

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K/A

(Mark One)

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

For the fiscal year ended September 30, 1998

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-14242

CELSION CORPORATION

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(Exact name of registrant as specified in its charter)

Maryland

52-1256615

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

10220-I Old Columbia Road  
Columbia, Maryland

21046-1705

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(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (410) 290-5390

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

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

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(Title of Class)

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 (ss. 229.405 of this chapter) is not contained  
herein, and will not be contained, to the best of Registrant's knowledge, in  
definitive proxy or information statements incorporated by reference in Part III  
of this Form 10-K or any amendment to this Form 10-K. [ ]

As of December 24, 1998, 41,514,467 shares of the Registrant's Common  
Stock were issued and outstanding. As of December 24, 1998, the aggregate market  
value of voting stock held by non-affiliates of the Registrant was approximately  
\$7,338,926 based on the average of the closing bid and asked prices for the  
Registrant's Common Stock as quoted on the over-the-counter market.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the following documents are incorporated by reference  
in this Report on Form 10-K: None.

PART I

ITEM 1. BUSINESS

General

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Celsion Corporation (the "Company") was incorporated in the State of  
Maryland in 1982 under the name A.Y. Cheung Associates, Inc. The Company changed  
its name to Cheung Laboratories, Inc. on June 31, 1984 and to Celsion  
Corporation on May 1, 1998. The Company is a biomedical research and development  
company headquartered in Columbia, Maryland, dedicated to creating and marketing  
medical treatment systems for cancer, benign prostatic hyperplasia ("BPH") and  
other diseases using focused heat energy.

Thermotherapy (also known as hyperthermia), or heat therapy, is an  
historically recognized successful method of treatment. In modern thermotherapy,  
a controlled heat dose is targeted to treatment sites using microwave and/or  
other energy for therapeutic benefits. Heat is a well-known treatment modality  
for cancer in combination with radiation and chemotherapy. In 23 worldwide  
independent studies on 2,234 tumors, heat plus radiation doubled the complete  
response rate of tumors (from 38% to 78%) compared to radiation alone. Complete  
response rate is defined as the total absence of a tumor for a minimum of two

years. The same doubling of complete response rate occurred with heat and chemotherapy. The past technical difficulty has been delivering a controlled amount of heat to internal tumors without burning surrounding healthy tissues. The Company has an exclusive license from the Massachusetts Institute of Technology ("MIT") for adaptive phased array ("APA") technology which the Company believes will overcome this problem.

The Company will therefore be concentrating its business on the development of two acquired technologies: (i) from MIT, APA targeting of microwave energy, which the Company believes will have broad cancer and other medical applications, and (ii) balloon catheter technology for enhanced thermotherapy of BPH and other genitourinary tract conditions. While the balloon catheter technology is related to the Company's previous BPH thermotherapy devices, the Company believes the APA technology has the potential to serve as the core technology for an array of new medical devices.

MIT "Adaptive Phased Array" Technology

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- the Enabling Platform  
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In mid 1996, the Company obtained an exclusive license to patented MIT "adaptive phased array" technologies which were originally developed for the Strategic Defense Initiative (Star Wars) plans of the Department of Defense to track targets and to nullify the energy beam from enemy jamming equipment. The APA technology allows microwave energy to be accurately targeted deep within the body, resulting in heating a well defined target area without damaging surrounding tissue. On October 24, 1997, the Company entered into a revised exclusive license agreement with MIT covering the above mentioned patents in the 1996 agreement as well as an additional patent pending technology using the APA technology for activating thermo-sensitive liposomes.

Under the terms of the license agreement with MIT, the APA technology is available for exclusive use by the Company in conjunction with (i) breast hyperthermia, or the application of heat to breast tumors, (ii) prostate hyperthermia, or the application of heat to prostate conditions, and (iii) all other medical uses. Under a revised license agreement with MIT, the Company has also been granted similar rights to use APA technology for activating heat sensitive pharmaceutical agents, developed by others, which are targeted to specific tumor sites. There are no restrictions in the permitted uses of the product, but no other areas of commercialization for the APA technology are allowed under the license, and MIT has retained certain rights in the licensed technology for non-commercial research purposes.

The Company intends to use the ability of APA technology to selectively heat targeted internal areas of the human body as a technological platform, both in the near term and the long term. On September 17, 1997, the Food and Drug Administration (the "FDA") granted the Company a Premarketing Approval ("PMA") for its system of deep focused heat, incorporating the APA technology, as a treatment modality for use in conjunction with radiation for the treatment of recurrent surface and subsurface tumors. This approval was obtained as a supplement to an existing approval for the Microfocus 1000, a thermotherapy device that the Company produced and marketed from 1989 through 1994, albeit without the APA technology. The Company plans to conduct clinical tests of the use of its APA-improved Microfocus equipment to treat localized tumors through heat alone and without concurrent radiation.

Total costs for incorporating APA technology in commercially marketable Microfocus equipment for treating tumors through heat alone will depend upon (i) any further product development costs, including costs incurred for or with MIT, (ii) the final costs of the required clinical studies, and (iii) the marketing investment required in order to gain acceptance of the new

technology. Such total costs cannot be predicted at this time, and the Company will only be able to establish responsible pricing when all clinical trials are completed and when marketing and other commercialization costs and profit margin factors are finalized. In addition, the new treatment technology, when commercialized, will require new medical treatment reimbursement rates and codes, which cannot yet be applied for and which will have a bearing on the pricing of the equipment, as will competitive factors which may prevail at the time the new equipment is marketed. Notwithstanding the foregoing uncertainties, the Company believes that, while the total costs and pricing of its new equipment will be greater than for its older Microfocus 1000 units, such increase will not be severe.

There are numerous technologies that currently exist or are being developed that can utilize the unique properties of the Company's heat delivery technology, as well as numerous other applications dependent on the heat delivery technology that should evolve over time. Several of the leading applications that have been identified include:

(1) Tumor Ablation-Using Heat Alone

The Company's older Microfocus 1000 equipment, designed to be used as an adjunct to radiation therapy, is no longer being marketed by the Company. The Company's present intention is to complete the development of, and to market, an improved microwave thermotherapy product with APA technology, for the ablation (destruction) of breast tumors through the use of heat alone, rather than in conjunction with radiation and chemotherapy, thereby seeking to avoid the well-established risks and side effects of radiation and chemotherapy. However, in applications where the older Microfocus 1000 equipment continues to be used in conjunction with radiation, or where a Company microwave thermotherapy product might be used in the future to deliver treatment in addition to a separate course of radiation or chemotherapy, the established risks and side effects of radiation or chemotherapy will remain and will not be diminished by any such use of the Company's equipment.

It has been scientifically demonstrated on numerous occasions that properly applied heat can kill cancer cells. For example, see the article entitled "Biological Effects of Heat" by Eric J. Hall and Laurie Roizin-Towle, In Cancer Research (Suppl.), Vol 44 (Oct. 1984). Our microwave equipment applies heat to specific tissue areas, and the APA technology licensed from MIT has improved the ability of our equipment to focus such heat in a controlled manner in a targeted internal location. In connection with its application to the FDA for pre-marketing approval of its APA-improved Microfocus product, the Company submitted the results of animal studies demonstrating the ability of such equipment to ablate tumors in animal tissue. The FDA granted such approval in 1997 on the basis of the study results. The Company intends to commence Phase I studies in humans for the purpose of establishing the ability of the equipment to ablate human tumors using heat alone.

In the spring of 1998, the Company's Microfocus equipment, improved through the addition of APA technology, was used in animal studies at Massachusetts General Hospital ("MGH") and Oxford University, confirming the system's ability to focus heat deep within the body. In August, 1998, Hammersmith Hospital in London received approval from its ethics committee to conduct human trials. At MGH's Center for Imaging and Pharmaceutical Research, animal studies were conducted under the direction of Dr. Gerald Wolf. The Company's treatment system was successfully demonstrated to completely ablate tumors in animals using heat alone. In this modality, the tumor is heated to 46(degree) - 48(degree) C (114(degree) - 118(degree) F) or hot enough to kill all cancer cells in one eight minute treatment session.

Whenever ablation is possible, the Company's system will be used without radiation or chemotherapy. The Company needs to obtain a new indication of use (that is, the ablation of breast tumors with heat alone) from the FDA for its already PMA - approved equipment. The FDA strictly regulates indications of permitted use of medical equipment, and its approvals are based upon successful safety and efficacy studies. The Company's current FDA approval for its Microfocus equipment is based upon its previous clinical testing in which microwave-generated heat was used in conjunction with radiation.

In order to have the right to such an indication of permitted use for heat alone, the Company must perform a new clinical study which must be reviewed by the FDA before we can market and sell our Microfocus equipment with a heat alone indication of use. The Company is submitting an application for Investigational Device Exemption ("IDE") to the FDA, and Dr. Gerald Wolf of MGH will oversee coming clinical trials at MGH, at Hammersmith Hospital London, and Columbia HCA's JFK Hospital in Palm Beach.

(2) Radiation Plus Deep Focused Heat

In addition to using heat alone to destroy certain tumors, the Company believes that the combination of thermotherapy (hyperthermia) and radiation can provide a significant market opportunity for the Company. Traditional radiation therapy is an expensive, multi-treatment process that is physically debilitating to the person receiving it, and has several inherent systemic limitations:

S-phase cancer cells are resistant to radiation. (S-phase cells represent about 40 percent of the cell cycle; tumoric cells go through a 24 hour cycle of S and G phases.) The S-phase cells are highly susceptible to destruction by heat; and

Poorly oxygenated (hypoxic) cancer cells are resistant to radiation.

Thermotherapy is known to improve the chances of killing the cancer cells, because

S-phase cancer cells missed by radiation can be killed by thermotherapy; and

Thermotherapy increases the oxygenation of cancer cells making them more susceptible to radiation.

As indicated above, the dual treatment modality of thermotherapy and radiation has already been shown in independent studies to double the complete response rates of sub-surface and surface cancers when used in conjunction with radiation or chemotherapy. To date, the problem with this dual treatment application has been the inability of the thermotherapy treatment to focus heat deep within the body. As stated earlier, the Company's APA technology provides a method through which this can now be accomplished. It should be noted, however, that the side effects and risks of radiation therapy will not be eliminated by the use of such additional focused heat technology.

### (3) Chemotherapy Plus Deep Focused Heat

Traditional chemotherapy is limited in its ability to kill cancer cells for two major reasons:

Poor blood perfusion in the vicinity of tumor cells such that chemotherapy delivered through the blood stream does not reach the tumor; and

Tumor cell pressure prevents chemotherapy from penetrating tumor cell membranes.

Thermotherapy improves the performance of chemotherapy in each of these areas by:

Increasing the blood flow in the vicinity of tumors in the temperature range of 41(degree) C to 43(degree) C, thereby increasing the delivery of drugs to the tumor site;

Decreasing the blood flow within the tumor itself to the point where the tumor is easily heated and killed at temperatures above 43(degree) C (tumor vascularity is not robust and does not expand significantly when heated), compared to normal tissue for which heat is easily removed and the tissue is protected; and

Increasing the toxicity of the chemotherapy agent at 43(degree)C, compared to the toxicity of the same agent at 37(degree) C.

Subject to obtaining FDA and other approvals, animal trials for chemotherapy in conjunction with focused heat generated by the Company's equipment are planned for Duke University Medical Center as well as Hammersmith Hospital in London, and clinical trials are planned for Hammersmith Hospital. It should be noted, however, that the side effects and risks of chemotherapy will not be eliminated by the use of such additional focused heat technology.

### (4) Heat Sensitive Liposomes ("Thermalsomes") - Targeted and Effective Drug Delivery

One of the initial opportunities for this patented technology relates to temperature sensitive liposomes ("Thermalsomes") that are being developed at Duke University. Thermalsomes are microscopic man-made lipid particles (organic compounds including fats, fat-like compounds and steroids) that can be engineered to encapsulate drugs, creating new pharmaceuticals with enhanced efficacy, better safety or both. Toxicity of effective drugs can be mitigated through Thermalsomes technology.

For application to the human body, the Thermalsomes are injected into the blood stream. As the Thermalsomes circulate repeatedly within the small arteries, arterioles, and capillaries, the drug contents of the Thermalsomes are released in significantly higher levels in areas that have been heated for 30 to 60 minutes, than in areas that do not receive heat. Hence, the Thermalsome technology is made effective by the Company's focussed thermotherapy treatment modality.

The Company has been collaborating with Duke University Medical Center ("Duke") in preliminary research on the use of heat-sensitive liposomes in conjunction with precisely focused heat. In ongoing animal research studies conducted under the Company's Sponsored Research Agreement with Duke, a drug encapsulated in heat-sensitive liposome particles is circulated through animal tissue. While animal studies are not yet completed, the Company believes, based on continuing discussions with Duke researchers, that the combination of liposome-encapsulated drug therapy with the ability of the improved Microfocus equipment to heat specific internal tissue to a predetermined temperature will permit more concentrated application of therapeutic drugs at actual tumor sites. In addition to completing the ongoing animal studies, the Company and Duke will be required to seek and obtain FDA approval for human trials before definitive benefits are established. Duke is in the process of patenting the formulation technology for its heat-sensitive liposomes, and the Company and Duke are presently exploring a revised sponsored research relationship.

In addition to the increased efficacy, there is potential for great improvement in the life process of chemotherapy patients. Chemotherapy is essentially a poisoning of the body with toxins that attack cancerous cells more readily than normal cells. The side effects include nausea, vomiting, and exhaustion - all side effects of the body being poisoned. If the poisoning can be limited to the tumor area, and performed only once (due to the increased efficacy) as is possible with the Thermalsome related treatments, chemotherapy should cease to be the horrid, debilitating process that it is today.

(5) Gene Therapy - Making Tumors Susceptible to Eradication

Another application of the APA technology relates to gene therapy. The Company has been collaborating with a researcher, Dr. Gloria Li of the Sloan-Kettering Institute for Cancer Research, who has developed heat sensitive, genetic biological modifiers which suppress a tumor's resistance to heat, radiation and chemotherapy damage. The Company has now entered into an option agreement with Sloan-Kettering under which we will have the right to acquire an exclusive license to commercialize the technology for commercial use. In applying this technology in clinical applications to management of cancer, the biological modifiers can be attached to a heat shock promoter to form a gene therapy construct. The construct can be delivered to deep seated tumors. The action of focused heat is intended to both release and trigger the action of the modifier. The gene modifier thus weakens the tumor's resistance to therapy and greatly enhances the effectiveness of any combination therapy approach using heat in conjunction with radiation or chemotherapy. Recently, a patent application has been filed by the researcher's institution, and the Company has entered into negotiation for the exclusive rights to license the technology for commercial use, although the Company cannot provide assurance that such license agreement will be consummated.

(6) Projected Deep Focused Heat Product Line

The Company has current plans to produce specialized thermotherapy products, each utilizing the APA technology for specific deep seated tumors, and one BPH product utilizing the Company's microwave equipment and balloon catheter technology developed by MMTC, Inc. ("MMTC") and licensed to the Company.

Breast cancer treatment equipment. According to the American Cancer Society, breast cancer is the most prevalent cancer in the U.S. with over 183,000 new cases diagnosed each year. The amount indicated is a three-year average of estimated national cancer case data for 1995, 1996 and 1997 published by the American Cancer Society in its bi-monthly journal, A Cancer Journal for Clinicians. Early stage breast cancer accounts for two thirds of the breast cancers in the U.S. today. This assertion is based on the statement that, of newly diagnosed cancers, two thirds were "node negative", made in the article "The Surgical Management of Primary Invasive Breast Cancer" by Dr. Michael P. Moore and Dr. David W. Kinne, in Vol. 45, No. 5 (September/October 1995) of A Cancer Journal for Clinicians.

Early stage breast cancer is presently treated via mastectomy, the removal of the entire breast, or via lumpectomy, the removal of the tumor and surrounding tissue. In lumpectomy, the area at the edge of the removed tissue is examined for the existence of cancerous cells, and if any are found, the procedure is repeated. Full breast radiation or chemotherapy usually follows this procedure in order to destroy any cancer cells that may not have been captured by the surgical procedure or that may have been spread during the procedure.

The Company's breast cancer treatment system is intended for use prior to lumpectomy to completely destroy the cancerous tissue through use of heat alone. Initially, radiation therapy or chemotherapy will follow the lumpectomy as is the current practice. However, the Company expects, with FDA approval of the Company's breast cancer treatment system, that, eventually, neither radiation nor chemotherapy will be required for use with the Company's system. The Company believes thermal ablation will offer a safe and thorough treatment in stand-alone mode, eliminating the necessity for radiation or chemotherapy and their debilitating side effects. This alteration in standard practice requires additional clinical trials for FDA clearance.

The Company recently completed animal trials of its prototype clinical breast cancer treatment system at MGH. The results confirmed that the Company's new Microfocus equipment with APA technology accurately focused heat where targeted, and that it is possible to kill tumors with the Company's equipment. The Company received an Investigational Device Exemption from the FDA, enabling it to commence Phase I human clinical trials using the equipment at MGH. However, instead of conducting Phase I human clinical trials at MGH, the Company has decided to conduct such trials at two other sites, Harbor UCLA Medical Center in Los Angeles, and the Breast Center at Columbia Hospital, West Palm Beach, Florida. The Company is now in the process of finalizing arrangements and costs and payment schedules with both institutions.

The FDA has been notified of the changes in site and in principal investigators, and the Company does not anticipate receiving any FDA objections to such change. The cost of the Phase I trials is estimated at approximately \$500,000, to be paid by the Company out of funding which the Company has obtained. The Company expects that the Phase I trials will begin by the end of 1999.

Prostate cancer treatment equipment. There are over 163,000 new cases of prostate cancer diagnosed in the United States each year. Building on its experience in BPH treatment, the Company is planning to develop prostate cancer thermotherapy equipment as the second of its APA product line. Although the Company has developed several critical components of this equipment, hospital research is not expected to begin prior to year 2000.

Deep Seated Tumor Treatment Equipment. The Company is also considering an APA product for deep seated tumors, including liver, pancreas, colon and lung cancers, but no commitment to a development program or timetable has been made.

MMTC Benign Prostatic Hyperplasia Technology

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- Major Treatment  
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(1) BPH Background

BPH is a non-cancerous urological disease in which the prostate enlarges and constricts the urethra. Symptoms associated with BPH affect the quality of life of millions of sufferers worldwide, and BPH can lead to irreversible bladder or kidney damage. The prostate is a walnut-size gland surrounding the male urethra that produces seminal fluid and plays a key role in sperm preservation and transportation. As the prostate expands, it compresses or constricts the urethra, thereby restricting the normal passage of urine. This restriction of the urethra may require a patient to exert excessive bladder pressure to urinate. Since the urination process is one of the body's primary means of cleansing impurities, the inability to urinate adequately increases the possibility of infection and bladder and kidney damage.

Because BPH is an age-related disorder, its incidence increases with age. It is estimated that over 17 million U.S. males aged 50 and over experience BPH symptoms and that 26 million men in similar age categories are affected by BPH worldwide. As the population continues to age, the prevalence of BPH will continue to increase dramatically. It is generally estimated that approximately 50% of all men over 50 and 90% of men in the 70's and 80's age group will have some symptoms of BPH.

Like cancer, BPH historically has been treated by surgical intervention or by drug therapy. The primary surgical treatment for BPH is transurethral resection of the prostate ("TURP"), a procedure in which the prostatic urethra and surrounding diseased tissue in the prostate are trimmed, thereby widening the urethral channel for urine flow. While the TURP procedure typically has been considered the most effective treatment available, the procedure has many shortcomings which undermine its value. A large number of patients who undergo TURP encounter significant complications, which can include painful urination, infection, impotence, incontinence, and excessive bleeding. Furthermore, the cost of the TURP procedure is also very high, ranging from \$8,000 to \$12,000, including hospital stay. This high cost also fails to reflect the cost of lost work time and reduction in quality of life. Finally, the TURP procedure is time consuming, requiring hospitalization for up to three days.

Other less radical surgical procedures are available in addition to the TURP procedure. For example, Interstitial RF Therapy and Laser Therapies are procedures which employ, respectively, concentrated radio frequency waves or laser radiation to reduce prostate swelling by cauterization of tissue instead of removal of tissue with a surgical knife. However, these procedures require puncture incisions to be made in a patient in order to insert cauterizing RF or laser probes into the affected tissue, and therefore also may involve the use of a full operating facility and anaesthesia, as well as the burning of tissue by the probes. While these procedures result in less internal bleeding and damage to the urethra compared with TURP procedures, they do not completely eliminate the adverse effects and costs associated with hospital surgery, anaesthesia and post-operative tissue recovery.

Drug therapy has emerged as an alternative to surgery in the last several years. There are several drugs available for BPH treatment, the two most widely prescribed drugs being Hytrin and Proscar. Hytrin works by relaxing

certain involuntary muscles surrounding the urethra, thereby easing urinary flow, and Proscar is intended to actually shrink the enlarged gland. However, industry studies have asserted that drug therapy costs \$500 to \$800 per year or more, and does not offer consistent relief to a large number of BPH patients, with the best of the drugs being estimated to be only 50% as effective as the TURP procedure. Since both surgical and drug treatment alternatives involve appreciable side effects and high costs, the Company believes there is a substantial opportunity for a less invasive and lower-cost treatment option.

