to retain some accounts.

COMPETITION

The mechanical heart valve market is highly competitive with one dominant company, St. Jude Medical, Inc. Other companies that sell mechanical valves include Medtronic, Inc., CarboMedics, Inc. ("CMI"), Baxter Edwards and Sorin Biomedica sPa. Medtronic, Inc. sells a monoleaflet mechanical valve that was introduced in the late 1970's as well as several tissue valves. CMI, which manufactures pyrolytic carbon components for the Company's valve, markets a bileaflet pyrolytic carbon valve with cavity pivot areas resembling those in the St. Jude valve. CMI introduced its

bileaflet valve in international markets in 1986 and in 1993 received FDA approval to sell the valve in the United States. Baxter Edwards markets a bileaflet valve supplied by Sorin in international markets. The valve has a special cuff manufactured by Baxter. Sorin Biomedica sPa is an Italian company that sells a monoleaflet and a bileaflet mechanical valve. These and other competitors have significantly greater financial resources than the Company. The Company is 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, 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, thereby 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.

The Company believes that the most important factors in a physician's selection of a particular prosthetic valve are the physician's perceived benefits of the valve and the physician'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. The Company competes with existing mechanical heart valves by combining the technical features of the Valve with the sales and heart valve marketing experience of its key management and independent distributors. The Company's success is dependent upon the surgeon's willingness to use a new prosthetic heart valve as well as the future clinical performance of the Valve compared with the more established competition.

The Company believes 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. The Company believes that, after distributor mark-up, the ATS Medical 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. The Company works with its independent distributors to price the Valve in each market to meet these limitations. In addition, the Company's primary competitors have the ability, due to their internal carbon manufacturing facilities and economies of scale, to manufacture their valves at lower cost than the Company can manufacture the ATS Medical valve. The market leader has utilized price as a method to compete in several markets over the past year or two.

MANUFACTURING AND COMPONENT SUPPLY

The basic design from which the ATS Medical valve evolved was developed by CMI. CMI is the largest and most experienced manufacturer of pyrolytic carbon components used in mechanical heart valves. CMI has designed and patented numerous mechanical valves. CMI was in possession of a partially developed valve when it received a license from St. Jude Medical which allowed it to pursue the valve it is currently marketing. CMI offered to license the patented and partially developed valve to ATS Medical if ATS would complete the development and agree to purchase its components from CMI according to the terms of a supply agreement (the "Supply Agreement").

The Company commenced its valve development program by entering into four agreements with CMI: a license agreement, a development agreement, a supply agreement and an option agreement.

Under the terms of the license agreement with CMI (the "License Agreement"), the Company received a royalty-free worldwide exclusive license to the licensed patent. The License Agreement does not include the right to manufacture the pyrolytic carbon components, except that if CMI is unable to produce the components, the Company has the right and license to make or have made components. The License Agreement may be terminated by CMI or CMI may declare the license to be non-exclusive if the Company fails to meet the minimum purchase requirements under the Supply Agreement. Upon satisfaction of the Company's minimum purchase requirements under the Supply Agreement, the Company will have a paid-up, exclusive, royalty-free, worldwide license to the licensed patent. At the same time it entered into the License Agreement, the Company entered into a development agreement (the "Development Agreement") with CMI to complete design development of the pyrolytic carbon components and perform testing of the Valve. The Development Agreement provided that CMI, at the Company's direction, perform preliminary tests of the Valve and assist the Company in making changes in the design. As a result of these tests and certain design changes initiated by the Company, the Company finalized the design of the 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 the Company. This today is the ATS Open Pivot Bileaflet valve.

In late 1992, upon completion of the Development Agreement, the Company began purchasing sets of Valve components from CMI under the Supply Agreement. The Company and CMI entered into an amendment to the Supply Agreement in December 1993 that modified the minimum purchase requirements. The Supply Agreement, as amended, has a term of 15 contract years and provides that the Company purchase a minimum number of Valve components in each of the first eight contract years. The sixth contract year was completed in December 1998. The total commitment for the next two contract years is approximately \$33 million. If the minimum purchase requirements are not met during any of the first eight contract years, CMI may terminate the License Agreement or may declare the License Agreement to be non-exclusive. The Company may not purchase Valve components from any source other than CMI during the first eight contract years unless CMI is unable to deliver suitable components. After the eighth contract year, the Company must purchase the lower of either certain specified amounts or the number of Valves sold and/or disposed of by any means by the Company. The price for each Valve component set is determined for all fifteen contract years, with a price reduction for volume purchases and sales into certain developing countries, and a yearly price adjustment for changes in the U.S. Department of Labor Employment Cost Index.

The Company's manufacturing operation consists of fabricating the sewing cuff and assembling, inspecting, testing and packaging all of the components into a finished Valve. The standard Valve is available in seven sizes ranging from 19mm to 31mm in diameter, with each size available with sewing cuffs for either aortic valve or mitral valve replacement. An extended sewing cuff is available with the pyrolytic carbon components of a 31mm mitral valve to create a 33mm valve for special mitral valve replacements.

The Company introduced the Advanced Performance ("AP") series of the ATS Medical valve in international markets in early 1994 and is available in seven sizes ranging from 16mm to 28mm in diameter. The AP series consists of a reconfigured sewing cuff, allowing a larger valve to be used in small anulus situations.

The Company introduced an Aortic Valved Graft ("AVG") to international markets in 1997. The AVG consists of an ATS Medical 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.

The Company receives, inspects and assembles components in its Minneapolis, Minnesota facility. The Valve is then assembled, inspected, packaged and sterilized for shipment to distributors.

At any time during the ninth through the fifteenth contract years of the Supply Agreement, the Company may exercise an option to acquire the carbon technology necessary to manufacture the Valve under an option agreement with CMI (the "Option Agreement"). The option may be exercised by paying a one time fee to CMI. The Option Agreement may be terminated by CMI if the Company fails to meet the minimum purchase levels for any of the first eight contract years of the Supply Agreement or if the Company purchases carbon components from a source other than CMI at any time during the term of the Supply Agreement.

PATENTS AND PROPRIETARY TECHNOLOGY

The Company's policy is to protect its proprietary position by, among other methods, obtaining United States and international patents to protect technology, inventions and improvements important to the development of its business. The Company has received a royalty-free license under the CMI Patent, subject to certain continuing component purchase requirements. See "Business--Manufacturing and Component Supply." The Company refined the design of the Valve to make it suitable for implantation and filed an additional United States patent application covering the design improvements. The United States patent on the design improvements was issued in October 1994. The Company also has filed patent applications in Japan, Belgium, France, Germany, Netherlands, Spain, Switzerland and the United Kingdom relating to the design improvements, and patents have been granted in all countries except Japan, where the application remains pending. No assurance can be given that pending patent applications will be approved or that any patents will not be challenged or circumvented by competitors.

The Company also relies on trade secrets and technical know-how in its manufacture and marketing of the Valve. The Company typically requires its employees, consultants and contractors to execute appropriate confidentiality agreements with respect to the Company's proprietary information.

The Company claims trademark protection to ATS Medical(TM) and ATS Open Pivot(TM).

FDA AND OTHER GOVERNMENT REGULATIONS

As a manufacturer of medical devices, the Company is subject to extensive regulation by the United States Food and Drug Administration (the "FDA") and, in some jurisdictions, by state and foreign governmental authorities. These regulations govern the introduction of new medical devices, the observance of certain standards with respect to the manufacture, testing and labeling of such devices, the maintenance of certain records, the ability to track devices and the reporting of potential product defects and other matters. These regulations have a material impact on the Company. Developments such as the enactment of the Safe Medical Devices Act of 1990 reflect a trend toward more stringent product regulation by the FDA. Recently, the FDA has pursued a more rigorous

enforcement program to ensure that regulated businesses comply with applicable laws and regulations.

The sale and use of mechanical heart valves is regulated extensively in the United States by the FDA. Pursuant to the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act, medical devices intended for human use are classified into three categories, Classes I, II and III, depending on the degree of regulatory control to which they will be subject. Mechanical heart valves are considered to be Class III devices which are subject to the strictest testing requirements. Before clinical studies to determine safety and effectiveness in humans can begin, a battery of laboratory and animal tests must be conducted. The Company has proceeded with these pre-clinical tests on the Valve since 1991.

The Company received approval of an Investigational Device Exemption ("IDE") Application in December, 1996. The IDE allows limited clinical studies in the U.S. during which the Company must submit reports to the FDA regarding testing and patient follow-up. The IDE study and follow-up is expected to take at least one more year. After obtaining sufficient data from its clinical studies, the Company may submit a Pre-Market Approval ("PMA") application. The PMA review process is extremely lengthy and no assurance can be given concerning the ultimate timing or outcome of a PMA application. Upon approval of a PMA, the Company would be able to commence full marketing of the Valve in the United States.

In addition to the FDA approval process, the Company is subject to significant additional FDA and other United States regulations. The Company's standard operating procedures and system of documentation used in the manufacturing process will be subject to the FDA's Quality Systems Regulations ("QSR's") which incorporates guidelines for Good Manufacturing Practices ("GMP's"). The Company also will become subject to periodic inspections by the FDA to audit compliance with QSR's. To the extent the Company will sell the Valve to Medicare or Medicaid beneficiaries, the Company will become 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. These regulations prohibit direct or indirect payment arrangements designed to induce or encourage the purchase or recommendation of products reimbursable under Medicaid or Medicare. The Company also will be required to comply with various FDA regulations for advertising, labeling, patient tracking, post market studies and reporting of any adverse experience. The FDA actively enforces regulations and the failure to comply with applicable regulatory requirements can result in fines, seizures, recalls and criminal prosecutions.

