



FORM 10-K

ATS MEDICAL INC - ATSI

Exhibit:

Filed: March 28, 1997 (period: December 31, 1996)

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

X Annual report pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 1996
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 55447
MINNEAPOLIS, MINNESOTA (Zip Code)
(Address of principal executive offices)

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 X 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 January 1, 1997 was approximately \$111,360,742 (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 January 1, 1997 was:

Common Stock, \$.01 par value 15,288,042 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 1997 Annual Meeting of Shareholders to be filed with the Securities and
Exchange Commission on or before April 28, 1997.

ATS MEDICAL, INC.
1996 FORM 10-K

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 believes, based
on preliminary clinical results, that the ATS Open Pivot(TM) valve (the "ATS
Medical valve" or the "Valve") offers superior performance compared to other
commercially available mechanical heart valves. The Company began selling the
ATS Medical(TM) valve in international markets in 1992. In December, 1996 the
U.S. Food and Drug Administration (FDA) conditionally 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

Source: ATS MEDICAL INC, 10-K, March 28, 1997

The ATS Open Pivot 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. Based on preliminary clinical results, the Company believes that the ATS Medical valve offers superior performance compared to other commercially available mechanical heart valves. The following characteristics are the primary advances of the ATS Medical valve:

POTENTIAL FOR REDUCED RATES OF THROMBOEMBOLIC COMPLICATIONS

The ATS Medical valve's pivot areas are designed to protrude into the orifice and be exposed to the washing action of the blood flowing through the Valve. All other currently marketed bileaflet valves contain pivot cavities in the orifice wall into which protrusions from the semi-circular leaflets extend to allow the leaflets to swing open and shut. These cavities are areas of flow stagnation and possible blood clot formation. 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. By eliminating the cavities in the orifice and placing the pivot areas within the normal blood flow, the Company believes the improved washing action lowers the likelihood of blood clot formation and the resulting incidence of thromboembolism. The open pivot design as well as the angled inflow and outflow pivot stops also result in low levels of hemolysis (damage to blood cells) which the Company believes further contributes to a low rate of thromboembolic complications.

IMPROVED BLOOD FLOW EFFICIENCIES

The Company believes the Valve has several features that result in improved blood flow efficiency as compared to other commercially available valves. The Valve's orifice is a solid pyrolytic carbon ring. In contrast, the industry standard valve orifice is composed of a soft graphite substrate which is coated on all sides by pyrolytic carbon. By eliminating the graphite substrate, the Company is able to make the orifice as durable but thinner, thereby resulting in a larger inside diameter. The Company believes that this design results in lower pressure gradients in the ATS Medical valve. The Valve also has less regurgitation (backflow of blood when the valve is closing and closed) than other valves due to geometry's that minimize the direct leakage paths. These design characteristics result in superior blood flow efficiencies which should reduce the workload on the heart.

EASE OF IMPLANT

The Valve and its supporting materials are designed for ease of use by the implanting cardiac surgeon. 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.

IMPROVED FOLLOW-UP DIAGNOSTIC CAPABILITY

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

IMPROVED PATIENT QUALITY OF LIFE THROUGH LOWER NOISE LEVELS

Patients with other implanted mechanical heart valves frequently complain of disturbances resulting from the clicking sound created as the valve closes. These disturbances range from irritability and insomnia to paranoia and depression. Spouses of patients with implanted mechanical valves also report disturbances resulting from the noise of the valve. Initial clinical reports and preliminary studies indicate that the ATS Medical valve is quieter than competitors' valves 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 continued these accelerated wear tests beyond 1992 and, as of December 31, 1995, 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 the St. Jude valves used as control valves. The results of the animal testing and the other in vitro testing also show performance characteristics either equivalent or superior to the St. Jude valves used as 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, 1997, the Company estimates that over 14,000 ATS Medical valves have been implanted in patients outside of the United States. The Company has received implant registration data from over 130 institutions in 29 countries which have implanted the ATS Medical valve in patients. While no long-term in vivo studies of the Valve have yet been completed, the Company believes, based on discussions with surgeons and analysis of short-term implant data, that the Valve is demonstrating superior performance compared to the industry standard mechanical valve. Based on these preliminary clinical reports, the Company believes that the ATS Medical valve is experiencing a lower rate of thromboembolic events, superior blood flow efficiencies, lower levels of hemolysis and lower noise levels than the industry standard valve. In 1996, three prominent surgical groups were recognized for their work with the ATS Open Pivot valve through the publication of their clinical results in scientific journals. The published materials were critical to the continued penetration of key European markets. The first published paper detailed results of the Japanese clinical trials. It was essential in aiding the rapid entry into the Japanese market following regulatory approval which occurred two months after publication. In short order, two more scientific articles appeared. These articles, originating from Belgium and the United Kingdom, became very effective selling tools in Europe as well as other parts of the world.

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 consistently grown at a rate of over 5 percent annually over the last 20 years, principally due to the expansion of cardiovascular surgery facilities and the acceptance of valve replacement.

The worldwide prosthetic heart valve market is projected to continue to increase at annual rates of 4 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. The countries of Eastern Europe, the Middle East and South America all offer the potential for greater than 10 percent annual growth in the number of implants of prosthetic valves.

Over 70 percent of the prosthetic valves implanted worldwide are mechanical valves. Outside of the United States, mechanical valves represent approximately 75 percent of the prosthetic valve implants. Furthermore, as life expectancies continue to 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 used in many instances to replace degenerative prosthetic tissue valves.

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. St. Jude terminated most of its independent distributors as it converted to direct sales of the St. Jude valve beginning in the United States in 1988 and internationally in 1990. Many of these international distributors, who have long-established relationships with cardiac surgeons and cardiologists, have contracted to serve as independent distributors of the ATS Medical valve.

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 introducing 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 since 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, Inc.

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.

In January, 1996 over sixty distributors and their representatives convened in Europe for the first all distributor sales meeting. The two day meeting included the distribution of a complete set of new selling tools, followed by intensive training by Senior Sales and Marketing management. In addition to continuing training of our core group of distributors, the meeting also provided direct training to the many new representatives who had joined the Company in 1995 or who were starting as distributors in early 1996. Distributors from as far away as Japan enjoyed the opportunity to learn, from the Company's staff as well as their peers, the best methods for selling and supporting the valve in their markets.

COMPETITION

The mechanical heart valve market is highly competitive with one dominant company. In 1994, according to industry estimates, St. Jude represented approximately 64% of the mechanical heart valves sold worldwide. St. Jude was founded in 1976 by Mr. Villafana and has sold substantially the same bileaflet valve since it was first introduced in 1977, although certain minor alterations have recently been made to the valve.

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 a tissue valve. 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 reintroduced a bileaflet valve in international markets. Sorin Biomedica sPa is an Italian company that sells a monoleaflet and a bileaflet mechanical valve. These competitors have significantly greater financial resources than the Company.

The Company also 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 valves. 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.

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 advanced technical features of the Valve with the substantial 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.

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, and was in the process of pursuing the regulatory and marketing steps for another mechanical valve that it had developed when it agreed to license its patent (the "CMI Patent") on the basic design of an open pivot bileaflet mechanical valve to the Company in 1990.

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 a supply agreement with CMI (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 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 fourth contract year was completed in December 1996. The total commitment for the next four contract years is approximately \$60 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 the 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 annulus situations.

The Company receives, inspects and assembles components in its Minneapolis, Minnesota facility. The finished subassemblies are inspected, packaged and shipped to Scotland where the Valve is assembled, inspected, packaged and sterilized for shipment to distributors. Since it has now received approval of its IDE application from the FDA, the Company has begun to assemble Valves for implant in the United States, and certain other countries, at its Minneapolis, Minnesota facility.

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 on the basic design of the Valve 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. 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 conditional 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 two years. 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 receipt 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 guidelines for Good Manufacturing Practices ("GMP's"). The Company also will become subject to periodic inspections by the FDA to audit compliance with GMP'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. The Company is in the process of pursuing regulatory approval for the Valve in Australia, Canada and Taiwan.

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 \$5 million product liability insurance policy,

which 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 and extremely difficult to obtain 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, 1997, the Company had 50 full-time employees, of whom 13 were engaged in regulatory affairs and quality assurance, 13 in production, 17 in administrative, purchasing and marketing activities, and 7 in the Scotland production facility.

DISCONTINUED OPERATIONS

The Company was organized in 1987 to design and operate a large-scale mammalian cell culture system for contract protein manufacturing services to biotechnology and pharmaceutical companies. In January 1991, the Company's Board of Directors decided to suspend the biotechnology operations. In February 1992, the Company entered into an agreement and sold all of the biotechnology assets and technology. As a result of the sale of the biotechnology business, the Company's current total operations consist of the Valve business.

ITEM 2. PROPERTIES

The Company currently maintains administrative offices, production and engineering facilities in 20,535 square feet of leased space in a suburb of Minneapolis, Minnesota. The lease expires on December 31, 1997. The Company believes the current facility is adequate for its near-term needs.

The Company's wholly-owned subsidiary, ATS Medical, Ltd., entered into a lease effective November 1993 for approximately 1,500 square feet of clean room and administrative space in Glasgow, Scotland. The Scotland facility is used for final assembly, packaging and shipping the ATS Medical valve. The Company leases the facility on a month-to-month basis. The Company believes the Scotland 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 | 56 | Chairman and Chief Executive Officer |
| Richard W. Kramp | 51 | President and Chief Operating Officer |
| Russell W. Felkey | 46 | Executive Vice President of Regulatory Affairs and Secretary |
| John H. Jungbauer | 47 | Vice President, Treasurer and Chief Financial Officer |

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.

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 OR REGISTRANTS 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, 1995. Prices represent transactions between dealers and do not reflect retail markups, markdowns or commissions.

| 1996 | HIGH | LOW | 1995 | HIGH | LOW |
|----------------|---------|--------|----------------|---------|---------|
| First Quarter | \$12.00 | \$9.00 | First Quarter | \$ 6.63 | \$ 3.75 |
| Second Quarter | 11.88 | 9.38 | Second Quarter | 9.75 | 5.63 |
| Third Quarter | 11.00 | 7.00 | Third Quarter | 9.88 | 7.75 |
| Fourth Quarter | 8.63 | 6.25 | Fourth Quarter | 9.75 | 7.75 |

As of December 31, 1996, there were 642 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, 1996, 1995, 1994, 1993 and 1992, 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.

Year ended December 31,

| STATEMENTS OF OPERATIONS DATA: | 1996 | 1995 | 1994 | 1993 | 1992 |
|---|---------------------|-------------------|--------------------|---------------------|-----------------------|
| REVENUES: | | | | | |
| Net sales | \$ 11,859,765 | \$ 9,300,540 | \$ 6,763,408 | \$ 5,057,640 | \$ 634,226 |
| Less cost of goods sold | 7,474,065 | 6,011,025 | 4,189,426 | 3,082,169 | 430,648 |
| GROSS PROFIT FROM OPERATIONS | 4,385,700 | 3,289,515 | 2,573,982 | 1,975,471 | 203,578 |
| OPERATING EXPENSES: | | | | | |
| Research, development and engineering | 617,571 | 718,189 | 640,032 | 679,675 | 2,670,773 |
| Selling, general and administrative | 3,065,402 | 2,549,570 | 1,993,447 | 2,428,630 | 2,246,538 |
| TOTAL EXPENSES FROM OPERATIONS | 3,682,973 | 3,267,759 | 2,633,479 | 3,108,305 | 4,917,311 |
| Interest income | 641,375 | 752,880 | 74,706 | 165,202 | 175,264 |
| Other income | 0 | 0 | 0 | 599,218 | 279 |
| Interest expense | 0 | (31,224) | (31,317) | 0 | 0 |
| Income taxes | (22,500) | (28,888) | (25,243) | 0 | 0 |
| NET INCOME (LOSS) | \$ 1,321,602 | \$ 714,524 | (\$ 41,351) | (\$ 368,414) | (\$ 4,538,190) |
| NET INCOME (LOSS) PER SHARE | \$ 0.08 | \$ 0.05 | \$ 0.00 | (\$ 0.03) | (\$ 0.48) |
| Cash dividends declared | 0 | 0 | 0 | 0 | 0 |
| Weighted average number of shares outstanding during the period | 16,303,317 | 15,328,596 | 11,177,881 | 10,841,123 | 9,404,587 |

December 31,

| BALANCE SHEET DATA: | 1996 | 1995 | 1994 | 1993 | 1992 |
|--------------------------------|--------------|--------------|--------------|--------------|--------------|
| | ----- | ----- | ----- | ----- | ----- |
| Cash and cash equivalents..... | \$ 2,320,010 | \$ 2,213,632 | \$ 628,368 | \$ 2,735,421 | \$ 6,984,021 |
| Working capital..... | 30,643,942 | 27,802,438 | 11,214,977 | 10,983,019 | 9,869,377 |
| Total assets..... | 33,320,300 | 31,329,128 | 14,558,450 | 13,887,233 | 11,910,266 |
| Long-term debt..... | 0 | 0 | 0 | 0 | 0 |
| Total liabilities..... | 1,393,561 | 2,269,707 | 1,790,773 | 1,171,733 | 856,348 |
| Accumulated deficit..... | (20,593,921) | (21,915,523) | (22,630,047) | (22,588,696) | (22,220,282) |
| Shareholders' equity..... | 31,926,739 | 29,059,421 | 12,767,677 | 12,715,500 | 11,053,918 |

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

RESULTS OF OPERATION

YEAR ENDED DECEMBER 31, 1996 COMPARED TO 1995

Net sales totaled \$11,859,765 for the year ended December 31, 1996, an increase of \$2,559,225 or 28% over the net sales of \$9,300,540 reported for the year ended December 31, 1995. Unit sales increased 17% overall from 1995. During 1996 the Company's heart valve ("Valve") was approved for commercial distribution in Japan which accounted for approximately 14% of the sales growth. The Company sells to independent distributors with assigned territories (generally a specific country or region) who in turn sell the valve to a hospital or clinic. The Company sells in U.S. dollars so currency risk is borne by the distributor.

In 1996 and each of the previous years a portion of the sales increase has come from opening new markets as well as increased usage within each market. The Company has begun sales in most developed countries and several lesser developed countries ("LDC's") so future sales growth is expected to come from increased usage in existing markets.

In 1996, the Company instituted a volume/price discount program in its major markets incorporating a 5% price increase which could be "averaged down" as volume increased. The net price increase varied from market to market as volume increases also varied. However an average price increase of 3% was achieved.

The Valve is sold in seven sizes and with three cuff designs. In order to be prepared for surgery a hospital must stock or have available on the shelf a minimum of seven to nine valves. Depending on the timing of opening hospital accounts and the subsequent rate of implants, distributors will place bulk orders which may fall just within or just outside of a particular period. As such, the Company may receive fewer orders in one period than the next even though market share is increasing in a given territory. In 1996, sales to several distributors were lower than in 1995. Sales to many distributors increased in 1996 compared to 1995 and in one case the increase was greater than 5% of total 1995 sales. Net unit sales increased at about three times the rate of market growth.

All sales of Valves to December 31, 1996 were to customers outside of the United States. In December, 1996 the Company's application for an Investigational Device Exemption ("IDE") with the U.S. Food and Drug Administration ("FDA") was approved. Consequently, the Company will commence a clinical study of the Valve at a limited number of hospitals in the United States in 1997. During the study, valves will be sold to the hospitals at prices comparable to other available heart valves. The Company will be expected to pay the costs of additional tests and to collect patient data so U.S. sales during the clinical study are not expected to increase net income.

Cost of goods sold increased 24% to \$7,474,065 for the year ended December 31, 1996 from \$6,011,025 total cost of goods sold for the year ended December 31, 1995. Cost cost of goods sold as a percentage of sales declined from 65% for the year ended December 31, 1995 to 63% for the year ended December 31, 1996, primarily due to increased absorption of overhead which was the result of an approximate 14% increase in production.

The Company purchases pyrolytic carbon components for the valve from Carbomedics, Inc. ("CMI"). Approximately 75% 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 volumes and is adjusted annually according to changes 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 75% of the valves sold in 1996 were made with carbon purchased in 1994 (under FIFO) and the remainder with carbon purchased in 1995. The cost of carbon components, after giving effect to volume discounts and inflationary adjustments rose 11% in 1994 (the second contract year), 3.3% in 1995, and decreased .07% in 1996. For 1997 (the fifth contract year) the Company expects to pay 3% more for carbon components than in 1996.

Gross profit increased from \$3,289,515 for the twelve months ended December 31,

1995 to \$4,385,700 for the twelve months ended December 31, 1996. Gross profit as a percent of sales was 37% in 1996 and 35% in 1995. The increase in the average selling price per unit was the most significant factor in the improvement in the gross margin.

Research, development and engineering expenses totaled \$617,571 for the year ended December 31, 1996 compared to \$718,189 for the year ended December 31, 1995. The Company's research efforts in 1996 were primarily on improved package design and tooling for valve assembly. Approximately 56% of 1996 and 62% of 1995 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 20% from \$2,549,570 for the year ended December 31, 1995 to \$3,065,402 for the year ended December 31, 1996. In November, 1996 the Company sponsored the Second International Symposium on the ATS Medical Heart Valve. This two day meeting brought together surgeons from 23 countries to exchange experiences with their colleagues on the Valve. This meeting accounted for almost two thirds of the SG&A increase with salaries and benefits increases accounting for the remainder. No equivalent meeting was held in 1995 and no similar meeting is scheduled for 1997. The personnel hired in the sales and marketing department in the middle of 1995 were on board for all of 1996. For the first 10 months of 1995, the Company attempted to conserve cash by scheduling a four day- 36 hour work week. For most of 1996, the Company's work schedule was a five day 40 hour week. This increased payroll expenses by 10%. The Company also had directors and officers liability insurance (D & O) in place from November 1995 (2 months) through all of 1996 (12 months).

In early 1995, the Company borrowed against its line of credit and incurred \$31,224 of interest expense. The Company did not have any interest expense in 1996.

Following the Company's stock offering in March 1995, the Company had cash, cash equivalents and short-term investments earning interest. Interest income in 1996 declined to \$641,375 for the year ended December 31, 1996 compared to \$752,880 for the year ended December 31, 1995. A decrease in the amount of cash invested and lower market interest rates account for the decline.

The Company recorded \$22,500 and \$28,888 in income tax expense for 1996 and 1995, respectively. These taxes arose from certain items of income in the United Kingdom.

Net income increased \$607,078 from \$714,524 for the twelve months ended December 31, 1995 to \$1,321,602 for the twelve months ended December 31, 1996. The increase in income from operations more than offset the decline in interest income. This was due to the increased volume of business and the corresponding increase in gross profit.

Net income per share increased from \$.05 for 1995 to \$.08 for 1996. The weighted average number of shares outstanding increased 6% due to option and warrant exercises.

The Company has accumulated net operating loss carryforwards in both the U.S. and the U.K. 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 which is published by the Internal Revenue Service as 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, the Company experienced an ownership change, and the Company's ability to fully utilize \$19 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.

YEAR ENDED DECEMBER 31, 1995 COMPARED TO 1994

Net sales increased 38% from \$6,763,408 in 1994 to \$9,300,540 for 1995. Unit sales increased 50% during the same period, while the average unit selling price declined as the Company was selling into additional price sensitive markets and the Company encountered price competition in developed markets.

Cost of goods sold totaled \$6,011,025 for the year ended December 31, 1995, a 43% increase over cost of goods sold of \$4,189,426 for the year ended December 31, 1994. Cost of goods sold as a percentage of sales increased from 62% during 1994 to 65% during 1995. The average selling price per unit declined slightly in 1995 as revenue from sales to customers in price sensitive markets increased.

Gross profit increased by 28% from \$2,573,982 for the year ended December 31, 1994 to \$3,289,515 for the year ended December 31, 1995. Gross profit as a percent of sales was 35% in 1995 and 38% in 1994. The change in the average

selling price and cost of goods sold account for the decline in gross profit percentage.

Research, development and engineering expenses totaled \$718,189 for the twelve months ended December 31, 1995 compared to \$640,032 for the twelve months ended December 31, 1994. The Company's research efforts are focused on packaging and accessories for the Valve. In 1995, the Company began reporting costs associated with its clinical studies of the Valve as research and development expense. As a result, for the year ended December 31, 1994, \$260,845 was reclassified from selling, general and administrative expenses to research and development expenses. Expenses for 1995 totaled \$444,449. A significant portion of research and development expenses is spent with independent laboratories and consultants for testing and verifying the Valve and materials associated with the Valve.

Selling, general and administrative expenses increased by \$556,123 to \$2,549,570 for the year ended December 31, 1995 from \$1,993,447 for the year ended December 31, 1994. This 28% increase was attributable to a number of factors. The Company increased its allowance for doubtful accounts to \$150,000 in 1995 compared to \$30,000 in 1994. The Company sells to a limited number of customers which results in a concentration of credit risk among a few accounts. In addition, as the Company expands its presence in emerging markets, the risk of non-payment or delayed payment increases. The Company was accruing \$10,000 per quarter to establish an allowance for bad debts during the last three quarters of 1994 and all of 1995. At the end of 1995, management reviewed specific accounts and accrued an additional \$80,000. An increase in insurance expenses constituted nearly 20% of the selling, general and administrative increase. Product liability premiums increased as sales volume increased. During 1995, the Company also obtained D&O liability insurance. Insurance expenses for 1994 included the benefit of a refund on 1993 premiums. Midway through 1995, the Company added a Director of Sales and a Senior Product Manager.

The Company borrowed against its line of credit from September 1994 to March 1995. Interest expense for 1994 and 1995 was approximately \$31,000 each year.

The proceeds of the Company's registered direct secondary stock offering were received on March 9, 1995. Interest income on the net proceeds was \$752,880 during 1995. The Company earned \$74,706 in interest income during 1994. The increase was due to the substantially larger amount of money invested.

The Company accrued \$28,888 and \$25,243 for income taxes in 1995 and 1994. These amounts arise from state alternative minimum income taxes and the tax on certain items of income in the United Kingdom.