Thermotherapy involving high heat treatment using microwaves is another new alternative treatment approach. In May 1996, the FDA approved a microwave-based BPH treatment device manufactured by EDAP Technomed, Inc. ("Technomed"), called Prostatron. The FDA has recently approved another similar microwave treatment device manufactured by Urologix, another thermotherapy company. However, based on information obtained by the Company at trade shows, from the manufacturers and from urologists who have considered acquiring the equipment, the relatively higher treatment temperatures used in such equipment appear to create initial swelling in the tissues surrounding the urethra for a substantial portion of the patients treated. This can result in no immediate symptomatic relief and in a need for post-treatment catheterization of the urethra in order to relieve blockage for a number of patients undergoing such treatment.

#### (2) MMTC Technology--Combination of Heat and Compression

On August 23, 1996, the Company acquired a patented compression technology from MMTC, which has been incorporated into a device to be utilized with the catheter used in the Company's existing Microfocus BPH system. The device consists of a microwave antenna combined with a balloon dilation (similar to angioplasty) mechanism which expands to compress the walls of the urethra as the prostate is heated.

On December 1, 1997, the Company entered into an amended License agreement with MMTC, Inc., the original licensor, to give the Company rights to two additional patents, of which one was approved November 17, 1997. These additional patents relate to an innovative approach to monitor and control intra-prostatic temperatures using a radiometer apparatus. The combination of these two patents and the one received in 1996 is expected to enhance the safety and efficacy of the Company's BPH system.

#### (3) Testing of BPH Equipment

Based on the Company's preliminary development work and the successful use of the technology in animal research conducted at the Montefiore Medical Center under the direction of Dr. Arnold Melman, the Company believes that the combined use of balloon compression and microwave heating will provide significantly improved treatment benefits over the "heat alone" systems currently available commercially. In the animal studies, a natural "stent" or reinforced opening in the urethra of the animals tested was shown to be formed after the treatment. The opening is the result of combining heat and compression to create the stent, thus permitting immediate relief for urinary tract blockage due to prostate enlargement. Also, the system's relatively low temperature (43(degree)C to 45(degree)C) appears to be sufficient to kill prostatic cells outside the urethra, creating space for the enlargement of the urethra opening. However, the heat is not high enough to cause swelling in the urethra as is often associated with competitive treatments using higher temperatures and no compression.

The Company's prototype clinical BPH treatment system has also been used in Phase I human clinical trials at Montefiore, also under the direction of Dr. Melman, and the Company feels that the results to date have warranted proceeding with an FDA application to conduct Phase II trials.

It is estimated that only 20% of men with moderate to severe BPH symptoms seek medical treatment. The Company believes that this number will be greatly increased with the introduction of the Company's BPH treatment device that improves on the major drawbacks of the current treatment methods. These drawbacks include issues such as extended procedure stays, required catheterization and a worsening of conditions immediately after the procedure.

Based on the Company's preliminary development work, and subject to further testing in Phase II trials and ultimate FDA approval, the Company believes that its new proprietary BPH device addresses each one of these drawbacks and can deliver a treatment that is performed on an outpatient basis, does not require post-treatment catheterization and delivers immediate relief that permits urination as soon as the procedure is completed.

#### Marketing Strategy

The emphasis of the Company's marketing strategy for its new products will be to create cash flow by selling disposable procedure kits and by charging a per-use fee. The Company plan calls for hospitals, clinics, Health Maintenance

Organizations ("HMOs") and pharmaceutical companies to acquire equipment at a minimal cost and to pay for utilizing such equipment, together with necessary disposable products -- on a per-use basis. The Company intends to increase the demand for its treatment products by educating patients about the benefits of its treatment via various means of media publicity, consistent with FDA regulation. The Company will pursue long-term growth along two discrete development paths:

- It is anticipated that, in the near term - from two to four years, the Company's treatment revenues will come from an exploitation of its proprietary technology for BPH, and from its deep focused heat technology for breast cancer and deep-seated tumors. The Company intends to generate initial sales through a combination of direct marketing and development of marketing alliances. The Company has been engaged for many months in serious discussions with a national healthcare company providing HMO services, but the entity has required its identity to be kept confidential until a binding agreement is consummated. The Company has also had discussions with a number of manufacturers and distribution organizations which have expressed an interest in the products now under development. No agreements or commitments have resulted from such discussions, and no single discussion has reached a stage where disclosure is appropriate in the view of the Company's management. The Company is currently considering other offers to establish a series of value-added marketing alliances with certain manufacturers that sell directly to the nation's hospital community.
  
- In the longer term - from four to six years, the Company intends to generate new revenue streams from its current development work with Duke University and Memorial Sloan Kettering in targeted drug delivery systems and gene therapy. The Company has a first option to acquire Duke University patents covering heat sensitive liposome targeted drug delivery technology. It is anticipated that treatment revenues will come from pharmaceutical manufacturers, hospitals, and clinics employing these technologies to deliver drug regimens or change genes throughout the body. Duke has commenced development of this integrated, targeted drug delivery system employing the Company's focused heat technology. To market its liposome, heat sensitive drug delivery systems, the Company is currently seeking alliances with pharmaceutical companies, major hospitals, and HMOs. The Company's intended marketing strategy will be to place its microwave equipment at minimal cost, and to share revenues from drug delivery on a per transaction basis. It is anticipated that there will also be significant revenues from both the Company's targeted drug delivery and gene therapy delivery to major drug companies.

Assuming FDA approval, the Company plans to launch its BPH treatment system in 2000. Pending FDA approvals, the Company's focused heat breast cancer system could reach the market in 2001. Microwave liposome drug delivery treatments could reach the market as early as 2002.

#### Patents and Proprietary Rights

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The Company owns no patents. Through the Company's license agreements with MIT, MMTC and Haim Bitcher Cancer Institute ("HBCI"), the Company has exclusive rights within defined fields of use to eight U.S. patents. Five of the patents relate to the cancer equipment and three relate to the BPH equipment. The patents expire at various times from May, 1999 to November, 2014. The Company, in conjunction with the patent holders, has filed or intends to file international applications for certain of the U.S. patents.

The material terms of the MIT license agreement provide for a grant of exclusive rights for the permitted uses under a number of U.S. patents and various U.S. and foreign pending patent applications, along with two copyrighted software programs. The grant includes the right to sublicense for end-users, and the license term expires at the earlier of 10 years after the first commercial sale of a licensed product or 12 years after the date of the license agreement, which expiration date may be extended with the consent of MIT. The agreement contains various milestone requirements and payments, provides for certain minimum sales, and may be terminated (i) by the Company at any time upon at least six months notice and payment of all amounts which may then be owed to MIT, and (ii) by MIT upon the occurrence of a breach by the Company.

The Company has been collaborating with Duke University under 1998 sponsored research agreements covering (i) the development of heat-sensitive liposomes for delivery of drug therapy to selected tissue areas to be heated with the Company's APA-improved microwave equipment, and (ii) the development of heat-sensitive gene-based biological agents for treatment of cancer. The agreements provide for research at various fixed costs for one-year periods ending in February, 1999, can be renewed, and can be terminated by either party on 60 days notice after such renewal. Under the agreements, Duke is obligated to disclose promptly to the Company any new invention, development or discovery resulting from the subject research, and the Company is granted a cost-free option, exercisable for a period of 90 days after notification, to enter into an agreement for an exclusive, worldwide, royalty-bearing license for the new



proprietary technology. The Company paid all sums invoiced by Duke for research work through February 1999 under the agreements. However, Duke and the Company have been conducting discussions for the purpose of revising the research agreements, and expect to conclude new arrangements by the beginning of August, 1999, pending which the prior research activities have been temporarily suspended.

The Company also relies upon trade secrets and proprietary know-how, which it seeks to protect, in part, through proprietary information agreements with employees, consultants and others. There can be no assurance that proprietary information agreements will not be breached, that the Company would have adequate remedies for any such breach or that such agreements, even if fully enforced, would be adequate to prevent third party use of the Company's proprietary technology.

#### Third Party Reimbursement

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The Company believes that third party reimbursement will be essential to commercial acceptance of the Deep Focused Heat Systems and Microfocus BPH System procedures, and that overall cost effectiveness and physician advocacy will be keys to obtaining such reimbursement. The Company believes that its procedures can be performed for substantially lower total cost than surgical treatments for BPH or cancer or continuous drug therapy. Consequently, the Company believes that third party payers seeking procedures that provide quality clinical outcomes at lower cost will help drive acceptance of the Company's products.

The Company's strategy for obtaining reimbursement in the United States is to obtain appropriate reimbursement codes and perform studies in conjunction with clinical studies to establish the efficacy and cost effectiveness of the procedures as compared to surgical and drug treatments for BPH and cancer. The Company plans to use this information when approaching health care payers to obtain reimbursement authorizations.

With the increasing use of managed care and capitation as a means to control health care costs in the United States, the Company believes that physicians may view the Company's products as a tool to treat efficaciously BPH and cancer patients at a lower total cost, thus providing them with a competitive advantage when negotiating managed care contracts. This is especially important in the United States, where a significant portion of the aging Medicare population is moving into a managed care system.

Subject to regulatory approval for the Deep Focused Heat Systems to treat cancer and the new Microfocus BPH System to treat BPH, it is anticipated that physicians will submit insurance claims for reimbursement for the procedure to third party payers, such as Medicare carriers, Medicaid carriers, HMOs, and private insurers. In the United States and in international markets, third party reimbursement is generally available for existing therapies used to treat cancer and BPH. The availability and level of reimbursement from such payors for the use of the Company's new Deep Focus Heat Systems and the new Microfocus BPH System will be a significant factor in the Company's ability to commercialize these systems.

The Company believes that new regulations regarding third party reimbursement for certain investigational devices in the United States will allow it to pursue early reimbursement from Medicare with individual clinical sites prior to receiving FDA approval. However, the Company believes that FDA approval will be necessary to obtain a national coverage determination from Medicare. The national coverage determination for third party reimbursement will depend on the determination of the United States Health Care Financing Administration ("HCFA"), which establishes national coverage policies for Medicare carriers, including the amount to be reimbursed, for coverage of claims submitted for reimbursement related to specific procedures. Private insurance companies and HMOs make their own determinations regarding coverage and reimbursement based upon "usual and customary" fees. Reimbursement experience with a particular third party payor does not reflect a formal reimbursement determination by the third party payor.

Internationally, reimbursement approvals for procedure utilizing the Company's new products will be sought on an individual country basis. Some countries currently have established reimbursement authorizations for transurethral microwave therapy. Clinical studies and physician advocacy will be used to support reimbursement requests in countries where there is currently no reimbursement for such procedures.

#### Commercial Design and Manufacturing

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The Company believes it is best suited to conduct basic research and development, pursue a development idea through clinical testing and regulatory approval and market the final product. The Company intends to outsource the development of a commercial product from its development stage product and the actual manufacture of the commercial product. The Company has engaged Herbst Lazar Bell, Inc. to develop the commercial versions of its future products. See "Certain Transactions". It is intended that manufacture of future products will be contracted to manufacturers who are currently being solicited for interest and cost estimates. The Company will continue to produce their prototype products at the Company.

The Company's existing prototype BPH treatment devices were designed and manufactured by the Company. The Company does not use raw materials in its business. The Company produces its prototypes from a number of components, which it either builds itself or purchases from various suppliers. Items such as power supplies, thermocouple sensors, microprocessors and other circuit board components are generally available from a number of competitive suppliers. Certain specialized microwave and thermometry components and applicator materials, and the catheter unit used for the Company's BPH equipment, are now purchased only from single or limited source suppliers because of the small quantities involved, but such supply sources could be duplicated or replaced if necessary. While the Company has not experienced any significant difficulties in obtaining such components, the loss of an important current supplier could require the Company to obtain a replacement supplier, which might result in delays and additional expense in the production of equipment. In the future, and assuming that the Company's need for components will increase, the Company will seek to develop multiple source suppliers.

#### Competition

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##### (1) Thermotherapy For Cancer

The Company believes that there are at least six other domestic firms, as well as a number of foreign firms, producing, or designing and intending to produce, thermotherapy systems to treat cancer. Of those firms, at least four have obtained PMA for their machines and several have obtained IDE for their machines. Some, and possibly all of those firms, have greater resources than those which the Company now has or may reasonably be expected to have in the near future. Other firms not presently in competition with the Company may decide to produce thermotherapy systems which compete with those of the Company. At least some of those firms may reasonably be expected to have resources greater than those of the Company. As acceptance of thermotherapy as a cancer treatment increases, the Company expects that the competition will also increase.

The two major competitors of the Company are BSD Medical Corporation in Salt Lake City, Utah ("BSD"), and Labthermics Technology, Inc. in Champaign, Illinois ("Labthermics"), each of which manufactures thermotherapy machines competitive with the Company's current Microfocus 1000. The major factors in competition for sales of thermotherapy equipment are product performance, product service, and product cost. The system manufactured by BSD uses microwave technology. Labthermics uses ultrasound technology to heat the cancer site.

BSD received its FDA approval in 1983 and was allowed to begin marketing its system at that time. To date, BSD has sold approximately 200 thermotherapy systems worldwide and has a much larger presence in the thermotherapy market than has the Company.

##### (2) Product Service, Warranty and Training

Service in the thermotherapy business includes maintenance of the thermotherapy machines to minimize downtime as well as training for personnel who will utilize the machines to render treatment to patients. The Company has warranty and service policies which are competitive within the industry. The Company's warranty for the Microfocus 1000 is for a period of 12 months and the Company offers a service policy following expiration of the warranty. The Company no longer markets the Microfocus 1000, and its warranty obligations on virtually all Microfocus 1000 machines previously sold have expired. On the Company's new products, it plans to offer warranties substantially similar to the warranties and service policies offered by competitors. The Company has provided, and will in the future, three to four days of training for the personnel who will be operating each machine that the Company places at a treatment center. The Company also has provided, and will provide in the future training programs at its facility in Maryland for doctors who desire to receive training on the Company's products. Both training courses are helpful in marketing the Company's products, because users who become familiar with one machine have a reluctance to switch to another machine which would require additional training. For this reason, the Company will seek to increase the frequency of its training sessions given at its facility in Maryland.

##### (3) Thermotherapy For Prostatic Diseases

The Company believes there are as many as 10 companies in the USA and as many as 15 companies worldwide that are planning to enter or already active in the prostatic device market marketplace.

In 1996, the FDA for the first time approved a microwave-based BPH treatment device manufactured by Technomed, called "Prostatron." In addition,

Urologix and Dornier recently received FDA approval on their BPH systems. These approvals should enhance market acceptance of microwave BPH treatment systems both in the United States and abroad but gives Technomed a competitive advantage of being first to the market in the United States. The Company's new BPH system has not been approved by the FDA for sale in the United States. The Company has obtained an IDE approval from the FDA for clinical trials at the Montefiore Medical Center.

Large companies such as Dornier, Olympus, and Technomed are expected to spend large amounts of resources for marketing and development of BPH products. In addition to the above companies, the following are companies offering BPH thermotherapy systems in the worldwide marketplace: BSD, Direx Medical, Technomatix (Primus), Lund Science, Quantum, GENEMED, Bruker, and Meditherm. There are several other companies which have not yet brought their products to the international marketplace. Presently, Technomed is considered the market leader with its Prostatron system. The Prostatron unit is a high cost system which sells for approximately U.S. \$300,000. Other companies are marketing their systems in the range of US \$100,000 to \$300,000. To date, it is believed there are over 600 installed BPH Systems worldwide of which Technomed and Direx have the largest share of approximately 30% combined. There are approximately 75 of the Company's older Microfocus BPH Systems installed worldwide.

#### Government Regulation

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##### (1) United States Regulation

In the United States, the FDA regulates the sale and use of medical devices, which include the Company's thermotherapy systems for both cancer and BPH. A company introducing a medical device in the United States must go through a two step process. The company must first obtain an Investigational Device Exemption ("IDE") permit from the FDA. An IDE is granted upon the manufacturer adequately demonstrating the safety of the device for patient use. Receipt of the IDE allows the use of the device on patients for the purpose of obtaining efficacy confirmation. A PMA is granted upon compilation of sufficient clinical data to establish efficacy for the indicated use of the device. This process is not only time consuming but is also expensive. Obtaining PMA is a significant barrier to entry into the thermotherapy market. Firms which lack PMA face significant impediments to the successful marketing of their thermotherapy equipment, because under applicable regulations customers can obtain reimbursement from Medicare, Medicaid and health insurers only for treatment with products that have PMA.

The Federal Communications Commission (the "FCC") regulates the frequencies of microwave and radio-frequency emissions from medical and other types of equipment to prevent interference with commercial and governmental communications networks. The frequency of 915 MHZ has been approved by the FCC for medical applications and machines utilizing that frequency do not require shielding to prevent interference with communications. The Microfocus 1000 and the Microfocus BPH System utilize the 915 MHZ frequency.

In December 1984, the Health Care Financing Administration ("HCFA") approved reimbursement under Medicare and Medicaid for thermotherapy treatment when used in conjunction with radiation therapy for the treatment of surface and subsurface tumors. At this time, most of the large medical insurance carriers in the United States have approved reimbursement for such thermotherapy treatment under their health policies. Thermotherapy treatment administered using equipment which has received PMA is eligible for such reimbursement.

The Company and its facilities are subject to inspection by the FDA at any time to insure compliance with FDA regulations in the production and sale of medical products. The Company believes that it is substantially in compliance with FDA regulations governing the manufacturing and marketing of medical devices. The Company has received a PMA from the FDA for its Microfocus 1000 cancer treatment equipment for surface and sub-surface tumors in conjunction with radiation. The Company is seeking a new indication of use to enable this equipment to be used for breast cancer ablation.

##### (2) Foreign Regulation

Sales of medical devices outside of the United States are subject to United States export requirements and foreign regulatory requirements. Export sales of investigational devices that are subject to PMA requirements and have not received FDA marketing approval generally may be subject to FDA export permit requirements under the Federal Food, Drug and Cosmetic Act ("FDC Act") depending upon, among other things, the purpose of the export (investigational or commercial) and on whether the device has valid marketing authorization in a country listed in the FDA Export Reform and Enhancement Act of 1996. In order to obtain such a permit, when required, the Company must provide the FDA with documentation from the medical device regulatory authority of the country in which the purchaser is located, stating that the device has the approval of the country. In addition, the FDA must find that exportation of the device is not contrary to the public health and safety of the country in order for the Company to obtain the permit.

The Company has sold products in approximately twenty selected countries in Asia, Europe, and South America. Meeting the registration requirements within these countries is the sole responsibility of the distributors in each of these countries. Legal restrictions on the sale of imported medical devices vary from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. The Company expects to receive approvals for marketing in a number of countries outside the United States prior to the time that it will be able to market its products in the United States. The timing for such approvals is not known.

Product Liability and Insurance  
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The business of the Company entails the risk of product liability claims. Although the Company has not experienced any product liability claims to date, any such claims could have an adverse impact on the Company. In the past, the Company had not maintained product liability insurance. Recently, the Company has secured product liability insurance in the amount of \$5,000,000 and directors and officers insurance in the amount of \$3,000,000. There is no assurance, however, that claims will be covered by such insurance and will not exceed such insurance coverage limits.

Employees  
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As of September 30, 1998, the Company had six full-time employees. None of the Company's employees is represented by a collective bargaining organization. The Company considers its relations with its employees to be good.

ITEM 2. PROPERTIES

The Company's corporate headquarters consists of approximately 5,918 square feet of office, laboratory and production space at 10220-I Old Columbia Road, Columbia, Maryland 21046-1705. The Company leases the premises from an unaffiliated party on a three year lease which will terminate on May 31, 2000. Monthly rent is \$5,779.91.

ITEM 3. LEGAL PROCEEDINGS

The Company presently is not a party to any litigation, and the Company is not aware of any threat of litigation, except as follows:

The Company was named as a defendant in a lawsuit filed by Eastwell Management Services, Ltd. ("Eastwell") in the United States District Court for the District of Maryland claiming, inter alia, breach of contract. On December 19, 1998, the U.S. District Court of Maryland found in favor of the Company. In a related decision the U.S. District Court of Maryland also found in favor of the Company regarding its countersuit, concluding that the Company is entitled to \$100,000 from Eastwell, which breached the original contract between the two parties. The Company intends to pursue all legally possible avenues to collect the \$100,000 from Eastwell.

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

On April 27, 1998 the Company held its Annual Shareholders meeting. Listed below are the names of the seven directors elected at the meeting and their respective terms of office.