Regulation of heart valves varies widely in foreign countries, but generally is less stringent than in the United States. Foreign countries vary from having no regulations to having pre-market notice to a pre-market approval process. The Company or its independent distributor must obtain the appropriate approval, if any, from each country's regulatory agency prior to marketing the Valve in that country. The Company received CE Mark approval for all European Union Countries in March, 1995. The Company will continue to be subjected to various audits and tests under the European Community directives. In June 1996, the Company received approval to begin commercial sales in the Japanese market through a Shonin regulatory approval obtained by its distributor, Century Medical, Inc. In September 1998, the Company received approval from the Therapeutic Goods Administration for commercial sales in Australia. The Company is in the process of pursuing regulatory approval for the Valve in Canada.

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. ATS Medical has not received any reports of mechanical failure of the Valves implanted to date and has not experienced any product liability claims. Any future significant failure of the ATS Medical Valve would subject the Company to substantial litigation, damages and adverse publicity.

The Company currently maintains a \$35 million product liability insurance policy. A \$5 million product liability insurance policy is required by the Supply Agreement. The Company is financially responsible for any uninsured claims or claims which exceed the insurance policy limits. At the present time, product liability insurance is expensive for mechanical valves. If insurance becomes completely unavailable, the Company must either develop a self-insurance program or sell without insurance, and the Company would be required to obtain the consent of CMI. The development of a self-insurance program would require significant capital.

CMI has made no warranty on the Valve components. The Company has agreed to hold CMI harmless and indemnify CMI in the event claims are made or damages are assessed against CMI as a result of the Valve.

EMPLOYEES

As of January 1, 1999, the Company had 74 full-time employees, of whom 18 were engaged in regulatory affairs and quality assurance, 35 in production and 21 in administrative, purchasing and marketing activities.

ITEM 2. PROPERTIES

The Company currently maintains administrative offices, production and engineering facilities in 23,912 square feet of leased space in a suburb of Minneapolis, Minnesota. The lease expires on February 28, 2003. The Company believes the current facility is adequate for its near-term needs.

ITEM 3. LEGAL PROCEEDINGS

None

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

None

EXECUTIVE OFFICERS OF THE COMPANY

The executive officers of the Company are as follows:

| NAME | AGE | POSITION |
|---------------------|-----|---|
| Manuel A. Villafana | 58 | Chairman and Chief Executive Officer |
| Richard W. Kramp | 53 | President and Chief Operating Officer |
| Russell W. Felkey | 48 | Executive Vice President of Regulatory Affairs and Secretary |
| John H. Jungbauer | 49 | Vice President, Treasurer and Chief Financial Officer |
| Frank R. Santiago | 47 | Vice President, Sales and Marketing |

MANUEL A. VILLAFANA, a founder of the Company, has served as Chief Executive Officer and Chairman of the Board since the Company's 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 President and Chief Operating Officer and a Director of the Company since joining the Company in March 1988. Prior to joining the Company, 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, 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 Executive Vice President of Regulatory Affairs of the Company since April 1991 and has served 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 of the Company since April 1, 1995 and has served as Treasurer and Chief Financial Officer of the Company since October 1990. From 1988 to 1990, Mr. Jungbauer was Executive Vice President of Titan Medical, Inc., a medical products company. Prior to 1987, Mr. Jungbauer was Vice President of Finance at St. Jude Medical, Inc.

FRANK R. SANTIAGO has served as Vice President of Sales and Marketing of the Company since June 1998 and has served 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 at 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 generation 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 Company's common stock (the "Common Stock") is traded on the Nasdaq National Market under the symbol "ATSI." The following table sets forth the high and low sale prices since January 1, 1997. Prices represent transactions between dealers and do not reflect retail markups, markdowns or commissions.

| 1998 | HIGH | LOW | 1997 | HIGH | LOW |
|----------------|--------|--------|----------------|--------|--------|
| First Quarter | \$8.18 | \$4.75 | First Quarter | \$8.50 | \$6.50 |
| Second Quarter | 8.37 | 6.37 | Second Quarter | 7.00 | 4.75 |
| Third Quarter | 8.00 | 5.00 | Third Quarter | 6.63 | 5.00 |
| Fourth Quarter | 7.69 | 4.31 | Fourth Quarter | 7.25 | 4.75 |

As of December 31, 1998 there were 602 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.

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data of the Company have been derived from its financial statements for the years ended December 31, 1998, 1997, 1996, 1995 and 1994, which financial statements have been audited by Ernst & Young LLP. The data should be read in conjunction with the Company's audited financial statements and the notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere herein.

| STATEMENTS OF OPERATIONS DATA: | Year ended December 31, | | | | |
|--|-------------------------|---------------|---------------|--------------|--------------|
| | 1998 | 1997 | 1996 | 1995 | 1994 |
| REVENUES: | | | | | |
| Net sales | \$ 17,960,483 | \$ 14,515,915 | \$ 11,859,765 | \$ 9,300,540 | \$ 6,763,408 |
| Less cost of goods sold | 11,328,647 | 9,428,959 | 7,474,065 | 6,011,025 | 4,189,426 |
| GROSS PROFIT FROM OPERATIONS | 6,631,836 | 5,086,956 | 4,385,700 | 3,289,515 | 2,573,982 |
| OPERATING EXPENSES: | | | | | |
| Research, development and engineering | 1,484,989 | 1,058,318 | 617,571 | 718,189 | 640,032 |
| Selling, general and administrative | 3,591,551 | 3,339,488 | 3,065,402 | 2,549,570 | 1,993,447 |
| TOTAL EXPENSES FROM OPERATIONS | 5,076,540 | 4,397,806 | 3,682,973 | 3,267,759 | 2,633,479 |
| Interest income | 1,355,647 | 1,427,363 | 641,375 | 752,880 | 74,706 |
| Interest expense | 0 | 0 | 0 | (31,224) | (31,317) |
| Income taxes | (72,000) | (13,846) | (22,500) | (28,888) | (25,243) |
| NET INCOME (LOSS) | \$ 2,838,943 | \$ 2,102,667 | \$ 1,321,602 | \$ 714,524 | (\$ 41,351) |
| NET INCOME PER SHARE: | | | | | |
| Basic | \$ 0.16 | \$ 0.12 | \$ 0.09 | \$ 0.05 | \$ 0.00 |
| Diluted | \$ 0.16 | \$ 0.12 | \$ 0.08 | \$ 0.05 | \$ 0.00 |
| Cash dividends declared | 0 | 0 | 0 | 0 | 0 |
| Weighted average number of shares outstanding: | | | | | |
| Basic | 17,737,887 | 17,284,784 | 15,168,958 | 14,184,395 | 11,177,881 |
| Diluted | 18,130,540 | 17,872,989 | 16,303,317 | 15,116,443 | 11,177,881 |

December 31,

| BALANCE SHEET DATA: | 1998 | 1997 | 1996 | 1995 | 1994 |
|---------------------------------|--------------|--------------|--------------|--------------|--------------|
| | ----- | ----- | ----- | ----- | ----- |
| Cash and cash equivalents | \$ 7,754,077 | \$ 4,568,332 | \$ 2,320,010 | \$ 2,213,632 | \$ 628,368 |
| Working capital | 54,229,241 | 52,375,893 | 30,643,942 | 27,802,438 | 11,214,977 |
| Total assets | 58,431,376 | 54,386,031 | 33,320,300 | 31,329,128 | 14,558,450 |
| Long-term debt | 0 | 0 | 0 | 0 | 0 |
| Total liabilities | 2,611,801 | 863,292 | 1,393,561 | 2,269,707 | 1,790,773 |
| Accumulated deficit | (15,652,311) | (18,491,255) | (20,593,921) | (21,915,523) | (22,630,047) |
| Shareholders' equity | 55,819,575 | 53,522,739 | 31,926,739 | 29,059,421 | 12,767,677 |

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

RESULTS OF OPERATIONS

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 is 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 total revenue increase. The Company sells to independent distributors with assigned territories (generally a specific country or region) who in turn sell the Valve to hospitals or clinics. The Company sells in U.S. dollars so currency risk is borne by the distributor. 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. 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 the Company was selling Valves in most developed countries and several lesser developed countries ("LDC's") 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. Given the current strength of the U.S. dollar and the pricing strategies of its competitors the Company does not expect to be able to raise prices in 1999.

Prior to January 1997, all sales of Valves were to customers outside of the United States. In 1997 and 1998 the Company has been conducting a clinical study of the Valve at fifteen hospitals in the United States. During the study, Valves are provided to the hospitals at prices designed to recover some of the costs of the clinical study.

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 the Company's internal sales projections, the price of the carbon contained in Valves sold in 1999 is expected to be 3% higher than in 1998. The Company purchases pyrolytic carbon components for the Valve from CarboMedics, Inc. ("CMI"). Approximately 80% of the total cost of a valve is contained in the cost of the carbon components. The price of the components is set under a multi-year supply agreement between the Company and CMI. The price was established in 1990, and varies according to annual volume and is adjusted annually according to increases in the U.S. Department of Labor Employment Cost Index. The Company uses the first-in first-out ("FIFO") method of accounting for inventory. Approximately 14% of the valves sold in 1998 were made with carbon purchased in 1995 (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 and rose 3.2% in 1998. For 1999 (the seventh contract year) the Company expects to pay 3.2% more for carbon components 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 the Company's 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 an aortic valved graft ("AVG"). The AVG is a standard ATS Medical, Inc. 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.