LIQUIDITY AND CAPITAL RESOURCES

Cash, cash equivalents, and short-term investments decreased by \$2,796,982 from \$12,984,611 at December 31, 1995 to \$10,187,620 at December 31, 1996. Inventory increased by \$4,820,321 from \$13,421,745 at December 31, 1995 to \$18,242,066 at December 31, 1996. Under the terms of the multi-year agreement with CarboMedics, Inc., the Company is required to purchase annual minimum quantities of components. The minimum number of units which the Company purchased during each of the first four years of the contract have exceeded unit sales and the Company expects that until the Valve is approved for sale in the United States by the FDA, the minimum required purchases will continue to exceed sales. During 1997, the Company is obligated to purchase \$11.4 million of heart valve components. Over the three contract years subsequent to 1997, the aggregate purchases total approximately \$50 million.

Accounts receivable decreased by \$85,548 from \$3,225,107 at December 31, 1995 to \$3,139,559 at December 31, 1996. All of the Company's sales have been to customers in international markets and, while the Company attempts to get standard 60 day terms for receivables, competitive pressures and geographical economic situations have caused the Company to selectively extend the terms for payment. Accounts receivable represented 98 Days Sales Outstanding (DSO) at December 31, 1996 and 188 DSO at December 31, 1995.

Accounts payable decreased by \$797,231 from \$1,988,189 at December 31, 1995 to \$1,190,958 at December 31, 1996. In 1995 and 1996, the Company scheduled the receipt of over 50% of the entire year's components during the fourth quarter. The decrease in accounts payable at December 31, 1996 is due to timing of component shipments from CMI.

In May 1995 the Company entered into a new line of credit agreement with a bank. Under the agreement, the Company may borrow up to \$5,000,000 as long as it maintains collateral defined as cash and marketable securities with a discounted value at least equal to the line amount. The agreement expires on June 30, 1997. There were no borrowings under the line at December 31, 1996.

As explained in Note 12 to the Company's Consolidated Financial Statements, the Company received \$14.75 million in cash on February 7, 1997 through the sale of 1,568,940 shares of Common Stock. When added to the cash on hand at December 31, 1996, the Company's cash, cash equivalents and short-term investments total approximately \$25 million.

The Company expects the obligations under the supply agreement with CMI to require more cash than will be generated by operations through the year 2000. During these same years (1997 through 2000) the Company will be conducting a clinical study of the Valve in the United States and submitting data obtained from the study to the FDA for PreMarket Approval Application (PMA) and the

opportunity to sell the Valve in the United States. The Company estimates that existing cash, cash equivalents and short-term investments will be sufficient to satisfy its capital requirements through at least the year 2000.

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 only product, a mechanical heart Valve in international markets; the acceptance by the 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; and the actions of the Company's supplier of pyrolytic carbon components for the Valve. 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 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 1997 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission on or before April 28, 1997, which information is incorporated herein.

ITEM 11. EXECUTIVE COMPENSATION

See Part I of this Report. Pursuant to General Instruction G(3), reference is made to information contained under the heading "Executive Compensation" in the Company's definitive proxy statement for its 1997 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission on or before April 28, 1997, which information is incorporated herein.

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 1997 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission on or before April 28, 1997, 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 1997 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission on or before April 28, 1997, which information is incorporated herein.

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. |
| 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, 1992 (the "1992 Form 10-K")). |
| 4.3 | Form of Warrant issued in 1992 Private Placement (Incorporated by reference to Exhibit 4 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1992). |
| 4.4 | 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 (1991 Restatement) (Incorporated by reference to Exhibit 3.2 to the 1991 Form 10-K). |
| 10.2** | Employment Agreement with Richard W. Kramp dated March 21, 1988 (Incorporated by reference to Exhibit 10(Q) to the Company's Registration Statement on Form S-18, File No. 33-34785-C (the "Form S-18")). |
| 10.3** | Agreement between the Company and Manuel A. Villafana dated January 26, 1995 (Incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1994 (the "1994 Form 10-K")). |
| 10.4 | Lease Agreement between the Company and Crow Plymouth Land Limited Partnership dated December 22, 1987 (Incorporated by reference to Exhibit 10(d) to the Form S-18). |
| 10.5 | 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). |
| 10.6 | 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). |
| 10.7 | 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). |
| 10.8 | Amendment No. 4 to Lease Agreement between the Company and Plymouth Business Center Limited Partnership, dated February 10, 1992. |

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 accounting officer) |) |
| Charles F. Cuddihy, Jr.* | Director |) |
| James F. Lyons* | Director |) |
| A. Jay Graf* | Director |) |

By: /s/ John H. Jungbauer

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

Dated: March 25, 1997

*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, 1996

ITEM 8 AND ITEM 14(a) (1) AND (2) AND (d)

FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULE

COMMISSION FILE NUMBER 0-18602

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, 1996 and 1995.

Consolidated Statements of Operations for the years ended December 31, 1996, 1995 and 1994.

Consolidated Statement of Changes in Shareholders Equity for the years ended December 31, 1996, 1995 and 1994.

Consolidated Statements of Cash Flows for the years ended December 31, 1996, 1995 and 1994.

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

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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|--|------|
| Report of Independent Auditors | F-2 |
| Consolidated Statements of Financial Position as of December 31, 1996 and 1995 | F-3 |

| | |
|--|-----|
| Consolidated Statements of Operations for the years ended December 31, 1996, 1995 and 1994 | F-4 |
| Consolidated Statement of Changes in Shareholders' Equity for the years ended December 31, 1996, 1995 and 1994 | F-5 |
| Consolidated Statements of Cash Flows for the years ended December 31, 1996, 1995 and 1994 | F-6 |
| Notes to Consolidated Financial Statements | F-7 |

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, 1996 and 1995, and the related consolidated statements of operations, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 1996. Our audit 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 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 financial statements referred to above present fairly, in all material respects, the consolidated financial position of ATS Medical, Inc. and subsidiary at December 31, 1996 and 1995, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 1996, 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, presents fairly in all material respects the information set forth therein.

Ernst & Young LLP

Minneapolis, Minnesota
February 6, 1997

ATS Medical, Inc.

Consolidated Statements of Financial Position

| | DECEMBER 31 | |
|---|---------------|---------------|
| | 1996 | 1995 |
| | ----- | ----- |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 2,320,010 | \$ 2,213,632 |
| Short-term investments | 7,867,619 | 10,770,979 |
| | ----- | ----- |
| | 10,187,629 | 12,984,611 |
| Accounts receivable, less allowance of \$200,000 in 1996 and \$150,000 in 1995 | 3,139,559 | 3,225,107 |
| Inventories | 18,242,066 | 13,421,745 |
| Prepaid expenses | 468,249 | 440,682 |
| | ----- | ----- |
| Total current assets | 32,037,503 | 30,072,145 |
| Furniture and equipment, net | 894,564 | 887,549 |
| Other assets | 388,233 | 369,434 |
| | ----- | ----- |
| Total assets | \$ 33,320,300 | \$ 31,329,128 |
| | ===== | ===== |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,190,958 | \$ 1,988,189 |

Source: ATS MEDICAL INC, 10-K, March 28, 1997

| | | |
|---|---------------|---------------|
| Accrued payroll and expenses | 202,603 | 281,518 |
| Total current liabilities | 1,393,561 | 2,269,707 |
| Shareholders' equity: | | |
| Common Stock, \$.01 par value: | | |
| Authorized shares--40,000,000 | | |
| Issued and outstanding shares--15,288,042 in 1996 and 14,963,604 in 1995 | 152,880 | 149,636 |
| Additional paid-in capital | 52,313,315 | 50,777,154 |
| Other | 54,465 | 48,154 |
| Accumulated deficit | (20,593,921) | (21,915,523) |
| Total shareholders' equity | 31,926,739 | 29,059,421 |
| Commitments | | |
| Total liabilities and shareholders' equity | \$ 33,320,300 | \$ 31,329,128 |

SEE ACCOMPANYING NOTES.

ATS Medical, Inc.
Consolidated Statements of Operations

| | YEAR ENDED DECEMBER 31 | | |
|---|------------------------|--------------|--------------|
| | 1996 | 1995 | 1994 |
| Net sales | \$ 11,859,765 | \$ 9,300,540 | \$ 6,763,408 |
| Cost of goods sold | 7,474,065 | 6,011,025 | 4,189,426 |
| Gross profit | 4,385,700 | 3,289,515 | 2,573,982 |
| Expenses: | | | |
| Research, development and engineering | 617,571 | 718,189 | 640,032 |
| Selling, general and administrative | 3,065,402 | 2,549,570 | 1,993,447 |
| | 3,682,973 | 3,267,759 | 2,633,479 |
| Operating income (loss) | 702,727 | 21,756 | (59,497) |
| Other income (expense): | | | |
| Interest income | 641,375 | 752,880 | 74,706 |
| Interest expense | -- | (31,224) | (31,317) |
| | 641,375 | 721,656 | 43,389 |
| Income (loss) before income taxes | 1,344,102 | 743,412 | (16,108) |
| Income taxes | 22,500 | 28,888 | 25,243 |
| Net income (loss) | \$ 1,321,602 | \$ 714,524 | \$ (41,351) |
| Net income (loss) per share | \$.08 | \$.05 | \$ (.00) |
| Weighted average number of shares outstanding | 16,303,317 | 15,328,596 | 11,177,881 |

SEE ACCOMPANYING NOTES.

ATS Medical, Inc.
Consolidated Statement of Changes in Shareholders' Equity

| | COMMON STOCK | | ADDITIONAL PAID-IN CAPITAL | OTHER | ACCUMULATED DEFICIT |
|---|--------------|------------|----------------------------------|------------|------------------------|
| | SHARES | AMOUNT | | | |
| Balance at January 1, 1994 | 11,177,881 | \$ 111,779 | \$ 35,198,622 | \$ (6,205) | \$ (22,588,696) |
| Compensation expense on stock options | -- | -- | 54,738 | -- | -- |
| Change in foreign currency translation | -- | -- | -- | 38,790 | -- |
| Net loss for the year | -- | -- | -- | -- | (41,351) |
| Balance at December 31, 1994 | 11,177,881 | 111,779 | 35,253,360 | 32,585 | (22,630,047) |
| Common Stock issued in public offering, net of selling expenses of \$1,400,447 | 3,600,000 | 36,000 | 14,763,553 | -- | -- |
| Compensation expense on stock options | -- | -- | 13,666 | -- | -- |
| Change in unrealized gains on short-term investments, net of tax | -- | -- | -- | 12,852 | -- |
| Stock options exercised | 81,143 | 811 | 273,161 | -- | -- |
| Stock warrants exercised | 104,580 | 1,046 | 473,414 | -- | -- |
| Change in foreign currency translation | -- | -- | -- | 2,717 | -- |
| Net income for the year | -- | -- | -- | -- | 714,524 |
| Balance at December 31, 1995 | 14,963,604 | 149,636 | 50,777,154 | 48,154 | (21,915,523) |
| Change in unrealized gains on short-term investments, net of tax | -- | -- | -- | (7,262) | -- |
| Stock options exercised | 58,643 | 586 | 129,804 | -- | -- |
| Stock warrants exercised | 265,795 | 2,658 | 1,406,357 | -- | -- |
| Change in foreign currency translation | -- | -- | -- | 13,573 | -- |
| Net income for the year | -- | -- | -- | -- | 1,321,602 |
| Balance at December 31, 1996 | 15,288,042 | \$ 152,880 | \$ 52,313,315 | \$ 54,465 | \$ (20,593,921) |

SEE ACCOMPANYING NOTES

ATS Medical, Inc.
Consolidated Statements of Cash Flows

| | YEAR ENDED DECEMBER 31 | | |
|---|------------------------|--------------|-------------|
| | 1996 | 1995 | 1994 |
| OPERATING ACTIVITIES | | | |
| Net income (loss) | \$ 1,321,602 | \$ 714,524 | \$ (41,351) |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: | | | |
| Depreciation | 233,867 | 229,736 | 233,645 |
| Loss on disposal of equipment | 17,925 | 916 | 10,791 |
| Compensation expense on stock options | -- | 13,666 | 54,738 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | 85,548 | (437,975) | (865,791) |
| Prepaid expenses | (27,567) | (182,574) | (45,527) |
| Other assets | (18,799) | 255,764 | 25,946 |
| Inventories | (4,820,321) | (4,089,603) | (2,704,817) |
| Accounts payable and accrued expenses | (876,146) | 1,728,934 | (630,960) |
| Net cash used in operating activities | (4,083,891) | (1,766,612) | (3,963,326) |
| INVESTING ACTIVITIES | | | |
| Purchases of short-term investments | (9,486,341) | (16,564,890) | -- |
| Maturities of short-term investments | 12,382,440 | 5,806,763 | 658,084 |
| Purchases of furniture and equipment | (258,808) | (190,699) | (90,601) |
| Net cash provided by (used in) investing activities | 2,637,291 | (10,948,826) | 567,483 |
| FINANCING ACTIVITIES | | | |
| Proceeds from notes payable | -- | -- | 1,250,000 |
| Payments on notes payable | -- | (1,250,000) | -- |
| Net proceeds from issuance of Common Stock | 1,539,405 | 15,547,985 | -- |
| Net cash provided by financing activities | 1,539,405 | 14,297,985 | 1,250,000 |
| Effect of exchange rate changes on cash | 13,573 | 2,717 | 38,790 |
| Increase (decrease) in cash and cash equivalents | 106,378 | 1,585,264 | (2,107,053) |
| Cash and cash equivalents at beginning of year | 2,213,632 | 628,368 | 2,735,421 |
| Cash and cash equivalents at end of year | \$ 2,320,010 | \$ 2,213,632 | \$ 628,368 |

SEE ACCOMPANYING NOTES.

ATS Medical, Inc.

Notes to Consolidated Financial Statements

December 31, 1996

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, South Africa and South America. The Company is sponsoring clinical trials of the valve in Australia, Canada and the United States in order to demonstrate safety and effectiveness and be allowed to market the valve in these countries. The Company has an assembly facility in Scotland.

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 separate component of 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 inventory consists of purchased components.

OTHER ASSETS

Prior to obtaining directors' and officers' liability insurance, the Company had placed \$353,987 and \$338,364 as of December 31, 1996 and 1995, respectively, in a self-insurance trust. A VAT deferment account of \$34,246 and \$31,070 at December 31, 1996 and 1995, respectively, was established to guarantee VAT liabilities for transferring inventory transferred to Scotland for manufacturing.

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 of the product.

USE OF ESTIMATES

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

INCOME TAXES

Income taxes are accounted for under the liability method. Deferred income taxes are provided for temporary differences between financial reporting and tax bases of assets and liabilities.

STOCK-BASED COMPENSATION

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

NET INCOME (LOSS) PER SHARE

Net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding and dilutive common stock

equivalents, if applicable.

RECLASSIFICATIONS

Certain reclassifications have been made to the 1994 and 1995 financial statements to conform to the 1996 presentation.

2. SHORT-TERM INVESTMENTS

The following is a summary of available-for-sale securities:

| | DECEMBER 31 | |
|--------------------------------|-------------|--------------|
| | 1996 | 1995 |
| U.S. Treasury debt securities: | | |
| Cost | \$7,858,301 | \$10,749,558 |
| Unrealized gains | 9,318 | 21,421 |
| Fair value | \$7,867,619 | \$10,770,979 |

All investments have original maturity dates of one year or less.

3. FURNITURE AND EQUIPMENT

Furniture and equipment consists of the following:

| | DECEMBER 31 | |
|-------------------------------|-------------|------------|
| | 1996 | 1995 |
| Furniture and fixtures | \$ 168,960 | \$ 160,211 |
| Equipment | 1,347,034 | 1,221,890 |
| Leasehold improvements | 474,042 | 459,542 |
| Construction in progress | 24,403 | 7,477 |
| | 2,014,439 | 1,849,120 |
| Less accumulated depreciation | 1,119,875 | 961,571 |
| | \$ 894,564 | \$ 887,549 |

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 (7.75% at December 31, 1996) 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, 1997. Interest on the line of credit is payable monthly. The Company had no borrowings against this facility at December 31, 1996.

5. COMMON STOCK

On June 25, 1990, the Company completed an initial public offering in which the Company sold 1,840,000 shares of Common Stock at \$3.50 per share, including a warrant to the underwriters to purchase an additional 160,000 shares of Common Stock exercisable at \$4.20 per share. All of the warrants expire on November 13, 1997. As of December 31, 1996 and 1995, the Company had 8,000 and 68,000 of these warrants outstanding, respectively.

On November 16, 1992, the Company completed a private placement of 1,613,944 units at \$6.00 per unit. Each unit consisted of one share of the Company's Common Stock and a warrant to purchase an additional share of Common Stock at \$9.00 per share. The Company also issued warrants to the agent in the private placement to purchase 161,394 shares of Common Stock at \$7.00 per share and 161,394 shares of Common Stock at \$9.00 per share. All of the warrants expire on November 13, 1997. As of December 31, 1996 and 1995, the Company had 1,850,485 and 1,924,152 of these warrants outstanding, respectively.

On December 21, 1993, the Company completed a private placement of 416,667 units at \$6.00 per unit. Each unit consisted of one share of the Company's Common Stock and a warrant to purchase an additional share of Common Stock at \$9.00 per share. The warrants expire on December 22, 1998 and none have been exercised as of December 31, 1996.

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 and 1995, the Company had warrants outstanding to purchase 826,813 and 900,000 shares of Common Stock, respectively. These warrants expire 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. The warrant expires on March 9, 2000. In 1996, 121,059 shares were tendered in the exercise of the warrant to purchase 180,000 shares for a net issuance of 58,941 shares.

6. STOCK OPTIONS

The Company has a Stock Option and Stock Award Plan (the "Plan") under which options to purchase Common Stock of the Company may be awarded to employees and

non-employees of the Company. The options may be granted under the Plan as incentive stock options (ISO) or as non-qualified stock options (non-ISO).

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

| | SHARES RESERVED FOR GRANT | STOCK OPTIONS OUTSTANDING UNDER THE PLAN | | WEIGHTED AVERAGE EXERCISE PRICE PER SHARE |
|---------------------------|---------------------------------|---|-----------|---|
| | | ISO | NON-ISO | |
| Balance January 1, 1994 | 666,754 | 340,250 | 555,000 | \$3.66 |
| Options granted | (706,750) | 446,250 | 260,500 | 3.62 |
| Options canceled | 506,750 | (308,750) | (198,000) | 5.83 |
| Balance December 31, 1994 | 466,754 | 477,750 | 617,500 | 2.60 |
| Options granted | (12,500) | 2,500 | 10,000 | 7.90 |
| Options exercised | - | (66,687) | (18,500) | 3.62 |
| Options canceled | 15,750 | (7,750) | (8,000) | 3.63 |
| 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 |

The following table summarizes information about stock options outstanding at December 31, 1996:

| RANGE OF EXERCISE PRICES | OPTIONS OUTSTANDING | | WEIGHTED AVERAGE EXERCISE PRICE | OPTIONS EXERCISABLE | |
|--------------------------|---------------------|---|------------------------------------|---------------------|------------------------------------|
| | NUMBER OUTSTANDING | WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE | | NUMBER EXERCISABLE | WEIGHTED AVERAGE EXERCISE PRICE |
| \$ 0.0041 | 286,000 | 1 year | \$ 0.0041 | 286,000 | \$ 0.0041 |
| 1.00 - 3.63 | 636,545 | 6 years | 3.40 | 483,296 | 3.32 |
| 6.25 - 8.25 | 202,500 | 9 years | 7.80 | 25,625 | 7.20 |
| 9.00 - 10.13 | 215,000 | 9 years | 9.88 | 21,500 | 9.57 |
| \$ 0.0041 - \$10.13 | 1,340,045 | 6 years | \$ 4.37 | 816,421 | \$ 2.44 |

The weighted-average fair value of options granted during the years ended December 31, 1996 and 1995 was \$9.00 and \$7.90, respectively.

Non-Plan options to purchase 35,000 shares exercisable at a weighted-average exercise price of \$3.63 per share were outstanding at December 31, 1996, 1995 and 1994, respectively.

At December 31, 1996, 1995 and 1994, Plan and non-Plan options for 816,421, 744,687 and 620,936 shares of Common Stock, respectively, were exercisable at a weighted-average exercise price of \$2.44, \$2.09 and \$1.83 per share, respectively. Options can be exercised by tendering shares previously acquired. In 1995, 4,044 shares were tendered in the exercise of 85,187 options for a net issuance of 81,143 shares. No options were exercised in 1994.

The issuance of certain stock options to employees and consultants caused the Company to account for the excess of the fair market value of the Company's Common Stock on the date of grant over the option exercise prices as compensation. The expense is recognized over the period of expected services. The compensation expense does not involve the outlay of cash. During the years ended December 31, 1996, 1995 and 1994, \$-0-, \$13,666 and \$54,738, respectively, of expense had been recognized for the unexercised options.

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

Pro forma information regarding net loss and loss 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 1996 and 1995: risk-free interest rate of 6.03% and 5.29%, respectively; dividend yield of 0%; volatility factor of the expected market price of the Company's common stock of .46 and a weighted-average expected life of the option of 4 years.

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:

| | 1996 | 1995 |
|--------------------------------|-------------|-----------|
| | ----- | |
| Pro forma net income | \$1,122,778 | \$679,801 |
| Pro forma net income per share | \$.07 | \$.04 |

The pro forma effect on net income for 1996 and 1995 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.

7. LEASES

The Company has an operating lease for its facilities in Plymouth, Minnesota. The lease is for a period of six years and expires December 31, 1997. Total rent expense as of December 31, 1996, 1995 and 1994 was \$147,101, \$143,000 and \$143,000, respectively.

8. INCOME TAXES

At December 31, 1996, the Company had net operating loss carryforwards of approximately \$18,782,000 plus credits for increasing research and development costs of approximately \$620,000 which are available to offset future taxable income through 2011. The net operating loss carryforwards exclude results of operations for ATS Medical, Ltd. for 1996, 1995 and 1994. The Company paid income taxes of \$23,000, \$29,000 and \$20,000 in 1996, 1995 and 1994, respectively, consisting principally of foreign income taxes. The effective tax rate differs from the federal statutory rate due to foreign income taxes as of December 31, 1996, 1995 and 1994, respectively.