Name -----	Term Expires -----
Spencer J. Volk	2001
Augustine Y. Cheung	2001
Warren C. Stearns*	1999
Walter B. Herbst	2000
Mel D. Soule*	2000

Name -----	Term Expires -----
Max E. Link	2001
John Mon	1999

\* Messrs. Stearns and Soule resigned from the Board of Directors of the Company in July 1998. Listed below is the vote count related to the other matters approved at the meeting:

Proposition -----	For ---	Against -----	Abstain -----
To approve an amendment to the Company's by-laws adopting a staggered board of directors.	28,531,934	171,083	142,050
To ratify the appointment of Stegman & Company as auditors to examine the Company's accounts for the fiscal year ending September 30, 1998.	32,186,822	5,425	152,768
To amend the Company's Articles of Incorporation to increase the number of authorized shares to 100,000,000 shares.	31,672,167	466,873	205,975
To amend the Company's Articles of Incorporation to change the Company's name to Celsion Corporation or variations thereof approved by the Directors.	32,016,210	112,147	216,658
To approve an omnibus stock option plan.	27,626,867	357,943	418,451

PART II  
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ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

The Company's Common Stock is traded on the over-the-counter market. Prices for the Company's shares are quoted in the Electronic Bulletin Board operated by NASDAQ. The quotations set forth below reflect inter-dealer prices, do not include retail markups, markdowns or commissions, and may not necessarily represent actual transactions. There were approximately 1,298 holders of record of the Common Stock as of December 8, 1998. The Company has never paid cash dividends on its stock and does not expect to pay any cash dividends in the foreseeable future.

Period -----	September 30 -----			
	1997 ----		1998 ----	
	High ----	Low ---	High ----	Low ---
1st Quarter (Oct.1 to Dec. 31)	\$1.13	\$0.69	\$1.13	\$0.75
2nd Quarter (Jan. 1 to March 31)	0.81	0.56	1.03	0.69
3rd Quarter (April 1 to June 30)	0.94	0.48	0.90	0.36
4th Quarter (July 1 to Sept. 30)	1.31	0.63	0.52	0.21

Issuance of Shares Without Registration

During the fourth quarter of the fiscal year ended September 30, 1998, the Company issued the following securities without registration under the Securities Act of 1933, as amended (the "Securities Act"):

1. During the quarter, the Company issued 2,006,238 shares to 11 persons in satisfaction of previously outstanding debt and contractual obligations totaling \$650,271. The issuance was made to a limited number of accredited investors. Messrs. Spencer Volk, Augustine Cheung, and Herbst Lazar Bell, Inc. were three of the investors. No commissions were paid with respect to the conversions. The Company believes the issuance was exempt from registration under the Securities Act pursuant to Sections 4(2) or 4(6) of the Securities Act and Regulation D promulgated thereunder.
2. During the quarter, the Company issued 580,000 shares to 7 accredited investors for cash consideration totaling \$145,000. The issuance was made to a limited number of accredited investors. No commissions were paid with respect to the issuance, but finders fees of \$4,500 were paid to persons who introduced the Company to certain investors. The Company believes the issuance was exempt from registration under the Securities Act pursuant to Section 4(2) or 4(6) of the Securities Act and Regulation D promulgated thereunder.
3. During the quarter, the Company issued 73,866 shares to its current and certain past directors as directors fees and certain members on the Scientific Advisory Board for their services. Such shares were valued at a total of \$23,637. The issuance was made to a limited number of accredited investors. No commissions were paid with respect to the issuance. The Company believes the issuance was exempt from registration under the Securities Act pursuant to Sections 4(2) or 4(6) of the Securities Act.

ITEM 6. SELECTED FINANCIAL DATA

The following table summarizes certain financial data for the Company for the years ended September 30, 1998, 1997, 1996, 1995, and 1994 and is qualified in its entirety by, and should be read in conjunction with the Financial Statements, the related Notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report.

	1994	1995	1996	1997	1998
	----	----	----	----	----
Statement of Operations Data:					
Revenues:					
Product Sales (Net)	\$1,025,651	\$157,618	\$74,006	\$121,257	\$174,182
Research and development contracts	60,742	0	0	0	0
Total revenues	\$1,086,393	\$157,618	\$74,006	\$121,257	\$174,182
Cost of product sales	494,946	67,350	64,406	46,734	136,500
Gross profit on product sales	591,447	90,268	9,600	74,523	37,682
Other costs and expenses:					
Research and development	202,569	18,546	94,012	185,974	1,534,872
Selling, general and administrative	704,295	1,386,854	1,321,361	2,283,245	2,515,822
Total operating expenses	906,864	1,405,400	1,415,373	2,469,219	4,050,694
Profit(Loss) from operations	(315,417)	(1,315,132)	(1,405,773)	(2,394,696)	(4,013,012)
Other income (expense)	170,997	8,620	(442,192)	(471,631)	11,870
			(1)	(2)	
Interest income (expense)	(184,700)	(90,805)	(85,506)	(185,562)	(199,346)
Extraordinary Item - Gain on forgiveness of debt	591,728				
Net income (loss)	390,880	(1,397,317)	(1,933,471)	(3,051,889)	(4,200,488)
Net Income (loss) per share	\$0.02	(\$0.06)	(\$0.05)	(\$0.11)	(0.12)
Weighted average shares outstanding	16,712,978	23,466,070	39,499,650	28,386,145	34,867,001

	1994	1995	1996	1997	1998
	----	----	----	----	----
Balance Sheet Data:					
Working Capital	(748,193)	(1,101,136)	(646,754)	(2,645,908)	(2,000,351)
Total Assets	955,456	9,710,742 (3)	9,321,600 (4)	823,209	330,738
Long-term debt, less current maturities	26,000	2,000	1,213,000	0	5,719
Redeemable Convertible Preferred Stock					
Accumulated deficit	(8,880,845)	(10,278,162)	(12,211,633)	(15,263,522)	(19,464,010)
Total stockholders' equity (deficit)	(666,542)	8,128,768	6,755,874 (3)	(2,460,646)	(1,851,077)

- (1) Includes \$17,009 gain on disposition of investment in Ardex Equipment, L.L.C.
- (2) Includes \$438,803 loss on write off of Ardex Notes Receivable.
- (3) Includes the Company's equity interest in Aestar Fine Chemical Company valued at \$8,000,000 on the Company's September 30, 1995 balance sheet.
- (4) On October 23, 1996, the Company, based on the provisions of an agreement reached on June 6, 1996, as amended, redeemed 16,000,000 shares of its Common Stock. The redemption provided for the Company to return its investment in Aestar Fine Chemical Company (valued at \$8,000,000 on the Company's September 30, 1996 balance sheet) and to relinquish its rights to the funds held under an investment contract (\$40,000 at September 30, 1996) in order to effect the transaction. This transaction has a significant impact on the financial position, current ratios and stockholder's equity of the Company. If the foregoing transaction had occurred on or before September 30, 1996, total assets would have been reduced by \$8,040,000 and stockholder's equity would have been reduced by \$8,040,000, resulting in a negative stockholder's equity of (\$1,284,126).

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

Forward-Looking Statements

Statements regarding the Company's expectations as to the effectiveness of its technology, demand for its products and certain other information presented in this amendment to the Company's Form 10-K constitute forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Although the Company believes that its expectations are

based on reasonable assumptions within the bounds of its knowledge of its business and operations, there can be no assurance that actual results will not differ materially from its expectations. Factors which could cause actual results to differ from expectations include, but are not limited to, the following:

1. Decreasing Sales, Increasing Losses and Undercapitalization. The Company's product sales have been substantially decreasing over the past three years as the Company pursued its new technologies and ceased marketing of its older Microfocus 1000 product. Assuming approval of the new technologies by the appropriate government agencies, the Company expects revenue to increase in the future. However, there is no assurance sales will increase with the application of new technologies being developed by the Company. The Company has had increasing losses which have resulted in an accumulated deficit of \$19,464,010 as of September 30, 1998. Losses will continue until current and future sales increase substantially. The Company lacks adequate capital to finance its research and development and marketing. Lack of adequate capital and governmental regulatory approvals will affect future sales.
2. Acceptance of Products. Thermotherapy has not been accepted by the medical community as an effective cancer treatment. The Company believes that this is primarily due to the inability to adequately focus heat prior to introduction of the Company's APA technology. The Company believes the APA technology allows microwave energy to be accurately targeted deep within the body, resulting in heating a well defined target area without damaging surrounding tissue. The medical community may not embrace the advantages of APA-focused thermotherapy without more extensive testing and clinical experience than the Company could afford to conduct. It is also possible that the technology will not be as effective in practice as theory and testing in animals have indicated. Similarly, the medical community has no experience with balloon catheter treatment for BPH.
3. Limited Products. The Company currently has a limited number of products. Failure to develop new products utilizing current products and newly acquired technology would affect the future profitability of the Company. The development of new products and application of new technology to existing products is subject to uncertainty and delay.
4. Lack of a Proven Marketing Plan. The Company intends to market its new products by concentrating on per-use revenue. Such plan has not been proven and is dependant on market acceptance and adequate capitalization.

#### General

Since inception, the Company has incurred substantial operating losses, principally from expenses associated with the Company's research and development programs, the clinical trials conducted in connection with the Company's thermotherapy system and PMA application for submission to the FDA. The Company believes these expenditures are essential for the commercialization of its technologies. The Company has experienced significant operating losses and as of September 30, 1998 had an accumulated deficit of \$19,464,010. The Company expects such operating losses to continue and possibly increase in the near term and for the foreseeable future as it continues its product development efforts, expands its marketing and sales activities and scales up its manufacturing operations. The Company's ability to achieve profitability is dependent upon its ability to successfully obtain governmental approvals, manufacture, market and sell its new technology and integrate such technology into its thermotherapy systems. The Company has not been able to successfully market its current thermotherapy system because of its inability to provide heat treatment for other than surface and sub-surface tumors. There can be no assurance that the Company will be able to successfully commercialize its newly acquired technology and apply it to its current thermotherapy systems or that profitability will ever be achieved. The operating results of the Company have fluctuated significantly in the past on an annual and a quarterly basis. The Company expects that its operating results will fluctuate significantly from quarter to quarter in the future and will depend on a number of factors, many of which are outside the Company's control.

The major obstacles facing the Company over the last several years have been inadequate funding, a negative net worth, and the slow development of the thermotherapy market as a sizeable market due to technical shortcomings of the thermotherapy equipment available commercially.

The Company has refocused the Company's efforts on the enhancement of current products through the development of new technology and sale of the thermotherapy products as the Company's core business. The Company is currently



focused on the enhancement of its thermotherapy equipment and obtaining governmental approvals. Towards this end the Company has licensed the APA technology and the MMTC technology.

The Company anticipates that its results of operations will be affected for the foreseeable future by a number of factors, including its ability to develop the new technology to enhance its current systems, regulatory matters, health care cost reimbursements, clinical studies and market acceptance.

#### Material Non-Operating Transactions and Losses in 1997 and 1996

For the year ended September 30, 1997, the Company had an extraordinary loss of \$(438,803) resulting from its 1996 investment in Ardex Equipment, LLC ("Ardex"). The Ardex investment arrangements were originally made with persons who were then directors of the Company and principals of Ardex, as described under "Certain Relationships and Related Transactions -- Recission of Ardex Acquisition". After Ardex experienced financial difficulties, the Company reviewed the financial status of Ardex and determined that \$438,803, representing the entire amount due from Ardex, including accrued interest, was uncollectible as of September 30, 1997. See Note 10 of Notes to Financial Statements.

For the September 30, 1996 fiscal year, the Company had a non-operating loss of \$(471,000) resulting from the recission of agreements to acquire an interest in Aestar Fine Chemical Company and to develop a cosmetics division in association with Mr. Gao Yu Wen, who had become a substantial stockholder of the Company in 1995, as described under "Certain Relationships and Related Transactions -- Redemption Agreement." In addition, in the 1997 fiscal year, Company incurred a non-operating loss of \$40,000 on Company funds which were to be invested by Mr. Gao. See Note 11 of Notes to Financial Statements.

#### Results of Operations

##### Comparison of Fiscal Year Ended September 30, 1998 to Fiscal Year Ended September 30, 1997

Product sales for the fiscal year ended September 30, 1998 ("fiscal 1998") were \$174,182. These sales occurred due to re-orders of the Company's original equipment. During the prior fiscal year, gross product sales, taking returns and allowances into consideration, were \$121,257. Significant product revenues are not expected until development of equipment incorporating the Company's new technologies is completed and such equipment is clinically tested and receives necessary approvals from governmental regulatory agencies.

Cost of sales increased to \$136,500 in fiscal 1998 from \$46,734 in fiscal 1997. Cost of sales as a percentage of sales increased over the prior period because newer components and enhancements were added to existing inventory in conjunction with upgrading the Company's products to incorporate the latest technology.

Research and development expense grew substantially to \$1,534,872 in fiscal 1998 from \$185,974 in fiscal 1997. During fiscal 1998 we increased our research and development efforts to enhance our products and to incorporate APA and other technological advances. The increases included \$561,238 for engineering work performed outside the Company on our breast cancer treatment device, \$289,868 for animal studies for our improved BPH system, \$245,976 for animal studies and other development work on our new breast cancer equipment and \$76,000 for work at Duke University in connection with the development of targeted drug delivery and gene-therapy technology. In addition, after a review of the Company's inventory, approximately \$175,000 of components and parts acquired in the course of developing our older equipment, including slower, DOS-based electronic components, were deemed to be unusable for the development of the Company's newer models which incorporate advanced microwave and other technology, and were therefore classified as obsolete and written off as additional research and development expense during fiscal 1998. The Company expects to continue its higher levels of expenditures for research and development in order to continue to enhance its products by incorporating APA technology and MMTC technology.

Selling, general and administrative expense increased to \$2,515,822 in fiscal 1998 from \$2,283,245 in fiscal 1997. Such increased expense included a write-off of approximately \$112,000 of inventory stocked as replacement parts for older equipment sold in prior years by the Company, which inventory was being carried at the lower of cost or market value and which was determined to have no appreciable market value at year-end because of the absence of demand. The remainder of the increase was attributable to a combination of somewhat higher outside consultant, advertising and administrative expense. The Company expects selling and marketing expense to increase substantially as it completes the development and testing of its new thermotherapy systems and expands its related advertising, and promotional and marketing activities.

Due mainly to the ramping up of research and development activities in the 1998 fiscal year, the loss from operations increased by \$1,618,316 to \$(4,013,012) from \$(2,394,696) in the prior year. However, the increase in the 1998 loss before income taxes was not as large compared with 1997 because of the non-operating losses reflected in the earlier year as described above.

Comparison of Fiscal Year Ended September 30, 1997 to Fiscal Year Ended September 30, 1996

Product sales for the fiscal year ended September 30, 1997 were \$121,257, compared with prior year product sales of \$134,006, reduced to \$74,006 after returns and allowances of \$60,000. Significant product sales were not expected until equipment incorporating the Company's new technologies is developed, tested and approved for sale by governmental regulatory agencies.

Cost of sales decreased to \$46,734 in fiscal 1997 from \$64,406 in fiscal 1996. This primarily reflects the decrease in gross sales. The Company does not believe that fluctuations in gross margin are meaningful at the current low level of sales.

Research and development expense increased to \$185,974 in fiscal 1997 from \$94,012 in fiscal 1996, reflecting increased activity in the development of the Company's new products. The Company's plans call for significant increases in its expenditures for research and development to support its new product efforts and the incorporation of the APA technology and the MMTC technology.

Selling, general and administrative expense in fiscal 1997 rose to \$2,283,245 from \$1,321,361 in fiscal 1996, an increase of 73%. Of this increase, approximately \$377,000 was attributable to compensation paid under an employment agreement with Spencer J. Volk, who became the Company's President and Chief Executive Officer in May, 1997, of which amount \$280,000 represented shares of Common Stock issued as incentive compensation. Such increased expense for fiscal 1997 also included (i) \$177,100 of executive compensation to Verle D. Blaha, the predecessor President, compared with compensation of only \$81,000 to Mr. Blaha for the portion of the prior year during which he was employed, (ii) compensation of \$266,666 to Warren C. Stearns, formerly the Company's acting Chief Financial Officer, compared with \$66,753 for the portion of the prior year during which he performed services, and (iii) increased legal and professional fees. For additional information on such compensation, see Item 11, "Executive Compensation", and Item 13, Certain Relationships and Related Transactions.

As indicated above, during fiscal 1997 the Company wrote off as uncollectible the principal and interest receivable from Ardex in the amount of \$438,803, and, as part of its settlement with Gao Yu Wen, the Company incurred a loss of \$40,000 in funds previously held for investment by Mr. Gao.. These two extraordinary items totaled \$478,803 in non-operating expense in fiscal 1997, compared with an extraordinary loss in 1996 of \$471,000 from a terminated effort to develop a cosmetics division.

Interest expense increased to \$185,562 in fiscal 1997 from \$85,506 in fiscal 1996. This primarily reflects an increase in short term debt incurred to finance the Company's operations.

Due mainly to the increase in selling, general and administrative expense for the 1997 fiscal year, the loss from operations increased to \$(2,394,696) from \$(1,405,773) in the prior year. The loss before income taxes in 1997 reflected the larger interest expense compared with 1996, and both years included expenses incurred in non-operating transactions as described above.

#### Liquidity and Capital Resources

Since inception, the Company's expenses have significantly exceeded its revenues, resulting in an accumulated deficit of \$19,464,010 at September 30, 1998. The Company has incurred negative cash flows from operations since its inception, and has funded its operations primarily through the sale of equity securities. As of September 30, 1998, the Company had cash of \$ 54,920 and total current assets of \$174,735, compared with current liabilities of \$2,176,086, resulting in a working capital deficit of \$(2,000,351). Net cash used in the Company's operating activities was \$ 2,112,529 for fiscal 1998.

The Company does not have any bank financing arrangements. As of September 30, 1998, the Company's indebtedness consisted of a promissory note payable to Yu Shai Lai in the principal amount of \$36,041; a promissory note payable to Lake Shu Loon in the principal amount of \$10,000; a promissory note payable to Charles Shelton in the principal amount of \$50,000; a secured promissory note payable to George T. Horton Trust (the "Horton Note") in the original principal amount of \$220,000, the payment of which is secured by certain equipment owned by the Company and was due by its terms on December 15, 1997; and a promissory note payable to Spencer J. Volk in the amount of \$50,000, which was subsequently converted into 200,000 shares of the Company's Common Stock and a Warrant to purchase 200,000 share of the Company's Common Stock (see "Certain Relationships and Related Transactions"). At September 30, 1998, the outstanding principal amount of the Horton Note was \$18,000. The holder's

remedies for non-payment include foreclosing on the collateral, increasing the interest rate to 17% per annum or converting the balance into common stock having a market value of 200% of the note balance.

As of March, 1999, the Company had planned to raise and spend approximately \$10,000,000 for calendar 1999, of which between \$5 million and \$6 million was to be devoted to research and development and clinical trials for the Company's breast cancer and BPH therapy products, and approximately \$4 million was to be devoted to research and development in the areas of targeted drug delivery, gene therapy and prostate cancer, as well as to corporate overhead. As of July 1, 1999, the Company expects to raise and spend a total of about \$6 million for all of calendar 1999, of which \$4 million is being devoted to breast cancer and BPH research and clinical trials, and \$2 million to new products and to corporate overhead. As is indicated by the change in estimated expenditures between March and July 1999, the foregoing amounts are estimates based upon assumptions as to the availability of funding, the scheduling of institutional personnel, the timing of clinical trials and other factors, not all of which are fully predictable. Accordingly, estimates and timing concerning projected expenditures and programs are subject to change.

Of the currently planned total expenditures of approximately \$6 million, the Company has raised \$2.3 million as of June 30, 1999, with approximately \$3.7 million remaining to be raised during the remainder of calendar 1999. The Company recently entered into an exclusive investment banking agreement with a brokerage and investment banking firm, looking toward the completion of a private placement of approximately \$2.5 million in August 1999, but such offering will be made on a "best efforts" basis, and the Company does not have any firm commitment for the offering proceeds or the additional funds it will require later this year. If the Company cannot fund its operating requirements, and particularly those associated with its obligation to conduct clinical trials under its licensing agreements, it will be in breach of its commitments under such licensing agreements and could stand to lose its license rights unless, at the time of any such breach, it could arrange for additional time, and could obtain the funding needed, to conduct such clinical trials. If, because of a failure to obtain funding or other cause, the Company were to commit a breach of its license agreements, the Company could well lose any benefit it has previously received from association with various research institutions with which it has previously worked.

The Company's dependence on raising additional capital will continue at least until the Company is able to begin marketing its new technologies. The Company's future capital requirements and the adequacy of its financing depend upon numerous factors, including the successful commercialization of the thermotherapy systems, progress in its product development efforts, progress with preclinical studies and clinical trials, the cost and timing of production arrangements, the development of effective sales and marketing activities, the cost of filing, prosecuting, defending and enforcing intellectual property rights, competing technological and market developments, and the development of strategic alliances for the marketing of its products. The Company will be required to obtain such funding through equity or debt financing, strategic alliances with corporate partners and others, or through other sources not yet identified. The Company does not have any committed sources of additional financing, and cannot guarantee that additional funding will be available on acceptable terms, if at all. If adequate funds are not available, the Company may be required to delay, scale-back or eliminate certain aspects of its operations or attempt to obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, product candidates, products or potential markets.