The Company began human implants in the United States under an Investigational Device Exemption ("IDE") in January 1997. The Company sells the Valves to the hospitals involved in the study and the cost of the Valve is eligible for reimbursement by Medicare and most private pay insurance companies. The Company is 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 \$3,591,551 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 \$153,921 for separation pay related to the shutdown of the Company's subsidiary in Glasgow, Scotland. 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. The Company 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 is less than the amount on hand at December 31, 1997. Interest income in 1999 is expected to be approximately 50% less than in 1998. The Company is investing cash in carbon and the completion of a large quantity of valves in anticipation of the market release of the Valve in the United States.

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.

The Company has 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 the 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. The Company believes that as a result of the Company's registered direct equity offering in early 1995 and the sale of 1,568,940 shares of common stock in 1997, the Company experienced an ownership change, and the Company's ability to fully utilize \$15 million of its 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 the net operating loss carryforwards of the Company may expire before they can be used by the Company to reduce its federal income tax liabilities.

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, the Company has provided 100% valuation allowances against this credit and all of its other tax attributes. The Company will recognize the benefit of its tax attributes when it is more likely than not that these benefits will be realized.

YEAR ENDED DECEMBER 31, 1997 COMPARED TO 1996

Net sales totaled \$14,515,915 for the year ended December 31, 1997, an increase of \$2,656,150 or 22% over the net sales of \$11,859,765 reported for the year ended December 31, 1996. Unit sales increased 25% from 1996. During 1997 the exchange rate for many currencies fell in value relative to the U.S. dollar. In Europe, these changes caused a decrease in value for some currencies of as much as 15%. The consequence of this currency change is the same as a price increase to our distributors. The Company responded in select countries by lowering the dollar price of the Valve.

Cost of goods sold increased 26% to \$9,428,959 for the year ended December 31, 1997 from \$7,474,065 for the year ended December 31, 1996. Cost of goods sold as a percentage of sales increased from 63% for the year ended December 31, 1996 to 65% for the year ended December 31, 1997, primarily due to lower average selling prices.

Gross profit increased from \$4,385,700 for the twelve months ended December 31, 1996 to \$5,086,956 for the twelve months ended December 31, 1997. Gross profit as a percent of sales was 35% in 1997 and 37% in 1996. The decrease in the average selling price per unit was the most significant factor in the erosion of the gross margin.

Research, development and engineering expenses totaled \$1,058,318 for the year ended December 31, 1997 compared to \$617,571 for the year ended December 31, 1996. During 1997 the Company completed design and testing on a product extension, the aortic valve graft (AVG). This effort accounted for 20% of 1997 research and development expense with most of the remainder being spent

on the clinical study of the Valve. The Company's research efforts in 1996 were on improved package design and tooling for Valve assembly. Approximately 58% of 1997 and 56% of 1996 R & D expenses related to the clinical study of the Valve outside the United States and physical testing of the Valve and related consulting to support the Company's IDE application to the FDA.

Selling, general and administrative expenses increased 9% from \$3,065,402 for the year ended December 31, 1996 to \$3,339,488 for the year ended December 31, 1997. This increase resulted from primarily two factors in 1997. In October 1997 the Company closed its facility in Scotland and consolidated those operations at its Plymouth, Minnesota headquarters. One-time costs associated with this closing of approximately \$225,000 were charged to selling, general and administrative expense in 1997. Second, the Company increased the number of employees from 50 in 1996 to 65 in 1997. In November, 1996 the Company sponsored the Second International Symposium on the ATS Medical Heart Valve at an expense of approximately \$333,000.

Following the Company's \$14.75 million stock sale in February 1997 and \$4.7 million warrant exercise in March 1997, the Company had substantially more cash, cash equivalents and short-term investments earning interest. Interest income in 1997 increased to \$1,427,363 for the year ended December 31, 1997 compared to \$641,375 for the year ended December 31, 1996.

The Company recorded \$13,846 and \$22,500 in income tax expense for 1997 and 1996, respectively. These taxes arose from the Alternative Minimum Tax and certain items of income in the United Kingdom.

Net income increased to \$2,102,667 for the twelve months ended December 31, 1997 from \$1,321,602 for the twelve months ended December 31, 1996. The increase in interest income was the major factor in the increase in net income.

Net income per share (diluted) increased from \$.08 for 1996 to \$.12 for 1997. Weighted average number of shares outstanding increased 14% due to option and warrant exercises, and the sale of shares to ITOCHU Corp.

LIQUIDITY AND CAPITAL RESOURCES

Cash, cash equivalents and marketable securities decreased by \$4,943,546 from \$25,550,508 at December 31, 1997 to \$20,606,962 at December 31, 1998. Inventory purchases and accounts receivable growth, less the increase in accounts payable and net earnings, caused the Company to have negative cashflow from operations.

During 1998 the Company purchased \$13.9 million of heart valve components in accordance with the terms of its long-term supply agreement with CarboMedics, Inc. (the "Supply Agreement"). During the contract years 1999 and 2000 the Company is obligated to purchase an aggregate of approximately \$33 million of components (\$14.4 million in 1999).

The minimum purchases under the Supply Agreement are not tied to sales of the Company's Valve and the Company does not expect sales of the Valve to exceed the minimum purchase requirements under the Supply Agreement until the Valve is approved for sale in the United States. After the Company

purchases the minimum required Valves under the CMI supply agreement for the Year 2000, the Company will be obligated under the Supply Agreement only to buy what it sells.

Accounts receivable increased from \$4,446,834 at December 31, 1997 to \$5,820,699 at December 31, 1998. Most of the Company's sales have been to customers in international markets and while the Company attempts to set standard 60 day terms for receivables, competitive pressures and geographical economic situations have caused the Company to selectively extend the terms for payment. At December 31, 1998, the account balance for one customer was 26% of outstanding receivables. The Company has done business with this customer since 1992 and the size of the receivable, while substantial, is consistent with the growth of business in this market and in line with the size of the customer's overall business.

Current liabilities increased from \$863,292 at December 31, 1997 to \$2,611,801 at December 31, 1998. The majority of the increase is in accounts payable and is related to the amount owing to CarboMedics, Inc. under the Supply Agreement.

Based upon the Company's current rate of sales, its expected obligations under the Supply Agreement and its expected expenses, the Company anticipates that existing cash, cash equivalents and short-term investments will be sufficient to satisfy its capital requirements through 2000. Beyond 2000 the Company should be cashflow positive or at worst cashflow neutral barring a significant change in the Company's business plan.

The Company does not use derivatives and therefore does not face market risk from currency or interest rate changes on these types of instruments. There would be no impact on the Company's operations from interest rate changes on debt instruments since the Company has not used debt to finance its operations. Assuming that interest rates on investment grade securities were to decrease by 10%, the Company's interest income would decrease by approximately \$100,000 based on the level of investable funds available to the Company at December 31, 1998.

YEAR 2000 SITUATION

The "Year 2000 Problem" refers to a complex set of problems which may arise when computer hardware or software is unable to distinguish between 21st century dates and 20th century dates because the date code fields have been abbreviated into two digits, i.e. 00. This problem could result in system failures or miscalculations causing disruptions of business operations (including, among other things, a temporary inability to process transactions, send invoices or engage in other similar business activities). As a result, many companies' computer systems and software will need to be upgraded or replaced in order to comply with Year 2000 requirements. The potential global impact of the Year 2000 problem is not known, and, if not corrected in a timely manner, could affect the Company and the U.S. and world economy generally.

The Company's products, including the ATS Medical heart valve, do not contain any electronics or software and therefore will not be affected by the "Year 2000 Problem".

The Company's internal financial, manufacturing and other computer systems are being reviewed to assess and remediate Year 2000 problems. The Company's assessment of internal systems includes its

information technology ("IT") as well as non-IT systems (systems which contain embedded technology and are used in manufacturing or process control equipment containing microprocessors or other similar circuitry). As a result of this review the Company determined that some of its equipment and software needed to be upgraded or replaced. During 1998 the Company spent approximately \$59,000 on hardware and software some of which was necessary to eliminate potential Year 2000 problems. In addition, the Company will take delivery on custom measuring equipment valued at \$375,000 during the first quarter, 1999. The primary purpose of this equipment is to improve processing of the Company's products but it will also contain Year 2000 compliant software. The Company's 1999 budget for hardware and software is \$164,528 including the replacement or upgrade of personal computers, workstations and software which are not currently Year 2000 compliant.

Since substantially all of this hardware and software is being purchased from large, industry-leading vendors (i.e. Compaq, Lotus, and Microsoft), the Company will rely on vendor certification and internal tests to determine Year 2000 compliance as opposed to hiring consultants to perform reviews. Such certifications and tests are scheduled to be obtained or completed by the end of the second quarter 1999.

In addition, during the first quarter of 1999 the Company is requesting assurances from its major suppliers that they are addressing the Year 2000 problem and that products purchased by the Company from such suppliers will function properly in the Year 2000. The Company has a significant inventory of product components on hand, however, certain key components for the Valve are available from a single supplier and a protracted Year 2000 problem for this vendor could have an adverse impact on the Company. Contacts are also being made with the Company's major customers. These contacts with the Company's suppliers and customers are intended to help mitigate the possible external impact of the Year 2000 problem. However, it is impossible to fully assess the potential consequences in the event service interruption from suppliers occur or in the event that there are disruptions in such infrastructure areas as utilities, communications, transportation, banking and government.

The total estimated cost for resolving the Company's Year 2000 issues is approximately \$598,500, of which approximately \$225,000 has been spent through December 31, 1998. The total cost estimate includes the cost of replacing non-compliant systems as a remediation cost in cases where the Company has accelerated plans to replace such systems. Estimates of Year 2000 costs are based on numerous assumptions, and there can be no assurance that the estimates are correct or that actual costs will not be materially greater than anticipated.