Components of deferred tax assets and liabilities are as follows:

| | DECEMBER 31 | |
|--|--------------|--------------|
| | 1996 | 1995 |
| | ----- | |
| Deferred tax assets: | | |
| Net operating loss carryforwards | \$ 7,513,000 | \$ 8,748,000 |
| Research and development credits | 620,000 | 612,000 |
| Accrued compensation | 341,000 | 378,000 |
| Other accrued expenses | 27,000 | 26,000 |
| | ----- | ----- |
| | 8,501,000 | 9,764,000 |
| Deferred tax liabilities: | | |
| Depreciation | (555,000) | (543,000) |
| Other | -- | (2,000) |
| | ----- | ----- |
| | (555,000) | (545,000) |
| Net deferred tax assets before valuation allowance | 7,946,000 | 9,219,000 |
| Less valuation allowance | (7,946,000) | (9,219,000) |
| | ----- | ----- |
| 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:

| | DECEMBER 31 | | |
|----------|-------------|-------|-------|
| | 1996 | 1995 | 1994 |
| | ----- | | |
| Current: | | | |
| Federal | \$ -- | \$ -- | \$ -- |
| State | -- | -- | -- |

| | | | |
|---------|----------|----------|----------|
| Foreign | 22,500 | 28,888 | 25,243 |
| | ----- | ----- | ----- |
| | \$22,500 | \$28,888 | \$25,243 |
| | ===== | ===== | ===== |

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

| | DECEMBER 31 | | |
|--|-------------|--------|---------|
| | 1996 | 1995 | 1994 |
| | ----- | ----- | ----- |
| Tax at statutory rate | 34.0% | 34.0% | (34.0%) |
| State income taxes | 6.0 | 6.0 | (6.0) |
| Foreign income taxes | 1.7 | 3.9 | 156.7 |
| Impact of net operating loss carryforwards | (40.0) | (40.0) | 40.0 |
| | ----- | ----- | ----- |
| | 1.7% | 3.9% | 156.7% |
| | ===== | ===== | ===== |

9. 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, 1996, the Company remains obligated to purchase a minimum of \$61 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 \$11,289,218, \$6,182,596 and \$5,710,545 in 1996, 1995 and 1994, respectively.

At December 31, 1996, 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, 1996, 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, 1996.

10. BENEFIT PLAN

The Company has a defined contribution salary deferral plan covering substantially all employees under Section 401(k) of the Internal Revenue Code. The plan allows eligible employees to contribute up to 12% of their annual compensation with the Company contributing an amount equal to 25% of each employee's contribution. The Company realized expense for contributions to the plan of \$38,125, \$32,911 and \$28,591 during 1996, 1995 and 1994, respectively.

11. SIGNIFICANT CUSTOMERS AND CONCENTRATION OF CREDIT RISK

The Company sells to independent distributors who cover assigned international territories. Approximately 49% and 56% of net sales for 1996 and 1995, respectively, were a result of sales to three distributors. Approximately 63% of net sales for 1994 were a result of sales to four distributors.

12. SUBSEQUENT EVENT

On February 7, 1997, the Company issued 1,568,940 shares of Common Stock at \$9.40 per share from which the Company received proceeds of \$14,750,000 which are available for general corporate purposes.

ATS MEDICAL, INC.

SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

| COL. A | COL. B | COL. C | | COL. D | COL. E |
|---------------------------------|--------------------------------|--------------------------------------|--|----------------------|--------------------------|
| Description | Balance at Beginning of Period | Additions | | Deductions- Describe | Balance at End of Period |
| | | (1) Charged to Costs and Expenses | (2) Charged to Other Accounts- Describe | | |
| 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 |
| Year ended December 31, 1995: | | | | | |
| Deducted from asset accounts: | | | | | |

Source: ATS MEDICAL INC, 10-K, March 28, 1997

| | | | | | |
|---------------------------------|-----------|-----------|-------|-------|-----------|
| Allowance for doubtful accounts | \$ 30,000 | \$120,000 | -- | -- | \$150,000 |
| | ----- | ----- | ----- | ----- | ----- |
| Totals | \$ 30,000 | \$120,000 | \$ 0 | \$ 0 | \$150,000 |
| Year ended December 31, 1994: | | | | | |
| Deducted from asset accounts: | | | | | |
| Allowance for doubtful accounts | \$ 0 | \$ 30,000 | -- | -- | \$ 30,000 |
| | ----- | ----- | ----- | ----- | ----- |
| Totals | \$ 0 | \$ 30,000 | \$ 0 | \$ 0 | \$ 30,000 |

EXHIBIT INDEX

| 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 . |
| 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, 1992 (the "1992 Form 10-K")). |
| 4.3 | Form of Warrant issued in 1992 Private Placement (Incorporated by reference to Exhibit 4 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1992). |
| 4.4 | 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 (1991 Restatement) (Incorporated by reference to Exhibit 3.2 to the 1991 Form 10-K). |
| 10.2** | Employment Agreement with Richard W. Kramp dated March 21, 1988 (Incorporated by reference to Exhibit 10(Q) to the Company's Registration Statement on Form S-18, File No. 33-34785-C (the "Form S-18")). |
| 10.3** | Agreement between the Company and Manuel A. Villafana dated January 26, 1995 (Incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1994 (the "1994 Form 10-K")). |
| 10.4 | Lease Agreement between the Company and Crow Plymouth Land Limited Partnership dated December 22, 1987 (Incorporated by reference to Exhibit 10(d) to the Form S-18). |
| 10.5 | 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). |
| 10.6 | 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). |
| 10.7 | 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). |
| 10.8 | Amendment No. 4 to Lease Agreement between the Company and Plymouth Business Center Limited Partnership, dated February 10, 1992. |
| 10.9 | Development Agreement dated September 24, 1990, with CarboMedics, Inc. (confidential treatment granted).* |
| 10.10 | O.E.M. Supply Contract dated September 24, 1990, with CarboMedics, Inc. (confidential treatment granted).* |
| 10.11 | License Agreement dated September 24, 1990, with CarboMedics, Inc. (confidential treatment granted).* |
| 10.12 | Option Agreement dated September 24, 1990, with CarboMedics, Inc. (confidential treatment granted).* |
| 10.13 | Helix BioCore, Inc. Self-Insurance Trust Agreement dated February 28, 1991. |
| 10.14 | 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.) |

- 10.15 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.)
- 10.16 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).
- 10.17 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.)
- 10.18 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).
- 10.19 Form of Distributor Agreement. (Incorporated by reference to Exhibit 10.22 to the 1994 Form 10-K).
- 10.20** 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")).
- 10.21 ATS Medical, Inc. Change in Control Severance Pay Plan. (Incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the year ended December 31, 1995 (the 1995 Form 10-K)).
- 10.22 Amendment No. 5 to Lease Agreement between the Company and St. Paul Properties, Inc., dated May 30, 1996.
- 21 Subsidiaries of the Company.
- 23 Consent of Ernst & Young LLP.
- 24 Power of Attorney.
- 27 Financial Data Schedule.

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

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

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BYLAWS
OF
HELIX BIOCORE, INCORPORATED

ARTICLE I.
OFFICES, CORPORATE SEAL

Section 1.01. Registered Office. The registered office of the corporation in Minnesota shall be that set forth in the Articles of Incorporation or in the most recent amendment of the Articles of Incorporation or resolution of the directors filed with the Secretary of State of Minnesota changing the registered office.

Section 1.02. Other Offices. The corporation may have such other offices, within or without the State of Minnesota, as the directors shall, from time to time, determine.

Section 1.02. Corporate Seal. The corporation shall have no seal.

ARTICLE II.
MEETINGS OF SHAREHOLDERS

Section 2.01. Place and Time of Meetings. Except as provided otherwise by Minnesota Statutes Chapter 302A, meetings of the shareholders may be held at any place, within or without the State of Minnesota, as may from time to time be designated by the directors and, in the absence of such designation, shall be held at the registered office of the corporation in the State of Minnesota. The directors shall designate the time of day for each meeting and, in the absence of such designation, every meeting of shareholders shall be held at ten o'clock a.m.

Section 2.02. Regular Meetings.

(a) A regular meeting of the shareholders shall be held on such date as the Board of Directors shall by resolution establish.

(b) At a regular meeting the shareholders, voting as provided in the Articles of Incorporation and these Bylaws, shall designate the number of directors to constitute the Board of Directors (subject to the authority of the Board of Directors thereafter to increase or decrease the number of directors as permitted by law), shall elect qualified successors for directors who serve for an indefinite term or whose terms have expired or are due to expire within six months after the date of the meeting and shall transact such other business as may properly come before them.

Section 2.03. Special Meetings. Special meetings of the shareholders may be held at any time and for any purpose and may be called by the President, Treasurer, any two or more directors, or by one or more shareholders holding 10% or more of the shares entitled to vote on the matters to be presented to the meeting.

Section 2.04. Quorum, Adjourned Meetings. The holders of a majority of the shares entitled to vote shall constitute a quorum for the transaction of business at any regular or special meeting. In case a quorum shall not be present at a meeting, those present may adjourn the meeting to such day as they shall, by majority vote, agree upon, and a notice of such adjournment and the date and time at which such meeting shall be reconvened shall be mailed to each shareholders entitled to vote at least 5 days before such reconvened meeting. If a quorum is present, a meeting may be adjourned from time to time without notice other than announcement at the meeting. At adjourned meetings at which a quorum is present, any business may be transacted which might have been transacted at the meeting as originally noticed. If a quorum is present, the shareholders may continue to transact business until adjournment notwithstanding of the withdrawal of enough shareholders to leave less than a quorum.

Section 2.05. Voting. At each meeting of the shareholders every shareholder having the right to vote shall be entitled to vote either in person or by proxy. Each shareholder, unless the Articles of Incorporation or statute provide otherwise, shall have one vote for each share having voting power registered in such shareholder's name on the books of the corporation. Jointly owned shares may be voted by any joint owner unless the corporation receives written notice from any one of them denying the authority of that person to vote those shares. Upon the demand of any shareholder, the vote upon any question before the meeting shall be by ballot. All questions shall be decided by a majority vote of the number of shares entitled to vote and represented at the meeting at the time of the vote except if otherwise required by statute, the Articles of Incorporation, or these Bylaws.

Section 2.06. Closing of Books. The Board of Directors may fix a time,

not exceeding 60 days preceding the date of any meeting of shareholders, as a record date for the determination of the shareholders entitled to notice of, and to vote at, such meeting, notwithstanding any transfer of shares on the books of the corporation after any record date so fixed. The Board of Directors may close the books of the corporation against the transfer of shares during the whole or any part of such period. If the Board of Directors fails to fix a record date for determination of the shareholders entitled to notice of, and to vote at, any meeting of shareholders, the record date shall be the 20th day of preceding the date of such meeting.

Section 2.07. Notice of Meetings. There shall be mailed to each shareholder, shown by the books of the corporation to be a holder of record of voting shares, at his address as shown by the books of the corporation, a notice setting out the time and place of each regular meeting and each special meeting, except where the meeting is an adjourned meeting and the date, time and place of the meeting were announced at the time of adjournment, which notice shall be mailed to all shareholders of record, whether entitled to vote or not, at least fourteen days prior thereto. Every notice of any special meeting called pursuant to Section 2.03 hereof shall state the purpose or purposes for which the meeting has been called, and the business transacted at all special meetings shall be confined to the purpose stated in the notice.

Section 2.08. Waiver of Notice. Notice of any regular or special meeting may be waived by any shareholder either before, at or after such meeting orally or in writing signed by such shareholder or a representative entitled to vote the shares of such shareholder. A shareholder, by his attendance at any meeting of shareholders, shall be deemed to have waived notice of such meeting, except where the shareholder objects at the beginning of the meeting to the transaction of business because the time may not lawfully be considered at that meeting and does not participate in the consideration of the item at that meeting.

Section 2.09. Written Action. Any action which might be taken at a meeting of the shareholders may be taken without a meeting if done in writing and signed by all of the shareholders entitled to vote on that action.

ARTICLE III. DIRECTORS

Section 3.01. General Powers. The business and affairs of the corporation shall be managed by or under the authority of the Board of Directors, except as otherwise permitted by statute.

Section 3.02. Number, Qualification and Term of Office. Until the first meeting of shareholders, the number of directors shall be the number named in the Articles of Incorporation or, if no such number is named therein, the number elected by the incorporator. Thereafter, the number of directors shall be established by resolution of the shareholders (subject to the authority of the Board of Directors to increase or decrease the number of directors as permitted by law). In the absence of such shareholder resolution, the number of directors shall be the number last fixed by the shareholders, the Board of Directors, the incorporator or the Articles of Incorporation. Directors need not be shareholders. Each of the directors shall hold office until the regular meeting of shareholders next held after such director's election and until such director's successor shall have been elected and shall qualify, or until the earlier death, resignation, removal, or disqualification of such director; provided, however, that no director shall be elected to a term in excess of five years.

Section 3.03. Board Meetings. Meetings of the Board of Directors may be held from time to time at such time and place within or without the State of Minnesota as may be designated in the notice of such meeting.

Section 3.04. Calling Meetings; Notice. Meetings of the Board of Directors may be called by the Chairman of the Board by giving at least twenty-four hours' notice, or by any other director by giving at least five days' notice, of the date, time and place thereof to each director by mail, telephone, telegram or in person.

Section 3.05. Waiver of Notice. Notice of any meeting of the Board of Directors may be waived by any director either before, at, or after such meeting orally or in a writing signed by such director. A director, by his attendance at any meeting of the Board of Directors, shall be deemed to have waived notice of such meeting, except where the director objects at the beginning of the meeting to the transaction of business because the meeting is not lawfully called or convened and does not participate thereafter in the meeting.

Section 3.06. Quorum. A majority of the directors holding office immediately prior to a meeting of the Board of Directors shall constitute a quorum for the transaction of business at such meeting.

Section 3.07. Absent Directors. A director may give advance written consent or opposition to a proposal to be acted on at a meeting of the Board of Directors. If such director is not present at the meeting, consent or opposition to a proposal does not constitute presence for purposes of determining the existence of a quorum, but consent or opposition shall be counted as a vote in favor of or against the proposal and shall be entered in the minutes or other record of action at the meeting, if the proposal acted on at the meeting is substantially the same or has substantially the same effect as the proposal to

which the director has consented or objected.

Section 3.08. Conference Communications. Any or all directors may participate in any meeting of the Board of Directors, or of any duly constituted committee thereof, by any means of communication through which the directors may simultaneously hear each other during such meeting. For the purposes of establishing a quorum and taking any action at the meeting, such directors participating pursuant to this Section 3.08 shall be deemed present in person at the meeting; and the place of the meeting shall be the place of origination of the conference telephone conversation or other comparable communication technique.

Section 3.09. Vacancies; Newly Created Directorships. Vacancies in the Board of Directors of this corporation occurring by reason of death, or resignation, removal or disqualification shall be filled for the unexpired term by a majority of the remaining directors of the Board although less than a quorum; newly created directorships resulting from an increase in the authorized number of directors by action of the Board of Directors as permitted by Section 3.02 may be filled by a majority vote of the directors serving at the time of such increase; and each director elected pursuant to this Section 3.09 shall be a director until such director's successor is elected by the shareholders at their next regular or special meeting.

Section 3.10. Removal. Any or all of the directors may be removed from office at any time, with or without cause, by the affirmative vote of the shareholders holding a majority of the shares entitled to vote at an election of directors except, as otherwise provided by Minnesota Statutes Section 302A.223, as amended, when the shareholders have the right to cumulate their votes. A director named by the Board of Directors to fill a vacancy may be removed from office at any time, with or without cause, by the affirmative vote of the remaining directors if the shareholders have not elected directors in the interim between the time of the appointment to fill such vacancy and the time of the removal. In the event that the entire Board or any one or more directors be so removed, new directors shall be elected at the same meeting.

In addition to the foregoing, any director may be removed at any time by the affirmative vote of a majority of the remaining directors if the remaining directors determine that the director to be removed is engaged in an activity that is competitive with any business of the Company. A director may be determined to be engaged in an activity if he or she is an employee, director, partner, consultant, owner, representative, agent or shareholder (other than a shareholder beneficially owning less than 1% of the outstanding stock) of a company, partnership, sole proprietorship or other organization. An activity may be deemed to be competitive with the Company if the product or service created by the activity is the same as or an alternative to any of the products or services of the Company. The Board of Directors shall determine whether a director is engaged in a competitive activity utilizing the guidelines described in the previous two sentences as well as any other guidelines it determines to be relevant. The Board's decision shall not be overturned by any court unless the decision is shown to be clearly erroneous.

Section 3.11. Committees. A resolution approved by the affirmative vote of a majority of the Board of Directors may establish committees having the authority of the board in the management of the business of the corporation to the extent provided in the resolution. A committee shall consist of one or more persons, who need not be directors, appointed by affirmative vote of a majority of the directors present. Committees are subject to the direction and control of, and vacancies in the membership thereof shall be filled by, the Board of Directors, except as provided by Minnesota Statutes Section 302A.243.

A majority of the members of the committee present at a meeting is a quorum for the transaction of business, unless a larger or small proportion or number is provided in a resolution approved by the affirmative vote of a majority of the directors present.

Section 3.12. Written Action. Any action which might be taken at a meeting of the Board of Directors, or any duly constituted committee thereof, may be taken without a meeting if done in writing and signed by all of the directors or committee members, unless the Articles provide otherwise and the action need not be approved by the shareholders.

Section 3.13. Compensation. Directors who are not salaried officers of this corporation shall receive such fixed sum per meeting attended or such fixed annual sum as shall be determined, from time to time, by resolution of the Board of Directors. The Board of Directors may, by resolution, provide that all directors shall receive their expenses, if any, of attendance at meetings of the Board of Directors or any committee thereof. Nothing herein contained shall be construed to preclude any director from serving this corporation in any other capacity and receiving proper compensation therefor.

ARTICLE IV. OFFICERS

Section 4.01. Number. The officers of the corporation shall consist of a Chairman of the Board (if one is elected by the Board), the President, one or more Vice Presidents (if desired by the Board), a Treasurer, a Secretary (if one is elected by the Board) and such other officers and agents as may, from time to time be elected by the Board of Directors. Any number of offices may be held by the same person.

Section 4.02. Election Term of Office and Qualifications. The Board of Directors shall elect or appoint, by resolution approved by the affirmative vote of a majority of the directors present, from within or without their number, the President, Treasurer and such other officers as may be deemed advisable, each of whom shall have the powers, rights, duties, responsibilities, and terms in office provided for in these Bylaws or a resolution of the Board of Directors not inconsistent therewith. The President and all other officers who may be directors shall continue to hold office until the election and qualification of their successors, notwithstanding an earlier termination of their directorship.

Section 4.03. Removal and Vacancies. Any officer may be removed from his office by the Board of Directors at any time, with or without cause. Such removal, however, shall be without prejudice to the contract rights of the person so removed. If there be a vacancy among the officers of the corporation by reason of death, resignation or otherwise, such vacancy shall be filled for the unexpired term by the Board of Directors.

Section 4.04. Chairman of the Board. The Chairman of the Board, if one is elected, shall preside at all meetings of the shareholders and directors and shall have such other duties as may be prescribed, from time to time, by the Board of Directors.

Section 4.05. President. The President shall be the chief executive officer and shall have general active management of the business of the corporation. In the absence of the Chairman of the Board, he shall preside at all meetings of the shareholders and directors. He shall see that all orders and resolutions of the Board of Directors are carried into effect. He shall execute and deliver, in the name of the corporation, any deeds, mortgages, bonds, contracts or other instruments pertaining to the business of the corporation unless the authority to execute and deliver is required by law to be exercised by another person or is expressly delegated by the Articles or Bylaws or by the Board of Directors to some other officer or agent of the corporation. He shall maintain records of and, whenever necessary, certify all proceedings of the Board of Directors and the shareholders, and in general, shall perform all duties usually incident to the office of the President. He shall have such other duties as may, from time to time, be prescribed by the Board of Directors.

Section 4.06. Vice President. Each Vice President, if one or more are elected, shall have such powers and shall perform such duties as prescribed by the Board of Directors or by the President. In the event of the absence or disability of the President, the Vice President(s) shall succeed to his power and duties in the order designed by the Board of Directors.

Section 4.07. Secretary. The Secretary, if one is elected, shall be secretary of and shall attend all meetings of the shareholders and Board of Directors and shall record all proceedings of such meetings in the minute book of the corporation. He shall give proper notice of meetings of shareholders and directors. He shall perform such other duties as may, from time to time, be prescribed by the Board of Directors or by the President.

Section 4.08. Treasurer. The Treasurer shall be the chief financial officer and shall keep accurate financial records for the corporation. He shall deposit all moneys, drafts and checks in the name of, and to the credit of, the corporation in such banks and depositories as the Board of Directors shall, from time to time, designate. He shall have power to endorse, for deposit, all notes, checks and drafts received by the corporation. He shall disburse the funds of the corporation, as ordered by the Board of Directors, making proper vouchers therefor. He shall render to the President and the directors, whenever requested, an account of all his transactions as Treasurer and of the financial condition of the corporation, and shall perform such other duties as may, from time to time, be prescribed by the Board of Directors or by the President.

Section 4.09. Compensation. The officers of this corporation shall receive such compensation for their services as may be determined, from time to time, by resolution of the Board of Directors.

ARTICLE V. SHARES AND THEIR TRANSFER

Section 5.01. Certificates for Shares. All shares of the corporation shall be certificated shares. Every owner of shares of the corporation shall be entitled to a certificate, to be in such form as shall be prescribed by the Board of Directors, certifying the number of shares of the corporation owned by such shareholder. The certificates for such shares shall be numbered in the order in which they shall be issued and shall be signed, in the name of the corporation, by the President and by the Secretary or an Assistant Secretary or by such officers as the Board of Directors may designate. If the certificate is signed by a transfer agent or registrar, such signatures of the corporate officers may be by facsimile if authorized by the Board of Directors. Every certificate surrendered to the corporation for exchange or transfer shall be canceled, and no new certificate or certificates shall be issued in exchange for any existing certificate until such existing certificate shall have been so canceled, except in cases provided for in Section 5.04.