Note 2 of the Notes to the Company's Financial Statements describes a going concern uncertainty based on the continuation of substantial operating losses and the need for substantial amounts of working capital to fund its present and intended operations. As discussed above, the continued operation of the Company is dependent upon the Company's ability to obtain sufficient funding to complete clinical trials of its products, obtain FDA and other approvals, and conduct a successful marketing campaign. As indicated in Note 2, the continuation of the Company as a going concern and the realization of a majority of the Company's assets is dependent upon its ability to obtain such funding.

#### Year 2000 Compliance

The Company is evaluating the potential impact of what is commonly referred to as Year 2000 or Y2K issues, concerning the inability of certain information systems to properly recognize and process dates containing the year 2000 and beyond. The Company believes that all of its current medical systems are year 2000 compliant. In addition, the Company's older medical systems, which, with one exception, are no longer under warranty and are no longer being serviced by the Company, have been tested and are expected to function properly beginning January 1, 2000, for two reasons. First, the older systems' software, operations, and control systems are not date-driven, and second, the older systems are "stand alone" systems and, therefore, are not linked to any other computer systems. Accordingly, in the Company's view, this equipment can continue to function beyond January 1, 2000. The record and storage programs used by such systems are, however, date driven, and, although not required to do so, the Company is currently testing the record storage programs to determine the most effective method for permitting such programs to properly record treatment information after January 1, 2000.

The Company has installed accounting software that is Y2K compliant. The Company is currently evaluating its other computerized systems. The aggregate costs to upgrade such other systems for Y2K compliance are estimated to be below \$8,000.

The Company uses various vendors and subcontractors to provide parts and components. The Company is surveying these vendors and subcontractors concerning Y2K issues, but has not yet determined the extent of Y2K readiness of these entities. The Company expects to complete a written survey of its vendors by September 30, 1999, and the Company continues to monitor the Y2K progress of its vendors to determine the potential impact to the Company of their Y2K readiness or lack thereof. In addition, the Company has multiple suppliers for most of the parts used in its APA-improved Microfocus equipment, and has been seeking alternate sources for those items now being purchased from single sources. To date, management does not anticipate that its Y2K readiness plans will result in any material costs to the Company, and the Company does not view the going concern reservation set forth in its Financial Statements as having an impact on the Company's ability to be Y2K compliant.

As a standard precautionary step, software data generated at the Company, by the Company, is backed-up on a daily basis. The worst case scenario if the Company experienced computer equipment failure due to Y2K would be that once the failed equipment was fixed, the backed-up data would have to be reinstalled onto any fixed system. Concerning the actual operation of the machinery, the worst case scenario would be distorted patient data recorded on the machinery's storage unit. Nevertheless, the machine will continue to operate properly with distorted patient records, but will require the operator of the machinery to re-enter corrected patient information.

Although the Company does not anticipate that Y2K will have a material impact on the Company's financial condition or its ability to operate at current levels, it cannot guarantee that the steps taken in preparation for the year 2000 will be sufficient to avoid any adverse impact on the Company.

#### Risk Factors

#### Unfunded Research Obligations

The Company engages third party research institutions and hospitals to perform research and clinical trials for the Company. As of September 30, 1998, the Company entered into agreements to fund a minimum of \$900,000 of research and clinical trials through March 30, 1999. The Company does not have the capital to fund such obligations, nor does it have commitments for such capital. The Company recently entered into an exclusive investment banking agreement with a brokerage and investment banking firm, looking toward the completion of a private placement of approximately \$2.5 million later in 1999, but such offering will be made on a "best efforts" basis, and the Company does not have any firm commitment for the offering proceeds or the additional funds it will require later this year. There is no assurance that these funds will be raised and if they are not raised, the clinical trials will likely be delayed or not completed. If the Company cannot fund such obligations, it will lose the data necessary to develop and commercialize its products. The Company may also lose any benefit it has previously received from association with well known research institutions.

Additional research and development spending of \$4.0 million is planned for 1999 to complete breast cancer and BPH clinical trials. It will be necessary to raise capital to conduct these trials and there is no assurance that this will occur as revenues are not expected to begin until the year 2000 at the earliest. If the Company is unable to fund research and development activities which are called for in any of its license agreements, it will be in breach of its license agreements. The Company's business plan incorporates the planned 1998 and 1999 expenditures for research and development, and clinical trials have been updated to include latest developments. Phase I of the BPH clinical trials has been conducted at the Montefiore Medical Center under the direction of Dr. Arnold Melman. The Company has submitted an IDE application to the FDA to start the Phase I clinical trials to use its new breast cancer treatment system to ablate breast cancer tumors through heat alone. The Company has also applied for FDA approval of Phase I clinical trials of such breast cancer treatment system. All of the above research is dependent on the raising of additional capital and there is no assurance that this will be achieved.

The Company has paid Duke University a total of \$134,745 for development work through February, 1999, conducted under two sponsored research agreements. The Company and Duke University have been negotiating a new research agreement under which the Company expects to be obligated to pay Duke approximately \$200,000 during the remainder of 1999 and approximately \$200,000 to \$300,000 during 2000, for further research work in the area of heat-sensitive liposomes. Assuming the Company enters into the anticipated agreements with Duke, it will be required to obtain funding for these obligations. If such funding cannot be obtained by the Company, the Company could be in breach of the anticipated new agreement with Duke, which could result in the loss of any ability by the Company to obtain license rights to heat-sensitive liposome and other medical technology being developed at Duke.

## History of Losses; Accumulated Deficit; No Assurance of Revenue or Operating Profit

Since inception, the Company's expenses have significantly exceeded its revenues, resulting in an accumulated deficit of \$19,464,010 and a shareholders' deficit of \$1,851,067 at September 30, 1998, including losses for the quarter ended September 30, 1998 of \$678,662. The Company has funded its operations primarily through the sale of Company securities. Losses are expected to continue until the product enhancements have been completed and approved by the FDA or until the Company can implement its marketing plan. The Company has experienced diminishing revenue from product sales in recent years. There can be no assurance that it will be able to develop such revenue sources or that its operations will become profitable, even if it is able to commercialize any products. The Company will be required to conduct significant research, development, testing and regulatory compliance activities which, together with projected general and administrative expenses, are expected to result in substantial operating losses in the future.

## Early Stage of Product Development; Continuing Uncertainty of Technology

The Company's current commercialized products have not produced any significant profit to date and the Company believes that without successful development of its newer technology, it is likely that future profits will not materialize. Progress with any of the Company's potential products will require significant further research, development, testing and regulatory clearances and will be subject to the risks of failure inherent in the development of products based on innovative technologies. These risks include the possibility that the technologies used by the Company may be found to be ineffective or impractical; that new products, even if safe and effective, could fail to receive necessary regulatory clearances or be difficult to market; that the proprietary rights of third parties may preclude the Company from marketing the products; or that third parties may market superior or equivalent products. There can be no assurance that the Company's research and development activities will result in any commercially viable products.

The field of hyperthermia is rapidly evolving, and it is expected to continue to undergo significant and rapid technological changes. Rapid technological development could result in actual and proposed products, services, or processes becoming obsolete before the Company recovers a significant portion of its related research, development and capital expenses. Although to date the Company has engaged in substantial research and development efforts, the Company does not expect to be able to commercialize any products utilizing the new technology for a number of years, if at all. The Company is unable to predict precisely when a product might be commercialized due to uncertainties as to the time that will be required for, and the nature of, additional research and development, human clinical trials to assess each potential product and satisfying government regulatory requirements.

## Need for Substantial Additional Funds

It is anticipated that additional financing of approximately \$6,000,000 will be needed for 1999. In addition, the Company's cash requirements may vary materially from those now planned because of results of research and development, results of pre-clinical testing, relationships with collaborators, changes in the focus and direction of the Company's research and development programs, competitive and technological advances, the FDA's regulatory process, and other factors. The Company has engaged an investment banking firm, looking toward the completion of a private placement of approximately \$2.5 million later in 1999, but such offering will be made on a "best efforts" basis, and the Company does not have any firm commitment for the offering proceeds or the additional funds it will require later this year. The Company is dependent on raising new capital to fund operations to commercialize its products and to satisfy the commitments made by the Company for 1998 and 1999, as revenues are not expected to begin until late 1999 at the earliest, with early year 2000 being more likely. Failure to meet commitments may result in a loss of licensed technology. There is no assurance that adequate funds for these purposes, whether obtained through the financial markets, collaborative or other arrangements with corporate partners, or from other sources, will be available when needed or on terms acceptable to the Company. Insufficient funds may cause the loss of licenses on new technology and may require the Company to delay, scale back, or eliminate certain of its research and product development programs or to license third parties to commercialize products or technologies that the Company would otherwise seek to develop or commercialize itself.

## Dependence upon Key Personnel and Collaborators

The Company's success depends (i) on the continued contributions of its executive officers, scientific and technical personnel, and consultants and (ii) on the Company's ability to attract new personnel as the Company seeks to implement its business strategy. During the Company's limited operating history, many key responsibilities within the Company have been assigned to a relatively small number of individuals. The competition for qualified personnel is intense, and the loss of services of certain key personnel could adversely affect the business of the Company. There are no employment agreements with any of current management other than Mr. Spencer J. Volk, the Company's Chief Executive Officer and President.

## Competition

There are many companies and institutions that are conducting research and development activities on thermotherapy technologies for both oncology and prostate products that are similar to the efforts of the Company. The Company believes that the interest in investigating the potential of thermotherapy technologies will continue and may accelerate. Competitors engaged in all areas of cancer and prostate treatment in the United States and other countries are numerous and include, among others, major pharmaceutical and chemical companies, specialized technology companies, universities, and other research institutions. There can be no assurance that the Company's competitors will not succeed in developing products or other technologies that are more effective than any which have been or are being developed by the Company or which would render the Company's technology and products obsolete and non-competitive.

Many of the Company's actual and potential competitors have substantially greater financial, technical, human, and other resources. In addition, many of these competitors have significantly greater experience than the Company in undertaking preclinical testing and human clinical trials of new products and obtaining FDA and other regulatory approvals. Accordingly, certain of the Company's competitors may succeed in obtaining FDA approval for products more rapidly than the Company. Furthermore, if the Company is permitted to commence commercial sales of products, it will also be competing with respect to manufacturing efficiency and marketing with companies having greater resources and experience in these areas. The Company currently has limited experience in these areas.

## Uncertain Ability to Protect Proprietary Technology

As indicated above under "Patents and Proprietary Rights," the Company owns no patents but holds various license rights under eight patents held by others. Accordingly, the Company's success will depend, in part, on its ability to maintain license agreements on patented technology. No assurance can be given that any patents issued to or licensed by the Company will not be successfully challenged or circumvented by others, or that the rights granted will provide adequate protection to the Company. The Company is aware of patent applications and issued patents belonging to competitors and it is uncertain whether any of these, or patent applications filed of which the Company may not have any knowledge, will require the Company to alter its potential products or processes, pay licensing fees, or cease certain activities. Litigation, which could result in substantial cost to the Company, may also be necessary to enforce any patents issued to or licensed by the Company or determine the scope and validity of others' claimed proprietary rights. The Company also relies on trade secrets and confidential information that it seeks to protect, in part, by confidentiality agreements with its corporate partners, collaborators, employees, and consultants. There can be no assurance that these agreements will not be breached, that the Company would have adequate remedies for any such breach, or that the Company's trade secrets will not otherwise become known or be independently discovered by competitors.

## Technological Change

Various modalities for the treatment of cancer are the subject of extensive research and development. Many possible treatments which are being researched may not be amenable to enhancement with the Company's technology, or may not require thermotherapy for an effective cure. The development and acceptance of any such treatment could make the Company's technology obsolete.

## No Assurance of FDA Approval; Government Regulation

The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of medical products through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more and varies substantially based upon the type, complexity, and novelty of the product.

The effect of government regulation may be to delay marketing of new products for a considerable period of time, to impose costly procedures upon the Company's activities, and to furnish a competitive advantage to larger companies that compete with the Company. There can be no assurance that FDA or other regulatory approval for any products developed by the Company will be granted on a timely basis or at all. Any such delay in obtaining, or failure to obtain, such approvals would adversely affect the marketing of any contemplated products and the ability to earn product revenue. Further, regulation of manufacturing facilities by state, local, and other authorities is subject to change. Any additional regulation could result in limitations or restrictions on the Company's ability to utilize any of its technologies, thereby adversely affecting the Company's operations.

## License Agreements for Patented Technology

The Company has entered into exclusive license agreements with Massachusetts Institute of Technology (the "MIT Agreement") and MMTC, Inc. (the "MMTC Agreement") for the use of certain patented technologies. The MIT Agreement and the MMTC Agreement each contain license fee and royalty requirements and other performance requirements which the Company must meet by certain deadlines with respect to the use of the patented technologies. If the Company were to breach the MIT Agreement or the MMTC Agreement, the Company would lose its rights to the respective licensed technology and would not receive compensation for its efforts in developing or exploiting the technology.

In March 1998, the Company entered into two sponsored research agreements with Duke University pursuant to which the Company has agreed to pay Duke University for all direct and indirect costs incurred in the performance of the research contemplated under such agreements not to exceed \$625,062 and Duke University has agreed to grant to the Company an option (the "Option") to acquire an exclusive, worldwide, royalty bearing license of Duke University's rights to any invention, development, or discovery resulting from the subject research. The Company paid all sums invoiced by Duke for research work through February 1999 under the agreements. However, Duke and the Company have been conducting discussions for the purpose of revising the research agreements, and expect to conclude new arrangements by the beginning of August, 1999, pending which the prior research activities have been temporarily suspended.

## Uncertain Availability of Health Care Reimbursement

The Company's ability to commercialize thermotherapy products successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. Significant uncertainty exists as to the reimbursement status of newly-approved medical products. There can be no assurance that adequate third-party insurance coverage will be available for the Company to establish and maintain price levels sufficient for realization of an appropriate return on its investment in developing new therapies. Government, private health insurers, and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA. If adequate coverage and reimbursement levels are not provided by government, private health insurers, and third-party payors for uses of the Company's products, the market acceptance of these products would be adversely affected.

## Uncertainty Related to Health Care Reform Measures

There have been a number of federal and state proposals during the last few years to subject the pricing of health care goods and services to government control and to make other changes to the health care system of the United States. It is uncertain what legislative proposals will be adopted or what actions federal, state, or private payors for health care goods and services may take in response to any health care reform proposals or legislation. The Company cannot predict the effect health care reforms may have on its business, and no assurance can be given that any such reforms will not have a material adverse effect on the Company.

## Applicability and Adequacy of Product Liability Insurance Coverage

The Company's business exposes it to potential product liability risks which are inherent in the testing, manufacturing, and marketing of human therapeutic products. Recently, the Company has secured product liability insurance in the amount of \$5,000,000 and directors and officers insurance in the amount of \$3,000,000. There is no assurance, however, that claims will be covered by such insurance and will not exceed such insurance coverage limits.

## Limited Manufacturing Experience

The Company has only limited experience in producing its current products (approximately 84 BPH systems and 31 cancer systems worldwide) and has not produced any products utilizing the new technology. The Company's facilities comply with FDA's Good Manufacturing Practices ("GMP"). The facilities of certain of its contract manufacturers will need to comply with applicable regulations including the GMP regulation and other regulations. Failure to comply with applicable requirements and regulations by the Company's contract manufacturers could delay or prohibit manufacturing of the new products system, which could have a material adverse effect on the Company's business, financial condition and results of operations. Any increase in production rates in response to demand for the Company's products could adversely impact the ability of the Company or its contract manufacturers to comply with such requirements.

## Contract Manufacturing; Dependence Upon Key Suppliers

The Company is not currently manufacturing any products but is using its facilities to assemble prototypes of its new equipment for research and development purposes. Certain specialized microwave and thermometry components and applicator materials, and the catheter unit used for the Company's BPH equipment, are now purchased only from single or limited source suppliers because of the small quantities involved, but such supply sources could be duplicated or replaced if necessary. While the Company has not experienced any significant difficulties in obtaining such components, the loss of an important current supplier could require the Company to obtain a replacement supplier, which might result in delays and additional expense in being able to make prototype equipment available for clinical trials and other research purposes.

## Possible Volatility of Share Price

Market prices for securities of medical and high technology companies have been volatile. Factors such as announcements of technological innovations or new products by the Company or its competitors, government regulatory action, litigation, patent or proprietary rights developments, and market conditions for medical and high technology stocks in general could have a significant impact on any future market for the Common Stock. The volatility of the Company's stock may also be affected by the lack of stock analyst coverage of the Company and the factors described at "-- NASDAQ Listing Requirements; Risks of Low-Priced Stocks" below.

## NASDAQ Listing Requirements; Risks of Low-Priced Stocks

The Company's Common Stock is currently traded through the OTC Electronic Bulletin Board. In the future, when it anticipates that it would be able to meet listing requirements, the Company intends to apply have its Common Stock listed on the NASDAQ SmallCap Market. At the present time, such a listing application would require, among other criteria, net tangible assets of at least \$4 million, a market capitalization of at least \$50 million, or net income of at least \$750,000, while the Company had, as of September 30, 1998, a net tangible deficit of \$(1,851,067), market capitalization of only approximately \$12 million, and a net loss of \$(4,200,488). Accordingly, absent a substantial change in the Company's financial condition, such as a large infusion of equity capital, there is little likelihood that the Company will be able to meet such listing requirements in the near future. If the Company is unable to satisfy NASDAQ's initial listing criteria in the future, its securities will continue to be traded through the Electronic Bulletin Board or the Pink Sheets.

The Securities Enforcement and Penny Stock Reform Act of 1990 requires additional disclosure in connection with trades in any stock defined as a penny stock. Regulations generally define a penny stock to be any equity security that has a market price of less than \$5.00 per share, subject to certain exceptions. Such exceptions include any equity security listed on NASDAQ and any equity security issued by an issuer that has (i) net tangible assets of at least \$2,000,000, if such issuer has been in continuous operation for three years, (ii) net tangible assets of at least \$5,000,000, if such issuer has been in continuous operation for less than three years, or (iii) average annual revenue of at least \$6,000,000, if such issuer has been in continuous operation for less than three years.

If the Company's securities are not quoted on NASDAQ, or the Company does not have \$2,000,000 in net tangible assets, trading in the Company's securities will continue to be covered by Rules 15g-1 through 15g-6 promulgated under the Exchange Act for non-NASDAQ and non-exchange listed securities. Under such rules, broker-dealers who recommend such securities to persons (other than established customers and accredited investors) must make a special written suitability determination that the penny stock is a suitable investment for the purchaser and must receive other information from the purchaser.

## Market Overhang from Warrants and Outstanding Options; Registration Rights

As of September 30, 1998, the Company had outstanding commitments to issue shares to management, and outstanding options and warrants to purchase shares in, an aggregate amount of approximately 13,053,983 shares of Common Stock, a significant portion of which are exercisable at exercise prices substantially below the current market price. In addition, this number does not reflect additional shares that may be issued pursuant to anti-dilution provisions. To the extent that such shares are issued, or such warrants or options are exercised, dilution to the interests of the Company's stockholders may occur. In the event that the market value of the Common Stock decreases significantly, the offering price in the Company's private placements or public offerings may be similarly affected. If this occurs, the number of shares issuable on exercise of certain options or warrants may significantly increase, thereby increasing the dilutive effect on other shareholders. Exercise of these options or warrants or even the potential of their exercise may have an adverse effect on the trading price and market for the Company's Common Stock. The holders of the options or warrants are likely to exercise them at times when the market price of the shares of Common Stock exceeds the exercise price of the options or warrants. Accordingly, the issuance of shares of Common Stock upon exercise of the options or warrants may result in dilution of the equity represented by the then-outstanding shares of Common Stock held by other stockholders. Holders of the options or warrants can be expected to exercise them at a time when the Company would in all likelihood be able to obtain any needed capital on terms which are more favorable to the Company than the exercise terms provided by such options or warrants.



Common Stock issued or to be issued pursuant to a substantial number of the warrants and options have demand and/or piggyback registration rights. Pursuant thereto, the Company was required to use good faith efforts to effect the registration of such securities on or before July 10, 1998, although such registration has not yet been effected. If such registration rights are exercised on a substantial portion of the Common Stock, the trading price and market for the Company's registered Common Stock may be adversely affected. Year 2000 Compliance

The Company is evaluating the potential impact of what is commonly referred to as Year 2000 or Y2K issues, concerning the inability of certain information systems to properly recognize and process dates containing the year 2000 and beyond. The Company believes that all of its current medical systems are year 2000 compliant. In addition, the Company's older medical systems, which, with one exception, are no longer under warranty and are no longer being serviced by the Company, have been tested and are expected to function properly beginning January 1, 2000, for two reasons. First, the older systems' software, operations, and control systems are not date-driven, and second, the older systems are "stand alone" systems and, therefore, are not linked to any other computer systems. Accordingly, in the Company's view, this equipment can continue to function beyond January 1, 2000. The record and storage programs used by such systems are, however, date driven, and, although not required to do so, the Company is currently testing the record storage programs to determine the most effective method for permitting such programs to properly record treatment information after January 1, 2000.