Based upon its assessments to date, the Company believes it will not experience any material disruption in its operations as a result of Year 2000 problems to internal financial, manufacturing and other process control systems, or in its interface with major customers and suppliers. However, if major suppliers, including those providing component parts, electricity, communications and transportation services, experience difficulties resulting in disruption of critical supplies or services to the Company, a shutdown of the Company's operations could occur for the duration of the disruption. The Company has not yet developed contingency plans to help provide continuity of normal business operations in the event that problem scenarios arise, but it will assess the need to develop such plans based on the outcome of compliance areas currently under review, and the results of remaining survey feedback from its major suppliers and customers. Assuming no major disruption in service from critical third party providers, the Company believes that it will be able to manage the Year 2000 transition without any material effect on the Company's results of operations or financial position. There can be no assurance, however, that

unexpected difficulties will not arise and, if so, that the Company will be able to timely develop and implement an effective contingency plan.

THE SINGLE EUROPEAN CURRENCY

A significant portion of the Company's sales occur 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. The Company sells to all of its customers in U.S. Dollars and does not expect to have accounting system issues relative to currency translation. The Company's selling prices are similar to most of its European distributors and therefore should not cause significant disruption whether in dollars or Euros. The Company and its distributors have not completed an analysis of what actions competitors might take as a result of the Euro. Europe is a very important market for the Company's Valve. Disruption or loss of a portion of the Company's European business could have a material and adverse impact on the Company's 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 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 actions of the Company's supplier of pyrolytic carbon components for the Valve and the effect of the Year 2000 problem on the Company, its suppliers and its customers. 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company does not use derivatives and therefore does not face market risk from currency or interest rate changes on these types of instruments. There would be no impact on the Company's operations from interest rate changes on debt instruments since the Company has not used debt to finance its operations. Assuming that interest rates on investment grade securities were to decrease by 10%, the Company's interest income would decrease by approximately \$100,000 based on the level of investable funds available to the Company at December 31, 1998.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements of the Company are included (with an index listing all such statements) in a separate financial section at the end of this Annual Report on Form 10-K.

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 1999 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission on or before April 30, 1999, 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 1999 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission on or before April 30, 1999, 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 headings "Security Ownership of Certain Beneficial Owners and Management" and "Election of Directors" in the Company's definitive proxy statement for its 1999 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission on or before April 30, 1999, 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 headings "Election of Directors" and "Executive Compensation" in the Company's definitive proxy statement for its 1999 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission on or before April 30, 1999, 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 included (with an index listing all such statements) in a separate financial section at the end of this Annual Report on Form 10-K.

(a) 2. FINANCIAL STATEMENT SCHEDULES

The financial statement schedule is included (with an index listing such schedule) in a separate financial section at the end of this Annual Report on Form 10-K.

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.
- 23 Consent of Ernst & Young LLP.
- 24 Power of Attorney.
- 27 Financial Data Schedule.

*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 29, 1999

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 29, 1999

*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, 1998

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, 1998 and 1997.

Consolidated Statements of Income for the years ended December 31, 1998, 1997 and 1996.

Consolidated Statement of Changes in Shareholders' Equity for the years ended December 31, 1998, 1997 and 1996.

Consolidated Statements of Cash Flows for the years ended December 31, 1998, 1997 and 1996.

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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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Years ended December 31, 1998, 1997 and 1996

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| Audited Consolidated Financial Statements | |
| Consolidated Statements of Financial Position..... | F-2 |
| Consolidated Statements of Income..... | F-3 |
| Consolidated Statement of Changes in Shareholders' Equity..... | F-4 |
| Consolidated Statements of Cash Flows..... | F-5 |
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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, 1998 and 1997, 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, 1998. Our audits also included the financial statement schedule listed in the Index at

Item 14(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with generally accepted auditing standards. 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of ATS Medical, Inc. and subsidiary at December 31, 1998 and 1997, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 1998, in conformity with generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set forth therein.

Ernst & Young LLP

Minneapolis, Minnesota
February 5, 1999

ATS Medical, Inc.

Consolidated Statements of Financial Position

| | DECEMBER 31 | |
|---|---------------|---------------|
| | 1998 | 1997 |
| | ----- | ----- |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 7,754,077 | \$ 4,568,332 |
| Short-term investments | 12,852,885 | 20,982,176 |
| | ----- | ----- |
| | 20,606,962 | 25,550,508 |
| Accounts receivable, less allowance of \$185,000 in 1998 and \$260,000 in 1997 | 5,820,699 | 4,446,834 |
| Inventories | 29,954,718 | 22,686,273 |
| Prepaid expenses | 458,663 | 555,570 |
| | ----- | ----- |
| Total current assets | 56,841,042 | 53,239,185 |
| Furniture and equipment, net | 1,202,784 | 776,187 |
| Other assets | 387,550 | 370,659 |
| | ----- | ----- |
| Total assets | \$ 58,431,376 | \$ 54,386,031 |
| | ===== | ===== |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,355,443 | \$ 621,708 |
| Accrued payroll and expenses | 256,358 | 241,584 |
| | ----- | ----- |
| Total current liabilities | 2,611,801 | 863,292 |
| Shareholders' equity: | | |
| Common Stock, \$.01 par value: | | |
| Authorized shares--40,000,000 | | |
| Issued and outstanding shares--17,824,137 in 1998 and 17,589,058 in 1997 | 178,241 | 175,891 |
| Additional paid-in capital | 71,249,846 | 71,797,796 |
| Accumulated other comprehensive income | 43,799 | 40,306 |
| Accumulated deficit | (15,652,311) | (18,491,254) |
| | ----- | ----- |
| Total shareholders' equity | 55,819,575 | 53,522,739 |
| | ----- | ----- |
| Total liabilities and shareholders' equity | \$ 58,431,376 | \$ 54,386,031 |
| | ===== | ===== |

SEE ACCOMPANYING NOTES.

ATS Medical, Inc.
Consolidated Statements of Income

| | YEAR ENDED DECEMBER 31 | | |
|--|------------------------|--------------|--------------|
| | 1998 | 1997 | 1996 |
| | ----- | ----- | ----- |
| Net sales | \$17,960,483 | \$14,515,915 | \$11,859,765 |
| Cost of goods sold | 11,328,647 | 9,428,959 | 7,474,065 |
| | ----- | ----- | ----- |
| Gross profit | 6,631,836 | 5,086,956 | 4,385,700 |
| Expenses: | | | |
| Research, development and engineering | 1,484,989 | 1,058,318 | 617,571 |
| Selling, general and administrative | 3,591,551 | 3,339,488 | 3,065,402 |
| | ----- | ----- | ----- |
| | 5,076,540 | 4,397,806 | 3,682,973 |
| | ----- | ----- | ----- |
| Operating income | 1,555,296 | 689,150 | 702,727 |
| Interest income | 1,355,647 | 1,427,363 | 641,375 |
| | ----- | ----- | ----- |
| Income before income taxes | 2,910,943 | 2,116,513 | 1,344,102 |
| Income tax expense | 72,000 | 13,846 | 22,500 |
| | ----- | ----- | ----- |
| Net income | \$ 2,838,943 | \$ 2,102,667 | \$ 1,321,602 |
| | ===== | ===== | ===== |
| Net income per share: | | | |
| Basic | \$.16 | \$.12 | \$.09 |
| Diluted | \$.16 | \$.12 | \$.08 |
| Weighted average number of shares outstanding: | | | |
| Basic | 17,737,887 | 17,284,784 | 15,168,958 |
| Diluted | 18,130,540 | 17,872,989 | 16,303,317 |

SEE ACCOMPANYING NOTES.

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, 1995 | 14,963,604 | \$149,636 | \$ 50,777,154 | \$ 48,154 | \$(21,915,523) | \$ 29,059,421 |
| Stock options exercised | 58,643 | 586 | 129,804 | -- | -- | 130,390 |
| Stock warrants exercised | 265,795 | 2,658 | 1,406,357 | -- | -- | 1,409,015 |
| Change in unrealized loss on short-term investments, net of tax | -- | -- | -- | (7,262) | -- | (7,262) |
| Change in foreign currency translation | -- | -- | -- | 13,573 | -- | 13,573 |
| Net income for the year | -- | -- | -- | -- | 1,321,602 | 1,321,602 |
| Comprehensive income | | | | | | 1,327,913 |
| 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 | -- | -- | 14,722,373 |
| Stock options exercised | 26,327 | 263 | 41,451 | -- | -- | 41,714 |
| Stock warrants exercised | 705,749 | 7,058 | 4,736,348 | -- | -- | 4,743,405 |
| 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 |

SEE ACCOMPANYING NOTES.

ATS Medical, Inc.