Section 5.02 Issuance of Shares. The Board of Directors is authorized to cause to be issued shares of the corporation up to the full amount authorized by the Articles of Incorporation in such amounts as may be determined by the Board of Directors and as may be permitted by law. No shares shall be allotted

except in consideration of cash or other property, tangible or intangible, received or to be received by the corporation under a written agreement, of services rendered or to be rendered to the corporation under a written agreement, or of an amount transferred from surplus to state capital upon a share dividend. At the time of such allotment of shares, the Board of Directors making such allotments shall state, by resolution, their determination of the fair value to the corporation in monetary terms of any consideration other than cash for which shares are allotted.

Section 5.03 Transfer of Shares. Transfer of shares on the books of the corporation may be authorized only by the shareholder named in the certificate, or the shareholder's legal representative, or the shareholder's duly authorized attorney-in-fact, and upon surrender of the certificate or the certificates for such shares. The corporation may treat as the absolute owner of shares of the corporation, the person or persons in whose name shares are registered on the books of the corporation.

Section 5.04. Loss of Certificates. Except as otherwise provided by Minnesota Statutes Section 302A.419, any shareholder claiming a certificate for shares to be lost, stolen, or destroyed shall make an affidavit of that fact in such form as the Board of Directors shall require and shall, if the Board of Directors so requires, give the corporation a bond of indemnity in form, in an amount, and with one or more sureties satisfactory to the Board of Directors, to indemnify the corporation against any claim which may be made against it on account of the reissue of such certificate, whereupon a new certificate may be issued in the same tenor and for the same number of shares as the one alleged to have been lost, stolen or destroyed.

ARTICLE VI.
DIVIDENDS, RECORD DATE

Section 6.01. Dividends. Subject to the provisions of the Articles of Incorporation, of these Bylaws, and of law, the Board of Directors may declare dividends whenever, and in such amounts as, in its opinion, are deemed advisable.

Section 6.02 Record Date. Subject to any provisions of the Articles of Incorporation, the Board of Directors may fix a date not exceeding 120 days preceding the date fixed for the payment of any dividend as the record date for the determination of the shareholders entitled to receive payment of the dividend and, in such case, only shareholders of record on the date so fixed shall be entitled to receive payment of such dividend notwithstanding any transfer of shares on the books of the corporation after the record date. The Board of Directors may close the books of the corporation against the transfer of shares during the whole or any part of such period.

ARTICLE VII .
BOOKS AND RECORDS, FISCAL YEAR

Section 7.01. Share Register. The Board of Directors of the corporation shall cause to be kept at its principal executive office, or at another place or places within the United States determined by the board:

- (1) a share register not more than one year old, containing the names and addresses of the shareholders and the number and classes of shares held by each shareholder; and
- (2) a record of the dates on which certificates or transaction statements representing shares were issued.

Section 7.02. Other Books and Records. The Board of Directors shall cause to be kept at its principal executive office, or, if its principal executive office is not in Minnesota, shall make available at its registered office within ten days after receipt by an officer of the corporation of a written demand for them made by a shareholder or other person authorized by Minnesota Statutes Section 302A.461, originals or copies of:

- (1) records of all proceedings of shareholders for the last three years;
- (2) records of all proceedings of the board for the last three years;
- (3) its articles and all amendments currently in effect;
- (4) its bylaws and all amendments currently in effect;
- (5) financial statements required by Minnesota Statutes Section 302A.463 and the financial statements for the most recent interim period prepared in the course of the operation of the corporation for distribution to the shareholders or to a governmental agency as a matter of public records;
- (6) reports made to shareholders generally within the last three years;
- (7) a statement of the names and usual business addresses of its directors and principal officers;

- (8) any shareholder voting or control agreements of which the corporation is aware; and
- (9) such other records and books of account as shall be necessary and appropriate to the conduct of the corporate business.

Section 7.03. Fiscal Year. The fiscal year of the corporation shall be determined by the Board of Directors.

ARTICLE VIII.
LOANS, GUARANTEES, SURETYSHIP

Section 8.01. The corporation may lend money to, guarantee an obligation of, become a surety for, or otherwise financially assist a person if the transaction, or a class of transactions to which the transaction belongs, is approved by the affirmative vote of a majority of the directors present, and:

- (1) is in the usual and regular course of business of the corporation;
- (2) is with, or for the benefit of, a related corporation, and organization in which the corporation has a financial interest, an organization with which the corporation has a business relationship, or an organization to which the corporation has the power to make donations;
- (3) is with, or for the benefit of, an officer or other employee of the corporation or a subsidiary, including an officer or employee who is a director of the corporation or a subsidiary, and may reasonably be expected, in the judgment of the board, to benefit the corporation; or
- (4) has been approved by the affirmative vote of the holders of two-thirds of the outstanding shares.

The loan, guarantee, surety contract or other financial assistance may be with or without interest, and may be unsecured, or may be secured in the manner as a majority of the directors approve, including, without limitation, a pledge of or other security interest in shares of the corporation. Nothing in this section shall be deemed to deny, limit or restrict the power of guaranty or warranty of the corporation at common law or under a statute of the State of Minnesota.

ARTICLE IX.
INDEMNIFICATION OF CERTAIN PERSONS

Section 9.01. The corporation shall indemnify such persons, for such expenses and liabilities, in such manner, under such circumstances, and to such extent as permitted by Minnesota Statutes Section 302A.521, as now enacted or hereafter amended.

ARTICLE X.
AMENDMENTS

Section 10.01. These Bylaws may be amended or altered by a vote of the majority of the whole Board of Directors at any meeting, provided that notice of such proposed amendment shall have been given in the notice given to the directors of such meeting. Such authority in the Board of Directors is subject to the power of the shareholders to change or repeal such Bylaws by a majority vote of the shareholders present or represented at any regular or special meeting of shareholders called for such purpose, and the Board of Directors shall not make or alter any Bylaws fixing a quorum for meetings of shareholders, prescribing procedures for removing directors or filling vacancies in the Board of Directors, or fixing the number of directors or their classifications, qualifications, or terms of office, except that the Board of Directors may adopt or amend any Bylaw to increase their number.

ARTICLE XI.
SECURITIES OF OTHER CORPORATIONS

Section 11.01. Voting Securities Held by the Corporation. Unless otherwise ordered by the Board of Directors, the President shall have full power and authority on behalf of the corporation (a) to attend any meeting of security holders of other corporations in which the corporation may hold securities and to vote such securities on behalf of this corporation; (b) to execute any proxy for such meeting on behalf of the corporation; or (c) to execute a written action in lieu of a meeting of such other corporation on behalf of this corporation. At such meeting, the president shall possess and may exercise any and all rights and power incident to the ownership of such securities that the corporation possesses. The Board of Directors may, from time to time, grant such power and authority to one or more other persons and may remove such power and authority from the President or from any such other person or persons.

Section 11.02. Purchase and Sale of Securities. Unless otherwise ordered by the Board of Directors, the President shall have full power and authority on behalf of the corporation to purchase, sell, transfer or encumber any and all securities of any other corporation owned by the corporation, and may execute and deliver such documents as may be necessary to effectuate such purchase, sale, transfer or encumbrance. The Board of Directors may, from time to time, confer like powers upon any other person or persons.

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AMENDMENT NO. 4
TO
LEASE AGREEMENT

This Amendment No. 4 made and entered into this 10th day of February, 1992 by and between Plymouth Business Center I Partnership, a Minnesota general partnership ("Landlord") and Helix BioCore, Inc. ("Tenant").

WITNESSETH:

WHEREAS, Crow-Plymouth Land Limited Partnership and Tenant are the parties to that certain lease agreement dated December 22, 1987 (the "Lease") with regard to the leasing of approximately 18,305 square feet (the "Original Leased Premises") in the building owned by Landlord and located at 3905 Annapolis Lane, Plymouth, Minnesota as more particularly described on Exhibit A to the Lease; and

WHEREAS, Plymouth Business Center I Partnership is the successor to Crow-Plymouth Land Limited Partnership's interest in the Lease and is hereinafter referred to as "Landlord"; and

WHEREAS, Landlord and Tenant entered into a certain Amendment No. 1 to Lease Agreement on January 5, 1989 to provide for the leasing to Tenant of an additional 21,205 square feet in the Building (the "Surrender Space"); and

WHEREAS, Landlord and Tenant entered into a certain Amendment No. 2 to Lease Agreement on January 12, 1989 in order to evidence their agreement in regard to the use of the Original Leased Premises for manufacturing purposes; and

WHEREAS, Landlord and Tenant entered into a certain Amendment No. 3 to Lease Agreement in order to allow Tenant to vacate and surrender to Landlord the Surrender Space and to evidence their agreement to extend the term of the Lease as to the Original Leased Premises, as amended, for a period of three (3) additional months; and

WHEREAS, Landlord and Tenant have agreed to enter into this Amendment No. 4 to Lease Agreement in order to evidence their agreement to extend the term of the Lease as to the Original Leased Premises, as amended, for a period of thirty (30) additional months.

NOW, THEREFORE, in consideration of the foregoing, and the following covenants and agreements and for other good and valuable consideration, the receipt and adequacy whereof is hereby acknowledged by the parties, Landlord and Tenant hereby agree as follows:

1. Interpretation of Amendment. The Lease is hereby modified and supplemented. Wherever there exists a conflict between this Amendment No. 4 and the Lease, as amended, the provisions of this Amendment No. 4 shall control. Unless otherwise indicated, capitalized terms shall be defined in the manner set forth in the Lease, as amended.

2. Extension of Term. The term of the Lease, as amended, is hereby extended for a period of thirty (30) months from July 1, 1995 through December 31, 1997.

3. Base Rent. Notwithstanding anything to the contrary in the Lease, as amended, Base Rent for the Original Leased Premises during the term as hereby extended, shall be equal to \$11,821.98 per month, payable in accordance with the terms of the Lease, during the period commencing July 1, 1995 and continuing through the expiration of the Lease term as extended hereby to December 31, 1997.

4. Additional Security Deposit. Tenant hereby deposits with Landlord, on the date hereof, the sum of \$10,000.00 as an additional security deposit to be held by Landlord in accordance with Paragraph 2B of the Lease.

5. Contingency. It is acknowledged that the parties rights and obligations under this Amendment No. 4 are contingent upon the execution of a certain Termination of Lease Agreement (the "Termination") by and between Landlord and Tenant, dated of even date herewith, for the surrender and termination of the Lease of approximately 30,757 square feet in the building located at 3955 Annapolis Lane, Plymouth, Minnesota and upon the satisfaction of each contingency set forth in the Termination necessary for the terms of the Termination to become fully effective between the parties.

6. Reference to an Effect on the Lease.

a. Upon the effectiveness on this Amendment, each reference in the Lease to "this Lease", "hereunder", "hereof", "herein" or words of like import referring to the Lease shall mean and be a reference to the Lease as amended hereby.

b. Except as specifically set forth above, the Lease remains of full force and effect and is hereby ratified and confirmed.

7. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the State of Minnesota.

8. Headings. Section headings in this Amendment are included herein for convenience of reference only and shall not constitute a part of this Amendment for any other purpose.

IN WITNESS WHEREOF, the parties have executed this Amendment No. 4 to Lease Agreement as of the year and date first above written.

LANDLORD:

Plymouth Business Center I
Partnership

By /S/ Gary T. O'Brien
Gary T. O'Brien, Its Agent

TENANT:

Helix, BioCore, Inc.

By /S/ M.A. Villafana
Its _____

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DEVELOPMENT AGREEMENT

THIS AGREEMENT made as of September 24, 1990, by and between CarboMedics, Inc., a Texas corporation, having a place of business at 1300-B East Anderson Lane, Austin, Texas 78752 (hereinafter referred to as "CMI"), and Helix BioCore, Inc., 3905 Annapolis Lane, Minneapolis, Minnesota 55447 ("Helix").

WHEREAS, under license agreement of even date herewith (the "License Agreement"), CMI has granted a license to Helix to use and sell a certain embodiment of a bileaflet mechanical cardiac valve prosthesis (hereinafter referred to as the "Valve") which is claimed under United States patent 4,692,165 (the "Licensed Product") and

WHEREAS CMI manufactures and sells Pyrolite coated components for mechanical cardiac valve prostheses using CMI's proprietary technology, which includes all knowledge and information relating to inventions, methods, systems, devices, processes, trade secrets and other confidential information used in the design, fabrication, inspection and testing of prosthetic heart valve components incorporating CMI's proprietary carbon materials Pyrolite and Biolite and other proprietary substrate materials (hereinafter referred to as "CMI's Proprietary Technology") and

WHEREAS Helix desires to complete design development and clinical trials and have the Valve approved and manufactured for commercial production in the U.S. and international markets and

WHEREAS CMI desires to manufacture mechanical heart valve components for the Valve and to undertake such work on a "best efforts" basis, all upon the terms and conditions set forth in the OEM supply contract of even date herewith between CMI and Helix (the "Supply Contract") and

WHEREAS the research and development required to develop manufacturing processes for a mechanical cardiac valve prosthesis and bring it to commercial market is expensive and the consideration agreed to in this Agreement is not, in itself, sufficient to induce CMI to enter into this Agreement and

WHEREAS CMI is unwilling to incur the expense of such research and development without the additional consideration of a long-term supply contract to manufacture components for the Valve in commercial quantities and

WHEREAS, under an option agreement of even date herewith, CMI has given Helix an option to license certain technology on the terms stated in such option agreement (the "Option Agreement") and

WHEREAS the parties acknowledge and agree that the Supply Contract is partial consideration for the completion of the research and development project outlined in this Agreement,

NOW, THEREFORE, in consideration of the premises and in reliance upon the mutual covenants and agreements hereinafter set forth, the parties agree as follows:

1. Purposes of Agreement. The purpose of this Agreement is to establish a program to complete the design and testing of the Valve, (the "Program") so that commercial distribution can begin.

2. The Program.

2.1 Scope of the Program. In consideration of the Supply Agreement and Helix's payments in accordance with and subject to the terms of Section 3 hereof, the parties agree that:

a. As promptly as possible after the execution hereof, CMI and Helix will begin joint development and fabrication of a sewing cuff for the Valve.

b. CMI will perform preliminary tests of prototype Pyrolite components. Helix may, at its option, observe such tests. CMI will report the results of the tests to Helix. Helix will make such changes in the design as it deems necessary or desirable. CMI will cooperate with Helix in making changes necessary to facilitate manufacture of the design. Helix will have the sole right and responsibility to approve the design which is finally adopted.

c. CMI will provide Helix with Valve components in the quantities and sizes identified on Exhibit A, attached to and made part of this Agreement. Any Valve components manufactured in the course of the Program in excess of the quantities set out on Exhibit B will be supplied to Helix under the terms of

the Supply Agreement before the beginning of the First Contract Year as that term is defined in the Supply Contract.

d. CMI will perform or cause to be performed with respect to the Valve components all accelerated wear testing and animal implants required by the United States Food and Drug administration ("FDA") under the guidelines in effect at the initiation of the Program and in accordance with GMP and GLP regulations.

e. Helix will provide CMI with a complete set of drawings for components for the Valve. CMI will provide drafting services to aid Helix in the preparation of such drawings.

f. Helix will have the responsibility for obtaining all approvals required by the FDA. CMI will provide information to the FDA in the areas of its expertise as required by the FDA.

g. CMI will provide Helix with access to and information regarding CMI's final inspection procedures for the components.

h. Helix will be solely responsible for (i) manufacturing the sewing cuff except as set forth in Section 1(e) of the Supply Contract, (ii) final assembly of all components, (iii) sterilization and packaging of the Valve, (iv) design and fabrication of the auxiliary instrumentation and (v) preparation of all labels including instructions for use.

2.2 Program Schedule. Work on the Program will be scheduled for completion as set forth in the schedule in Exhibit B attached to and made part of this Agreement (the "Program Schedule"). CMI will use its best efforts to meet the deadlines set forth in the Program Schedule but does not guaranty that such deadlines can be met because the Program Schedule assumes that there are no unforeseen technical difficulties and that all current assumptions related to the design of the Valve are proven correct. The Program Schedule does not allow for redesigns or reiteration of any step. For purposes of this section, and section 3 below, and section 17.1 below the term "unforeseen technical difficulties" will include but not be limited to material-related difficulties; failure in any FDA or CMI-recommended test; and process-related events that prevent CMI from meeting the final specifications.

3. Program Price. In consideration of the work to be performed under this Agreement, Helix will pay CMI \$2.39 million. Such sum will be payable in the installments set out on Exhibit B. The first installment will be due upon signing this Agreement. Each remaining installment will be due and payable before CMI begins the applicable activity. This price is based upon the assumption that the Program will proceed without encountering delays caused by unforeseen technical problems and without changes to the drawings and/or specifications. The parties agree that if such delays or changes occur, Helix will bear the reasonable cost of such delays or changes as additional charges to be paid before correction of the delay or problem is attempted by CMI, with Helix's approval.

4. Periodic Reports.

4.1 Progress Reports. Within 15 business days after the end of every second calendar month, CMI will submit to Helix a written status report detailing CMI's efforts during the two preceding months and the results thereof. CMI will also submit to Helix CMI's best estimate of the tasks to be accomplished during the next two calendar months.

4.2 Progress Reviews. The parties will undertake joint progress reviews as indicated in Exhibit B and at such other times as may be mutually agreed to at CMI's facility.

5. Changes in Specifications. During the term of this Agreement Helix will have the right, exercisable at any time or from time to time, to make any changes(s) in the drawings or specifications. Helix acknowledges that any such change may affect the costs or schedule or both.

6. Proprietary Rights; Inventions. Helix agrees that any invention, discovery or improvement, patentable or not, that is related to CMI's Proprietary Technology and is created, conceived or reduced to practice in the performance of this Agreement by CMI will be the exclusive property of CMI.

7. Tooling and Fixtures. All tooling and fixtures which are designed and built using funds provided by Helix will be the exclusive property of CMI. Upon completion of the Program and commencement of production of components for Helix, CMI will deliver to Helix, free of charge, the two wear testers used in the development process.

8. Confidentiality and Proprietary Rights.

8.1 General. All knowledge and information which either party may acquire from the other pursuant to the terms of this Agreement respecting inventions, methods, systems, devices, processes,

improvements, trade secrets and other private matters (hereinafter referred to as the "Information"), will for all time and for all purposes be regarded as strictly confidential and held in trust solely for the benefit and use of the party disclosing such Information, and it is agreed that the use or public disclosure of any such Information by the party receiving it would be wrongful and would cause irreparable injury to the disclosing party.

8.2 Confidential Information of CMI. Without limiting the generality of subsection 8.1 above, all CMI's information, inventions, improvements, drawings, special tooling, fixtures, data, manufacturing techniques, processes and research and development relating to the manufacture, inspection and testing of the components will be the sole property of CMI.

8.3 Confidential Information of Helix. Without limiting the generality of Section 8.1 above, all Helix's proprietary information, inventions, improvements, drawings, technology, research and development and other rights of Helix in prosthetic cardiac components and devices will be the sole property of Helix. Helix will acquire no interest in CMI's Proprietary Technology, or in the manufacturing tolerances or other related information as a result of the execution and performance of this Agreement.

8.4 Procedures for Maintaining Confidentiality. Each party agrees to maintain the confidentiality of any Information and to that end agrees as follows:

- (a) Not to make any use whatsoever of any Information except for the purpose for which it is supplied, either for itself or any other person, firm or corporation;
- (b) Not to reveal any Information to third parties, without the prior written approval of the disclosing party except that CMI may reveal such Information to third parties who are bound by confidentiality agreements to the extent such parties need to know the Information to provide services required by CMI pursuant to this Agreement or the Supply Contract;
- (c) To keep all Information strictly secret and confidential and to that end, without limiting the generality of the foregoing, to cause all written materials relating to or containing any Information to be plainly marked to indicate the secret and confidential nature thereof, and to prevent unauthorized use or reproduction thereof;
- (d) To maintain such Information in controlled files accessible only to authorized personnel;
- (e) To limit access to said Information to those of its employees who are cleared for access to restricted areas within each party's facilities, which employees shall first have executed a confidentiality agreement which requires, among other things, that such employee will maintain the secrecy of all confidential information which such employee may obtain in the course of employment;
- (f) In the event the receiving party receives a request to disclose all or any part of the Information under the terms of a valid and effective subpoena or order issued by a court of competent jurisdiction, the receiving party agrees to (i) notify immediately the disclosing party of the existence, terms and circumstances surrounding such request; (ii) consult with the disclosing party on the advisability of taking legally available steps to resist or narrow such request, and (iii) if disclosure of such Information is required, exercise its best efforts to obtain an order or other reliable assurance that confidential treatment will be accorded to such portion of the Information as must be produced or disclosed.

8.5 Exceptions. The foregoing restrictions will not apply to any information which is (i) known to the receiving party prior to receipt thereof from the disclosing party as evidenced by such receiving party's written records kept in the ordinary course of its business, or (ii) of public knowledge without breach by the receiving party of its obligations hereunder, or (iii) rightfully received by the receiving party from a third party without restriction on disclosure or use, or (iv) disclosed by the disclosing party to a third party without restriction on disclosure or use, or (v) independently developed by personnel of the receiving party who have not had access to or knowledge of the contents of the disclosing party's disclosure, or (vi) disclosed after receiving the written consent therefor of an authorized

officer of the disclosing party; provided that in each event, the receiving party can demonstrate same to the reasonable satisfaction of the disclosing party.

9. Excusable Delay or Failure to Perform. Neither party will be liable for a delay in performance of or failure to perform an obligation under this Agreement (except an obligation to make payment promptly when due), if and to the extent such delay or failure is attributable to any cause beyond the reasonable control of such party to prevent. Such causes may include, but are not limited to act of God, act of government, war or related actions, civil insurrection, riot, sabotage, strike, epidemic, fire, flood, windstorm, or a failure of suppliers, subcontractors or carriers, or inability to obtain required materials or qualified labor, which are reasonably beyond the control of the defaulting party to prevent. The party affected will give prompt notice of the cause to the other party, and will resume performance with reasonable diligence upon cessation of the cause of the delay or failure.