The Company has installed accounting software that is Y2K compliant. The Company is currently evaluating its other computerized systems. The aggregate costs to upgrade such other systems for Y2K compliance are estimated to be below \$8,000.

Finally, the Company uses various vendors and subcontractors to provide parts and components. The Company is surveying these vendors and subcontractors concerning Y2K issues, but has not yet determined the extent of Y2K readiness of these entities. The Company expects to complete a written survey of its vendors by September 30, 1999, and the Company continues to monitor the Y2K progress of its vendors to determine the potential impact to the Company of their Y2K readiness or lack thereof. In addition, the Company has multiple suppliers for most of the parts used in its APA-improved Microfocus equipment, and has been seeking alternate sources for those items now being purchased from single sources. To date, management does not anticipate that its Y2K readiness plans will result in any material costs to the Company, and the Company does not view the going concern reservation set forth in its Financial Statements as having an impact on the Company's ability to be Y2K compliant.

As a standard precautionary step, software data generated at the Company, by the Company, is backed-up on a daily basis. The worst case scenario if the Company experienced computer equipment failure due to Y2K would be that once the failed equipment was fixed, the backed-up data would have to be reinstalled onto any fixed system. Concerning the actual operation of the machinery, the worst case scenario would be distorted patient data recorded on the machinery's storage unit. Nevertheless, the machine will continue to operate properly with distorted patient records, but will require the operator of the machinery to re-enter corrected patient information.

Although the Company does not anticipate that Y2K will have a material impact on the Company's financial condition or its ability to operate at current levels, it cannot guarantee that the steps taken in preparation for the year 2000 will be sufficient to avoid any adverse impact on the Company.

#### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements, supplementary data and report of independent public accountants are filed as part of this report on pages F-1 through F-15.

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

No change of accountants and/or disagreements on any matter of accounting principles or financial statement disclosures have occurred within the last two years.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The following table sets forth the names and ages of the members of the Company's Board of Directors and its executive officers, and sets forth the position with the Company held by each:

Name	Age	Position
Augustine Y. Cheung+	51	Chairman of the Board of Directors, Chief Scientific Officer
Spencer J. Volk+	64	President, Chief Executive Officer and Director
John Mon*	46	Secretary, Treasurer, General Manager and Director
Max E. Link+	57	Director
Walter B. Herbst**	60	Director
Peter Gombrich ** (1)	59	Director

\* Term as director expires in 1999

\*\* Term as director expires in 2000

+ Term as director expires in 2001

(1) Mr. Gombrich resigned as a member of the Board of Directors of the Company on December 8, 1998.

The Board of Directors presently maintains an Audit Committee, a Compensation Committee, and a Research and Development Oversight Committee. Messrs. Warren C. Stearns and Mel D. Soule comprised the Audit Committee prior to their resignation as a members of the Board of Directors of the Company in July 1998. Mr. Peter Gombrich was appointed as a member of the Board of Directors to replace Mr. Soule, but subsequently resigned. The vacancies in the Board of Directors of the Company created by Messrs. Stearns' and Gombrich's resignations had not been filled as of January 13, 1999. The Audit Committee held no meetings during fiscal year 1997 and three meetings to date in the fiscal year ended September 30, 1998 ("fiscal year 1998"). Messrs. Volk and Herbst comprise the current Compensation Committee. The Compensation Committee held two meetings during fiscal year 1997 and four meetings in fiscal year 1998. Messrs. Cheung and Herbst comprise the Research and Development Oversight Committee. The Research and Development Oversight Committee was created in January 1998 and held a number of informal meetings during fiscal year 1998.

Augustine Y. Cheung. Dr. Cheung has served as the Chairman of the Board of Directors of the Company since 1982. Dr. Cheung was the founder of the Company, was President of the Company from 1982 to 1986 and Chief Executive Officer from 1982 to 1996. From 1982 to 1985, Dr. Cheung was a Research Associate Professor of the Department of Electrical Engineering and Computer Science at George Washington University and from 1975 to 1981 was a Research Associate Professor and Assistant Professor at the Institute for Physical Science and Technology and the Department of Radiation Therapy at the University of Maryland. Dr. Cheung holds a Ph.D. and Masters degree from the University of Maryland. Dr. Cheung is the brother-in-law of John Mon.

Spencer J. Volk. Mr. Volk has been a director, President, and Chief Executive Officer of the Company since May 22, 1997. From 1994 to 1996, Mr. Volk was President and Chief Operating Officer of Sunbeam International. From 1991 to 1993, Mr. Volk was the President and Chief Executive Officer of the Liggett Group, Inc. From 1989 to 1991, he was the President and Chief Operating Officer of Church and Dwight (Arm and Hammer), and from 1984 to 1986, he was the President and Chief Executive Officer of Tropicana Products, Inc. Prior to that, he spent thirteen years at Pepsico, ultimately as Senior Vice President for the Western Hemisphere. Mr. Volk holds an Honors BA in Economics and Math from Queens University in Ontario, Canada and a BA in Economics from Royal Military College in Ontario, Canada.

Max E. Link. Dr. Link has been a director of the Company since September 23, 1997. Dr. Link currently provides consulting and advisory services to a number of pharmaceutical and biotechnology companies. From 1993 to 1994, Dr. Link served as Chief Executive Officer of Corange, Ltd., a medical diagnostics company acquired by Hoffman-LaRoche. From 1971 to 1993, Dr. Link served in numerous positions with Sandoz Pharma AG culminating in his appointment as Chairman of the Board of Directors in 1992. Dr. Link serves on the Board of Directors of the following publicly held companies: Human Genome Sciences; Alexion Pharmaceuticals; Cell Therapeutics; Access Pharmaceuticals; Protein Design Laboratories; Osiris Therapeutics; Procept, Inc.; Discovery Laboratories Inc. and CytRx Corp. Dr. Link holds a Ph.D. in economics from the University of St. Gallen (Switzerland).

Walter B. Herbst. Mr. Herbst has been a director of the Company since May 28, 1997. Mr. Herbst has been and currently is the Chairman of Herbst Lazar Bell, Inc. ("HLB"), the engineering firm he founded in 1962. Mr. Herbst also serves as a faculty fellow in industrial design at the Northwestern University McCormick School of Engineering and Applied Sciences teaching materials and process. Additionally, he serves on the faculty at Northwestern University's Kellogg Graduate School teaching a course in product development. Mr. Herbst holds a BFA in Industrial Design from the University of Illinois and a Master of Management from the Kellogg Graduate School of Northwestern University.

Peter Gombrich. Mr. Gombrich served as a director of the Company from September 14 to December 8, 1998. Mr. Gombrich was the founder of InPath, LLC and has over 30 years experience in the healthcare industry. In 1994, Mr. Gombrich founded AccuMed International, Inc, and served as Chairman, President and Chief Executive Officer until 1998. He was also the founder and Chief Executive Officer of Clinicom, a bedside clinical information system company. In 1976, Mr. Gombrich co-founded St. Jude Medical, Inc., a world renowned life support medical device company. He was also the Senior Vice President of Medtronic, Inc. Mr. Gombrich has a B.S. in Electrical Engineering from the University of Colorado and an M.B.A. from the University of Denver.

John Mon. Mr. Mon has served as Treasurer/General Manager of the Company since 1989, and Secretary and a director since June 1997. From 1986 to 1988, Mr. Mon was responsible for the FDA regulatory approval process for the Microfocus 1000. From 1983 to 1986, he was an economist with the U.S. Department of Commerce in charge of forecasting business sales, inventory and prices for all business sectors in the estimation of Gross National Product. Mr. Mon holds a B.S. degree from the University of Maryland. Mr. Mon is the brother-in-law of Dr. Cheung.

The Board of Directors conducted 9 meetings during the year ended September 30, 1998. All members, except Mr. Gombrich, attended at least 75% of the Board of Directors meetings held during their tenure in 1998. Mr. Gombrich attended one of the two meetings of the Board of Directors held during his tenure. Additional actions were taken by unanimous consent resolutions.

#### Scientific Advisory Board

The Company currently has a scientific advisory board ("SAB") comprised of individuals listed below. The purpose of the SAB is to assist management of the Company in identifying and developing technology trends and business opportunities within the Company's industry. The SAB members operate as consultants and not as officers or directors of the Company. The following persons serve on the SAB:

Robert Barnett, M.D. Dr. Barnett currently the Surveyor for the American College of Surgeons and is the former President of the Maryland chapter of the American Cancer Society. Dr. Barnett consults with the Company on issues relating to oncological surgeons.

Donald Beard. Mr. Beard is a retired businessman and is the former senior program manager for the United States Department of Energy. Mr. Beard consults with the Company in connection with technology and business development matters.

Augustine Cheung, Ph.D. Dr. Cheung serves as the chairman of the SAB and as the Company's Chief Scientific Officer. Dr. Cheung's background is set forth above.

Michael Davidson, M.D. Dr. Davidson currently practices medicine and is the Chief Executive Officer of The Chicago Center for Clinical Trials. Dr. Davidson specializes in designing and implementing clinical trials. Dr. Davidson consults with the Company in connection with establishing clinical trials and on FDA regulatory matters.

Mark Dewhirst, Ph.D. Dr. Dewhirst currently serves as a Professor of Radiology and Oncology and the Director of the Tumor Microcirculation Laboratories in the Department of Radiation & Oncology at Duke University. Dr. Dewhirst consults with the Company in connection with research on temperature sensitive liposomes.

Donald Kapp, M.D., Ph.D. Dr. Kapp currently serves as Professor of Radiation Oncology at Stanford University. Dr. Kapp consults with the Company in connection with conducting clinical studies.

Gloria Li, Ph.D. Dr. Li currently serves as the Director of the Radiation Biology Laboratory at Memorial Sloan-Kettering Hospital. Dr. Li consults with the Company on heat shock and gene therapy.

Arnold Melman, M.D. Dr. Melman currently serves as the Chairman of the Department of Urology at Albert Einstein College of Medicine. Dr. Melman consults with the Company on clinical studies in urology and is the Company's primary investigator on BPH.

David Needham, Ph.D. Dr. Needham currently serves as the Director of Cell and Micro-carrier Research and an Associate Professor in the Duke University Department of Mechanical Engineering and Materials Science. Dr. Needham consults with the Company in connection with research on temperature sensitive liposomes.

Thomas Ripley, Ph.D. Dr. Ripley currently serves as Director of Operations, Grace Biomedical at W.R. Grace & Co. Dr. Ripley consults with the Company on technology and business development.

Mel Soule. Mr. Soule serves as Co-Chairman of the SAB. From 1994 through 1997, Mr. Soule was the president and chief executive officer of Grace Biomedical Division, a subsidiary of the W.R. Grace & Co. From 1993 through 1994, Mr. Soule was the director of commercial planning for the Washington Research Center of W.R. Grace & Co. From 1992 to 1993, Mr. Soule was a senior development manager for W.R. Grace & Co. Mr. Soule is currently a consultant to several biomedical companies.

Mays Swicord, Ph.D. Dr. Swicord currently serves as Director of Research at Motorola Corporation. Dr. Swicord consults with the Company on the biological effects of microwave technology.

Claude Tihon, Ph.D. Dr. Tihon currently serves as the Chief Executive Officer of Conti-Med, Inc. Dr. Tihon consults with the Company in connection with urological devices and regulation.

All members of the SAB serve at the discretion of the Board of Directors. Each member of the SAB, other than Dr. Cheung and Dr. Swicord, received an option to purchase 5,000 shares of the Common Stock of the Company at the time they were appointed. The options are exercisable for a five-year term at \$.50 per share. In addition, each member of the SAB will receive an option exercisable over a five-year term to purchase 3,000 shares of the Common Stock of the Company for each 12 months served by such member on the SAB, exercisable at the market price of the Common Stock on the date of grant. During fiscal year 1998, each member of the SAB, other than Messrs. Cheung and Swicord, received an option to purchase 3,000 shares of the Common Stock of the Company at \$1.25 per share. In addition, members of the SAB (except for Dr. Cheung) are compensated at the rate of \$125 per hour or a maximum of \$1,000 per day, together with expenses, on consulting matters undertaken by such member.

#### Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires the Company's officers and directors, and persons who own more than ten percent of a registered class of the Company's equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission and the National Association of Securities Dealers. Officers, directors, and greater than ten-percent shareholders are required by Securities and Exchange Commission regulations to furnish the Company with copies of all Section 16(a) forms they file. Based solely on a review of the copies of such forms furnished to the Company between October 1, 1997, and September 30, 1998, and on representations that no other reports were required, the Company has determined that during the last fiscal year all applicable 16(a) filing requirements were met except as follows:

Spencer J. Volk is the Chief Executive Officer and a director of the Company. Mr. Volk acquired 167,114 shares of Common Stock of the Company on September 23, 1998 and 2,000 shares of Common Stock of the Company on September 30, 1998. Mr. Volk filed a Form 4 on or about October 29, 1998. The Form 4 should have been filed on or before October 10, 1998.

Walter B. Herbst is a director of the Company. Herbst Lazar, Bell, Inc., of which Mr Herbst is the Chairman and Chief Executive Officer, acquired 833,334 shares of Common Stock of the Company on September 23, 1998. Mr. Herbst filed a Form 4 on or about October 28, 1998. The Form 4 should have been filed on or before October 10, 1998.

Mr. Peter Gombrich was appointed to be a director of the Company as of September 14, 1997, and thereby became subject to Section 16(a) reporting requirements. Mr. Gombrich filed a Form 3 on or about December 7, 1998. The Form 3 should have been filed on or before September 24, 1998.

ITEM 11. EXECUTIVE COMPENSATION

The following table sets forth the aggregate cash compensation paid for services rendered to the Company in all capacities during the last three fiscal years to the Company's Chief Executive Officer and to each of the Company's other executive officers where annual salary and bonus for the most recent fiscal year exceeded \$100,000.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Fiscal Year	Annual Compensation			Long-Term Compensation		
		Salary (\$)	Bonus (\$)	Other Annual Compensation(\$)	Restricted Stock Awards (\$)	Stock Options (#)	All Other Compensation (\$)
Augustine Y. Cheung, Chairman of the Board of Directors	1998	\$125,000 (1)			\$640 (2)		
	1997	\$125,000			\$2,120 (2)		
	1996	\$125,000			\$2,120 (2)	400,000 (3)	
Spencer J. Volk, President and Chief Executive Officer	1998	\$240,000 (4)			\$700,640 (2)(5)		
	1997	\$96,923 (6)			\$281,995 (2)(5)		
Verle D. Blaha, Former President and Chief Executive Officer	1997	\$177,100 (7)			\$1,182 (2)		
	1996	\$81,000			\$2,120 (2)	400,000 (8)	
Warren C. Stearns, Acting Chief Financial Officer	1998	\$195,297 (9)			\$961 (2)		
	1997	\$266,666 (9)			\$1,461 (2)		
	1996	\$66,753					(9)

- (1) Dr. Cheung's annual salary is \$125,000. Of the amount, approximately \$84,134 was paid in fiscal year 1998 and the balance of Dr. Cheung's annual salary was accrued.
- (2) In each of fiscal years 1996, 1997 and 1998, Dr. Cheung received 2,000 shares of the Common Stock of the Company for his services as a member of the Board of Directors of the Company. Mr. Blaha received 2,000 shares of the Common Stock of the Company for his service as a member of the Board of Directors of the Company in fiscal year 1996 and 1,112 shares for his services as a member of the Board of Directors of the Company in fiscal year 1997. Mr. Volk received 701 shares of the Common Stock of the Company for his service as a member of the Board of Directors of the Company in fiscal year 1997 and received 2,000 shares of the Common Stock of the Company for his service as a member of the Board of Directors of the Company in fiscal year 1998. Mr. Stearns received 1,375 shares for his service as a member of the Board of Directors of the Company in fiscal year 1997 and received 3,003 shares of the Common Stock of the Company for his service as a member of the Board of Directors of the Company in fiscal year 1998.
- (3) In fiscal year 1996, Dr. Cheung received an option to purchase 400,000 shares of the Common Stock of the Company at \$0.25 per share as adjusted, exercisable on or before May 16, 2001.
- (4) Mr. Volk's annual salary is \$240,000. Of that amount, approximately \$87,692 was paid in fiscal year 1998 and the balance of Mr. Volk's annual salary was accrued.
- (5) Mr. Volk received 500,000 shares of Common Stock of the Company in fiscal year 1997 pursuant to his employment agreement and has the right to receive up to 1,400,000 additional shares of the Common Stock of the Company if the Company meets certain financing goals during his tenure and if he is employed by the Company after one year. As of September 30, 1998, Mr. Volk received 1,000,000 shares of such amount.
- (6) Mr. Volk became President and Chief Executive Officer of the Company on May 22, 1997.
- (7) Mr. Blaha resigned as the President and Chief Executive Officer of the Company on April 23, 1997.
- (8) The Company granted an option to purchase 400,000 shares of the Common Stock of the Company, with an exercise price of \$.41 per share as adjusted, to New Opportunities, Ltd., a company affiliated with Mr. Blaha.
- (9) Amounts listed as annual compensation in fiscal year 1996 and fiscal year 1997 for Mr. Stearns consist of fees paid to Stearns Management Company ("SMC"). In fiscal year 1998, SMC was paid approximately \$95,297 in fees and for reimbursement expenses. In May 1997, Mr. Stearns resigned as the Acting Chief Financial Officer of the Company. In July 1998, Mr. Stearns resigned as a member of the Company's Board of Directors. The Company and SMC have agreed that the remaining fees and reimbursement for expenses the Company still owes to SMC is \$100,000. During fiscal year 1996, assignees of SMC also received warrants with anti-dilution rights to purchase 4.6875% of the Common Stock of the Company.

During fiscal year 1998, there were no profit sharing plans for the benefit of the Company's officers, directors, or employees. In fiscal year 1997, the Company established a SARSEP pension plan for its employees. The Company does not contribute any funds to the plan. In addition, the Company provides health insurance coverage for its employees. At the annual meeting held on April 27, 1998, the stockholders approved an omnibus option plan. The Board of Directors may recommend and adopt additional programs in the future for the benefit of officers, directors, and employees.

#### Option Grants in Fiscal 1998 / Director Compensation

During fiscal 1998, no options were granted to the named executive officers listed in the Summary Compensation Table. Each non-employee director and each employee director receives a grant of 12,000 shares and 2,000 shares of

Common Stock of the Company respectively for the full year served or the pro rata portion if less than one year. In addition, Mr. Herbst received an option to purchase 50,000 shares of Common Stock of the Company at \$0.50 per share commencing October 1, 1998 through September 30, 2003 for his service on the Board of Directors for the full fiscal 1998 year. Mr. Gombrich received an option to purchase 50,000 shares of Common Stock of the Company at \$0.50 per share commencing October 1, 1998 through September 30, 2003 for becoming a member of the Board of Directors. Mr. Link will receive an option to purchase 50,000 shares of Common Stock of the Company at \$0.75 per share commencing December 31, 1998 through December 30, 2003 for his service on the Board of Directors for the full fiscal 1998 year.

Aggregated Option Exercises and Year-End Option Values in 1998

The following table summarizes for each of the named executive officers of the Company the number of stock options, if any, exercised during 1998, the aggregate dollar value realized upon exercise, the total number of unexercised options held at September 30, 1998 and the aggregate dollar value of in-the-money unexercised options, if any, held at September 30, 1998. Value realized upon exercise is the difference between the fair market value of the underlying stock on the exercise date and the exercise price of the option. The value of unexercised, in-the-money options at September 30, 1998 is the difference between its exercise price and the fair market value of the underlying stock on September 30, 1998, which was \$0.32 per share based on the closing price of the Common Stock of the Company on September 30, 1998. The underlying options have not been and may never be exercised; and actual gains, if any, on exercise will depend on the value of the Common Stock of the Company on the actual date of exercise. There can be no assurance that these values will be realized.

Aggregated Option Exercises in Fiscal 1998 and Year-End Option Values

Name	Shares Acquired on Exercise	Value Realized (\$)	Number of Unexercised Options at 9/30/98		Value of Unexercised In-the-Money Options at 9/30/98	
			----- Exercisable	Unexercisable	----- Exercisable	Unexercisable
Augustine Y. Cheung	0	\$0	400,000	0	\$28,000	\$0
Spencer J. Volk	0	\$0	0	0	\$0	\$0
John Mon	0	\$0	600,000	0	\$42,000	\$0
Warren C. Stearns(1)	0	\$0	0	0	\$0	\$0

(1) Mr. Stearns holds no options. However, the status of warrants issued in 1996 to third parties, at the direction of Mr. Stearns, is being reviewed by the Company and its attorneys. None of such warrants have been exercised.

Long-Term Incentive Plan Awards in Fiscal Year 1998

At the annual meeting held on April 27, 1998, the stockholders approved an omnibus stock option plan. See "Stock Option Plans".