Consolidated Statements of Cash Flows

| | YEAR ENDED DECEMBER 31 | | |
|---|------------------------|--------------|--------------|
| | 1998 | 1997 | 1996 |
| OPERATING ACTIVITIES | | | |
| Net income | \$ 2,838,943 | \$ 2,102,667 | \$ 1,321,602 |
| Adjustments to reconcile net income to net cash used in operating activities: | | | |
| Depreciation | 267,187 | 246,140 | 233,867 |
| Loss on disposal of equipment | 1,965 | 50,985 | 17,925 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (1,373,865) | (1,307,275) | 85,548 |
| Prepaid expenses | 96,907 | (87,322) | (27,567) |
| Other assets | (16,891) | 17,574 | (18,799) |
| Inventories | (7,268,445) | (4,444,207) | (4,820,321) |
| Accounts payable and accrued expenses | 1,748,509 | (530,269) | (876,146) |
| Net cash used in operating activities | (3,705,690) | (3,951,707) | (4,083,891) |
| INVESTING ACTIVITIES | | | |
| Purchases of short-term investments | (20,103,048) | (29,435,865) | (9,486,341) |
| Maturities of short-term investments | 28,232,339 | 16,315,717 | 12,382,440 |
| Purchases of furniture and equipment | (695,750) | (178,748) | (258,808) |
| Net cash provided by (used in) investing activities | 7,433,541 | (13,298,896) | 2,637,291 |
| FINANCING ACTIVITIES | | | |
| Net (payments) proceeds from issuance (redemption) of Common Stock | (545,599) | 19,507,493 | 1,539,405 |
| Net cash (used in) provided by financing activities | (545,599) | 19,507,493 | 1,539,405 |
| Effect of exchange rate changes on cash | 3,493 | (8,568) | 13,573 |
| Increase in cash and cash equivalents | 3,185,745 | 2,248,322 | 106,378 |
| Cash and cash equivalents at beginning of year | 4,568,332 | 2,320,010 | 2,213,632 |
| Cash and cash equivalents at end of year | \$ 7,754,077 | \$ 4,568,332 | \$ 2,320,010 |

SEE ACCOMPANYING NOTES.

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 consist of purchased components.

Notes to Consolidated Financial Statements (continued)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

OTHER ASSETS

Prior to obtaining directors' and officers' liability insurance, the Company had placed \$387,550 and \$370,659 as of December 31, 1998 and 1997, respectively, in a self-insurance trust.

FURNITURE AND EQUIPMENT

Furniture and equipment are stated at cost. Depreciation is provided for at rates calculated to amortize the cost of the property over its estimated useful life (three to ten years) using the straight-line method. Leasehold improvements are amortized over the related lease term or estimated useful life, whichever is shorter.

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.

ATS Medical, Inc.

Notes to Consolidated Financial Statements (continued)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

NET INCOME PER SHARE

Basic earnings per share 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.

2. SHORT-TERM INVESTMENTS

As of December 31, 1998 and 1997, the cost of short-term investments held by the Company approximated their fair market value of \$12,852,885 and \$20,982,176, respectively. As a result no unrealized gains or losses were recognized at December 31, 1998 and 1997.

All investments have maturity dates of one year or less.

3. FURNITURE AND EQUIPMENT

Furniture and equipment consists of the following:

| | DECEMBER 31 | |
|-------------------------------|-------------|------------|
| | 1998 | 1997 |
| Furniture and fixtures | \$ 181,947 | \$ 155,363 |
| Equipment | 1,506,627 | 1,321,068 |
| Leasehold improvements | 588,830 | 479,795 |
| Construction in progress | 318,907 | 67,420 |
| | ----- | ----- |
| | 2,596,311 | 2,023,646 |
| Less accumulated depreciation | 1,393,527 | 1,247,459 |
| | ----- | ----- |
| | \$1,202,784 | \$ 776,187 |
| | ===== | ===== |

Notes to Consolidated Financial Statements (continued)

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 (7.25% at December 31, 1998) 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, 1999. Interest on the line of credit is payable monthly. The Company had no borrowing against this facility at December 31, 1998.

5. COMMON STOCK

In connection with its initial public offering, the Company sold a warrant to the underwriters to purchase 160,000 shares of Common Stock exercisable at \$4.20 per share. At December 31, 1996, there were 8,000 of the warrants outstanding. In November 1997, the remaining warrants were exercised.

On March 2, 1995, the Company completed a public offering in which the Company sold 3,600,000 shares of Common Stock at \$4.50 per share, including warrants to purchase an additional 900,000 shares of Common Stock exercisable at \$6.75 per share. As of December 31, 1996, the Company had 826,813 of these warrants outstanding. During 1997, the holders exercised 697,749 of these warrants. The remaining 129,064 warrants expired on March 2, 1997. The Company also issued a warrant to the agent to purchase 180,000 shares of Common Stock at \$5.40 per share. In 1996, 121,059 shares were tendered in the exercise of the warrant to purchase the 180,000 shares for a net issuance of 58,941 shares.

The Company has 2,030,403 shares of Common Stock reserved for issuance under various option and warrant grants.

6. 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 July and October 1998, 3,929 and 4,005 shares of Common Stock were purchased under the plan at \$5.95 and \$4.68 per share, respectively.

ATS Medical, Inc.

Notes to Consolidated Financial Statements (continued)

7. 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, 1995 | 470,004 | 405,813 | 601,000 | \$ 2.56 |
| Options granted | (395,000) | 299,500 | 95,500 | 9.00 |
| Options exercised | -- | (29,643) | (29,000) | 2.22 |
| Options canceled | 38,125 | (21,000) | (17,125) | 6.07 |
| 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 |

ATS Medical, Inc.

Notes to Consolidated Financial Statements (continued)

7. STOCK OPTIONS (CONTINUED)

The following table summarizes information about stock options outstanding including non-plan options to purchase 25,000 shares at December 31, 1998:

| 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 | 519,045 | 3.92 years | \$3.34 | 519,045 | \$3.34 |
| 5.06 - 8.25 | 563,479 | 8.02 years | 6.27 | 234,479 | 6.53 |
| 9.00 - 10.13 | 87,500 | 7.07 years | 9.74 | 50,750 | 9.70 |
| \$1.00 - \$10.13 | 1,170,024 | 6.13 years | \$5.23 | 804,274 | \$4.67 |

The weighted average fair value of options granted during the years ended December 31, 1998, 1997 and 1996 was \$6.45, \$5.51 and \$9.00, respectively.

Non-Plan options to purchase 25,000 and 32,500 shares exercisable at \$3.63 per share were outstanding at December 31, 1998 and 1997, respectively.

At December 31, 1998, 1997 and 1996, Plan and non-Plan options for 804,274, 984,218 and 816,421 shares of Common Stock, respectively, were exercisable at a weighted average price of \$4.67, \$3.06 and \$2.44 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.

Notes to Consolidated Financial Statements (continued)

7. STOCK OPTIONS (CONTINUED)

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 1998, 1997 and 1996: risk-free interest rate of 4.65%, 5.20% and 6.03%, respectively; dividend yield of 0%; volatility factor of the expected market price of the Company's common stock of .79, .80 and .46 and a weighted average expected life of the option of 6, 5 and 4 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:

| | 1998 | 1997 | 1996 |
|---------------------------------|-------------|-------------|-------------|
| | ----- | ----- | ----- |
| Pro forma net income | \$2,053,588 | \$1,634,401 | \$1,122,778 |
| Pro forma net income per share: | | | |
| Basic | \$.12 | \$.09 | \$.07 |
| Diluted | \$.11 | \$.09 | \$.07 |

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.

ATS Medical, Inc.

Notes to Consolidated Financial Statements (continued)

8. LEASES

The Company has amended its operating lease for facilities in Plymouth, Minnesota. The lease has a remaining life of 50 months and expires February 28, 2003. Future minimum lease payments under the agreement are as follows:

| | |
|------|-----------|
| 1999 | \$204,108 |
| 2000 | 204,108 |
| 2001 | 219,608 |
| 2002 | 222,708 |
| 2003 | 37,118 |
| | ----- |
| | \$887,650 |
| | ===== |

The rent expense was \$198,408, \$159,096 and \$147,101 for 1998, 1997 and 1996, respectively.

9. INCOME TAXES

At December 31, 1998, the Company had net operating loss carryforwards of approximately \$15,020,000 plus credits for increasing research and development costs of approximately \$616,000 and a credit of approximately \$69,000 from alternative minimum tax, which are available to offset future taxable income or reduce taxes payable through 2012. The net operating loss carryforwards exclude results of operations for ATS Medical, Ltd. for 1998, 1997 and 1996. The Company paid income taxes of \$72,000, \$13,800 and \$23,000 in 1998, 1997 and 1996, respectively.

ATS Medical, Inc.

Notes to Consolidated Financial Statements (continued)

9. INCOME TAXES (CONTINUED)

Components of deferred tax assets and liabilities are as follows:

| | DECEMBER 31 | |
|--|--------------|--------------|
| | 1998 | 1997 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | \$ 6,008,000 | \$ 7,100,000 |
| Research and development credits | 616,000 | 616,000 |
| AMT credit | 69,000 | -- |
| Accrued compensation | 237,000 | 335,000 |
| Other accrued expenses | 61,000 | 49,000 |
| | 6,991,000 | 8,100,000 |
| Deferred tax liabilities: | | |
| Depreciation | (557,000) | (567,000) |
| Net deferred tax assets before valuation allowance | 6,434,000 | 7,533,000 |
| Less valuation allowance | (6,434,000) | (7,533,000) |
| 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:

| | 1998 | 1997 | 1996 |
|----------|----------|----------|----------|
| Current: | | | |
| Federal | \$52,000 | \$ 3,846 | \$ -- |
| State | 20,000 | 10,000 | -- |
| Foreign | -- | -- | 22,500 |
| | \$72,000 | \$13,846 | \$22,500 |

ATS Medical, Inc.