10. CMI's Representations and Warranties.

10.1 Performance of Obligations. CMI hereby represents and warrants to Helix that CMI will faithfully perform all of the obligations, covenants and agreements on its part to be performed as set forth in this Agreement within the time limitations imposed with respect to such obligations.

10.2 Disclaimer of Warranties. The parties acknowledge and agree that components manufactured under this Agreement will be for development purposes only and not manufactured in commercial quantities. Therefore CMI makes no warranty of any kind. CMI EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES WITH RESPECT TO SUCH COMPONENTS, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE AND MERCHANTABILITY.

11. Helix's Representations and Warranties. Helix will faithfully and fully perform all of the obligations, covenants and agreements on its part to be performed as set forth in this Agreement within the time limitations imposed with respect to such obligations.

12. Use of Information Developed by Helix. The design, engineering, research, technology and the like which may be developed solely by Helix in connection with its continuing improvement of existing designs or development of new designs for the Valve will belong exclusively to Helix and may be incorporated in Helix's future specifications.

13. Helix's Covenants.

13.1 Non-Liability of CMI.

(a) Limitation on CMI's Responsibility. Under no circumstances will CMI be liable or responsible for direct, incidental, consequential and/or special damages arising out of any breach of this Agreement or out of the use or implantation of prostheses employing components supplied hereunder including, but not limited to, damage to property of Helix or of other persons, or for injury to or death of any person.

(b) Helix's Responsibility. CMI will have no control over the uses to which the components will be devoted, or over the circumstances of their use, storage, handling, distribution or application. Helix will assume full responsibility with respect to the use of any Component or information furnished by CMI hereunder, and it is mutually agreed that CMI assumes no liabilities of any kind with respect to the use by Helix or any third party of such components or information.

(c) Hold Harmless. If Helix undertakes to supply the components in any form to others, it does so in its own discretion and upon its own judgment as to risk. Helix agrees, at its own expense, to defend, indemnify and hold harmless CMI from and against any and all claims, suits, actions, damages, costs, losses, and expenses (including but not limited to court costs, attorney's fees and all other expenses of litigation) for injury to or death of any person, or for damage to any property, arising from or out of or in connection with the design, manufacture, sale, implantation or use of any Component supplied under this Agreement, regardless of whether such injury, death or damage are caused in whole or in part by the negligence of CMI or whether CMI is held strictly liable for such injury, death or damage. It is the express intention of the parties hereto, both CMI and Helix, that the indemnity obligations and liabilities assumed by Helix in this paragraph be without monetary limit and without regard to causes thereof including but not limited to any failure to warn, strict liability, or the negligence of CMI, its officers, agents or employees, whether the negligence be sole, joint, or concurrent, active or passive.

Helix further agrees, at its own expense, to defend, indemnify and hold harmless CMI from and against any and all claims, suits, actions, damages, costs, proceedings, losses and expenses (including but not limited to attorney's fees) based on any claim that a design or design modification developed by Helix, alone or with CMI, infringes a patent of another.

CMI will, at its own expense, defend, indemnify and hold Helix harmless from and against any and all claims, suits, actions, damages, costs, proceedings, losses and expenses (including but not limited to attorney's fees) based on any claim that CMI's manufacturing processes or the materials used in the fabrication or coating of the components infringe the patent of any third party.

(d) Product Liability Insurance. Helix and/or its successor and assigns will maintain general liability insurance, written on an occurrence basis, during the term of this Agreement in the minimum amount of \$5 million. Said insurance must be obtained by Helix before any Valve components suitable for human implant will be delivered by CMI to Helix. The product liability insurance so maintained will be written by an insurance carrier acceptable to CMI, include CMI as an additional insured, and contain an endorsement to provide CMI with at least 30 days prior written notice of any cancellation, non-renewal, or coverage reduction. This insurance coverage will survive termination of this Agreement and will, in any event, provide coverage during the period any components supplied by CMI under the terms of this Agreement remain implanted in any living patient. CMI may demand evidence of coverage at any time during the term of this Agreement and during the period Helix is required to maintain coverage thereafter. In the event Helix fails to provide CMI with evidence of the product liability insurance required to be maintained pursuant to the provisions of this paragraph and the failure continues for 10 business days following Helix's receipt of a notice advising Helix of its failure to provide such evidence, then at any time thereafter during the pendency of such failure, CMI will have the option in its sole discretion to purchase the insurance required herein and bill Helix for the entire cost of such insurance or to terminate this Agreement.

13.2 Patent Infringement. Helix will in no manner infringe any patent or claim to patent held or asserted by CMI except the patent pertaining to the Licensed Product but only to the extent permitted in the License Agreement.

13.3 Use of Information Developed by CMI. The procedures, methodology, processes, techniques and the like which may be developed or learned by CMI relating to the use of CMI's Proprietary Technology in connection with its manufacture of components for Helix will belong exclusively to CMI and may be incorporated in CMI's general manufacturing operations. The tolerances and other information relating to CMI's Proprietary Technology developed by CMI and incorporated in the drawings developed by CMI for the manufacture of the components for the Valve will remain the exclusive confidential and proprietary property of CMI. All claims in the patent pertaining to the Licensed Product remain the sole and exclusive property of CMI except to the extent licensed to Helix under the License Agreement.

14. Infringement. Should any action be commenced alleging that the claims in the patent pertaining to the Licensed Product infringe the claims of any Letters Patent or that the patent is invalid, each party will have the rights and obligations set out in the License Agreement.

15. Term and Termination.

15.1 Term. The term of this Agreement will commence on the date first written above and will continue in effect until completion of the Program.

15.2 Termination by Helix. Notwithstanding the foregoing, Helix will have the right to terminate this Agreement on 30 days prior written notice to CMI, subject to the survival of all confidentiality and indemnification provisions, and of all monetary obligations for work, services, and equipment previously performed or contracted by CMI under the Development Agreement.

15.3 Termination by CMI. Each payment pursuant to Section 3 of this Agreement is due and payable before CMI begins the activity for which payment is allocated. If Helix fails to make any such payment and such failure continues for 30 days after the date of CMI's invoice for such payment, then CMI may terminate this Agreement immediately upon written notice. If any other payment to CMI is in arrears for 15 days after the due date, or if Helix defaults in performing any of the other provisions of this Agreement and such default continues for a period of 30 days, or if Helix is adjudicated bankrupt or becomes insolvent, or enters into a composition with creditors, or if a receiver is appointed, then CMI will have the right to terminate this Agreement immediately upon written notice to Helix.

16. Relationship of Parties. The relationship between CMI and Helix as established by this Agreement is that of independent contractors. As such, subject to the provisions of this Agreement, CMI and Helix each will conduct

their respective business at their own initiative, responsibility and expense, and each will have no authority to incur any obligation on behalf of the other.

17. Miscellaneous.

17.1 Assignment. Helix will have the right to assign its rights or delegate its obligations under this Agreement, either in whole or in part to any company controlling, controlled by or under common control with Helix or succeeding to the entire business of Helix. Assignment of rights and obligations by Helix is contingent upon the successor's agreement in writing to CMI to continue the development project for the Licensed Product per this Development Agreement and specifically as it pertains to the work and payment schedules set forth in Exhibit B. It is the intent of Helix and CMI, barring any unforeseen technical difficulties, the development project will proceed in a rapid, continuous manner to successfully develop the Licensed Product. Failure of the successor to Helix to reaffirm this intent in writing will constitute a default under this Agreement. CMI may freely assign this Agreement to any entity controlling, controlled by or under co on control with CMI or to a successor of the entire business of CMI.

17.2 Choice of Law. This Agreement has been entered into in Travis County, Texas, and will be deemed made under the laws of the State of Texas and for all purposes will be governed by, enforced under and construed in accordance with the laws of said state, without regard to principles of conflicts of law. In the event that any action is ever commenced by CMI or Helix with respect to matters which are the subject of this Agreement, Helix covenants and agrees to commence such action only within the State of Texas if it is the plaintiff. Helix agrees and hereby does submit to the jurisdiction of the State of Texas in the event that it is the defendant in any such action and hereby constitutes and appoints the Secretary of State for the State of Texas as its agent for service of process in connection with the bringing of any such litigation by CMI.

17.3 Setoffs. CMI reserves the right to set off any amounts it owes Helix against any amounts Helix owes it.

17.4 Waiver and Delay. No delay or omission by any party in enforcing any of the terms or conditions of this Agreement will be construed as a waiver thereof, and no waiver of any conditions, breach or default will be construed or determined to be a waiver of any other or subsequent conditions, breach or default or a bar to the enforcement of such terms and conditions on any future occasion.

17.5 Notices. All notices required or permitted hereunder, will be effective upon their receipt and will be given in writing and delivered in person or by certified or registered mail, postage prepaid, addressed to the attention of the president of each respective company at the respective address first above written or such other address as may be given by notice.

17.6 Severability. Whenever possible, each provision of this Agreement will be interpreted in such a manner as to be effective and valid under the applicable law, but if such provision is or becomes invalid or unenforceable under such law, then such provision will be reformed in order to conform to applicable law. If such reformation is not possible, then such provision will be ineffective only to the extent of such unenforceability or invalidity, and the remainder of the Agreement will continue to be binding and in full force and effect.

17.7 Merger. This Agreement, together with the License, Supply and Option Agreements, constitutes the entire understanding of the parties with respect to this subject matter and supersedes all prior agreements, understandings, discussions, and communication between the parties respecting such subject matter. No modification of this Agreement will be effective unless made in writing and signed by a duly authorized officer of each party.

17.8 Benefit. This Agreement will be binding upon and will inure to the benefit of the parties, their legal representatives, successors and assigns, provided that the provisions with respect to assignment and delegation are fully complied with.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

HELIX BIOCORE, INC.

CARBOMEDICS, INC.

By: /S/ M.A. Villafana

By: /S/ Terry Marlatt

Title: CEO

Terry Marlatt, President

Printed Name: M.A. Villafana

GMP DEVELOPMENT VALVE COMPONENT SET

[*]

EXHIBIT A

[*] Denotes confidential information omitted pursuant to Rule 24b-2 of the Securities and Exchange Act of 1934, as amended. The Securities and Exchange Commission granted the company's confidential treatment request in connection with this information.

PROGRAM AND PAYMENT SCHEDULE

[*]

EXHIBIT B

[*] Denotes confidential information omitted pursuant to Rule 24b-2 of the Securities and Exchange Act of 1934, as amended. The Securities and Exchange Commission granted the company's confidential treatment request in connection with this information.

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O.E.M. SUPPLY CONTRACT

THIS AGREEMENT, effective as of September 24, 1990, by and between CARBOMEDICS, INC., a corporation organized and existing under the laws of the State of Texas, with its principal office located at 1300-B East Anderson Lane, Austin, Texas 78752 ("CMI") and HELIX BIOCORE, INC., a corporation organized and existing under the laws of the State of Minnesota, with its principal office located at 3905 Annapolis Lane, Minneapolis, Minnesota 55447 (hereafter "Manufacturer").

1. Recitals and Definitions.

(a) Manufacturer's Business. Manufacturer desires to be engaged in the business of designing, manufacturing and selling medical devices, including a proprietary cardiac valve prosthesis (the "Valve" as that term is defined in the development agreement of even date herewith between CMI and Manufacturer hereinafter called the "Development Agreement").

(b) CMI's Business. CMI is engaged in the business of manufacturing mechanical components for cardiac valve prostheses, particularly such components coated with its proprietary Pyrolite and Biolite pyrocarbon.

(c) Mechanical Heart Valve Components. The term "Mechanical Heart Valve Components", (hereafter "Components"), means and includes mechanical Components for use in cardiac valve prostheses manufactured by CMI according to the written specifications and drawings of the Manufacturer furnished to CMI which Components are coated with Pyrolite and Biolite. The specifications are being developed pursuant to the Development Agreement and will be attached to and made part of this Agreement as Exhibit A.

(d) Component Set. The term "Component Set" means an orifice, two leaflets, a stiffening ring, two lock rings, and a lock wire.

(e) Sewing Cuffs. Pursuant to one or more purchase orders from Manufacturer, CMI will manufacture up to [*] sewing cuffs for aortic or mitral applications.

[*] Denotes confidential information omitted pursuant to Rule 24b-2 of the Securities and Exchange Act of 1934, as amended. The Securities and Exchange Commission granted the company's confidential treatment request in connection with this information.

(f) License and Option Agreements. The parties have entered into a license agreement of even date herewith (the "License Agreement") and an option agreement (the "Option Agreement") also of even date herewith.

(g) Consideration. Under the terms of the Development Agreement, CMI has agreed to perform certain services for Manufacturer related to the development of manufacturing processes and the testing of Components for the Valve. The parties acknowledge and agree that the research and development required to develop the Valve and bring it to commercial market is expensive. The consideration agreed to in the Development Agreement is not, in itself, sufficient to induce CMI to participate in the project outlined in the Development Agreement. CMI is unwilling to incur the expense of such a research and development project without the additional consideration of a long-term supply contract to manufacture Components for the valve in commercial quantities. Therefore, Manufacturer and CMI acknowledge and agree that a long-term supply contract is partial consideration for completion of the research and development project outlined in the Development Agreement.

2. Purchase of Goods.

(a) Manufacturer agrees to purchase, during the first five Contract Years of this Agreement, at least the minimum quantity of the Components per year specified in Exhibit B attached to and made part of this Agreement. Thereafter the minimum purchase requirement each year will be at least the lower of either the minimum number of Component Sets set forth on Exhibit B or the number of valve sets actually sold and/or disposed of by any means by Manufacturer.

(b) Manufacturer further agrees to purchase its requirements for Components exclusively from CMI during the first five Contract Years of this Agreement. Thereafter, Manufacturer may, at its option,

obtain Component Sets in excess of the minimum purchase requirements set forth in the second column on Exhibit B from a source other than CMI.

3. Price.

(a) CMI agrees to supply such Components and Biolite(R) coating of sewing cuffs at the prices set forth in Exhibit B.

(b) CMI agrees to supply sewing cuffs at the following prices:

First [*] @ [*] each

Second [*] @ [*] each

[*] to [*] @ [*] each

(c) Prices for both Components and sewing cuffs will be adjusted for inflation, effective the first day of each Contract Year (as that term is defined in Section 14 below). The prices for the first Contract Year will be determined in accordance with the price adjustment mechanism set forth in Exhibit B. The adjusted price for each subsequent Contract Year will be the price for the prior Contract Year plus such prior price times an inflation factor equal to the 12-month average percentage increase in employment costs for private industry workers (excluding farmers) as reported on the last day of the last full calendar quarter of the prior Contract year as indicated on Table 1 of the EMPLOYMENT COST INDEX published by the Bureau of Labor Statistics of the United States Department of Labor or, if the EMPLOYMENT COST INDEX should cease to be published, any comparable category in a comparable index agreeable to both parties.

(d) If the EMPLOYMENT COST INDEX is not available when the first purchase order(s) in any Contract Year is issued, the price for purchases under such purchase order(s) will be retroactively adjusted.

(e) If the specifications and drawings for the Valve require significantly more precision to manufacture than is reflected in the drawings and specifications for the Valve as of the date hereof or if CMI determines that the Components of the Valve are significantly more difficult to manufacture than those Components CMI manufactures for its other customers, the parties will, in good faith, negotiate an increased price to reflect the increased precision and/or difficulties.

4. Schedule. Manufacturer will purchase Component Sets in approximate equal weekly increments.

5. Ordering Procedure.

(a) Purchase Orders. Sales of Components will be made pursuant to purchase orders issued by Manufacturer to CMI, specifying weekly delivery schedules by size and quantity, price extension (based on Exhibit B pricing) and method of shipment. Manufacturer will use its best efforts to maintain a uniform weekly delivery schedule in terms of size and quantity of Components ordered. Contemporaneously with the completion of activity 18 on Exhibit B in the Development Agreement, or earlier at Manufacturer's option, Manufacturer will issue purchase orders for the first 26 weeks of the term of this Agreement. Thereafter, beginning 13 weeks after the commencement of the term of this Agreement, subsequent purchase orders will be issued by Manufacturer to CMI at thirteen-week intervals, thirteen weeks in advance. Issuance of purchase orders before the completion of activity 18 on Exhibit B of the Development Agreement will not accelerate the commencement of the first Contract Year.

[*] Denotes confidential information omitted pursuant to Rule 24b-2 of the Securities and Exchange Act of 1934, as amended. The Securities and Exchange Commission granted the company's confidential treatment request in connection with this information.

(b) Limitations on Quantities Ordered. In order to enable CMI to plan production and in order to assure Manufacturer a steady and predictable supply of Components, Manufacturer agrees that each new thirteen-week order for Components will not decrease by more than 10 percent from the immediately preceding thirteen-week order. The 10 percent variation will be calculated by comparing each new order(s) for Components to the immediately preceding order(s) for Components. Any new thirteen-week order which increases the immediately preceding thirteen-week order by more than 10 percent is subject to acceptance by CMI, and CMI may reject that portion of the order which exceeds 110% of the preceding order. Manufacturer may, however, increase or decrease an order by up to 40% (or 2000 Valves, if higher than 40%) over the prior thirteen-week order if Manufacturer has notified CMI of this change and issued a purchase order to reflect the increase, at least 26 weeks in advance. Notwithstanding the foregoing, CMI will use its best efforts to manufacture Components sufficient to fill Manufacturer's orders which exceed the 10 percent maximum variation limitation.

(c) Raw Materials. Manufacturer acknowledges that certain raw materials ("Raw Materials") which are identified on Exhibit C, attached to and made part of this Agreement, are unique to the Component and are sold in minimum quantities which may exceed a 13-week supply. Manufacturer hereby authorizes CMI to maintain a sufficient supply of Raw Materials to insure a steady production schedule.

6. Change in Specifications. Manufacturer will have the right, from time to time, to make such changes in the specifications as it deems necessary or desirable. All such changes, however, will be made by written notice. If any change increases CMI's costs, CMI's price to Manufacturer will be increased proportionately. The effective date for all such changes will be negotiated in good faith between Manufacturer and CMI. If any inventory of Raw Materials, work in process or finished goods should become obsolete as a result of such a change, Manufacturer will reimburse CMI for the cost of such obsolete inventory on a percentage-of-completion basis.

7. Transportation Costs. CMI will ship Components to Manufacturer f.o.b. CMI's facility (point of origin). CMI will invoice Manufacturer for each shipment the total purchase price and the cost of shipping or will charge the cost of shipment to Manufacturer's account with the carrier, at Manufacturer's option.

8. Payment. CMI will invoice Manufacturer on shipment or completion of services, as applicable, for all amounts due under this Agreement, including without limitation amounts due under Sections 10(b) and 14. Each invoice dated within the first six months of this Agreement is due and payable at CMI's offices, within 90 days after the date of invoice. Each invoice dated within the second six months of this Agreement will be due and payable to CMI's offices within 60 days after the date of invoice. Each invoice dated after the second six months of this Agreement will be due and payable at CMI's offices within 30 days after the date of invoice. If Manufacturer is delinquent in payment of any invoices, CMI may refuse to ship, require cash in advance, letters of credit or other terms, without limiting CMI's remedies. Manufacturer will pay service charge of 1.5 percent per month or the maximum rate allowed by law, whichever is lower, on all invoiced amounts due but not paid from and after the date due.

9. Excusable Delay or Failure to Perform. Neither party will be liable for a delay in performance of or failure to perform an obligation under this Agreement (except an obligation to make payment promptly when due), if and to the extent such delay or failure is attributable to any cause beyond the reasonable control of such party (the "affected party"). Such causes may include but are not limited to act of God, act of government, war or related actions, civil insurrection, riot, sabotage, strike or other labor difficulties, epidemic, fire, flood, windstorm, failure of suppliers, subcontractors or carriers, inability to obtain required materials or qualified labor. The affected party will give prompt notice of the cause to the other party, and will resume performance with reasonable diligence upon cessation of the cause of the delay or failure. If the affected party's performance is suspended or delayed because of the operation of this paragraph, the term of this agreement will be correspondingly extended. Six months after suspension or delay begins, whether excused or not, Manufacturer will pay CMI for all unused Raw Materials, work in process and finished goods on a percentage-of-completion basis. Upon receipt of payment, CMI will ship the finished goods and Raw Materials to Manufacturer. CMI may, however, hold all work in process in trust for Manufacturer for a period of time not to exceed 12 months after the beginning of suspension or delay. CMI and Manufacturer will each have the right to count the work in process. At the end of the 12-month period and provided Manufacturer has paid for it, CMI will destroy the work in process under the observation of representatives of Manufacturer.

10. Inspection of Shipment and Approval by Manufacturer.

(a) Manufacturer's Inspection Procedures. Upon receipt by Manufacturer of any particular shipment of Components, Manufacturer will have the right to inspect each Component shipped and to submit such Components to Manufacturer's reasonable quality control procedures to determine that the Components conform to the agreed specifications. Manufacturer has the responsibility prior to commencement of manufacture of Components by CMI to describe to CMI the reasonable quality control procedures which will be adopted by Manufacturer in order that CMI, at its option, may integrate these quality control procedures of Manufacturer with those adopted by CMI to insure that the Components supplied by CMI conform to the specifications of the Manufacturer. Manufacturer reserves the right to make any reasonable change or modification in Manufacturer's quality control procedure, provided that the precision must remain within the limits of the CMI's capability to produce the Components at the agreed upon contract price and terms. If any such change or modification increases CMI's cost, CMI's price to Manufacturer will be increased. Manufacturer will notify CMI, in writing, of any such change or modification in the quality control procedure, and CMI will be allowed a reasonable time subsequent to receipt by manufacturer of such notice within which to modify CMI's quality control procedures.