Future Benefits or Pension Plan Disclosure in Fiscal Year 1998

The Company provides a SAR-SEP saving plan to which eligible employees may make pretax payroll contribution up to 15 % of compensation. The Company does not make contributions to the plan. At the annual meeting held on April 27, 1998, the stockholders approved an omnibus stock option plan. See "Stock Option Plans". The Board of Directors may recommend and adopt additional programs in the future for the benefit of officers, directors, and employees.

Employment Contracts and Termination of Employment and Change-In-Control Arrangements

On May 22, 1997, Spencer J. Volk became the President and Chief Executive Officer of the Company. The Company and Mr. Volk have entered into an employment agreement, dated May 11, 1997, with an initial annual salary of \$240,000, which will increase to \$360,000 per annum upon the successful raising of \$5,000,000 through public or private offerings. In addition, Mr. Volk was awarded 500,000 shares of Common Stock of the Company upon execution of the employment agreement and may earn up to an additional 1,400,000 shares based on the Company's ability to raise additional capital and Mr. Volk's continued employment. Mr. Volk, as of September 30, 1998, received 1,000,000 of such shares.

Additionally, Mr. Warren C. Stearns, a former officer and director of the Company, received compensation through Stearns Management Company, which had an exclusive advisory services arrangement with the Company.

Other than as set forth above, there are no employment contracts, termination of employment or change in control arrangements.

#### Stock Option Plans

At the annual meeting held on April 27, 1998, the stockholders approved an omnibus stock option plan. The plan commits up to 2,000,000 shares for option grants to directors, employees and consultants. 280,000 of such shares have been granted at the direction of Spencer J. Volk. The Company has committed to allow Mr. Volk to nominate the recipients of options for 1,720,000 shares under the plan.

#### Report of the Compensation Committee on Executive Compensation

The Company formed a Compensation Committee in June 1997, consisting of Spencer J. Volk, an employee director, and Walter Herbst, a non-employee director. The Committee is responsible for establishing and administering the compensation policies applicable to the Company's officers and key personnel. The committee's responsibilities include, establishing general compensation policy and, except as prohibited by applicable law, taking any and all action that the Board could take relating to the compensation of employees, directors and other parties. The Committee also evaluates the performance of and makes compensation recommendations for senior management.

#### Executive Compensation Philosophy

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The Company attempts to design executive compensation to achieve two principal objectives. First, the program is intended to be fully competitive so that the Company may attract, motivate and retain talented executives. Second, the program is intended to create an alignment of interests between the Company's executives and stockholders such that a significant portion of each executive's compensation varies with business performance.

The Committee's philosophy is to pay competitive annual salaries, coupled with an incentive system that pays more than competitive total compensation for superior performance reflected in increases in the Company's stock price. The incentive system consists of annual compensation and stock compensation. Based on assessments by the Board and the Committee, the Committee believes that the Company's compensation program for the Named Executive Officers has the following characteristics that serve to align executive interests with long-term stockholder interests:

- a. Emphasizes "at risk" pay such as options and grants of restricted stock;
- b. Emphasizes long-term compensation such as options restricted stock awards; and rewards financial results and promotion of Company objectives rather than individual performance against individual objectives.

#### Annual Salaries

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Salary ranges and increases for executives, including the Chief Executive Officer and the other named executive officers, are established annually (unless subject to longer term contracts) based on competitive data. Within those ranges, individual salaries vary based upon the individual's work experience, performance, level of responsibility, impact on the business, tenure and potential for advancement within the organization. Annual salaries for newly-hired executives are determined at time of hire taking into account the above factors other than tenure.

#### Long-Term Incentives

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The grant of restricted stock or options to key employees encourages equity ownership and closely aligns management interests with the interests of stockholders. The amount and nature of any option or restricted stock award is determined by the Committee on a case by case basis, depending upon the individual's perceived future benefit to the Company and the perceived need to provide additional incentive to align performance with the objectives of the shareholders.



Company Performance and Chief Executive Officer Compensation

The compensation of Spencer Volk was established prior to organization of the Compensation Committee. The Committee believes that Spencer Volk's compensation package aligns his interests with those of the stockholders.

Stockholder Return Performance Graph

Federal regulation requires that inclusion of a line graph comparing cumulative total shareholder return on Common Stock with the cumulative total return of (1) NASDAQ Combined Index and (2) a published industry or line-of-business index. The performance comparison appears below. The Board of Directors recognizes that the market price of stock is influenced by many factors, only one of which is Company performance. The stock performance shown on the graph is not necessarily indicative of future price performance.

[GRAPHIC OMITTED]

Total Return Analysis

	9/30/94	9/29/95	9/30/96	9/30/97	9/30/98
The Company	\$ 100	\$ 473	\$ 300	\$ 309	\$ 93
Nasdaq Health	\$ 100	\$ 106	\$ 139	\$ 139	\$ 94
Nasdaq Composite (US)	\$ 100	\$ 137	\$ 161	\$ 221	\$ 222

Source: Carl Thompson Associates www.ctaonline.com (800) 959-9677. Data from Bloomberg Financial Markets

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding shares of voting securities of the Company beneficially owned as of September 30, 1998 by: (i) each person known by the Company to beneficially own 5% or more of the outstanding voting securities; (ii) by each director, (iii) by each current executive officer and (iv) by all current directors and executive officers as a group. As of September 30, 1998, there were 39,945,826 shares of Common Stock outstanding.

Name and Addresses of Officers, Directors and Principal Shareholders	Amount of Common Shares	Percentage of Voting Securities(1)
Augustine Y. Cheung (2)(3) 10220-I Old Columbia Road Columbia, MD 21046-1705	6,673,408	16.3%
Spencer J. Volk (2)(4) 10220-I Old Columbia Road Columbia, MD 21046-1705	1,913,717	4.7%
John Mon (2)(5) 10220-I Old Columbia Road Columbia, MD 21046-1705	769,212	1.9%
Walter B. Herbst (2)(6) 355 North Canal Street Chicago, IL 60606	1,135,586	2.8%
Max E. Link (2)(7) Tobelhofstr. 30 8044 Zurich Switzerland	62,038	**
Peter Gombrich (2)(8) 920 N. Franklin Street Suite 304 Chicago, IL 60610	50,493	**
Bei-Lan Tan Ning Yeung Terrace 78 Bonham Rd., Mid Level Hong Kong, China	3,340,000	8.2%
Executive Officers and Directors as a group (6 individuals)	10,604,454	26.2%

\* Assumes exercise of all options held by listed security holders which can be exercised within 60 days from September 30, 1998.

\*\* Less than 1%.

(1) Except as noted, the above table does not give effect to an aggregate of approximately 13,030,822 shares of Common Stock underlying outstanding stock options and warrants, obligations to issue shares or warrants that are contingent on future offerings. Outstanding warrants and options entitle the holders thereof to no voting rights.

(2) Director or Executive Officer. Mr. Gombrich resigned as a member of the Board of Directors of the Company on December 8, 1998.

(3) Includes 400,000 shares underlying an option exercisable commencing May 16, 1995 through May 16, 2001 at \$0.35 per share as adjusted.

(4) Includes 1,000,000 shares earned by Mr. Volk pursuant to his employment agreement subsequent to the end of fiscal year 1997. Does not include an additional 400,000 shares of Common Stock that have been committed to and may be earned by Mr. Volk pursuant to his employment agreement upon the occurrence of certain events.

(5) Includes 400,000 shares of Common Stock underlying an option to Mr. Mon exercisable commencing May 16, 1996 through May 16, 2001 at \$0.25 per share as adjusted and 200,000 shares of Common Stock underlying an option exercisable commencing April 1, 1997 through March 31, 2002 at \$0.25 per share as adjusted.

- (6) Includes 35,000 shares of Common Stock underlying options exercisable beginning June 16, 1997 and ending June 16, 2002 at a price of \$.41 per share, 15,000 shares of Common Stock underlying an option exercisable commencing June 1, 1998 through August 31, 2003 at \$.50 per share, and 50,000 shares of Common Stock underlying an option exercisable commencing October 1, 1998 through September 30, 2003 at \$.50 per share. Includes 20,000 shares of Common Stock underlying options to HLB exercisable beginning October 31, 1997 and ending October 30, 2002 at a price of \$1.00 per share and 875,198 shares of Common Stock owned by HLB. Mr. Herbst disclaims beneficial ownership of the stock option and shares of Common Stock owned by HLB.
- (7) Does not include 150,000 shares of Common Stock underlying an option exercisable at \$.75 per share which vest as to 50,000 shares of Common Stock on December 31 of 1998, 1999 and 2000.
- (8) Includes 50,000 shares of Common Stock underlying an option exercisable commencing October 1, 1998 through September 30, 2003 at \$.50 per share.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The transactions described below were entered into with persons who are, or who were at various times as discussed, directors, officers and stockholders of the Company. The Board of Directors has reviewed such transactions and has determined that they were entered into on terms which were not less favorable to the Company than terms which would have been available from a non-affiliated third party.

##### SMC Contract

On May 28, 1996, the Company entered into a consulting agreement with Stearns Management Company ("SMC"). Warren C. Stearns, former Acting Chief Financial Officer and a former member of the Board of Directors, is President of SMC. Additionally, the George T. Horton Trust, which is a secured creditor of the Company, is an equity owner of SMC. Pursuant to the Agreement, SMC had an exclusive arrangement to render advisory services involving solicitation and obtaining of outside capital, restructuring the Company, business plans, marketing, selection of advisory personnel, adding additional directors, and sale of stock by insiders.

In exchange for such services, during the fiscal year 1997, SMC was paid approximately \$266,666 in fees and \$38,824 for reimbursement of expenses. In fiscal year 1996, the Company granted to assignees of SMC warrants to purchase, in the aggregate, a 4.6875% interest in the equity of the Company as of the next registered public offering of Common Stock of the Company. The warrants, all of which were initially exercisable at \$.41 per share, subject to adjustment, contain anti-dilution provisions and are exercisable for five years and renewable for an additional five years. Mr. Stearns was paid a per diem expense of \$1,500 per day or \$190 per hour and reimbursement for expenses at cost plus 20%. During fiscal year 1998, SMC was paid approximately \$95,297 in fees and for reimbursement expenses, the Company and SMC agreed that the remaining fees and reimbursement for expenses that the Company owed to SMC is \$100,000.

Mr. Stearns resigned as the Company's Acting Chief Financial Officer in May 1998 and as a member of the Board of Directors in July 1998. The Company terminated its consulting agreement with Stearns Management Company effective July 19, 1998. Mr. Stearns has made a demand, on behalf of the holders of the warrants issued to SMC's designees, that the Company register for public sale the shares of Common Stock underlying such warrants. The Company and its attorneys have been reviewing the circumstances surrounding the issuance of the above warrants and the services which were performed or purported to be performed by Mr. Stearns and SMC, to make a determination as to what actions to take with respect to such warrants and registration demand.

##### George T. Horton Trust Loan

The Company is obligated under a secured note to the George T. Horton Trust in the original principal amount of \$220,000, which bears interest at 1% per month, and was payable December 15, 1997, and is secured by equipment and software for APA technology. George T. Horton Trust is an equity owner of SMC, the President of which, Warren C. Stearns, was also an officer and director of the Company until his recent resignation. As of the date of this report, the Company has paid \$107,000 of the principal of this note and the note holder has converted \$100,000 of principal into Common Stock of the Company. The remaining principal is \$13,000 as of the date of this report. The remaining principal accrues interest at the rate of 17% per annum or may be converted into Common Stock of the Company at the rate of 200% of the loan balance.

Herbst Lazar Bell, Inc.

The Company has retained the engineering firm of Herbst LaZar Bell, Inc., of Chicago to assist in the development of the commercial versions of its future deep focused heat systems and BPH treatment system. Walter Herbst, a director of the Company, is the founder and chief executive officer of HLB. HLB, with a team of engineers specializing in systems engineering and industrial design, will serve as the primary engineering resource for the Company. In fiscal year 1998, HLB billed the Company \$561,238 for the engineering and design work it performed, HLB was paid \$106,500 in cash and converted \$250,000 owed to it by the Company into 833,334 shares of the Common Stock of the Company.

#### Townhouse Lease

The Company leased from Augustine Cheung, Chairman of the Board, and John Mon, an officer and director, on a month to month basis a townhouse near its corporate offices in Columbia, Maryland for \$900 per month, plus utilities. The housing was used for visiting executives. The lease was terminated in May 1998.

#### Promissory Notes

From 1987 through 1998, the Company borrowed money from related parties. The Company formalized such borrowing by executing promissory notes to the following related parties:

An unsecured term note dated January 26, 1987 payable to Dr. Augustine Cheung, accruing interest at the rate of twelve percent (12%) per annum, in the principal amount of \$78,750 due December 31, 1998.

An unsecured term note dated June 30, 1994 payable to Dr. Augustine Cheung, accruing interest at the rate of ten percent (10%) per annum, in the principal amount of \$42,669 due December 31, 1998.

An unsecured term note dated June 23, 1998 payable to Spencer J. Volk, accruing interest at the rate of eight percent (8%) per annum, in the principal amount of \$50,000 due September 30, 1998. Mr. Volk has extended the maturity date of the unsecured term note dated June 23, 1998 issued by the Company to him in the principal amount of \$50,000.00 from September 30, 1998 to December 31, 1998. As of September 30, 1998, the outstanding principal balance of such note is \$50,000.

A secured term note dated September 9, 1994 payable to Charles C. Shelton, accruing interest at the rate of ten percent (10%) per annum, in the principal amount of \$50,000 payable as follows: beginning October 1, 1994 and ending December 31, 1995 - interest only; beginning January 1, 1996 and for 25 months thereafter - principal at the rate of \$2,000 per month, together with the monthly payment on interest on the unpaid balance of the note until paid in full; provided, however, that such interest shall not be payable in the event that the principal amount of the note is repaid by the Company on or before September 30, 1999. The outstanding principal balance of such note as of the date of this report is approximately \$50,000.

On September 23, 1998, Dr. Cheung converted (i) the unpaid principal and accrued interest on the unsecured term note dated June 30, 1994 issued by the Company to him in the principal amount of \$42,669.00 into 5,800 shares of the Common Stock at \$0.30 per share and (ii) the unpaid principal and accrued interest on the unsecured term note dated January 26, 1987 issued by the Company to him in the principal amount of \$78,750.00 into 254,200 shares of the Common Stock at \$0.30 per share.

On December 10, 1998, Mr. Volk converted the principal of the unsecured term note dated June 23, 1998 issued by the Company to him in the principal amount of \$50,000 into 200,000 shares of Common Stock of the Company, a warrant to purchase 100,000 shares of the Company's Common Stock at \$0.50 per shares, and a warrant to purchase 100,000 shares of the Company's Common Stock at \$1.00 per shares.

In addition, on September 23, 1998, Mr. Volk converted \$50,134 of unpaid expense reimbursements owed to him by the Company into 167,114 shares of the Common Stock at \$0.30 per share.

#### Redemption Agreement

On February 16, 1995, Gao Yu Wen executed a subscription agreement with the Company to purchase 20,000,000 shares of Common Stock at \$0.50 per share or \$10,000,000. The price was paid by paying \$2,000,000 cash and property, and

transferring to the Company 9.5% of the outstanding equity of Aestar Fine Chemical Company ("Aestar"). On June 6, 1996 the Company and Gao entered into a Redemption Agreement wherein the Company renounced any interest in Aestar and Gao agreed that upon delivery by the Company of \$2,200,000 to Gao, he would return the 20,000,000 shares of the Company. The promise to pay \$2,200,000 by November 30, 1996, was secured by all 20,000,000 shares. On October 23, 1996, the Company and Mr. Gao executed an Amendment by which the terms of the Redemption Agreement were modified. Under the terms of the First Amendment, Mr. Gao agreed to immediately convey to the Company certificates representing 16 million shares of Common Stock. The \$2,200,000 payment was reduced to \$2,160,000 and the timing was extended until December 31, 1996, with an additional three months period at a penalty of 3/4% per month. On October 23, 1996, Mr. Gao conveyed the 16 million shares to the Company. Such shares were subsequently canceled. The Company had the right and might have had the obligation to repurchase the remaining 4,000,000 shares of the Company for \$2,160,000 on or before November 30, 1997.

In a related transaction, on April 26, 1995, the Company entered into an Investment Agreement with Gao whereby the Company transferred \$700,000 to Gao to invest as agent of the Company at the rate of no less than 17% per annum. Gao repaid \$190,000 by September 30, 1996. The remaining amount has been forgiven as part of the Redemption Agreement.

Mr. Gao was the Deputy Director of the Economic Committee of the City of Zhongshan of Guangdong Province in South China. The City of Zhongshan is a rapidly expanding industrial areas in Guangdong Province, and one of the fastest growing areas in China. In this position, Mr. Gao was responsible for strategic planning and key decisions for approximately 120 manufacturing enterprises in China, and he had also run a number of enterprises in Hong Kong and Macau. Furthermore, in the course of its review of Aestar Fine Chemical Company, which Mr. Gao controlled, the Company learned that Aestar had paid substantial dividends to investors in the past.

No level of return was achieved. In reacquiring 16,000,000 of its shares in exchange for the Aestar stock and without repaying any of the \$2 million originally invested in the Company by Mr. Gao, the Company was required to reimburse Mr. Gao for his start-up expenses in a cosmetics division which he was to set up for the Company. These start-up costs totaled \$471,000, which amount was offset against the \$510,000 balance of the \$700,000 investment remaining after Mr. Gao had repaid \$190,000 of the original investment. The difference of approximately \$40,000 was deducted from the agreed price of \$2.2 million which was to be paid Gao to repurchase the remaining 4,000,000 shares out of the 20,000,000 originally purchased from the Company.

The 4,000,000 shares were not repurchased by the Company. The Company received the full \$2,000,000 purchase price in the initial transaction in 1995. The "remaining amount" refers to the \$470,000 which was offset against the investment and reflected as "Loss on Cosmetics Division" in the 1996 Statement of Operations.

#### Rescission of Ardex Acquisition

The Company originally contemplated acquiring a 51% equity interest in Ardex Equipment, LLC ("Ardex") for \$1.2 million, of which a portion was to be paid to Ardex's principals for the purchase of a portion of their equity interest and the balance was to be paid to Ardex for the issuance of additional equity. The Company was only able to invest a total of \$450,000, representing 37.5% of the originally contemplated amount, receiving a 19.25% interest for the smaller investment. As in the originally contemplated transaction, a portion of the reduced purchase price of \$450,000, or \$50,000, was paid to the principals of Ardex directly, (including Messrs. Shelton and Colino) and the balance of the purchase price was paid to Ardex.

The limited guarantees which were supposed to be delivered in connection with the obligations of Ardex and of Messrs. Shelton, Colino and Kohlman were never delivered. The Company did not continue its efforts to obtain the guarantees or to collect the amounts due on the separate obligations in 1997 because (i) it appeared to the Company that the obligors had limited assets and ability to pay, (ii) the Company had very limited resources with which to pursue enforcement of its claims, (iii) management needed to focus its efforts on the development of its new products, and (iv) the Company had obligations to Mr. Shelton and Mr. Kohlman, which it decided not to satisfy pending collection of the Ardex amounts, including (1) an obligation to Mr. Shelton for prior legal fees and expenses, asserted by him to total approximately \$110,000, (2) an accrued salary obligation of approximately \$28,000 due to Mr. Kohlman, (3) a commitment to issue to Mr. Shelton and his wife options to purchase a total of 420,000 shares of the Company's Common Stock at an exercise price of \$0.35 per share and (4) an obligation to issue 50,000 shares of Common Stock to Mr. Kohlman pursuant to his earlier exercise of a stock option and payment of the required exercise price.

In fiscal 1997, the Company determined that the Ardex obligations were essentially uncollectible, and wrote off the receivable of \$400,000 plus accrued interest of \$38,803.

In September 1998, the Company entered into a settlement arrangement, pursuant to which (i) Mr. Shelton agreed to waive his rights to the claimed \$110,000 in fees and expenses, (ii) Mr. and Mrs. Shelton agreed to waive their rights to the 420,000 options, and (iii) Mr. Kohlman agreed to waive his right to \$28,000 in accrued salary. In consideration of the settlement, the Company agreed (i) to recognize Mr. Kohlman's earlier exercise of his stock option and to deliver the 50,000 shares he had purchased thereunder, and (ii) to issue a total of 50,000 shares of Common Stock to Mr. and Mrs. Shelton in satisfaction of all of their earlier claims for compensation.

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

(a)(1) Index to Financial Statements and Supplemental Schedules

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(a)(2)

No schedules are provided because of the absence of conditions under which they are required.

(b) Reports on Form 8-K.

The Company filed no reports on Form 8-K during the fourth quarter of its fiscal year ended September 30, 1998.

(c) Exhibits.