Notes to Consolidated Financial Statements (continued)

9. INCOME TAXES (CONTINUED)

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

| | 1998 | 1997 | 1996 |
|--|--------|--------|--------|
| | ----- | | |
| Tax at statutory rate | 34.0% | 34.0% | 34.0% |
| State income taxes | 6.0 | 6.0 | 6.0 |
| Foreign income taxes | -- | -- | 1.7 |
| Impact of net operating loss carryforwards | (39.0) | (39.0) | (40.0) |
| | ----- | | |
| | 1.0% | 1.0% | 1.7% |
| | ===== | | |

10. COMMITMENTS

On September 24, 1990, the Company entered into various agreements with CarboMedics, Inc. giving the Company the exclusive worldwide license to manufacture and sell a bileaflet mechanical heart valve under patents held by CarboMedics, Inc. As part of the agreements, the Company entered into a 15 year supply contract that was amended in December 1993. Under the amended supply contract, as of December 31, 1998, the Company remains obligated to purchase a minimum of \$33 million of component sets through December 7, 2000. Thereafter, the Company must purchase the lower of either certain specified amounts or the number of component sets sold and/or disposed of by the Company. Payments to CarboMedics, Inc. were \$14,454,642, \$12,478,323 and \$11,289,218 in 1998, 1997 and 1996, respectively.

At December 31, 1998, the Company's inventory is in excess of its current requirements based on the recent level of sales. Management feels that excess quantities will be utilized upon FDA approval of its technology and believes no loss will be incurred on its disposition. As of December 31, 1998, 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, 1998.

Notes to Consolidated Financial Statements (continued)

11. 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 realized expense for contributions to the plan of \$47,946, \$40,920 and \$38,125 during 1998, 1997 and 1996, respectively.

12. SIGNIFICANT CUSTOMERS AND CONCENTRATION OF CREDIT RISK

The Company adopted Statement of Financial Accounting Standards No. 131, "Disclosures about Segments of an Enterprise and Related Information" ("SFAS 131") in the fiscal year ended December 31, 1998. SFAS 131 establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. SFAS 131 also establishes standards for related disclosures about products and services and geographic areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions how to allocate resources and assess performance. To date, the Company has viewed its operations as principally 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:

| | YEARS ENDED DECEMBER 31, | | |
|---------|--------------------------|-------|-------|
| | 1998 | 1997 | 1996 |
| | ----- | | |
| Japan | 19.2% | 17.2% | 14.0% |
| France | 16.0 | 11.2 | -- |
| Germany | 15.1 | 16.7 | 24.0 |
| Spain | -- | -- | 11.3 |

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

ATS Medical, Inc.

Notes to Consolidated Financial Statements (continued)

13. EARNINGS PER SHARE

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

| | 1998 | 1997 | 1996 |
|---|------------|------------|------------|
| Denominator for basic earnings per share-weighted-average shares | 17,737,887 | 17,284,784 | 15,168,958 |
| Effect of dilutive securities: | | | |
| Stock options | 392,653 | 585,908 | 720,851 |
| Warrants | -- | 2,297 | 413,508 |
| Denominator for diluted earnings per share-adjusted weighted-average shares and assumed conversions | 18,130,540 | 17,872,989 | 16,303,317 |

14. QUARTERLY FINANCIAL DATA (UNAUDITED)

Quarterly data for 1998 and 1997 was as follows:

| | Quarter | | | |
|-------------------------------|-------------|-------------|-------------|-------------|
| | First | Second | Third | Fourth |
| 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 | \$ 0.04 | \$ 0.04 | \$ 0.04 | \$ 0.04 |
| Diluted | 0.04 | 0.04 | 0.04 | 0.04 |
| Year ended December 31, 1997: | | | | |
| Net Sales | \$3,444,650 | \$3,695,230 | \$3,469,000 | \$3,907,035 |
| Gross Profit | 1,272,562 | 1,397,647 | 1,216,454 | 1,200,293 |
| Net Income | 577,039 | 660,171 | 305,471 | 559,986 |
| Earnings per share: | | | | |
| Basic | \$ 0.04 | \$ 0.04 | \$ 0.02 | \$ 0.03 |
| Diluted | 0.03 | 0.04 | 0.02 | 0.03 |

ATS MEDICAL, INC.

SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

| COL. A | COL. B | COL. C Additions | | COL. D | COL. E |
|---------------------------------|---|---|---|----------------------------------|---|
| Description | Balance at Beginning of Period ----- | (1) | (2) | Deductions- Describe ----- | Balance at End of Period ----- |
| | | Charged to Costs and Expenses ----- | Charged to Other Accounts- Describe ----- | | |
| 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 |
| Year ended December 31, 1996: | | | | | |
| Deducted from asset accounts: | | | | | |
| Allowance for doubtful accounts | \$150,000 ----- | \$ 50,000 ----- | -- ----- | -- ----- | \$200,000 ----- |
| Totals | \$150,000 | \$ 50,000 | \$0 | \$0 | \$200,000 |

(1) Uncollectible accounts written off, net of recoveries.

EXHIBIT INDEX

| EXHIBIT NUMBER | DESCRIPTION | PAGE |
|----------------|--|------|
| 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.
- 23 Consent of Ernst & Young LLP.
- 24 Power of Attorney.
- 27 Financial Data Schedule.

*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.

ATS MEDICAL, INC.
MANAGEMENT INCENTIVE COMPENSATION PLAN

The 1998 ATS Medical, Inc. Management Incentive Compensation Plan (MICP) is designed to pay, in addition to performance based annual salaries, incentive compensation in the form of cash and/or stock (or stock options) to management and other "key employees" who by their assigned responsibilities contribute to the success of the Company. Funding of the Plan is based on the achievement of corporate objectives. Individual incentive payments will be based on corporate funding and achievement of individual objectives.

1. DEFINITION OF TERMS

GOALS - The level of corporate performance defined in the corporate operating plan and individual objectives as set forth at the beginning of each program year. The Board of Directors may amend the goals to reflect material adjustments in or changes to the Company's accounting policies; to reflect major corporate changes such as mergers, acquisitions, or divestitures; and to reflect such other events having a significant impact on the goals.

BASE SALARY - The annual salary rate effective on the first day of the Plan year.

PARTICIPANT - Any employee or position which has been designated by the Board as a participant in the Plan for the year or during the year. If a particular employee is not covered by the MICP and has been recognized for extraordinary achievement, he/she may be eligible to participate in the Plan for that particular year at the discretion of the CEO.

ELIGIBILITY - Only regular full time employees may be designated as a participant in the Plan.

PROGRAM YEAR - Shall generally mean the fiscal year of the corporation.

FUNDING - The total dollar amounts accrued for payment in any program year.

PAYOUT - The actual amount to be paid to a participant based on achievement of corporate and individual objectives.

2. DESIGNATION OF PARTICIPANTS

The Board, upon the recommendation of the management of the Corporation, shall make all determinations as to the eligibility of employees and positions to participate in the MICP. Following the Board's determination of eligible participants, each participant shall be notified of eligibility to participate in the 1998 MICP and will be provided with a copy of the Plan. The 1998 Plan is designed to include officer, director, and manager level positions.

3. CALCULATION AND PAYMENT OF INCENTIVE AWARDS

Individual incentives will not be paid unless the CEO and the Compensation Committee of the Board of Directors approve each participant's individual incentive awards with payout contingent upon completion of the Company's year-end financial audit for the program year. Each participant's award will be equal to the sum of the corporate and individual portions as follows:

CASH AWARDS

CORPORATE - This portion will be based on the Financial Element Grid (Exhibit A) which determines incentive payments based upon the combined achievement of sales and operating income growth.

INDIVIDUAL - This portion will be determined through the achievement of five (5) personal objectives which have been assigned to each participant by his/her manager. An additional 1% bonus payment will be awarded for each successfully completed objective. There will be no payout for partially completed objective.

4. PROMOTIONS

For individuals promoted from a non-bonus to a bonus position during the program year, the effective salary upon assuming the new position will be used in calculating eligible incentive payout. Any payout will be pro rated beginning the first day of the month in which the individual is promoted into the position.

5. DEMOTIONS

For individuals demoted to a non-bonus position during the plan year, MICP payout will be pro rated based on the number of months in the bonus position.

6. TERMINATION OF EMPLOYMENT

In the event that any participant shall cease to be a full time employee during any year in which he/she is participating in the Plan, such participant shall be entitled to receive no incentive compensation for such year. If he/she terminates after the Plan year but prior to the payout, the participant remains entitled to receive incentive compensation. An exception would be if the individual was subject to termination "for cause" if such "cause" took place during the period covered by the MICP.

7. AMENDMENT OF THE PLAN

The Board may, from time to time, make amendments to the Plan as it believes appropriate and may terminate the Plan at any time, provided that no such amendment or termination will affect the right of any participant to receive incentive compensation in accordance with the terms of the Plan for the portion of any year up to the date of the amendment or termination.

8. MISCELLANEOUS

Nothing contained in the MICP shall be construed to confer upon any employee any right to continue in the employ of the Company or restrict the Company's right to terminate his/her employment at any time.

ESTABLISHMENT OF INDIVIDUAL OBJECTIVES

In establishing individual objectives, the following guidelines shall be used:

- o Each objective should be clear, concise, and measurable (time, cost, and task accomplishment).
- o Each objective should be a precise written statement which is discussed and agreed to by the individual and the manager.
- o Individual objectives should measure accomplishment and not effort.
- o Individuals will have five (5) objectives.

Before a participant may receive an incentive award, it will be necessary for his/her immediate manager to:

- o Submit written measurable objectives on the appropriate form prior to the commencement of the program year. These objectives will be reviewed and approved by the CEO and the President/COO.
- o Submit a documented evaluation of results, at Plan mid-year, to the CEO and President/COO.
 - o Modifications or adjustments to the original objectives must be reviewed by the participant and his/her manager and then submitted to the CEO and President/COO for their respective approvals.
- o Submit the year-end results against objectives within one month following the end of the program year. These will be approved by the CEO and the President/COO.
- o All proposed MICP awards will be reviewed for approval by the Compensation Committee of the Board of Directors.