(b) Manufacturer's Right to Reject. Manufacturer will have the right to reject Components which fail to conform to the agreed specifications and return same to CMI at Manufacturer's expense. However, in conjunction with the rejection of such Components,

Manufacturer has the affirmative responsibility of providing CMI with a written, comprehensive description of the basis of the rejection by Manufacturer of the Components being returned and/or a description of the mode in which the Components being returned fail to meet Manufacturer's specification. If CMI, in its reasonable opinion and confirmed by actual test, finds that the parts rejected by the Manufacturer do not meet specifications, CMI will at its option repair or replace the rejected Component or issue a credit memo to Manufacturer for the cost of the Components returned as well as all shipment costs to and from Manufacturer. For purposes of this Agreement, Manufacturer is deemed to have accepted all Components shipped which are not affirmatively rejected by Manufacturer within the rejection period after receipt. The rejection period will be 90 days for Components received during the first 12 months, of this Agreement, and 60 days for Components received after the first 12 months of this Agreement. If, during any 3-month period, the total number of Pyrolite-coated Components returned by Manufacturer as non-conforming and subsequently determined to be in fact conforming to specifications exceeds 5 percent of the total number of Pyrolite-coated Components delivered to Manufacturer during the same period, Manufacturer will pay CMI an additional handling charge of \$75.00 per Pyrolite-coated Component for each in-specification Pyrolite-coated Component in excess of that 5 percent level (subject to increase by a percentage equal to the average percent of increase in prices for the Components shown on Exhibit B as amended from time to time).

11. Warranties. Although CMI agrees to carry out this Agreement in accordance with its standard operating practices, CMI makes no warranties of any kind, express or implied, concerning the performance of the Components or of the accuracy or completeness of any information CMI furnishes pursuant to this Agreement. Specifically, CMI MAKES NO WARRANTY OF FITNESS FOR THE PURPOSE INTENDED AND NO WARRANTY OF MERCHANTABILITY. CMI's sole responsibility will be, at CMI's option, to repair, replace or issue credit respecting any Components having defects in material and workmanship at the time of shipment by CMI, provided any such Component is returned by Manufacturer to CMI f.o.b. destination within 90 days after receipt of such Component(s), for Components received during the first 12 months of this Agreement, and within 60 days after receipt of such Components received after the first 12 months of this Agreement. This paragraph concerning warranties states CMI's entire obligation and the sole and exclusive remedy of Manufacturer and any third party claiming under Manufacturer respecting the components or any defects therein.

12. Limitation of Liability and Indemnity.

(a) Limitation on CMI's Responsibility. Under no circumstances will CMI be liable or responsible for direct, incidental, consequential and/or special damages arising out of use or implantation of prostheses employing Components supplied hereunder including, but not limited to, damage to property of Manufacturer or of other persons, or for injury to or death of any person.

(b) Manufacturer's Responsibility. CMI will have no control over the uses to which the Components will be devoted, or over the circumstances of their use, storage, handling, distribution or application. Manufacturer will assume full responsibility with respect to the use of any Component or information furnished by CMI hereunder, and it is mutually agreed that CMI assumes no liabilities of any kind with respect to the use by Manufacturer or any third party of such Components or information.

(c) Hold Harmless. If Manufacturer undertakes to supply the Components to others, it does so in its own discretion and upon its own judgment as to risk. Manufacturer agrees, at its own expense, to defend, indemnify, and hold harmless CMI, its officers, agents, and employees from and against any and all claims, losses, damages, causes of action, suits and liability of every kind, including all expenses of litigation, court costs, and attorney's fees, for injury to or death of any person, or for damage to any property, arising from or out of or in connection with the design, manufacture, marketing, sale, implantation, or use of any Component supplied under this Agreement or the failure by CMI to warn Manufacturer or any person of any defect in or risk associated with a Component supplied under this Agreement, regardless of whether such injury, death, or damages are caused in whole or in part by the negligence of CMI, its officers, agents, or employees or whether CMI is determined to be strictly liable for such injury, death, or damage. It is the express intention of the parties hereto, both CMI and Manufacturer, that the indemnity obligations and liabilities assumed by Manufacturer in this paragraph be without monetary limit and without regard to causes thereof including but not limited to any failure to warn, strict liability, or the negligence of CMI, its officers, agents or employees, whether the negligence be sole, joint, or concurrent, active or passive.

Manufacturer further agrees, at its own expense, to defend, indemnify, and hold harmless CMI from and against any and all claims, losses, damages, causes of action, suits, and liability of every kind, including all expenses of litigation, court costs, and attorney's fees, based on a claim alleging that the Components or any of the Components infringe a patent of any third party.

CMI agrees, at its own expense, to defend, indemnify, and hold harmless Manufacturer from and against any and all claims, losses, damages, causes of action, suits, and liability of every kind, including all expenses of litigation, court costs, and attorney's fees, based on a claim that CMI's manufacturing processes or the materials used in the fabrication or coating of the Components infringe the patent or valid (as against CMI) trade secret of any third party.

(d) Product Liability Insurance. Manufacturer and any successor or assigns will maintain general liability insurance, written on an occurrence basis, during the term of this Agreement in the minimum amount of \$5 million. The product liability insurance so maintained will be written by an insurance carrier acceptable to CMI, include CMI as an additional insured, and contain an endorsement to provide CMI with at least 30 days prior written notice of any cancellation, non-renewal, or coverage reduction. CMI may demand evidence of coverage at any time during the term of this Agreement. In the event Manufacturer fails to provide CMI with evidence of the product liability insurance required to be maintained pursuant to the provisions of this paragraph and the failure continues for 10 days following Manufacturer's receipt of a notice advising Manufacturer of its failure to provide such evidence, then at any time thereafter during the pendency of such failure, CMI will have the option in its sole discretion to terminate this Agreement or to purchase the insurance at Manufacturer's expense.

13. Confidentiality. Any information to be disclosed by either party to the other pursuant to this Agreement, and which is deemed by the disclosing party to constitute confidential or proprietary information must be disclosed in writing and conspicuously labeled as confidential information of the disclosing party, or with words of similar impact. Subject to Paragraph 14(d) below, any such confidential information which is initially disclosed orally must be noted at the outset by the disclosing party as confidential information, and must be reduced to writing and submitted by the disclosing party to the receiving party within 15 business days after the original oral disclosure.

All information, inventions and improvements relating to pyrocarbon or coatings developed by the CMI will be the property of CMI.

The receiving party will hold all such information in strict confidence and will use it solely for the purposes for which it is supplied under this Agreement. The receiving party will not disclose such information to any third party or use same for the benefit of any third party. The foregoing restrictions will not apply to any information which

- (i) is not disclosed and labeled as provided in the first paragraph of this Section (except orally disclosed information for the first 15 business days thereafter, pending the submission of same in writing) or
- (ii) known to the receiving party prior to receipt thereof from the disclosing party or
- (iii) of public knowledge without breach by the receiving party of its obligations hereunder or
- (iv) rightfully received by the receiving party from a third party without restriction on disclosure or use or
- (v) disclosed by the disclosing party to a third party without restriction on disclosure or use or
- (vi) independently developed by personnel of the receiving party who have not had access to or knowledge of the contents of the disclosing party's disclosure or
- (vii) disclosed after receiving the written consent therefor of an authorized officer of the disclosing party;

provided that in the events (ii), (iii), (iv), (v), (vi) and (vii), the receiving party can demonstrate same to the reasonable satisfaction of the disclosing party.

The restrictions on use and disclosure of information under this Section will survive the expiration or termination of this Agreement.

14. Termination. This Agreement will become effective upon the date first written above, but the obligation to purchase the minimum quantities will not begin until the beginning of the first Contract Year. The first Contract Year will be in on the day on which CMI ships the last component set of the [*] component sets provided for in the Development Agreement. The twelve-month period beginning on such day and month each year will be called a Contract Year. Unless extended or earlier terminated as provided in this Agreement, this Agreement will continue in effect for fifteen full Contract Years.

- (a) CMI may terminate this Agreement on five days notice if Manufacturer fails to make any payment promptly when due, or on 30 days notice if Manufacturer infringes any patent of CMI (except to the extent permitted by written license agreement) by making or having made

any product or using any method covered by such patent in or in preparation for commercial sale of cardiac valve prostheses, or if Manufacturer is in default of any of its material obligations under this Agreement. CMI's remedies will not be deemed exclusive, but are in addition to any and all other remedies available at law or under this Agreement.

(b) Manufacturer may terminate this Agreement upon 90 days written notice to CMI if CMI defaults on any of its material obligations hereunder and such default is not cured within 30 days after CMI receives notice.

(c) If Manufacturer terminates this Agreement for any reason other than the default of CMI, or decides not to renew or extend this Agreement, Manufacturer will pay for all completed Components conforming to Manufacturer's specifications and pay the cost of all work in process on a percentage-of-completion basis, the cost of all expendable tooling, and the cost of any unused Raw Materials. Inventories will be disposed of as provided in Section 9.

(d) Sections 8, 10, 11, 12, and 13 will survive termination or expiration of this Agreement and remain in effect for the respective periods specified therein, or, if no period is specified, for a period which is reasonable in the circumstances.

(e) If, in any Contract Year, Manufacturer fails to meet the minimum purchase requirements set forth on Exhibit B and CMI elects not to terminate this Agreement for default, then the term of this Agreement may, at CMI's election, be extended up to two years to permit Manufacturer to make up the deficiencies. Purchase of such deficiencies will not be credited against minimum purchase requirements for any prior or subsequent year. If, because of the effects of this section, the term of this Agreement is extended beyond 15 Contract Years, the minimum purchase requirements after the fifteenth Contract Year will be determined by mutual agreement, or if no mutual agreement can be reached, will be the same as that in effect in the fifteenth Contract Year. The price for Components purchased to satisfy such deficiencies will be those in effect when the deficiency is made up.

[*] Denotes confidential information omitted pursuant to Rule 24b-2 of the Securities and Exchange Act of 1934, as amended. The Securities and Exchange Commission granted the company's confidential treatment request in connection with this information.

If such failure to meet minimum purchase requirements occurs during the first five Contract Years, CMI has, at its option, the right to do any one, all, or a combination of the following as well as any other remedies that may be or become available:

1. terminate the License Agreement in its entirety,
2. terminate the exclusive right of Helix under the License Agreement and make the Licensed Product available to others and/or itself for any purpose,
3. terminate the Option Agreement for the manufacturing process technology for the Licensed Product,
4. delay the start of the Option Period under the Option Agreement to Manufacturer by two years and/or
5. extend the term of the License Agreement by two years so that Manufacturer's paid up license does not become effective until the deficiency is made up.

CMI's waiver of any or all defaults for failure to purchase the minimum requirements in one Contract Year will not limit or restrict CMI's remedies for failure of Manufacturer to meet the minimum purchase requirements in effect for a subsequent Contract Year.

15. Quality Assurance.

CMI's Quality Assurance Manual establishes the quality control system to be employed throughout the performance of this Agreement. A copy of this manual--with CMI's proprietary information, if any, deleted--will be made available to Manufacturer.

16. Assignment. Neither party will have the right to assign this Agreement, in whole or in part, to any third party without the prior written consent of a duly authorized officer of the other party, which consent will not be unreasonably withheld. An attempted assignment without consent will be grounds for termination of this Agreement by such other party, without thereby affecting any rights or remedies it may have under this Agreement or at law. Notwithstanding the foregoing, either party may freely assign this Agreement to any company controlling, controlled by or under common control with that party or succeeding to the entire business of that party. This Agreement will be binding upon and inure to the benefit of the parties and their successors and

assigns to which such consent, if necessary, is given.

17. General.

(a) Waivers. No waiver of any right or remedy hereunder will be effective unless based upon a writing signed by the party against whom it is sought to be enforced.

(b) Notices. All notices required or permitted under this Agreement must be made in writing and delivered in person or by certified or registered mail, postage prepaid, addressed to the attention of the President of the other party at the respective address first written above, or such other address as may be given by notice.

(c) Severability. If any provision of this Agreement is declared invalid or unenforceable by a court of competent jurisdiction, such provision will be severed from this Agreement and the remaining provisions will be unaffected thereby. The parties will promptly meet and negotiate a substitute provision meeting as closely as possible the intent of the invalid or unenforceable provision and, with reasonable precision, avoiding the defects of the original provision.

(d) Entire Agreement. This Agreement, together with the License, Development and Option Agreements, constitutes the entire agreement and understanding between the parties in respect of the subject matter of this Agreement and supersedes all prior agreements, understanding, discussions and communications between the parties respecting such subject matter. No modification of this Agreement will be effective unless made in writing signed by a duly authorized officer of each party, except as otherwise expressly permitted herein. Nothing in this Agreement will limit the scope of subsequent, written agreements, signed by both parties, related to nondisclosure of confidential information. In the event of a conflict between this Agreement and the terms and conditions contained in Manufacturer's purchase orders, the terms of this Agreement will control.

(e) Governing Law. This Agreement has been entered into under the laws of the State of Texas and will be governed by and construed in accordance with those laws.

Executed by the parties as of the day and year first written above.

MANUFACTURER:

CARBOMEDICS, INC.

By /S/ M.A. Villafana

By /S/ Terry Marlatt
Terry Marlatt, President

Typed Name M.A. Villafana

Title CEO

SPECIFICATIONS

To be mutually agreed upon upon completion of the Program as defined in the Development Agreement.

EXHIBIT A

PRICE AND QUANTITY SCHEDULES

MINIMUM PURCHASE REQUIREMENTS PER COMPONENT SET

| Contract Year ----- | # Sets Per Year(1) ----- |
|--------------------------|-----------------------------|
| First Contract Year | [*] |
| Second Contract Year | [*] |
| Third Contract Year | [*] |
| Fourth Contract Year | [*] |
| Fifth Contract Year | [*] |
| Sixth(2) Contract Year | [*] |
| Seventh Contract Year | [*] |
| Eighth Contract Year | [*] |
| Ninth Contract Year | [*] |
| Tenth Contract Year | [*] |
| Eleventh Contract Year | [*] |
| Twelfth Contract Year | [*] |
| Thirteenth Contract Year | [*] |
| Fourteenth Contract Year | [*] |

EXHIBIT B

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- (1) Purchase requirements and/or actual purchases for each Contract Year are independent of those for prior or succeeding years.
- (2) The minimum purchase requirements for the first through the fifth years determine Licensee's right to receive a paid-up exclusive license to Licensed Product and an option to license the Licensed Process. Beginning in the sixth year and continuing through the fifteenth year, the minimum purchase requirement each year will be the lower of either the minimum number of per year set forth in the second column above or the number valves sold and/or disposed of by any means by manufacturer. Amounts in excess of the minimum purchase requirements set forth in the second column above are not required to be purchased CMI in the sixth year and thereafter.
- [*] Denotes confidential information omitted pursuant to Rule 24b-2 of the Securities and Exchange Act of 1934, as amended. The Securities and Exchange Commission granted the company's confidential treatment request in connection with this information.

BASE PRICES

[*]

PRICE ADJUSTMENTS

The prices set forth on this Exhibit B are based upon the cost of manufacture of Components for the Valve as of the date of this Agreement. The base price for a Component Set as of the date of this Agreement is [*] adjusted to reflect volume discount. The actual sales price to Manufacturer will be adjusted for each 12-month period prior to the first Contract Year so that the first Contract Year reflects the impact of inflation, if any, between the date of this Agreement and the date of first sales under this Agreement with a pro rata adjustment of any period less than twelve months. To make such adjustment, CMI will use an inflation factor equal to the 12-month average percentage increase in employment costs for private industry workers (excluding farmers) as reported on Table 1 of the EMPLOYMENT COST INDEX published by the Bureau of Labor Statistics of the United States Department of Labor or, if the EMPLOYMENT COST INDEX should cease to be published, any comparable category in a comparable index agreeable to both parties. Such inflation factor will be that reported on the last day of the calendar quarter in which this Agreement is dated and on the anniversary of each such last day ("Adjustment Period(s)"). If the first Contract Year begins before the completion of an Adjustment Period, the inflation factor will be that reported on the last day of the last full calendar quarter before the start of the first Contract Year, adjusted pro rata.

EXHIBIT B

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- [*] Denotes confidential information omitted pursuant to Rule 24b-2 of the Securities and Exchange Act of 1934, as amended. The Securities and Exchange Commission granted the company's confidential treatment request in connection with this information.

L.D.C. CLAUSE

On purchasing a minimum of [*] non-L.D.C. valve sets per Contract Year, Manufacturer is eligible to purchase valve sets, sold for sale and implantation in less developed countries ("L.D.C.") at the price in effect at the time of purchase for purchases of [*] Component Sets or more. To permit verification of purchases eligible for L.D.C. pricing, Manufacturer will provide CMI with copies of valid purchase orders from hospitals or distributors, as applicable, together with written certifications by Manufacturer's Chief Executive Officer that such valve sets were sold to hospitals or distributors in and for the less developed country identified on the respective purchase order.

For purposes of this clause, less developed countries will be countries other than Canada, United States and Territories, Japan, South Korea, Australia, New

Zealand, South Africa, United Kingdom, Ireland, Norway, Sweden, Finland, Denmark, Netherlands, Belgium, Germany, France, Switzerland, Austria, Italy, Turkey, Spain, Portugal, and Luxemburg.

Transferring of valves purchased under the L.D.C. Clause into non-L.D.C. countries will be deemed a breach of this clause and allow for CMI's immediate cancellation of this clause from the Agreement. On cancellation, all pricing on orders in process for Manufacturer at CMI for L.D.C. valve sets will immediately revert to the standard price in effect for non-L.D.C. valve sets.

L.D.C. valve sets will apply against minimum purchase requirements, but will not apply toward quantity discount pricing in a Contract Year.

EXHIBIT B

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[*] Denotes confidential information omitted pursuant to Rule 24b-2 of the Securities and Exchange Act of 1934, as amended. The Securities and Exchange Commission granted the company's confidential treatment request in connection with this information.

RAW MATERIALS

AXF5Q-20W Graphite
AXFQ Graphite
Ti-6Al-4V ELI

EXHIBIT C

</TEXT>
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EXHIBIT 10.11

LICENSE AGREEMENT

This Agreement ("Agreement") is effective as of September 24, 1990, by and between CarboMedics, Inc., a Texas corporation with a place of business at 1300-B East Anderson Lane, Austin, Texas 78752 ("Licensor") and Helix BioCore, Inc., 3905 Annapolis Lane, Minneapolis, Minnesota 55447 ("Licensee").

WHEREAS Licensor has been instrumental in the development of a cardiac valve prosthesis and

WHEREAS Licensee desires to license the cardiac valve prosthesis and Licensor is willing to grant a license upon the terms and conditions contained in this Agreement and

WHEREAS Licensor and Licensee have entered into a supply contract (the "Supply Contract"), development agreement (the "Development Agreement") and option agreement all of even date herewith,

NOW, THEREFORE, in consideration of the premises and the faithful performance of the mutual covenants and obligations contained in this Agreement, the parties agree as follows:

Article I. Definitions

1.1 "Licensed Product" means a specific configuration of a bileaflet heart valve prosthesis embodying at least one of the claims of U.S.P.N. 4,692,165 (hereinafter called the "Patent") and having substantially flat leaflets and opposed pivot posts on an interior surface of an annular body of said heart valve, said pivot posts comprising spherical surface portions, each pivot post being receivable in a notch in a leaflet or constituent parts for such a bileaflet heart valve prosthesis. The Licensed Product will comprise leaflets as shown in Fig. 17 of the Patent and pivots as shown in Fig. 25 of the Patent.

1.2 CMI currently is the holder of U.S.P.N. 4,822,353 dated April 1, 1989 which utilizes some corresponding figure attachments used in U.S.P.N. 4,692,165. Licensee has no rights or claims to U.S.P.N. 4,822,353.

Article II. License Grant

2.1 In consideration of entering the Supply Contract and purchasing the Components (as defined in the Supply Agreement) required by the Supply Agreement, Licensor hereby grants to Licensee during the term of this Agreement the exclusive worldwide right and license to use and sell the Licensed Product and the right to assemble Components for the Licensed Product and sterilize and package the Licensed Product. This License does not include the right to sublicense or, except as provided in Section 2.3 below, the right to make or have made the Components for the Licensed Product. Nor does it include any inventions, patents, know-how, information, trade secrets, innovations and enhancements which the Licensor may have or acquire relating to the Licensed Product which is not disclosed in the Patent.

2.2 Licensee will use its best efforts to obtain all approvals necessary for marketing of the Licensed Product.

2.3 If Licensor or its successors or assigns should be unable or unwilling to manufacture Components for Licensee under the Supply Contract and Licensee and its successors and assigns are not in breach of any provisions of the Supply Contract, then Licensee will have the right and license to make or have made Licensed Product. Notwithstanding the foregoing, if the failure of Licensor to supply Components under the Supply Contract is the result of force majeure and within 18 months after the force majeure event Licensor is again able to supply all of Licensee's needs under the Supply Contract, then the license granted under this Section 2.3 will automatically terminate.

Article III. Assistance by Licensor

3.1 Licensee will actively pursue and be responsible for submitting IDE, 510(K) or PMA applications to the FDA and seeking such other regulatory approvals as are necessary to bring the Licensed Product to domestic and foreign markets for sale. Licensor agrees to use its best efforts to assist Licensee in responding to any questions which the FDA or other applicable regulatory agency may have regarding the manufacture of the Components for the Licensed Product.

3.2 Licensee covenants and agrees that during the term of this Agreement it will use its best efforts to sell and market the Licensed Product. In furtherance of its best efforts commitment set forth above, Licensee agrees to conduct all material, performance, and histological tests and studies reasonably required to support the development and sale of the Licensed Product, including an application for pre-market approval from the U.S. F.D.A. Licensee agrees to meet such standards in developing, manufacturing, and marketing the Licensed Product as are reasonable and customary in the industry.

Article IV. Patents

4.1 In the event Licensor wishes to discontinue the maintenance of the Patent on the Licensed Product, timely notice will be given to Licensee and Licensee will have the right to continue such maintenance at its own expense.

Article V. Term and Termination

5.1 The term of this Agreement will commence on the date first hereinabove set forth and continue until the expiration of the fifth Contract Year as defined in the Supply Agreement unless Licensee fails to meet the minimum purchase requirements for any year as set out in the Supply Agreement in which event Licensor will have the option, immediately upon notice, to terminate this entire Agreement or to terminate that portion of this Agreement which gives Licensee exclusive rights in and to the Licensed Product. Upon expiration or rightful termination of this Agreement by Licensee, Licensee will have a paid-up, exclusive license in and to the Licensed Product.