The following documents are included as exhibits to this report:

Exhibit Number -----	Description -----
3.1	Articles of Incorporation of the Company as filed on May 19, 1982 with the State of Maryland Department of Assignments and Taxation, incorporated herein by reference to the exhibits to the Company's Registration Statement on Form S-1, as amended, originally filed with the Securities and Exchange Commission on October 17, 1984, Registration No. 2- 93826-W.
3.1.1	Articles of Amendment and Restatement to the Articles of Incorporation of the Company as filed on June 21, 1984 with the State of Maryland Department of Assignments and Taxation, incorporated herein by reference to Exhibit 3.1.1 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.
3.1.2	Articles of Amendment to the Articles of Incorporation of the Company as filed on December 14, 1994 with the State of Maryland Department of Assignments and Taxation, incorporated herein by reference to Exhibit 3.1.2 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.
3.1.3	Certificate of Amendment to Certificate of Incorporation as filed on May 1, 1998 with the State of Maryland Department of Assignment and Taxation, incorporated herein by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 30, 1998.
3.2	By-laws, incorporated herein by reference to Exhibit 3.2 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.

Exhibit Number -----	Description -----
3.2.1	Amendment to the By-laws of the Company adopted December 9, 1994, incorporated herein by reference to Exhibit 3.2.1 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.
3.2.2	Amendment to the By-laws of the Company adopted April 27, 1998, incorporated herein by reference to Exhibit 3.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 30, 1998.
10.1	Patent License Agreement between the Company and Massachusetts Institute of Technology dated June 1, 1996, incorporated herein by reference to Exhibit 10.1 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996 (Confidential Treatment Requested).
10.2	License Agreement between the Company and MMTC, Inc. dated August 23, 1996, incorporated herein by reference to Exhibit 10.2 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996 (Confidential Treatment Requested).
10.3	Letter Agreement between the Company and H.B.C.I., Inc., dated September 17, 1996, incorporated herein by reference to Exhibit 10.3 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.
10.4	Letter Agreement between the Company and Herbst, Lazar, Bell, Inc. dated October 4, 1996, incorporated herein by reference to Exhibit 10.4 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.
10.5	Sponsored Research Agreement dated March 17, 1998 between the Company and Duke University and Sponsored Research Agreement dated February 26, 1998 between the Company and Duke University.
10.6	Engagement Letter dated August 6, 1998 between the Company and Josephberg Grosz & Co., Inc.
10.7	Patent License Agreement between the Company and Massachusetts Institute of Technology dated October 17, 1997 (Confidential Treatment Requested).+
10.8	Amendment dated November 25, 1997 to the License Agreement between the Company and MMTC, Inc. dated August 23, 1996 (Confidential Treatment Requested).+
10.9	Omnibus Stock Option Plan, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 30, 1998.
10.10	Letter of Intent between the Company and Mr. Sun Shou Yi, representative of Mr. Gao Yu Wen, dated May 27, 1996 and Redemption Agreement between the Company and Mr. Sun Shou Yi., representative of Mr. Gao Yu Wen, dated June 6, 1996, incorporated herein by reference to Exhibit 10.8 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.
10.11	Amendment among the Company, Sun Shou Yi, Ou Yang An, Gao Yu Wen, dated October 23, 1996, incorporated herein by reference to Exhibit 10.9 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.
10.12	Unsecured Promissory Note, dated June 23, 1998, in the amount of \$50,000 and bearing interest at the rate of eight percent, payable to Spencer J. Volk.
10.13	Form of Series 200 Warrant issued to certain employees, directors, and consultants to Purchase Common Stock of the Company.
10.14	Form of Series 250 Warrant Issued to DunnHughes Holding, Inc. to Purchase Common Stock of the Company.
10.15	Form of Series 300 Warrant Issued to Nace Resources, Inc. and George T. Horton Trust to Purchase Common Stock of the Company.
10.16	Form of Series 400 Warrant Issued to Stearns Management Company Assignees to Purchase Common Stock of the Company.
10.17	Form of Series 500 Warrant Issued to Certain Employees and Directors on May 26, 1996 to Purchase Common Stock of the Company.
10.18	Form of Series 600 Warrant to Purchase Common Stock of the Company pursuant to the Private Placement Memorandum of the Company dated January 6, 1997, as amended.
10.19	Form of Series 650 Warrant to Purchase Common Stock of the Company pursuant to the Private Placement Memorandum of the Company dated January 6, 1997, as amended.
10.20	Form of Series 700 Warrant to Purchase Common Stock of the Company pursuant to the Private Placement Memorandum of the Company dated September 10, 1998, as amended.
10.21	Form of Registration Rights Agreement pursuant to the Private Placement Memorandum of the Company dated January 6, 1997, as amended.



Exhibit Number -----	Description -----
10.22	Form of Registration Rights Agreement pursuant to the Private Placement Memorandum of the Company dated September 10, 1998, as amended.
21.1	Subsidiaries of the Registrant, incorporated herein by reference to Exhibit 21.1 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.
23.1	Updated Consent of Stegman & Company, independent public accountants of the Company.+
27.1	Financial Data Schedule.

-----  
+ Denotes exhibits filed with this amendment

SIGNATURES

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

CELSION CORPORATION

November 24, 1999

By: /s/ Spencer J. Volk  
-----  
Spencer J. Volk  
Chief Executive Officer & President

By: /s/ Jon Mon  
-----  
Jon Mon  
Chief Accounting Officer, General  
Manager & Treasurer

Pursuant to the requirements of the Securities Exchange Act of 1934, this amendment to Registrant's annual report on Form 10-K has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature -----	Title -----	Date -----
/s/ Spencer J. Volk ----- Spencer J. Volk	Chief Executive Officer, President and Director	November 24, 1999
/s/ Jon Mon ----- Jon Mon	General Manager, Treasurer Director	November 24, 1999
/s/ Augustine Y. Cheung ----- Dr. Augustine Y. Cheung	Chairman, Director	November 24, 1999
/s/ Walter Herbst ----- Walter Herbst	Director	November 24, 1999
/s/ Max Link ----- Max Link	Director	November 24, 1999

CELSION CORPORATION

REPORT ON AUDITS OF  
FINANCIAL STATEMENTS

FOR THE YEARS ENDED  
SEPTEMBER 30, 1998, 1997 AND 1996

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INDEPENDENT AUDITORS' REPORT

The Board of Directors and Stockholders  
Celsion Corporation  
Columbia, Maryland

We have audited the accompanying balance sheets of Celsion Corporation as of September 30, 1998 and 1997, and the related statements of operations, changes in stockholders' deficit, and cash flows for each of the three years in the period ended September 30, 1998. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with 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 financial position of Celsion Corporation as of September 30, 1998 and 1997, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 1998 in conformity with generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 of the financial statements, the Company has suffered recurring losses from operations, which raise substantial doubt about its ability to continue as a going concern. Management's plans regarding those matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Stegman & Co.

/s/Stegman & Co.

-----  
Baltimore, Maryland

November 18, 1998

Except as to Note 5 which is dated

November 29, 1999

CELSION CORPORATION  
BALANCE SHEETS  
SEPTEMBER 30, 1998 AND 1997

ASSETS

	1998 -----	1997 -----
<b>CURRENT ASSETS:</b>		
Cash	\$ 54,920	\$267,353
Accounts receivable	1,812	5,891
Inventories	42,059	329,741
Prepaid expenses	76,944	8,207
Other current assets	--	26,755
	-----	-----
Total current assets	175,735	637,947
	-----	-----
<b>PROPERTY AND EQUIPMENT - at cost:</b>		
Furniture and office equipment	195,794	180,348
Laboratory and shop equipment	47,048	92,228
	-----	-----
Less accumulated depreciation	242,842	272,576
	212,029	213,885
	-----	-----
Net value of property and equipment	30,813	58,691
	-----	-----
<b>OTHER ASSETS:</b>		
Patent licenses (net of accumulated amortization of \$ 65,760 and \$53,379 in 1998 and 1997, respectively)	124,190	126,571
	-----	-----
TOTAL ASSETS	\$330,738	\$823,209
	=====	=====

See accompanying notes.

LIABILITIES AND STOCKHOLDERS' DEFICIT

	1997	1998
	-----	-----
CURRENT LIABILITIES:		
Accounts payable - trade	\$1,034,767	\$ 614,173
Notes payable - other	132,778	1,481,831
Notes payable - related parties	146,041	221,943
Accrued interest payable - related parties	150,020	245,784
Accrued interest payable - other	127,538	116,604
Accrued compensation	470,220	331,715
Accrued professional fees	100,000	256,301
Other accrued liabilities	13,639	15,504
Capital lease - current	1,083	-
	-----	-----
Total current liabilities	2,176,086	3,283,855
LONG-TERM LIABILITIES:		
Capital lease - long-term	5,719	-
	-----	-----
Total liabilities	2,181,805	3,283,855
	-----	-----
STOCKHOLDERS' DEFICIT:		
Capital stock - \$.01 par value; 51,000,000 shares authorized, 39,945,826 and 29,095,333 issued and outstanding for 1998 and 1997, respectively	399,458	290,953
Additional paid-in capital	17,213,485	12,511,923
Accumulated deficit	(19,464,010)	(15,263,522)
	-----	-----
Total stockholders' deficit	(1,851,067)	(2,460,646)
	-----	-----
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$ 330,738	\$ 823,209
	=====	=====

See accompanying notes.

CELSION CORPORATION

STATEMENTS OF OPERATIONS  
FOR THE YEARS ENDED SEPTEMBER 30, 1998, 1997 AND 1996

	1998	1997	1996
	-----	-----	-----
REVENUES:			
Equipment sales and parts	\$ 174,182	\$ 121,257	\$ 134,006
Returns and allowances	--	--	(60,000)
	-----	-----	-----
Total revenues	174,182	121,257	74,006
COST OF SALES	136,500	46,734	64,406
	-----	-----	-----
GROSS PROFIT	37,682	74,523	9,600
	-----	-----	-----
OPERATING EXPENSES:			
Selling, general and administrative	2,515,822	2,283,245	1,321,361
Research and development	1,534,872	185,974	94,012
	-----	-----	-----
Total operating expenses	4,050,694	2,469,219	1,415,373
	-----	-----	-----
LOSS FROM OPERATIONS	(4,013,012)	(2,394,696)	(1,405,773)
LOSS ON COSMETICS DIVISION	--	--	(471,000)
LOSS ON FUNDS HELD IN INVESTMENT CONTRACT	--	(40,000)	--
LOSS ON WRITE-OFF OF ARDEX EQUIPMENT, L.L.C. NOTES RECEIVABLE AND RELATED ACCRUED INTEREST RECEIVABLE	--	(438,803)	--
OTHER INCOME	11,870	7,172	28,808
INTEREST EXPENSE	(199,346)	(185,562)	(85,506)
	-----	-----	-----
LOSS BEFORE INCOME TAXES	(4,200,488)	(3,051,889)	(1,933,471)
INCOME TAXES	--	--	--
	-----	-----	-----
NET LOSS	\$ (4,200,488)	\$ (3,051,889)	\$ (1,933,471)
	=====	=====	=====
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$ (.12)	\$ (.11)	\$ (.05)
	=====	=====	=====
BASIC AND DILUTED WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	34,867,001	28,386,145	39,499,650
	=====	=====	=====

See accompanying notes.



CELSION CORPORATION

STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT  
FOR THE YEARS ENDED SEPTEMBER 30, 1998, 1997 AND 1996

	Common Stock Shares	Amount	Additional Paid-In Capital	Deficit	Total
	-----	-----	-----	-----	-----
Balances at October 1, 1995	39,207,664	\$ 392,076	\$ 18,014,854	\$(10,278,162)	\$ 8,128,768
Sale of common stock	1,299,711	12,997	406,513	--	419,510
Issuance of 698,985 shares of common stock as payment of indebtedness and expenses	698,985	6,990	134,077	--	141,067
Net loss	--	--	--	(1,933,471)	(1,933,471)
	-----	-----	-----	-----	-----
Balances at September 30, 1996	41,206,360	412,063	18,555,444	(12,211,633)	6,755,874
Sale of common stock	1,409,902	14,099	668,901	--	683,000
Issuance of 2,479,071 shares of common stock as payment of indebtedness and expenses	2,479,071	24,791	1,127,578	--	1,152,369
Retirement of shares	(16,000,000)	(160,000)	(7,840,000)	--	(8,000,000)
Net loss	--	--	--	(3,051,889)	(3,051,889)
	-----	-----	-----	-----	-----
Balances at September 30, 1997	29,095,333	290,953	12,511,923	(15,263,522)	(2,460,646)
Sale of common stock	4,315,000	43,150	1,981,850	--	2,025,000
Issuance of 6,535,493 shares of common stock as payment of indebtedness and expenses	6,535,493	65,355	2,719,712	--	2,785,067
Net loss	--	--	--	(4,200,488)	4,200,488
	-----	-----	-----	-----	-----
Balance at September 30, 1998	39,945,826	\$ 399,458	\$ 17,213,485	\$(19,464,010)	\$ (1,851,067)
	=====	=====	=====	=====	=====

See accompanying notes.

CELSION CORPORATION

STATEMENTS OF CASH FLOWS  
FOR THE YEARS ENDED SEPTEMBER 30, 1998, 1997 AND 1996

	1998	1997	1996
	-----	-----	-----
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$(4,200,488)	\$(3,051,889)	\$(1,933,471)
Noncash items included in net loss:			
Funds held under investment contract used for cosmetic division expenses	--	40,000	471,000
Depreciation and amortization	24,291	24,169	18,545
Bad debt expense	--	120,865	51,397
Loss on disposal of property and equipment	45,180	--	--
Gain on disposition of investment in Ardex Equipment, L.L.C	--	--	(17,009)
Write-off of obsolete inventory	287,682	--	--
Write-off of Ardex Equipment - note receivable and accrued interest	--	438,803	--
Common stock issued for operating expenses	796,745	297,542	9,000
Net changes in:			
Accounts receivable	4,079	(2,421)	(68,631)
Inventories	--	(58,789)	45,327
Accrued interest receivable - related parties	--	(33,470)	(5,333)
Prepaid expenses	5,430	(6,538)	6,000
Other current assets	10,085	--	(1,204)
Accounts payable and accrued interest payable	903,900	837,172	25,445
Accrued compensation	168,732	145,256	(166,039)
Accrued professional fees	(156,300)	179,950	74,852
Other accrued liabilities	(1,865)	(85,401)	27,533
	-----	-----	-----
Net cash used in operating activities	(2,112,529)	(1,154,751)	(1,462,588)
	-----	-----	-----
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Rescission of investment in Ardex Equipment, L.L.C	--	--	100,000
Purchases of patent licenses	(10,000)	--	(100,000)
Purchase of property and equipment	(21,935)	(3,807)	(10,256)
Funds returned - investment contract	--	--	139,000
	-----	-----	-----
Net cash (used) provided by investing activities	(31,935)	(3,807)	128,744
	-----	-----	-----
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from notes payable	50,000	615,000	1,205,000
Payment on notes payable - related parties	(63,240)	(24,020)	(48,973)
Payment on notes payable - other	(79,254)	(95,000)	(2,000)
Payment on capital lease obligation	(475)	--	--
Proceeds of stock issuances	2,025,000	683,000	419,510
	-----	-----	-----
Net cash provided by financing activities	1,932,031	1,178,980	1,573,537
	-----	-----	-----
NET (DECREASE) INCREASE IN CASH	(212,433)	20,422	239,693
CASH AT BEGINNING OF YEAR	267,353	246,931	7,238
	-----	-----	-----
CASH AT END OF YEAR	\$ 54,920	\$ 267,353	\$ 246,931
	=====	=====	=====

See accompanying notes.

Celsion Corporation

Statements of Cash Flows (Continued)  
For the Years Ended September 30, 1998, 1997 and 1996

	1996	1998	1997
	-----	-----	-----
Schedule of noncash investing and financing transactions:			
Acquisition and rescission of a 9.5% interest in the Aestar Fine Chemical Company in exchange for 16,000,000 shares of common stock	\$     -- =====	\$ (8,000,000) =====	\$     -- =====
Conversion of accounts payable, debt and accrued interest payable through issuance of common stock	\$ 1,988,322 =====	\$   854,826 =====	\$ 132,067 =====
Equipment repossessed for internal use	\$     -- =====	\$   30,000 =====	\$     -- =====
Acquisition of equipment:			
Cost of equipment	\$   7,277	\$     --	\$     --
Capital lease payable	(7,277) -----	-- -----	-- -----
Cash down payment for equipment	\$     -- =====	\$     -- =====	\$     -- =====
Payment on notes payable:			
Decrease in notes payable	\$ 16,670	\$     --	\$ 25,223
Offset of accounts receivable	(16,670) -----	-- -----	(25,223) -----
Net cash paid	\$     -- =====	\$     -- =====	\$     -- =====
Rescission of investment in Ardex Equipment, L.L.C. in exchange for notes receivable	\$     -- =====	\$     -- =====	\$ 400,000 =====
Cash paid during the year for:			
Interest	\$ 103,470 =====	\$     -- =====	\$ 45,000 =====
Income taxes	\$     -- =====	\$     -- =====	\$     -- =====

See accompanying notes.

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS  
FOR THE YEARS ENDED SEPTEMBER 30, 1998, 1997 AND 1996

1. DESCRIPTION OF BUSINESS

Celsion Corporation (the "Company") is in the business of developing thermotherapy products for medical applications.

2. GOING CONCERN UNCERTAINTY

The accompanying financial statements have been prepared in conformity with generally accepted accounting principles, which contemplates continuation of the Company as a going concern. However, the Company has sustained substantial operating losses in recent years and has used substantial amounts of working capital in its operations. Further, at September 30, 1998, current liabilities exceed current assets by \$2,000,351. The continued operation of the Company is dependent upon its ability to obtain funding necessary to complete clinical trials of its products. Management continues to attempt to obtain funding through both private and public offerings. The realization of the majority of the Company's assets is dependent upon the success of these offerings.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash and Cash Equivalents  
-----

The Company classifies highly liquid investments with original maturities of 90 days or less to be cash equivalents. Cash equivalents are stated at cost, which approximates market value.

Inventories  
-----

Inventories are stated at the lower of cost or market. Cost is determined using the average cost method.

Property and Equipment  
-----

Property and equipment is stated at cost. Depreciation is provided over the estimated useful lives of the related assets of five years. Major renewals and betterments are capitalized at cost and ordinary repairs and maintenance are charged against operations as incurred.

Patent Licenses  
-----

The Company has purchased several licenses to use the rights to patented technologies. Patent licenses are amortized straight-line over the remaining patent life.

#### Revenue Recognition

-----

Revenue is recognized when systems, products or components are shipped and when consulting services are rendered. Deferred revenue is recorded for customer deposits received on contingent sale agreements.

#### Research and Development

-----

Research and development costs are expensed as incurred. Equipment and facilities acquired for research and development activities which have alternative future uses are capitalized and charged to expense over their estimated useful lives.

#### Net Loss Per Common Share

-----

Basic and diluted net loss per common share was computed by dividing net loss by the weighted average number of shares of common stock outstanding during each period. The impact of common stock equivalents has been excluded from the computation of weighted average common shares outstanding, as the effect would be antidilutive.

#### 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 reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### Financial Institutions

-----

For most financial instruments, including cash, accounts payable and accruals, management believes that the carrying amount approximates fair value, as the majority of these instruments are short-term in nature.

#### New Accounting Pronouncements

-----

In October 1995, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123, Accounting for Stock Based Compensation (SFAS No. 123), which was effective for the Company's year ended September 30, 1997. SFAS No. 123 allows companies either to continue to account for stock-based employee compensation plans under existing accounting standards or to adopt a fair value based method of accounting as defined in the new standard. The Company will follow the existing accounting standards for these plans, and has provided pro forma disclosure of net income and earnings per share as if the expense provisions of SFAS No. 123 had been adopted. Implementation of SFAS No. 123 did not have a material impact on results of operations or financial condition.

In February 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 128, Earnings per Share (SFAS No. 128), which establishes new standards for computing and presenting earnings per share. SFAS No. 128 is effective for the Company's September 30, 1998 financial statements, including restatement of interim periods; earlier application was not permitted. The effect of the new standard did not have a material impact on previously reported earnings per share.

In June 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income (SFAS No. 130), which establishes standards for reporting and displaying comprehensive income and its components. SFAS No. 130 requires comprehensive income and its components, as recognized under the accounting standards, to be displayed in a financial statement with the same prominence as other financial statements. The Company has adopted the standard, as required, in the fiscal year ended September 30, 1998. The Company had no items of comprehensive income for the three years ended September 30, 1998.

Statement of Financial Accounting Standards No. 131, Disclosures about Segments of an Enterprise and Related Information (SFAS No. 131), also issued in June 1997, establishes new standards for reporting information about operating segments in annual and interim financial statements. The standard also requires descriptive information about the way the operating segments are determined, the products and services provided by the segments, and the nature of differences between reportable segment measurements and those used for the consolidated enterprise. This standard is effective for years beginning after December 15, 1997. Adoption in interim financial statements is not required until the year after initial adoption, however, comparative prior period information is required. The Company is evaluating the standard and plans adoption as required in 1999; adoption of this disclosure requirement will not have a material impact on the Company's results of operations or financial position.