1998 MANAGEMENT INCENTIVE COMPENSATION PLAN FORMULA

The percent of Growth of Sales combined with the percent of Growth of Operating Income as displayed in Exhibit A, the Financial Element Grid.

Plus (+)

The level of achievement of each assigned individual objective.

EXAMPLE

A participant has an annual base salary of \$50,000. The Company achieved 20% growth in sales and 22% growth in operating income, resulting in a Corporate incentive award of 20.5% from the Financial Element Grid.

The participant's personal objectives achievement was as follows:

| | % Completed | Payout |
|-------------|-------------|--------|
| | ----- | ----- |
| Objective 1 | 100% | 1% |
| Objective 2 | 90% | 0 |
| Objective 3 | 100% | 1% |
| Objective 4 | 100% | 1% |
| Objective 5 | 100% | 1% |
| | | -- |
| | | 4% |

Corporate award = \$50,000 x 20.5% = \$10,250

Individual award = \$50,000 x 4% = \$ 2,000

Total MICP award \$12,250

ATS Medical, Inc.
 Incentive Compensation Plan
 1998 OBJECTIVES

All participants will be assigned five (5) Individual Objectives which must be substantial in nature and significant to the success of the Company.

Employee _____

Manager _____

| INDIVIDUAL OBJECTIVES | TIMETABLE | STATUS OF OBJECTIVES | |
|---|-----------|----------------------|--------------------------|
| | | MID-YEAR EVALUATION | % OF YEAR-END COMPLETION |
| 1. | | | |
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |
| Manager Approval: _____ CEO Approval: _____ President/COO Approval: _____ | | | |

FINANCIAL ELEMENT GRID

Growth
in
Operating
Income

v8

| | | | | | | | | | | | | | | | | | |
|-----|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| 31% | 20.3 | 20.7 | 21.1 | 21.5 | 21.9 | 22.3 | 22.7 | 23.1 | 23.5 | 23.9 | 24.3 | 24.7 | 25.1 | 25.5 | 25.9 | 26.3 | 26.7 |
| 30% | 19.5 | 19.9 | 20.3 | 20.7 | 21.1 | 21.5 | 21.9 | 22.3 | 22.7 | 23.1 | 23.5 | 23.9 | 24.3 | 24.7 | 25.1 | 25.5 | 25.9 |
| 29% | 18.8 | 19.2 | 19.6 | 20.0 | 20.4 | 20.8 | 21.2 | 21.6 | 22.0 | 22.4 | 22.8 | 23.2 | 23.6 | 24.0 | 24.4 | 24.8 | 25.2 |
| 28% | 18.0 | 18.4 | 18.8 | 19.2 | 19.6 | 20.0 | 20.4 | 20.8 | 21.2 | 21.6 | 22.0 | 22.4 | 22.8 | 23.2 | 23.6 | 24.0 | 24.4 |
| 27% | 17.2 | 17.6 | 18.0 | 18.4 | 18.8 | 19.2 | 19.6 | 20.0 | 20.4 | 20.8 | 21.2 | 21.6 | 22.0 | 22.4 | 22.8 | 23.2 | 23.6 |
| 26% | 16.5 | 16.9 | 17.3 | 17.7 | 18.1 | 18.5 | 18.9 | 19.3 | 19.7 | 20.1 | 20.5 | 20.9 | 21.3 | 21.7 | 22.1 | 22.5 | 22.9 |
| 25% | 15.7 | 16.1 | 16.5 | 16.9 | 17.3 | 17.7 | 18.1 | 18.5 | 18.9 | 19.3 | 19.7 | 20.1 | 20.5 | 20.9 | 21.3 | 21.7 | 22.1 |
| 24% | 14.9 | 15.3 | 15.7 | 16.1 | 16.5 | 16.9 | 17.3 | 17.7 | 18.1 | 18.5 | 18.9 | 19.3 | 19.7 | 20.1 | 20.5 | 20.9 | 21.3 |
| 23% | 14.2 | 14.6 | 15.0 | 15.4 | 15.8 | 16.2 | 16.6 | 17.0 | 17.4 | 17.8 | 18.2 | 18.6 | 19.0 | 19.4 | 19.8 | 20.2 | 20.6 |
| 22% | 13.4 | 13.8 | 14.2 | 14.6 | 15.0 | 15.4 | 15.8 | 16.2 | 16.6 | 17.0 | 17.4 | 17.8 | 18.2 | 18.6 | 19.0 | 19.4 | 19.8 |
| 21% | 12.6 | 13.0 | 13.4 | 13.8 | 14.2 | 14.6 | 15.0 | 15.4 | 15.8 | 16.2 | 16.6 | 17.0 | 17.4 | 17.8 | 18.2 | 18.6 | 19.0 |
| 20% | 11.9 | 12.3 | 12.7 | 13.1 | 13.5 | 13.9 | 14.3 | 14.7 | 15.1 | 15.5 | 15.9 | 16.3 | 16.7 | 17.1 | 17.5 | 17.9 | 18.3 |
| 19% | 11.1 | 11.5 | 11.9 | 12.3 | 12.7 | 13.1 | 13.5 | 13.9 | 14.3 | 14.7 | 15.1 | 15.5 | 15.9 | 16.3 | 16.7 | 17.1 | 17.5 |
| 18% | 10.3 | 10.7 | 11.1 | 11.5 | 11.9 | 12.3 | 12.7 | 13.1 | 13.5 | 13.9 | 14.3 | 14.7 | 15.1 | 15.5 | 15.9 | 16.3 | 16.7 |
| 17% | 9.5 | 9.9 | 10.3 | 10.7 | 11.1 | 11.5 | 11.9 | 12.3 | 12.7 | 13.1 | 13.5 | 13.9 | 14.3 | 14.7 | 15.1 | 15.5 | 15.9 |
| 16% | 8.8 | 9.2 | 9.6 | 10.0 | 10.4 | 10.8 | 11.2 | 11.6 | 12.0 | 12.4 | 12.8 | 13.2 | 13.6 | 14.0 | 14.4 | 14.8 | 15.2 |
| 15% | 8.0 | 8.4 | 8.8 | 9.2 | 9.6 | 10.0 | 10.4 | 10.8 | 11.2 | 11.6 | 12.0 | 12.4 | 12.8 | 13.2 | 13.6 | 14.0 | 14.4 |
| 14% | 7.2 | 7.6 | 8.0 | 8.4 | 8.8 | 9.2 | 9.6 | 10.0 | 10.4 | 10.8 | 11.2 | 11.6 | 12.0 | 12.4 | 12.8 | 13.2 | 13.6 |
| 13% | 6.5 | 6.9 | 7.3 | 7.7 | 8.1 | 8.5 | 8.9 | 9.3 | 9.7 | 10.1 | 10.5 | 10.9 | 11.3 | 11.7 | 12.1 | 12.5 | 12.9 |
| 12% | 5.7 | 6.1 | 6.5 | 6.9 | 7.3 | 7.7 | 8.1 | 8.5 | 8.9 | 9.3 | 9.7 | 10.1 | 10.5 | 10.9 | 11.3 | 11.7 | 12.1 |
| 11% | 4.9 | 5.3 | 5.7 | 6.1 | 6.5 | 6.9 | 7.3 | 7.7 | 8.1 | 8.5 | 8.9 | 9.3 | 9.7 | 10.1 | 10.5 | 10.9 | 11.3 |
| 10% | 4.2 | 4.6 | 5.0 | 5.4 | 5.8 | 6.2 | 6.6 | 7.0 | 7.4 | 7.8 | 8.2 | 8.6 | 9.0 | 9.4 | 9.8 | 10.2 | 10.6 |
| 9% | 3.4 | 3.8 | 4.2 | 4.6 | 5.0 | 5.4 | 5.8 | 6.2 | 6.6 | 7.0 | 7.4 | 7.8 | 8.2 | 8.6 | 9.0 | 9.4 | 9.8 |
| 8% | 2.6 | 3.0 | 3.4 | 3.8 | 4.2 | 4.6 | 5.0 | 5.4 | 5.8 | 6.2 | 6.6 | 7.0 | 7.4 | 7.8 | 8.2 | 8.6 | 9.0 |
| 7% | 1.9 | 2.3 | 2.7 | 3.1 | 3.5 | 3.9 | 4.3 | 4.7 | 5.1 | 5.5 | 5.9 | 6.3 | 6.7 | 7.1 | 7.5 | 7.9 | 8.3 |
| 6% | 1.1 | 1.5 | 1.9 | 2.3 | 2.7 | 3.1 | 3.5 | 3.9 | 4.3 | 4.7 | 5.1 | 5.5 | 5.9 | 6.3 | 6.7 | 7.1 | 7.5 |
| 5% | 0.3 | 0.7 | 1.1 | 1.5 | 1.9 | 2.3 | 2.7 | 3.1 | 3.5 | 3.9 | 4.3 | 4.7 | 5.1 | 5.5 | 5.9 | 6.3 | 6.7 |
| 4% | 0.2 | 0.6 | 1.0 | 1.4 | 1.8 | 2.2 | 2.6 | 3.0 | 3.3 | 3.6 | 3.8 | 4.0 | 4.4 | 4.8 | 5.2 | 5.6 | 6.0 |
| 3% | 0.2 | 0.5 | 0.8 | 1.3 | 1.7 | 2.1 | 2.5 | 2.7 | 3.0 | 3.4 | 3.2 | 3.4 | 3.6 | 4.0 | 4.4 | 4.8 | 5.2 |
| 2% | 0.2 | 0.3 | 0.4 | 0.5 | 0.6 | 0.8 | 1.1 | 1.5 | 1.8 | 2.0 | 2.4 | 2.6 | 2.8 | 3.2 | 3.6 | 4.0 | 4.4 |
| 1% | 0.1 | 0.2 | 0.3 | 0.4 | 0.5 | 0.7 | 0.8 | 0.9 | 1.0 | 1.1 | 1.2 | 1.6 | 2.0 | 2.4 | 2.8 | 3.2 | 3.6 |
| 0% | 0.0 | 0.1 | 0.1 | 0.2 | 0.3 | 0.4 | 0.5 | 0.6 | 0.7 | 0.8 | 0.9 | 1.0 | 1.3 | 1.7 | 2.1 | 2.5 | 2.9 |
| | 0% | 1% | 2% | 3% | 4% | 5% | 6% | 7% | 8% | 9% | 10% | 11% | 12% | 13% | 14% | 15% | 16% |