5.2 In the event that either party breaches any of the terms of this Agreement, (except failure to meet minimum purchases which will be governed by section 5.1 above) the non-breaching party will notify the other party in writing of the nature of the breach. The breaching party will have 3 months from the date of such notice to correct such breach. Upon failure to correct the breach within said 3-month period, the non-breaching party will have the option to terminate the Agreement by written notice of termination to the breaching party.

5.3 Should Licensee discontinue the development program or, after initial commercialization, the sale of the Licensed Product, or fail to submit an IDE application to the U.S. F.D.A. within three Contract Years as defined in the Supply Agreement, Licensor may terminate this Agreement by giving Licensee 30 days written notice.

Article VI. Infringement Claims

Should any action be commenced against Licensor or Licensee which alleges that the Licensed Product infringes the claims of any Letters Patent or that the patent on the Licensed Product is invalid, the Licensee will have the right but not obligation, to defend and settle such action. If Licensee fails or refuses to defend or settle such action, then Licensor will have the right to defend or settle it. The party not defending or settling such action will cooperate with the other party in any manner reasonably requested for such defense and/or settlement, at the expense of the party defending or settling such action.

Article VII. Third Party Infringement

Should any Letters Patent licensed hereunder be infringed by a third party by virtue of a product substantially similar to the Licensed Product, the Licensee will have the right but not the obligation to prosecute any such action at its own expense and retain any money collected through such action. Notwithstanding the foregoing Licensor will have the right to prosecute an action at its own expense if Licensee fails or refuses to do so or if some product other than one substantially similar to the Licensed Product should infringe the Patent and retain any money collected from such action.

Article VIII. Indemnification

Licensee agrees to be solely responsible for and to defend and indemnify Licensor and to hold it harmless from any and all demands, claims, causes of action, or damages including attorneys fees and expenses, arising out of, resulting from or related to the design, manufacture, sale, distribution, implantation or use of Licensed Product, regardless of whether the damages are caused in whole or in part by the negligence of Licensor. It is the express intention of the parties hereto, both Licensor and Licensee, that the indemnity obligations and liabilities assumed by Licensee in this paragraph be without monetary limit and without regard to causes thereof including but not limited to any failure to warn, strict liability, or the negligence of Licensor its officers, agents or employees, whether the negligence be sole, point, or concurrent, active or passive. This indemnity will survive expiration or termination of this Agreement and will be applicable to all claims regardless of the legal theory on which they are based including, but not limited to, claims of Licensor's negligence, breach of warranty, strict liability, and violation of statute or government regulations, but excluding claims that the Licensed Product infringes the patent of another.

Article IX. Notices

9.1 Any notice or communication to be given under this Agreement will be sent certified mail, postage prepaid to the following addresses:

Licensor: CarboMedics, Inc.
1300-B East Anderson Lane
Austin, Texas 78752
Attention: President

With a copy to: Intermedics, Inc.
Post Office Box 4000
Angleton, Texas 77515-4000
Attention: General Counsel

Licensee: Helix BioCore, Inc.
3905 Annapolis Lane
Minneapolis, Minnesota 55447
Attention: President

9.2 Each party will have the right to change its address upon written notice of its new address to the other party.

Article X. Miscellaneous

10.1 Neither Licensee nor Licensor will assign this Agreement without the prior written consent of the other party. Notwithstanding the foregoing, either party may freely assign this Agreement to any entity controlling, controlled by or under common control with that party or succeeding to the entire business of that party.

10.2 This Agreement, together with the Development, Supply and Option Agreements, contains the entire agreement between the parties with respect to the subject matter. No waiver, alteration or modification of any of the provisions hereof will be binding unless in writing and signed by the parties hereto. No waiver will be implied or continuing.

10.3 Nothing in this Agreement will be deemed or construed to constitute or create between the parties a partnership, joint venture or agency.

10.4 This Agreement will be governed by the laws of the State of Texas.

10.5 Should any provision of this Agreement be rendered unlawful or invalid because of any existing or subsequently enacted law or by a decree or order of a court of last resort, the remaining provisions will continue in full force and effect.

10.6 Licensee will cause all packages containing Licensed Product to be marked with the legend, "Mfd. under Lic. U.S. Pat. 4,692,165."

IN WITNESS WHEREOF, the undersigned have caused this Agreement to be executed and delivered as of the date first hereinabove set forth.

LICENSOR:

CARBOMEDICS, INC.

By: /S/ Terry Marlatt
Terry Marlatt, President

LICENSEE:

HELIX BIOCORE, INC.

By: /S/ M.A. Villafana

Title: CEO

Printed Name: M.A. Villafana

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OPTION AGREEMENT

This Agreement ("Agreement") is effective as of September 24, 1990, by and between CARBOMEDICS, INC., ("Licensor") and HELIX BIOCORE, INC. ("Licensee").

WHEREAS Licensor and Licensee entered into certain development, supply and license agreements of even date herewith respectively called the "Development Agreement", the "Supply Agreement" and the "License Agreement" and

WHEREAS Licensee desires to acquire an option to license certain technology and Licensor is willing to grant an option and license upon the terms and conditions contained in this Agreement,

NOW, THEREFORE, in consideration of the premises and the faithful performance of the mutual covenants and obligations contained in this Agreement, the parties agree as follows:

ARTICLE I. Definitions

1.1 "Licensed Process" means the patents, trade secrets, know-how and other technology necessary to manufacture the Licensed Product as defined in the License Agreement.

ARTICLE II. Option

2.1 Licensor hereby grants to Licensee, on the terms and conditions set forth in this Agreement, an option to acquire a non-exclusive worldwide right and license to use the Licensed Process. Provided that Licensee has met the minimum purchase requirements set forth in the Supply Agreement for the first five Contract Years, the "Option Period" will be the period beginning upon completion of the fifth Contract Year (as defined in the Supply Agreement) and ending upon expiration or termination of the Supply Agreement for any reason. If Licensee fails to meet the minimum purchase requirements for any of the first five Years, this Option may be terminated at Licensor's election. If this option is exercised, the minimum purchase requirements on Exhibit B of the Supply Contract will be terminated effective as of the date the license fee provided in Section 3.3 of this Agreement is paid in full to Licensor. If Licensee elects to have components to the product manufactured by anyone other than CMI during the term of the Supply Contract, then this option may be terminated at CMI's election. Licensee may exercise this option by delivering to Licensor during the Option Period a written notice stating that Licensee elects to exercise the option and whether it wishes Licensor to build the Production Line described in Article III (the "Notice") together with the license fee or initial payment as applicable. The Notice will be effective on the date Licensor receives such Notice and fee at which time the provisions of the license set forth in Article III below will apply and come into full force and effect.

2.2 If, on or before the expiration or termination of the Option Period, Licensee does not deliver to Licensor the Notice or fee, the option will expire or be terminated and be of no further force or effect. If the option expires or is terminated, Licensee will have no right, claim or interest in or to the Licensed Process, this Agreement will immediately terminate and be of no further force and effect and neither party will have any further obligation to the other party under this Agreement.

ARTICLE III. License

3.1 Effective upon exercise of the option provided in Article II of this Agreement, Licensor hereby grants to Licensee the nonexclusive worldwide right and license to use the Licensed Process, subject to rights, if any reserved by General Atomic. This license expressly excludes the right to sublicense and the right to permit others to use the Licensed Process for any reason whatever. This license further is limited to the right to use the Licensed Process only to the extent necessary to manufacture for use and sale the Licensed Product as defined in the License Agreement. Licensee will have the obligation to obtain all approvals necessary for manufacture and marketing of products using the Licensed Process.

3.2 Licensor agrees, at Licensee's election which must be made at the time the Notice is given, to build or cause to be built a state-of-the art component manufacturing production line (the "Production Line") which will be substantially equivalent to its own component manufacturing production line. Licensor will prove out and supervise the operation of the Production Line until it is fully operational and producing components to target yields and direct labor hours comparable to its own for the Licensed Product.

3.3 In consideration of the license granted herein, Licensee will pay Licensor a one-time license fee of [*] payable either a) in full upon exercise of the option if Licensee does not elect to have Licensor build the Production Line or

b) if Licensee elects to have Licensor build the Production Line, as follows: [*] upon exercise of the option; during construction, progress payments amounting to a total of [*] payable in three installments over the course of construction, [*] each at: [*] respectively, of completion as agreed to; and upon completion of construction and the turning over to Licensee of the Production Line, a final fee of [*].

[*] Denotes confidential information omitted pursuant to Rule 24b-2 of the Securities and Exchange Act of 1934, as amended. The Securities and Exchange Commission granted the company's confidential treatment request in connection with this information.

3.4 In addition to the license fee provided for above, Licensee will pay Licensor for all expenses incurred by Licensor in providing assistance to Licensee, including direct material and labor expenses, as such expenses are incurred. Licensee will be responsible for purchasing all equipment and paying for all reasonable start up costs as incurred required for the construction of such Production Line as reasonably determined by Licensor. All amounts payable under this Section 3.4 will be due upon receipt of invoice from Licensor. Amounts due and payable will bear interest at the maximum rate allowed by law from and after the thirtieth day after receipt of invoice.

ARTICLE IV. Patents

4.1 Licensee will have the right to file a patent application or applications relating to developments or improvements it has made related to the Licensed Process in the United States or any foreign country at its own expense. Licensee will have no right, however, to file patent application(s) on the Licensed Process itself or any part of it.

4.2 If Licensee wishes not to file or to discontinue the prosecution or maintenance of any patent or patent application related to the Licensed Process, timely notice will be given to Licensor and Licensor will have the right to continue such prosecution or maintenance at its own expense.

ARTICLE V. Term and Termination

5.1 This Agreement will commence on the date first hereinabove set forth.

5.2 In the event that either party breaches any of the terms of this Agreement, the non-breaching party will notify the other party in writing of the nature of the breach. The breaching party will have 3 months from the date of such notice to correct such breach. Upon failure to correct the breach within said 3-month period, the non-breaching party will have the option to terminate the Agreement.

5.3 Should Licensee discontinue the use of the Licensed Process or sale of the Licensed Product, Licensor may terminate this Agreement by giving Licensee 30 days written notice.

ARTICLE VI. Third Party Infringement

Should any Letters Patent licensed hereunder be infringed by a third party by virtue of a process substantially similar to the Licensed Process, the Licensee will have the right but not the obligation to prosecute any such action in the name of the Licensor but at its own expense.

ARTICLE VII. Indemnification

Licensee agrees to be solely responsible for and to defend and indemnify Licensor and to hold him harmless from any and all demands, claims, causes of action, or damages including attorneys fees and expenses, arising out of, resulting from or related to the use of Licensed Process and any products manufactured, sold or distributed by Licensee. This obligation will survive termination of this Agreement and will be applicable to all claims regardless of the legal theory on which they are based including, but not limited to, claims of negligence, breach of warranty, strict liability, and violation of statute or government regulations.

ARTICLE VIII. Notices

8.1 Any notice to be given under this Agreement will be sent certified mail, postage prepaid to the following addresses:

| | |
|---------------|---|
| Licensor: | CarboMedics, Inc. 1300-B East Anderson Lane Austin, Texas 78752 Attn: President |
| With copy to: | Intermedics, Inc. P.O. Box 4000 Angleton, Texas 77515-4000 Attn: General Counsel |
| Licensee: | Helix BioCore, Inc. 3905 Annapolis Lane Minneapolis, Minnesota 55447 |

Attn: President

8.2 Each party will have the right to change its address by giving at least 10 days prior written notice of its new address to the other party.

ARTICLE IX. Miscellaneous

9.1 Neither party may assign or sublicense this Agreement without the prior written consent of the other party which consent may be withheld absolutely in the other party's sole discretion. Notwithstanding, either party may freely assign this Agreement to any entity controlling, controlled by or under common control with that party.

9.2 Because it is contemplated that Licensor will be transferring to Licensee confidential and proprietary information in connection with its obligations hereunder, Licensee agrees to hold all such confidential information in strict confidence and to afford it the same protection that Licensor uses for protecting its confidential proprietary information as directed by Licensor.

9.3 This Agreement contains the entire agreement between the parties with respect to the subject matter. No waiver, alteration or modification of any of the provisions hereof will be binding unless in writing and signed by the parties hereto. No waiver will be implied or continuing.

9.4 Nothing in this Agreement will be deemed or construed to constitute or create between the parties a partnership, joint venture or agency.

9.5 The headings or captions of the paragraphs of this Agreement are inserted for convenience only and will not be deemed a part hereof or used in the construction or interpretation hereof.

9.6 This Agreement will be governed by the laws of the State of Texas.

9.7 Should any provision of this Agreement be rendered unlawful or invalid because of any existing or subsequently enacted law or by a decree or order of a court of last resort, the remaining provisions will continue in full force and effect.

IN WITNESS WHEREOF, the undersigned have caused this Agreement to be executed and delivered as of the date first hereinabove set forth.

LICENSOR

LICENSEE

CARBOMEDICS, INC.

HELIX BIOCORE, INC.

By: /S/ Terry Marlatt,
Terry Marlatt, President

By: /S/ M.A. Villafana

Printed Name: M.A. Villafana

Title: CEO

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HELIX BIOCORE, INC.

SELF-INSURANCE
TRUST AGREEMENT

This Agreement is made as of this 28th day of February, 1991, by and between Helix BioCore, Inc. a Minnesota corporation ("HBI") and Richfield Bank & Trust Co. ("Trustee").

WHEREAS, HBI desires to indemnify its past and present directors and officers, as listed on Exhibit A (the "Beneficiaries"), against liability claims and expenses which they may become obligated to pay as a result of wrongful acts or omissions or alleged wrongful acts or omissions arising out of duties which they performed for HBI in their official capacity; and

WHEREAS, as of the effective date of this Agreement, commercial insurance coverage is prohibitively expensive and inadequate; and

WHEREAS, qualified directors and officers would be unwilling to serve in such capacities without adequate assurances of protection from such claims; and

WHEREAS, HBI desires to contribute to a trust fund assets sufficient to pay all expenses incurred in investigating, settling and defending against such claims and amounts due from such claims or to use such funds to purchase insurance to provide protection against said claims and expenses arising therefrom for the Beneficiaries; and

WHEREAS, the Trustee is willing to receive and to hold such assets in trust in accordance with the terms and conditions of this Agreement;

THEREFORE, the parties agree as follows:

ARTICLE I

ESTABLISHMENT OF TRUST

1.1 Purpose of Trust. HBI hereby establishes this Trust for the purposes of (a) indemnifying Beneficiaries in accordance with, and to the fullest extent permissible under, the provisions of the Minnesota Business Corporation Act, as it may from time to time be amended, and (b) paying officers and directors liability insurance premiums, and hereby delivers to the Trustee the sum of \$200,000, to be held in a fund (the "Trust Fund") for the benefit of the Beneficiaries in accordance with the terms of this Trust Agreement. HBI may deliver additional funds to the Trustee from time to time to be similarly held.

1.2 Initial Contribution. The Trustee acknowledges receipt of the initial \$200,000 contribution and agrees to hold, invest and reinvest such assets as HBI may from time to time pay over, together with any income and earnings thereon, in trust for the purposes stated herein in accordance with the terms and conditions of this Agreement.

1.3 Contract Rights. The rights of the Beneficiaries under this Trust are contract rights based upon good and valuable consideration and shall be enforceable the same as if the provisions hereof were set forth in a separate written contract between HBI and each Beneficiary. It is expressly intended that the indemnification provided hereunder shall extend to derivative actions against officers or directors that otherwise qualify for indemnification pursuant to the Minnesota Business Corporation Act.

ARTICLE 2

CONSENT

2.1 Consent Defined. Wherever Consent is required in this Agreement, Consent shall be defined as follows:

- (a) HBI shall obtain a majority vote, approving the proposed action, of each of two classes of Beneficiaries, namely, current directors and officers of HBI (Class 1) and past directors and officers of HBI (Class 2).
- (b) The following Beneficiaries shall be excluded from such classes and shall not be entitled to vote under this Article:
 - (i) Heirs and personal representatives of deceased officers and directors;
 - (ii) Mentally incompetent Beneficiaries;

(iii) Beneficiaries who cannot be located through the notice procedures described in Section 8.7 and after additional reasonable efforts;

(iv) Beneficiaries who do not respond to a notice requesting Consent by the time designated in the notice; and

(v) If payment of a claim is involved, a Beneficiary on whose behalf the claim would be paid.

- (c) Class 2 shall not be entitled to vote on any Consent issues until it contains at least 5 members, after the exclusions in (b) above

2.2 Notice. HBI, when seeking Consent as required in this Agreement, shall notify all Beneficiaries eligible to vote, in accordance with Section 8.7, providing said Beneficiaries with a reasonable time in which to respond. The Beneficiaries shall respond with notice of approval or disapproval within the time limits set out in the notice.

2.3 Certificate of Consent. HBI shall promptly certify to the receipt or non-receipt of such Consent upon written request of any party to this Trust Agreement.

ARTICLE 3

BENEFICIARIES

3.1 Date of Coverage. New directors and officers of HBI shall become Beneficiaries under this Trust Agreement and shall be listed on Schedule A upon election as a director or officer of HBI. Beneficiary status shall last for the duration of the Trust Agreement unless a Beneficiary elects out, in accordance with Section 3.3 below.

3.2 Heirs and Representatives of Beneficiaries. The term Beneficiary shall include heirs and representatives of deceased past directors and officers against whom claims have been brought for wrongful acts or omissions arising out of official duties performed for HBI.

3.3 Election Out of Coverage. Any past or present officer or director may elect to not become a Beneficiary under this Trust Agreement. Written notice of election out of Beneficiary status shall be delivered to the Trustee and to HBI and shall be effective upon receipt of such notice by the Trustee.

3.4 Process of Indemnification. A Beneficiary seeking indemnification under this Agreement shall submit to HBI a certificate containing the following information:

- (a) a description of the nature of the claim for which a right to receive payments hereunder is asserted and the identity of the persons who have made or threatened the claim;
- (b) copies of all papers served on the Beneficiary in connection with the claim;
- (c) a written undertaking satisfactory to HBI to repay to the Trust any amounts paid or applied to or for the use of the Beneficiary pursuant to this Trust in the event a determination is made by the Trustee that under applicable law payments to the Beneficiary are not lawful and proper in the circumstances; and
- (d) a written undertaking satisfactory to HBI to keep HBI fully informed of the progress of the claim and to deliver promptly to HBI copies of all pleadings and other material documents in relation to the proceeding.

3.5 Certificate and Payment of Claim. A certificate delivered pursuant to Section 3.4 shall be approved or disapproved in accordance with paragraph 5.1(c) and, if approved, paid in accordance with paragraphs 4.1(d), (e) and (f).

ARTICLE 4

DUTIES AND POWERS OF TRUSTEE

4.1 Trustee Duties.

- (a) General Duty. To discharge the duties with respect to this Trust solely in accordance with the terms and conditions of this Trust Agreement for the purposes of indemnifying Beneficiaries in accordance with the standards set out in this Trust Agreement and paying directors and officers liability insurance premiums.
- (b) Establishment of Trust Fund. To establish a fund from which to pay amounts described in (a). The Trustee shall deposit in said fund all cash, cash equivalents such as certificates of deposit and marketable government securities, and notes contributed thereto by HBI.

- (c) Investment. To invest and reinvest the trust funds only in Authorized Investments. "Authorized Investments" shall consist only of the following:
- (i) Obligations issued or guaranteed by the United States Government, including obligations issued by its agencies or by its instrumentalities;
 - (ii) Obligations (such as time deposits, Euro dollar time deposits, letters of credit, certificates of deposit, and bankers' acceptances) of commercial banks, savings banks and savings and loan institutions participating in the FDIC or FSLIC and organized under and regulated by the United States Government and/or the State of Minnesota, including the Trustee itself, and provided that total principal and accrued income invested in any such obligation shall at no time exceed the insured limit of such obligation;
 - (iii) Money market funds whose funds are solely invested in obligations described in paragraph (i) or (ii) above;
 - (iv) In exercising its investment authority with respect to the Authorized Investments listed above, the Trustee shall consider safety of principal, ready marketability and interest yields (in that order) and may make purchases and sales of investments through its own bond department.
- (d) Payment of Claims. To pay amounts from the Trust Fund, consistent with the purposes stated in paragraph 1.1 as follows: Upon receipt of a written notice of approval of a claim by HBI or the arbitrator specified in Section 5.1(c) of this Trust Agreement, the Trustee shall pay to the Beneficiary from the Trust Fund the amount specified in the written notice. In the event that the amount of cash held in the Trust Fund is insufficient to make any payment required pursuant to this Trust Agreement, the Trustee shall sell investments in the Trust Fund so that the cash in the Trust Fund is sufficient to make such payments.
- (e) Notification of Insufficient Assets. If the Trustee is instructed, in accordance with Section 4.1(d), to pay claims and the assets in the Trust Fund are insufficient to pay all of such claims, the Trustee shall immediately give written notice to HBI and to the Beneficiary or Beneficiaries whose claims are unpaid, of its inability to pay. HBI shall respond to such notification in accordance with subparagraph 5.2(a).
- (f) Priority of Claims. If the Trustee has two or more claims and insufficient assets in the Trust Fund to satisfy all claims, then the Trustee shall pay the claims according to written instructions drafted by an authorized representative of HBI, approved in accordance with the Consent procedures described in Article 2. If no agreement is reached, the priority of claims and division of funds in the Trust shall be submitted to binding arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association, as then in effect, with instructions for the arbitrator to make a decision based on the following factors. First, the arbitrator shall determine if any Beneficiary has significantly greater culpability for the underlying loss and, if so, such Beneficiary's claim shall be the first to be reduced. If there still is insufficient assets or there is a determination that no beneficiary had significantly greater culpability, the reduction shall be pro rata in accordance with each of the remaining Beneficiary's loss. The decision of the arbitrator shall be binding and conclusive on the parties and HBI shall pay the costs of the arbitration, not including the costs of counsel for the Beneficiaries.
- (g) Payment of Insurance Premiums. Provided HBI obtains Consent, the Trustee shall pay directors and officers liability insurance premiums to a commercial insurer selected by HBI in accordance with instructions from an authorized representative of HBI.
- (h) Recordkeeping. The Trustee shall keep accurate records of the operation of the Trust, including instructions to the Trustee from HBI as to payments to be made from the Trust, which shall be available for inspection during regular business hours at the principal office of the Trustee by authorized representatives of HBI or by any Beneficiary. The Trustee shall not be responsible for keeping records of claims information submitted by Beneficiaries; such records shall be maintained by HBI, as provided in Section 5.1(d).