Growth in Sales

[WIDE TABLE CONTINUED FROM ABOVE]

Growth
in
Operating
Income

| | | | | | | | | | | | | | | | |
|-----|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| 31% | 26.9 | 27.1 | 27.2 | 27.4 | 27.6 | 27.8 | 28.0 | 28.1 | 28.3 | 28.5 | 28.7 | 28.9 | 29.0 | 29.2 | 29.4 |
| 30% | 26.1 | 26.3 | 26.5 | 26.7 | 26.8 | 27.0 | 27.2 | 27.4 | 27.6 | 27.7 | 27.9 | 28.1 | 28.3 | 28.5 | 28.6 |
| 29% | 25.3 | 25.5 | 25.7 | 25.9 | 26.1 | 26.2 | 26.4 | 26.6 | 26.8 | 27.0 | 27.1 | 27.3 | 27.5 | 27.7 | 27.9 |
| 28% | 24.6 | 24.8 | 24.9 | 25.1 | 25.3 | 25.5 | 25.7 | 25.8 | 26.0 | 26.2 | 26.4 | 26.6 | 26.7 | 26.9 | 27.1 |
| 27% | 23.8 | 24.0 | 24.2 | 24.4 | 24.5 | 24.7 | 24.9 | 25.1 | 25.3 | 25.4 | 25.6 | 25.8 | 26.0 | 26.2 | 26.3 |
| 26% | 23.0 | 23.2 | 23.4 | 23.6 | 23.8 | 23.9 | 24.1 | 24.3 | 24.5 | 24.7 | 24.8 | 25.0 | 25.2 | 25.4 | 25.6 |
| 25% | 22.3 | 22.5 | 22.6 | 22.8 | 23.0 | 23.2 | 23.4 | 23.5 | 23.7 | 23.9 | 24.1 | 24.3 | 24.4 | 24.6 | 24.8 |
| 24% | 21.5 | 21.7 | 21.9 | 22.0 | 22.2 | 22.4 | 22.6 | 22.8 | 22.9 | 23.1 | 23.3 | 23.5 | 23.7 | 23.8 | 24.0 |
| 23% | 20.7 | 20.9 | 21.1 | 21.3 | 21.5 | 21.6 | 21.8 | 22.0 | 22.2 | 22.4 | 22.5 | 22.7 | 22.9 | 23.1 | 23.3 |
| 22% | 20.0 | 20.1 | 20.3 | 20.5 | 20.7 | 20.9 | 21.0 | 21.2 | 21.4 | 21.6 | 21.8 | 21.9 | 22.1 | 22.3 | 22.5 |
| 21% | 19.2 | 19.4 | 19.6 | 19.7 | 19.9 | 20.1 | 20.3 | 20.5 | 20.6 | 20.8 | 21.0 | 21.2 | 21.4 | 21.5 | 21.7 |
| 20% | 18.4 | 18.6 | 18.8 | 19.0 | 19.2 | 19.3 | 19.5 | 19.7 | 19.9 | 20.1 | 20.2 | 20.4 | 20.6 | 20.8 | 21.0 |
| 19% | 17.7 | 17.8 | 18.0 | 18.2 | 18.4 | 18.6 | 18.7 | 18.9 | 19.1 | 19.3 | 19.5 | 19.6 | 19.8 | 20.0 | 20.2 |
| 18% | 16.9 | 17.1 | 17.3 | 17.4 | 17.6 | 17.8 | 18.0 | 18.2 | 18.3 | 18.5 | 18.7 | 18.9 | 19.1 | 19.2 | 19.4 |
| 17% | 16.1 | 16.3 | 16.5 | 16.7 | 16.8 | 17.0 | 17.2 | 17.4 | 17.6 | 17.7 | 17.9 | 18.1 | 18.3 | 18.5 | 18.6 |
| 16% | 15.4 | 15.5 | 15.7 | 15.9 | 16.1 | 16.3 | 16.4 | 16.6 | 16.8 | 17.0 | 17.2 | 17.3 | 17.5 | 17.7 | 17.9 |
| 15% | 14.6 | 14.8 | 14.9 | 15.1 | 15.3 | 15.5 | 15.7 | 15.8 | 16.0 | 16.2 | 16.4 | 16.6 | 16.7 | 16.9 | 17.1 |
| 14% | 13.8 | 14.0 | 14.2 | 14.4 | 14.5 | 14.7 | 14.9 | 15.1 | 15.3 | 15.4 | 15.6 | 15.8 | 16.0 | 16.2 | 16.3 |

| | | | | | | | | | | | | | | | |
|-----|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| 13% | 13.1 | 13.2 | 13.4 | 13.6 | 13.8 | 14.0 | 14.1 | 14.3 | 14.5 | 14.7 | 14.9 | 15.0 | 15.2 | 15.4 | 15.6 |
| 12% | 12.3 | 12.5 | 12.6 | 12.8 | 13.0 | 13.2 | 13.4 | 13.5 | 13.7 | 13.9 | 14.1 | 14.3 | 14.4 | 14.6 | 14.8 |
| 11% | 11.5 | 11.7 | 11.9 | 12.1 | 12.2 | 12.4 | 12.6 | 12.8 | 13.0 | 13.1 | 13.3 | 13.5 | 13.7 | 13.9 | 14.0 |
| 10% | 10.7 | 10.9 | 11.1 | 11.3 | 11.5 | 11.6 | 11.8 | 12.0 | 12.2 | 12.4 | 12.5 | 12.7 | 12.9 | 13.1 | 13.3 |
| 9% | 10.0 | 10.2 | 10.3 | 10.5 | 10.7 | 10.9 | 11.1 | 11.2 | 11.4 | 11.6 | 11.8 | 12.0 | 12.1 | 12.3 | 12.5 |
| 8% | 9.2 | 9.4 | 9.6 | 9.7 | 9.9 | 10.1 | 10.3 | 10.5 | 10.6 | 10.8 | 11.0 | 11.2 | 11.4 | 11.5 | 11.7 |
| 7% | 8.4 | 8.6 | 8.8 | 9.0 | 9.2 | 9.3 | 9.5 | 9.7 | 9.9 | 10.1 | 10.2 | 10.4 | 10.6 | 10.8 | 11.0 |
| 6% | 7.7 | 7.9 | 8.0 | 8.2 | 8.4 | 8.6 | 8.8 | 8.9 | 9.1 | 9.3 | 9.5 | 9.7 | 9.8 | 10.0 | 10.2 |
| 5% | 6.9 | 7.1 | 7.3 | 7.4 | 7.6 | 7.8 | 8.0 | 8.2 | 8.3 | 8.5 | 8.7 | 8.9 | 9.1 | 9.2 | 9.4 |
| 4% | 6.1 | 6.3 | 6.5 | 6.7 | 6.9 | 7.0 | 7.2 | 7.4 | 7.6 | 7.8 | 7.9 | 8.1 | 8.3 | 8.5 | 8.7 |
| 3% | 5.4 | 5.5 | 5.7 | 5.9 | 6.1 | 6.3 | 6.4 | 6.6 | 6.8 | 7.0 | 7.2 | 7.3 | 7.5 | 7.7 | 7.9 |
| 2% | 4.6 | 4.8 | 5.0 | 5.1 | 5.3 | 5.5 | 5.7 | 5.9 | 6.0 | 6.2 | 6.4 | 6.6 | 6.8 | 6.9 | 7.1 |
| 1% | 3.8 | 4.0 | 4.2 | 4.4 | 4.5 | 4.7 | 4.9 | 5.1 | 5.3 | 5.4 | 5.6 | 5.8 | 6.0 | 6.2 | 6.3 |
| 0% | 3.1 | 3.2 | 3.4 | 3.6 | 3.8 | 4.0 | 4.1 | 4.3 | 4.5 | 4.7 | 4.9 | 5.0 | 5.2 | 5.4 | 5.6 |
| | 17% | 18% | 19% | 20% | 21% | 22% | 23% | 24% | 25% | 26% | 27% | 28% | 29% | 30% | 31% |

Growth in Sales

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Consent of Independent Auditors

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 February 5, 1999 with respect to the consolidated financial statements and schedule of ATS Medical, Inc. included in the Annual Report (Form 10-K) for the year ended December 31, 1998.

Ernst & Young LLP

Minneapolis, Minnesota
March 25, 1999

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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, 1998 (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 12, 1999

/s/ Richard W. Kramp

Richard W. Kramp

Dated: February 12, 1999

/s/ John H. Jungbauer

John H. Jungbauer

Dated: February 12, 1999

/s/ Charles F. Cuddihy, Jr.

Charles F. Cuddihy, Jr.

Dated: February 12, 1999

/s/ David L. Boehnen

David L. Boehnen

Dated: February 12, 1999

/s/ A. Jay Graf

A. Jay Graf

Dated: February 12, 1999

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