- (i) Accounting. No later than 60 days after the end of each calendar year (which is the fiscal year of the Trust and of HBI) and after the end of each quarter therein, to forward a financial statement to HBI stating the balance in the Trust Fund at the beginning and end of the period, current period contributions, investments and reinvestments, activities of the Trust, the amount and nature of all payments including final payments and those for claims management, legal expenses, claims paid and the like, together with the Trust Fund balance. The first financial statement will be for that portion of the calendar quarter year extending from the date of establishment of the Trust to the following March 31st. The Trustee shall make such statements available for review by any Beneficiary listed on Schedule A or a legal representative thereof, upon advance written notice to the Trustee and during the Trustee's regular business hours.

4.2 Trustee Powers.

- (a) Exclusive Duties. The provisions of this Agreement set forth exclusively the duties of the Trustee with respect to any and all matters pertinent hereto and no implied duties or obligations shall be read into this Trust Agreement against the Trustee.
- (b) Indemnity. The Trustee shall be indemnified and held harmless by HBI against any and all costs, liabilities and expenses (including expenses of litigation and counsel fees) incurred by it with respect to payments made by reason of any action or omission to act by the Trustee in good faith under this Trust Agreement or otherwise incurred in good faith by the Trustee, except such as arise from the negligence or misconduct of the Trustee. The Trustee shall be under no obligation to institute or defend any action, suit or proceeding in connection with this Trust Agreement unless first indemnified to its satisfaction. The Trustee may consult counsel in respect of any question arising under this Agreement and the Trustee shall not be liable for any action taken or omitted in good faith upon advice of such counsel.
- (c) Reliance. The Trustee may conclusively rely upon and be protected in acting upon any statement, certificate, notice, request, consent, order or other document believed by it to be genuine and to have been signed or presented by the proper party or parties.
- (d) To Employ Agents and Attorneys. The Trustee may select and employ or retain such agents or attorneys as the Trustee from time to time may deem necessary or advisable in connection with the management and operation of the Trust herein created, and pay the reasonable fees, commissions, or salaries incurred on account thereof as an expense of administration of the Trust.
- (e) Compensation. The Trustee shall receive an annual administrative fee of two hundred fifty dollars (\$250) plus seven-tenths of one percent (.7%) of the Trust assets, valued as of December 31 of each year. Said fees shall be paid by HBI or if HBI fails to so pay, said fee shall be chargeable to, and constitute a direct charge against, the Trust Fund. Fee schedules are subject to annual review and adjustment, reasonably acceptable to both parties.

ARTICLE 5

DUTIES AND POWERS OF HBI

5.1 HBI Duties.

- (a) Funding. HBI shall, contemporaneously with the execution of this Agreement and in accordance with the Assignment (Exhibit B), transfer to the Trustee \$200,000 in cash, cash equivalents or securities, as the initial funding of the Trust. HBI in its discretion may make additional periodic contributions of cash, cash equivalents or securities to the Trust. Each such contribution shall be accompanied by an Assignment (Exhibit B).
- (b) Notification of Potential Claims. HBI shall notify the Trustee of any potential claims by Beneficiaries as soon as it is aware of such potential claims.
- (c) Approval and Certification of Claims. The Board of Directors of HBI shall appoint (1) a member or committee of said Board (not including any director making a claim) or (2) special independent legal counsel, to approve and certify claims of certifying Beneficiaries pursuant to the provisions of this

Trust Agreement. Written notice of approval or denial of each claim shall be given to the Beneficiary within 30 days of receipt of the claim. If such appointed representative rejects a claim as not within the indemnification provisions of this Trust Agreement, the claimant may request in writing, within 30 days of such denial, arbitration of the claim as follows: The American Arbitration Association shall be asked to appoint an arbitrator to rule on the matter in accordance with its Commercial Arbitration Rules, as then in effect. The decision of the Arbitrator shall be binding and conclusive upon the parties and HBI shall pay the costs of the arbitration, not including any costs of counsel for the Beneficiary, unless the Beneficiary is successful in the arbitration.

- (d) Recordkeeping. HBI shall maintain records of all claims data submitted by Beneficiaries for payment and shall make such data available for inspection during regular business hours by any Beneficiary.
- (e) Authorized Representatives. HBI shall provide the Trustee with a list of authorized representatives empowered to instruct the Trustee as to all matters listed herein which require instructions from an authorized representative of HBI.
- (f) Accounting. HBI shall provide the Trustee's year end accounting statement to each Beneficiary and shall make all accountings available for review by any Beneficiary or by such Beneficiary's legal representative, upon advance written notice to HBI and during HBI's regular business hours.

5.2 HBI Powers.

- (a) Insufficient Assets. Upon receipt of Notification of Insufficient Assets by the Trustee in accordance with subparagraph 4.1(e), HBI shall have the option to:
 - (i) Pay all or a portion of outstanding claims and contribute a sum to the Trust Fund sufficient to enable the Trust to continue in operation; or
 - (ii) Pay all or a portion of outstanding claims and terminate the Trust according to the procedures set out in paragraph 7.1(b); or
 - (iii) Seek payment from any insurer whose policy might cover said claims; or
 - (iv) If it is unable to satisfy the claims under (i), (ii) or (iii), not pay the claims and terminate the Trust in accordance with paragraph 7.1(a).
- (b) Insurance. Provided it has obtained Consent, HBI may direct the Trustee to pay insurance premiums to a commercial insurer for directors and officers liability insurance premiums in accordance with subparagraph 4.1(g).

ARTICLE 6

RESIGNATION OR REMOVAL OF TRUSTEE

6.1 Resignation. The Trustee may resign from this Trust Agreement, and thereby become discharged from the obligations hereby created other than its duty to account, by notice in writing given to HBI no less than 60 days before such resignation is to take effect, but such resignation shall take effect immediately upon the substitution of a new trustee hereunder if such new trustee shall be substituted before the time indicated by such notice and shall then accept in writing the obligations thereof. If a successor trustee is not appointed within said 60 days, the Trustee may petition any court of competent jurisdiction to appoint a successor.

6.2 Removal. HBI may at any time, with Consent, remove the Trustee by giving written notice to the Trustee, to be effective upon the substitution of a new trustee hereunder. Such substitution, as evidenced by the written acceptance of the successor trustee, shall occur no later than 60 days from the date of notice of removal.

6.3 Successor Trustee Appointment. If, at any time hereafter the Trustee shall resign, be removed, be dissolved or otherwise become incapable of acting, or the bank or trust company acting as Trustee shall be taken over by any governmental official, agency, department or board, the position of the trustee shall thereupon become vacant. If the position of trustee shall become vacant for any of the foregoing reasons or for any other reason, HBI shall appoint a successor trustee to fill such vacancy, with Consent. Upon substitution of the Trustee, a statement of accounts shall be rendered by the Trustee to HBI.

6.4 Obligations on Change of Trustee. Every successor trustee appointed hereunder shall execute, acknowledge and deliver to its predecessor and to HBI an instrument in writing accepting such appointment hereunder, and thereupon such successor trustee, without any further act, shall become fully vested with all the rights, immunities, and powers, and subject to all of the duties and obligations, of its predecessor; but such predecessor shall, nevertheless, on the written request of its successor, and upon payment of the expenses, charges and other disbursements of such predecessor which are payable pursuant hereto, execute and deliver an instrument transferring to such successor trustee all the rights, immunities and powers of such predecessor hereunder; and every predecessor trustee shall deliver all property and monies held by it hereunder to its successor. Should any instrument in writing from HBI be required by any successor for more fully and certainly vesting in such trustee the rights, immunities and powers hereby vested or intended to be vested in the predecessor trustee, any such instrument in writing shall and will, on request, be executed, acknowledged and delivered by HBI.

ARTICLE 7

EXTENSION, AMENDMENT AND TERMINATION OF TRUST

7.1 Extension, Amendment and Termination. Except as set forth in subparagraphs (a), (b) and (c) below, this Trust Agreement shall be irrevocable, including, without limitation, by HBI.

- (a) Extension. The Trust term may be extended by HBI with Consent, provided, however, that the Trust term shall not be extended beyond 21 years after the death of the last surviving director or officer serving as of the date of this Agreement.
- (b) Amendment. The Trust Agreement may be amended by HBI, with the consent of two-thirds of each class of Beneficiaries described in paragraph 2.1(a), if needed at any time to bring it into compliance with any applicable statutory or case law or governmental regulations.
- (c) Termination. This Trust Agreement may be terminated in accordance with the provisions of this subparagraph.
 - (i) The Trust may be terminated at any time for the following reasons:
 - (A) HBI is dissolved or liquidated as a corporate entity; or
 - (B) Less than \$50,000 in funds remains in the Trust and HBI does not intend to further fund the Trust; or
 - (C) There is a Change in Control of HBI defined as follows:
 - (1) For purposes of this Article, "Change in Control" shall mean a change in control which would be required to be reported in response to item 5(f) on Schedule 14A of Regulation 14A promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), whether or not HBI is then subject to such reporting requirement, including, without limitation, if:
 - (I) Any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes a "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of HBI representing 30% or more of the combined voting power of HBI's then outstanding securities; or
 - (II) There ceases to be a majority of the Board of Directors comprised of individuals described in (III) below.
 - (III) For purposes of this subsection (1), "Board of Directors" shall mean: (A) individuals who on the effective date hereof constituted the Board of HBI; and (B) any new director who subsequently was elected or nominated for election by a majority of the directors who held such office immediately prior to a Change in Control.
 - (2) Change in Control shall also mean the

commencement of any insolvency proceeding by or against HBI including the appointment of a receiver.

- (ii) The Trust may be terminated for a reason listed in (i) in accordance with the following rules:
 - (A) If the Trust Fund contains less than \$50,000 in assets or if HBI is able to obtain liability insurance for directors and officers covering all acts up to the date of termination for six years following termination, HBI may terminate the Trust, provided it has obtained Consent. HBI shall give 60 days advance written notice of termination to the Trustee and to all Beneficiaries.
 - (B) If Trust Fund assets total \$50,000 or more, the Trust shall go into frozen status for six years. HBI shall give 60 days advance written notice of frozen status to the Trustee and to all Beneficiaries. Frozen status shall mean that no new Beneficiaries will be added to Exhibit A. During the six-year frozen status period, the Trustee will pay duly certified claims which are based upon acts or omissions occurring both prior and subsequent to the date of notice of frozen status. At such time as the Trust Fund is depleted of all assets, the Trust shall terminate, even if prior to the expiration of the six-year period.
- (iii) If this Trust Agreement has not terminated in accordance with (i) and (ii) above by December 31, 2000, or if the Trust term has not been extended in accordance with paragraph 7.1(a), then the following rules shall apply:
 - (A) If the Trust Fund contains less than \$50,000 in assets as of December 31, 2000 or HBI obtains Consent, then HBI may terminate the Trust as of December 31, 2000, upon 60 days advance written notice to all Beneficiaries and to the Trustee.
 - (B) If Trust Fund assets total \$50,000 or more as of December 31, 2000, the Trust shall go into frozen status for six years as described in subsection (ii) (B) above.
- (iv) Upon termination of this Trust Agreement, any assets remaining in the Trust Fund shall be distributed in the following order of priority:
 - (A) To HBI; or
 - (B) If HBI is in voluntary or involuntary bankruptcy as of that date, to the trustee in bankruptcy; or
 - (C) If HBI shall have ceased to exist, then to the successor thereto, or, if more than one successor, then pro rata among such successors; or
 - (D) If there is no successor thereto, then to the HBI shareholders of record as of the date of notice of termination or notice of frozen status, whichever is applicable.
 - (E) If there are no shareholders, then to the State of Minnesota.

ARTICLE 8

MISCELLANEOUS

8.1 Spendthrift Provision. The Trust principal and income shall not be applied (a) to discharge the debts of HBI under any circumstances except as specifically provided in this Trust Agreement to satisfy HBI's obligation to indemnify its officers and directors, or (b) to discharge the debts of any Beneficiary, except as specifically provided in this Agreement. No Beneficiary shall have any power to sell, assign, transfer, encumber or in any other manner to anticipate or dispose of his or her interest in the Trust, or the income produced thereby, before distribution by the Trustee to said Beneficiary. Any distribution from the Trustee to a Beneficiary shall be used to satisfy the claims of creditors specified in the corresponding certificate submitted to the Trustee by the Beneficiary. HBI shall have no power to sell, assign, transfer, encumber or otherwise dispose of any Trust principal or interest, and no creditor of HBI shall have any right to or claim against Trust income or principal.

8.2 Binding Effect. This Trust shall be binding upon and inure to the benefit of the heirs, personal representatives, successors and assigns of all parties hereto.

8.3 Representations. No representations or warranties have been made by or shall be implied against or as to any party with respect to the facts or transactions upon which this Trust Agreement is based. The Trustee is and shall be independent.

8.4 Partial Invalidity. The invalidity or unenforceability of any provision of this Trust Agreement shall not affect the validity or enforceability of any other provision of this Trust Agreement, which shall remain in full force and effect.

8.5 Construction. Nothing in this Trust Agreement shall be construed to eliminate or modify the indemnification requirements of Minnesota law.

8.6 Complete Agreement. This Trust Agreement constitutes the entire understanding between the parties hereto with respect to the subject matter hereof, and no agreements or representations, verbal or otherwise, express or implied, other than those set forth expressly in this Trust Agreement have been made by any party hereto with respect to the subject matter hereof.

8.7 Notice. All certificates, notices, requests for Consent and otherwise, demands, instructions to the Trustee and other communications hereunder shall be in writing and shall be deemed to have been duly given if addressed and delivered or deposited in the United States mails by certified mail, return receipt requested, postage prepaid, to the parties as follows:

Helix BioCore, Inc.
3905 Annapolis Lane
Plymouth, Minnesota 55447
Attention: Chief Executive Officer

Richfield Bank & Trust Co.
6625 Lyndale Avenue South
Richfield, Minnesota 55423
Attention: Trust Department

8.8 Governing Law. This Trust Agreement shall be governed by, and construed in accordance with, the laws of the State of Minnesota.

8.9 Execution. This Trust Agreement is executed in multiple copies, each copy being an original counterpart and shall be deemed one and the same instrument.

IN WITNESS WHEREOF, the Trustee and HBI have caused this Trust Agreement to be signed as of the date and year first above written.

HELIX BIOCORE, INC.

By: /S/ M.A. Villafana

Its: Chairman and CEO

RICHFIELD BANK & TRUST CO.

By: /S/ Daniel E. Caswell

Its: Trust Officer

EXHIBIT A

NAMES AND ADDRESSES OF PAST AND PRESENT DIRECTORS AND OFFICERS

Manuel A. Villafana
1482 Hunter Drive
Medina, MN 55391

James F. Lyons
1179 West Burke Avenue
Roseville, MN 55113

Richard W. Kramp
1285 Karth Lake Circle
Arden Hills, MN 55112

Charles F. Cuddihy, Jr.
16993 Chilton Hill Road
Minnetonka, MN 55345

John S. Salstrom
1250 W. Minnehaha Parkway
Minneapolis, MN 55419

John R. Holroyd

6905 Limerick Lane S.
Edina, MN 55435

Niguel O. Villarejos
1749 N. Farm Road
Long Lake, MN 55356

John H. Junghauer
12122 Everton Avenue N.
White Bear Lake, MN 55110

Howard C. Root
4128 Beard Avenue South
Minneapolis, MN 55410

Thierry Hermann
Fournitures Hospitalieres
Z.A. de Mulhouse-Heimabrunn
B.P. 9
68990 Heimsbrunn
FRANCE

David L. Boehnen
71 Otis Lane
St. Paul, MN 55104

Frank H. Voigt
5036 Belmont Avenue South
Minneapolis, MN 55419

Joel D. Hixson
225 Forest View Lane
Plymouth, MN 55441

EXHIBIT B

ASSIGNMENT

Helix BioCore, Inc., a Minnesota corporation ("HBI") hereby transfers to Richfield Bank & Trust Co. (the "Trustee") the sum of Two Hundred Thousand Dollars (\$200,000) to be held by the Trustee pursuant to the Helix BioCore, Inc. Self-Insurance Trust Agreement dated February 28, 1991 (the "Trust Agreement"). The Trustee undertakes to hold and invest the funds transferred hereby in accordance with the terms of the Trust Agreement and to keep such funds separate and free from any claim, interests or judgments of the Trustee or any person claiming an interest through the Trustee.

Dated: March 18, 1991

HELIX BIOCORE, INC.

By: /S/ Howard C Root

Its: Secretary and General Counsel

RICHFIELD BANK & TRUST CO.

By: /S/ Daniel E. Caswell

Its: Trust Officer

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AMENDMENT NO. 5
TO
LEASE AGREEMENT

This Amendment No. 5 is made and entered into this 30th day of May, 1996 by and between St. Paul Properties, Inc., (a Delaware corporation), (as "Landlord") and ATS Medical, Inc., (a Minnesota corporation), (as "Tenant").

W I T N E S S E T H:

WHEREAS, Crow-Plymouth Land Limited Partnership and Tenant are the parties to that certain lease agreement dated December 22, 1987 (the "Lease") with regard to the leasing of approximately 18,305 square feet (the "Original Leased Premises") in the building owned by Landlord and located at 3905 Annapolis Lane, Plymouth, Minnesota as more particularly described on Exhibit A to the Lease; and

WHEREAS, Plymouth Business Center I Partnership is the successor to Crow-Plymouth Land Limited Partnership's interest in the Lease and St. Paul Properties, Inc. is the successor of Plymouth Business Center I Partnership is hereinafter referred to as "Landlord"; and

WHEREAS, Landlord and Tenant entered into a certain Amendment No. 1 to Lease Agreement on January 5, 1989 to provide for the leasing to Tenant of an additional 21,205 square feet in the Building (the "Surrender Space"); and

WHEREAS, Landlord and Tenant entered into a certain Amendment No. 2 to Lease Agreement on January 12, 1989 in order to evidence their agreement in regard to the use of the Original Leased Premises for manufacturing purposes; and

WHEREAS, Landlord and Tenant entered into a certain Amendment No. 3 to Lease Agreement in order to allow Tenant to vacate and surrender to Landlord the Surrender Space and to evidence their agreement to extend the term of the Lease as to the Original Leased Premises, as amended, for a period of three (3) additional months; and

WHEREAS, Landlord and Tenant have entered into a certain Amendment No. 4 to Lease Agreement in order to evidence their agreement to extend the term of the Lease as to the Original Leased Premises, as amended, for a period of thirty (30) additional months.

WHEREAS, Landlord and Tenant have agreed to enter into this Amendment No. 5 to Lease Agreement in order to evidence their agreement to expand the Demised Premises by Tenant leasing 2,230 square feet adjacent to the Demised Premises ("Expansion Space") commencing June 1, 1996 and expiring December 31, 1997. The total Leased Premises is 20,535 square feet.

NOW, THEREFORE, in consideration of the foregoing, and the following covenants and agreements and for other good and valuable consideration, the receipt and adequacy whereof is hereby acknowledged by the parties, Landlord and Tenant hereby agree as follows:

1. Interpretation of Amendment. The Lease is hereby modified and supplemented. Wherever there exists a conflict between this Amendment No. 5 to Lease Agreement and the Lease, as amended, the provisions of this Amendment No. 5 shall control. Unless otherwise indicated, capitalized terms shall be defined in the manner set forth in the Lease, as amended.

2. Base Rent. Notwithstanding anything to the contrary in the Lease, as amended, Base Rent for the Expansion Space during the term as herein indicated, shall be equal to \$1,436.00 per month, payable in accordance with the terms of the Lease, during the period commencing June 1, 1996 and continuing through December 31, 1997.

3. Articles 28, 29, 30 and 32 of the Rider to the original Lease dated December 22, 1987 and Article 5, 8 and 9 of Amendment #1 and Articles 2 and 6 of Amendment #3 and Article 5 of Amendment #4 shall be deleted entirely and of no future force and effect.

4. Reference to an Effect on the Lease.

- a) Upon the effectiveness on this Amendment, each reference in the Lease to "this Lease", "hereunder", "hereof", "herein" or word of like import referring to the Lease shall mean and be a reference to the Lease as amended hereby.
- b) Except as specifically set forth above, the Lease remains of full force and effect and is hereby ratified and confirmed.

5. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the State of Minnesota.

6. Headings. Section headings in this Amendment are included herein for convenience of reference only and shall not constitute a part of this Agreement for any other purpose.

IN WITNESS WHEREOF, the parties have executed this Amendment No. 5 to Lease Agreement as of the year and date first above written.

LANDLORD:

St. Paul Properties, Inc.
(a Delaware corporation)

By: /S/ R. William Inserra
R. William Inserra

Its: Vice President

TENANT:

ATS Medical, Inc.
(a Minnesota corporation)

By: /S/ John H. Jungbauer

Its: Vice President

EXHIBIT "A"

[Site Plan showing Current Premises and Expansion Space under Lease Agreement]

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SUBSIDIARIES OF THE COMPANY

ATS Medical, Ltd. (incorporated in Scotland)

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Consent of Independent Auditors

We consent to the incorporation by reference on the Registration Statements on Form S-8 NO. 33-44940 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 6, 1997, 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, 1996.

Ernst & Young LLP

Minneapolis, Minnesota
March 25, 1997

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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, 1996 (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: March 20, 1997

/s/ Richard W. Kramp

Richard W. Kramp

Dated: March 20, 1997

/s/ John H. Jungbauer

John H. Jungbauer

Dated: March 20, 1997

/s/ Charles F. Cuddihy, Jr.

Charles F. Cuddihy, Jr.

Dated: March 20, 1997

/s/ James F. Lyons

James F. Lyons

Dated: March 20, 1997

/s/ A. Jay Graf

A. Jay Graf

Dated: March 20, 1997

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