#### 4. ACCOUNTS RECEIVABLE

Accounts receivable consist of the following:

	1998	1997
	-----	-----
Trade receivables	\$ 1,812	\$4,431
Related party receivables:		
Microfocus	-	1,460
	-----	-----
	\$ 1,812	\$ 5,891
	=====	=====

#### 5. INVENTORIES

Inventories are comprised of the following at September 30:

	1998	1997
	-----	-----
Materials	\$ 5,059	\$235,748
Work-in-process	-	16,990
Finished products	37,000	77,003
	-----	-----
	\$ 42,059	\$329,741
	=====	=====

During the year ended September 30, 1998, management completed a thorough review of all its components inventory. As a result of this review the Company identified and wrote off approximately \$287,000 of parts and components inventory acquired in the course of developing older equipment now considered to be obsolete. This includes approximately \$175,000 of components and parts acquired in the course of developing the Company's older equipment, which was deemed unusable in the Company's newer models that incorporate advanced microwave technology, and \$112,000 of replacement parts inventory for older equipment sold in prior years by the Company which was determined to have no appreciable market value because of absence of demand. The write off of \$175,000 is included in research and development expenses and the write off of \$112,000 is included in operating expenses.

6. RELATED PARTY TRANSACTIONS

Notes Payable - Related Parties  
-----

Notes payable to related parties as of September 30 are comprised of the following:

	1998	1997
	-----	-----
Term note payable to an officer and stockholder of the Company, accruing interest at 10% per annum	\$ --	\$ 28,650
Term notes payable to an officer and stockholder of the Company, accruing interest at 12% per annum	--	68,750
Demand note payable to relative of an officer and stockholder of the Company, accruing interest at 12% per annum	36,041	36,041
Demand note payable to related party of remainder of funds borrowed for discontinued project, note bears interest at 12% per annum	--	28,502
Term notes payable to interested parties of the Company accruing interest at 12% per annum	10,000	10,000
Term note payable to an officer and stockholder of the Company accruing interest at 8% per annum	50,000	--
Term note payable to stockholder of the Company accruing interest at 10% per annum payable in monthly payments of \$2,000 for 25 months The note is secured by all accounts receivable and general intangibles of the Company	50,000	50,000
	-----	-----
Less current portion	146,041	221,943
	-----	-----
Long-term portion - due in 1998	\$ --	\$ --
	=====	=====

Accrued interest payable on these notes amounted to \$150,020 and \$245,784 at September 30, 1998 and 1997, respectively.

Stock Based Compensation Plan

-----

As part of the Company's employment agreement with the current chief executive officer (CEO), the Company has granted to the CEO 1,900,000 shares of the Company's capital stock which vests in certain milestones throughout the term of employment. Ultimately all shares become fully vested, provided that the CEO remains with the Company through the term of the contract. The total amount charged to compensation expense for 1998 and 1997 under this plan was \$699,375 and \$280,000, respectively.

7. NOTES PAYABLE - OTHER

Notes payable - other consist of the following as of September 30:

	1997	1998
	-----	-----
Senior secured convertible notes, resulting from private placement offerings in July 1996 and June 1997, accruing interest at 8% per annum. The notes are secured by the Company's common stock held by an executive officer. The notes matured December 31, 1997.	\$ --	\$1,169,800
Term note with interest accruing at 24% per annum, compounded monthly. The note matured April 30, 1996	114,778	112,031
Term note with accrued interest payable each month at 12% per annum. The note is secured by inventory and property. The note matured December 18, 1997	18,000	200,000
	-----	-----
	\$ 132,778	\$1,481,831
	=====	=====

Accrued interest payable on these notes amounted to \$127,538 and \$116,604 at September 30, 1998 and 1997, respectively.

8. RETIREMENT PLAN

The Company provides a SAR-SEP savings plan to which eligible employees may make pretax payroll contributions up to 15% of compensation. The Company does not make contributions to the plan.

9. INVESTMENT IN AESTAR FINE CHEMICAL COMPANY - AT COST

During 1995, the Company acquired a 9.5% equity interest in Aestar Fine Chemical Company (Aestar) in exchange for 16,000,000 shares of its common stock. The investment was carried at cost, as measured by the \$.50 per share



fair market value of the 16,000,000 shares of the Company's common stock. The Company has subsequently rescinded this investment during the year ended September 30, 1997.

10. INVESTMENT IN ARDEX EQUIPMENT, L.L.C. - AT EQUITY

The Company purchased a 19.25% equity interest in Ardex Equipment, L.L.C. (Ardex) in 1995. The investment was carried at cost, adjusted for the Company's proportionate share of Ardex's loss from the purchase date through September 30, 1995. During 1996, the Company rescinded its investment in Ardex, the effects of which are reflected in these financial statements.

11. LOSS ON COSMETICS DIVISION

During 1995, the Company issued 20,000,000 shares of common stock to an investor which enabled the investor to obtain a majority interest in the Company by recapitalizing the Company through this investment of \$2,000,000 in cash and an \$8,000,000 interest in a foreign corporation. In connection with this recapitalization, the Company agreed to the initiation of the development of a cosmetics division and to the investment of excess funds in an investment contract. During the year ended September 30, 1996, this agreement was rescinded and the Company recognized a loss on the cosmetics division in the amount of \$471,000. Additionally as a result of the rescission agreement, the balance of the investment contract of \$40,000 was written-off in the year ended September 30, 1997.

12. INCOME TAXES

A reconciliation of the Company's statutory tax rate to the effective rate for the years ended September 30 is as follows:

	1998 -----	1997 -----	1996 -----
Federal statutory rate	34.0%	34.0%	34.0%
State taxes, net of federal tax benefit	4.6	4.6	4.6
Valuation allowance	(38.6)	(38.6)	(38.6)
	-----	-----	-----
	.0%	.0%	.0%
	=====	=====	=====

As of September 30, 1998, the Company had net operating loss carryforwards of approximately \$18,000,000 for federal income tax purposes that are available to offset future taxable income through the year 2018.

The components of the Company's deferred tax asset for the years ended September 30 is as follows:

	1998 -----	1997 -----
Net operating loss carryforwards	\$6,952,000	\$5,330,000
Valuation allowance	(6,952,000)	(5,330,000)
	-----	-----
	\$ --	\$ --
	=====	=====

The evaluation of the realizability of such deferred tax assets in future periods is made based upon a variety of factors for generating future taxable income, such as intent and ability to sell assets and historical and projected operating performance. At this time, the Company has established a valuation reserve for all of its deferred tax assets. Such tax assets are available to be recognized and benefit future periods.

### 13. COMMON STOCK

During the year ended September 30, 1998, the Company issued 4,315,000 shares of common stock for \$2,025,000, 5,274,961 shares were issued to extinguish debt, and 1,260,532 shares were issued as payment for various operating expenses.

During the year ended September 30, 1997, the Company issued 1,409,902 shares of common stock for \$683,000, 1,317,143 shares were issued to extinguish debt, and 1,161,828 shares were issued as payment for various operating expenses. Additionally, the Company retired 16,000,000 shares of common stock in connection with the rescission in its investment in Aestar.

During the year ended September 30, 1996, the Company issued 1,299,711 shares of common stock for \$419,510, 689,985 shares were issued to extinguish debt, and 9,000 shares were issued as payments for various operating expenses.

### 14. STOCK OPTIONS AND WARRANTS

The Company has issued stock options to employees, directors, vendors and debt holders. Options are granted at market value at the date of the grant and are immediately exercisable.

A summary of the Company's stock option activity and related information for the years ended September 30, 1998 and 1997 is as follows:

	1998 -----		1997 -----	
	Common Stock Options -----	Weighted Average Exercise Price -----	Common Stock Options -----	Weighted Average Exercise Price -----
Outstanding at beginning of year	3,565,000	\$.38	3,050,000	\$.34
Granted	--	.00	515,000	.61
Exercised	(125,000)	.45	--	.00
Expired/canceled	(695,000)	.25	--	.00
	-----	-----	-----	-----
Outstanding at end of year	2,745,000	\$.41	3,565,000	\$.38
	=====	====	=====	====

Additionally, the Company has issued warrants to purchase the Company's stock as follows:

	1998		1997	
	Common Stock Warrants	Weighted Average Exercise Price	Common Stock Warrants	Weighted Average Exercise Price
Outstanding at beginning of year	3,276,818	\$.35	2,218,035	\$.29
Issued	4,582,165	.52	1,058,783	.48
Outstanding at end of year	<u>7,858,983</u>	<u>\$.45</u>	<u>3,276,818</u>	<u>\$.35</u>

The following summarizes information about options and warrants at September 30, 1998:

Range of Exercise Prices	Options/Warrants Outstanding		Options/ Warrants Exercisable	
	Number	Weighted Average Remaining Contractual Life	Number	Weighted Average Exercise Price
\$0.22 - \$3.00	10,603,982	3.77 years	7,060,731	\$.41

The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS No. 123), but applies Accounting Principles Board Opinion No. 25 and related interpretations. No compensation expense related to the granting of stock options was recorded during the three years ended September 30, 1998. The fair value of these equity awards was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted average assumptions for 1998 and 1997: risk-free interest rate of 5.75% and 6.5% for 1998 and 1997, respectively; expected volatility of 50%; expected option life of 3 to 5 years from vesting and an expected dividend yield of 0.0%. If the Company had elected to recognize cost based on the fair value at the grant dates consistent with the method of prescribed by SFAS No. 123, net loss and loss per share would have been changed to the pro forma amounts as follows:

	1998	1997	1996
Net loss	\$(5,272,699)	\$(3,476,159)	\$(2,708,362)
Net loss per common share - basic	(.12)	(.12)	(.07)

#### 15. COMMITMENTS AND CONTINGENCIES

##### Potential Liability and Insurance

In the normal course of business, the Company may be subject to warranty and product liability claims on its hyperthermia equipment. Currently, the Company does not have a product liability insurance policy in effect

although management does anticipate obtaining such coverage when adequate financial resources are available. The assertion of any product liability claim against the Company, therefore, may have an adverse effect on its financial condition. As of September 30, 1998, no product, warranty claims or other liabilities against the Company have been asserted.

Warranty Reserve  
-----

The Company warrants its hyperthermia units to be free from defects in material and workmanship under normal use and service for the period of one year from the date of shipment. Claims have been confined to basic repairs. Given the one year limitation of the warranty, management has elected to not set up a warranty reserve but, instead, to expense repairs as costs are incurred.

16. OTHER BUSINESS VENTURES - TERMINATION OF PURCHASE OPTION

On April 26, 1995, the Company entered into an agreement to purchase a 50% interest in the United Aerosol and Home Products Company, LTD ("Unisol"), located in Zhongshan, China. Unisol is a specialty chemical and fine chemical aerosol packaging and bottle/can filling business. The purchase price was to be 20% of the appraised value of Unisol equipment, payable in the Company's common stock at the close of business on April 26, 1996. This agreement was terminated during the year ended September 30, 1997.

17. LEASE OBLIGATIONS

During the year ended September 30, 1997, the Company has entered into a 3-year lease for their facilities in Columbia, Maryland. Future minimum lease obligations are as follows:

1999	\$ 69,131
2000	55,877
	-----
	\$125,008
	=====

Total amounts charged to rent expense for 1998, 1997 and 1996 were \$75,018, \$64,594 and \$55,982, respectively.

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

and  
CHEUNG LABORATORIES, INC.  
PATENT LICENSE AGREEMENT

M.I.T.'S OFFER TO CHEUNG LABORATORIES, INC. TO  
ENTER INTO THIS LICENSE AGREEMENT SHALL EXTEND UNTIL  
NO LATER THAN OCTOBER 31, 1997

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(EXCLUSIVE)

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11-7-94  
Patent Exclusive

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MASSACHUSETTS INSTITUTE OF TECHNOLOGY

and  
CHEUNG LABORATORIES, INC.

PATENT LICENSE AGREEMENT  
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This Agreement is made and entered into this 24th day of October 1997, (the "EFFECTIVE DATE") by and between MASSACHUSETTS INSTITUTE OF TECHNOLOGY, a corporation duly organized and existing under the laws of the Commonwealth of Massachusetts and having its principal office at 77 Massachusetts Avenue, Cambridge, Massachusetts 02139, U.S.A. (hereinafter referred to as "M.I.T."), and CHEUNG LABORATORIES, INC., a corporation duly organized under the laws of Maryland and having its principal office at 10220-I Old Columbia Road, Columbia, MD 21046-1705 (hereinafter referred to as "LICENSEE"), and cancels, supersedes and replaces a previous Agreement by and between M.I.T. and LICENSEE for M.I.T. Case No.'s 5493L, 5672L, and 6512L dated June 12, 1996.

WITNESSETH  
-----

WHEREAS, M.I.T. is the owner of certain PATENT RIGHTS (as later defined herein) relating to M.I.T. Case No. 5493L, U.S. Patent No. 5,251,645, "Adaptive Hyperthermia System," by Alan J. Fenn; M.I.T. Case No. 5672L, "Non-Invasive Monopole Hyperthermia, Array for Brain Tumor Heating by Alan J. Fenn; M.I.T. Case No. 6572L, U.S. Patent No. 5,540,737, "Minimally Invasive Monopole Phased Array Hyperthermia Applicators for Treating Carcinoma," by Alan J. Fenn; and M.I.T. Case No. 7615L, "Adaptive Nulling And Focusing Hyperthermia Phased Arrays For Activating Thermosensitive Liposomes For Targeted Delivery Of Drugs To Deep Human Tissues," by Alan J. Fenn and has the right to grant licenses under said PATENT RIGHTS (as later defined herein), subject only to royalty-free, nonexclusive license heretofore granted to the United States Government;

WHEREAS, M.I.T. desires to have the PATENT RIGHTS developed and commercialized to benefit the public and is willing to grant a license thereunder,

WHEREAS, M.I.T. is the owner of certain rights, title and interest in the PROGRAM (as later defined herein) relating to M.I.T. Case No. 7299LS, "NULLGSC," by Alan J. Fenn and M.I.T. Case No. 7298LS, "FOCUSGSC," by Alan J. Fenn subject only to the royalty-free, nonexclusive license rights of the United States Government pursuant to 48 CFR 52.227-14 (Civilian Agencies) and DFARS 252.227-7013 (Defense Agencies), and has the right to grant licenses thereunder;

WHEREAS, M.I.T. desires to have the PROGRAM developed and commercialized to benefit the public and is willing to grant a license thereunder;

WHEREAS, M.I.T. and LICENSEE had entered into a License Agreement for M.I.T. Case No.'s 5493L, 5672L, 6512L, 7298LS and 7299LS dated June 12, 1996, and now wish to terminate that Agreement and replace it with this Agreement; and

WHEREAS, LICENSEE has represented to M.I.T., to induce M.I.T. to enter into this Agreement, that LICENSEE is experienced in the development, production, manufacture, marketing and sale of products similar to the LICENSED PRODUCT(s) (as later defined herein) and/or the use of the LICENSED PROCESS(es) (as later defined herein) and that it shall commit itself to a thorough, vigorous and diligent program of exploiting the PATENT RIGHTS, and to a thorough, vigorous and diligent program of exploiting the PROGRAM, so that public utilization shall result therefrom, all in the manner provided herein; and

WHEREAS, LICENSEE desires to obtain a license under the PATENT RIGHTS and also desires to obtain a license to the PROGRAM, upon the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the premises and the mutual terms, conditions and covenants contained herein, the parties hereto agree as follows

I - DEFINITIONS  
-----

For the purposes of this Agreement, the following words and phrases shall have the following meanings:

1.1 "ADAPTATIONS" shall mean the PROGRAM as it maybe adapted by LICENSEE for hardware other than the original M.I.T. Cray computer.

1.2 "COPYRIGHT" shall mean M.I.T.'s copyrights in the PROGRAM.

1.3 "DERIVATIVE WORKS" shall mean a program that uses the M.I.T'. COPYRIGHTED PROGRAM and/or and ADAPTATION, but which has enhanced and new features or fewer features. LICENSEE shall be entitled to establish all proprietary rights for itself in the intellectual property represented by LICENSEE-created enhancements and new features, whether in the nature of trade secrets, copyrights or patent rights or other rights M.I.T. shall be entitled to establish all proprietary rights for itself in the intellectual property represented M.I.T.-created enhancements and new features, whether in the nature of copyrights or patent rights or other rights.

1.4 "END USER" shall mean a customer licensed or otherwise authorized by LICENSEE to use a single copy of the PROGRAM for internal purposes only and not for further distribution.

1.5 On the EFFECTIVE DATE, "EXCLUSIVE FIELDS OF USE" shall mean FIELD OF USE ONE, FIELD OF USE TWO, and FIELD OF USE THREE. This definition may be modified according to paragraphs 3.6, 3.7 and 3.8.

1.6 "FIELD OF USE ONE" shall mean Breast Hyperthermia.

1.7 "FIELD OF USE TWO" shall mean Prostate Hyperthermia.

1.8 "FIELD OF USE THREE" shall mean all other medical applications.

1.9 "INTELLECTUAL PROPERTY RIGHTS" shall mean all of the PATENT RIGHTS and COPYRIGHT.

1.10 "LICENSED PROCESS" shall mean any process which is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the PATENT RIGHTS, or by the COPYRIGHT,

1.11 "LICENSED PRODUCT" shall mean LICENSEE's hyperthermia machine or part thereof, and accessories, including, but not limited to disposable accessories such as temperature probes and needles, which:

- (a) is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the PATENT RIGHTS in the country in which any such LICENSED PRODUCT or part thereof is made, used or sold; or
- (b) is manufactured by using a process or is employed to practice a process which is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the PATENT RIGHTS in the country in which any LICENSED PROCESS is used or in which such product or put thereof is used or sold.
- (c) is covered in whole or in part by the COPYRIGHT.

1.12 "LICENSED SERVICE" shall mean any fee-bearing service performed by LICENSEE or any SU13LICENSEE or any MEDICAL SERVICE PROVIDER which uses a LICENSED PRODUCT or practices a LICENSED PROCESS.

1.13 "LICENSEE" shall mean Cheung Laboratories, Inc., and shall include a related company of Cheung Laboratories, Inc., the voting stock of which is directly or indirectly at least fifty percent (50%) owned or controlled by Cheung Laboratories, Inc.

1.14. "MEDICAL SERVICE PROVIDER" shall mean a customer or user of a LICENSED PRODUCT, at a clinical site, licensed or otherwise authorized to practice a LICENSED PROCESS and/or perform a LICENSED SERVICE by LICENSEE, which customer or user has explicitly not been granted rights by LICENSEE to make, sell, or lease LICENSED PRODUCTS.

1.15 "MILESTONE PAYMENT" shall mean a payment to LICENSEE from any third party due upon achievement of an agreed upon technical, regulatory, or business milestone related to LICENSED PRODUCTS, LICENSED PROCESSES, or LICENSED SERVICES. Illustrative examples of such milestones include, but are not limited to, achieving a technical result, obtaining FDA approval, and meeting sales targets.

MILESTONE PAYMENTS shall not include (i) any payments to LICENSEE which are subject to royalties under paragraphs 4.1 (h), (i) or (j), (ii) any advances to LICENSEE pursuant to bank loans or other bona fide credit arrangements, and (iii) any payments to LICENSEE to acquire LICENSEE's capital stock at a price not exceeding the fair market value thereof.



1. 16 "NET SALES" shall mean the sum of the following:

a) LICENSEE'S and its SUBLICENSEE'S billings for LICENSED PRODUCTS (including, explicitly, the PROGRAM), LICENSED PROCESSES, and LICENSED SERVICES, less the sum of the following items, providing that these items are payable by LICENSEE (or by its SUBLICENSEE ) or deductible from LICENSEE'S billings (or from SUBLICENSEE'S billings) within sixty (60) days of receiving payments from LICENSEE'S (or SUBLICENSEE'S) customer(s):

- i. discounts allowed in amounts customary in the trade for quantity purchases, cash payments, prompt payments, wholesalers and distributors;
- ii. sales, tariff duties and/or use taxes directly imposed and with reference to particular sales;
- iii. outbound transportation prepaid or allowed;
- iv. amounts allowed or credited on returns or refunds; and
- v. allowance for bad debt, not to exceed Five Percent (5%) of NET SALES per calendar year.

No other deductions shall be made for commissions paid to individual whether they be with independent sales agencies or regularly employed by LICENSEE and on its payroll, or for the cost of collections. LICENSED PRODUCTS, LICENSED PROCESSES, or LICENSED SERVICES shall be considered, "sold" ninety (90) days after billing, or invoicing, or upon receipt of payment, whichever comes first, provided, however-that LICENSED PRODUCTS are actually shipped to customers; plus

b) LICENSEE'S gross receipts from MEDICAL SERVICE PROVIDERS, other than gross receipts from MEDICAL SERVICE PROVIDERS, other than receipts counted in paragraph 1. 16 (a) above.

1.17 "OTHER REVENUE" shall mean LICENSEE'S gross revenues from the sale of its own services for consulting, research and development, and training, in connection with:

- a. the sublicensing of the INTELLECTUAL PROPERTY RIGHTS; and/or
- b. the use or sale, lease or other transfer of LICENSED PRODUCTS, LICENSED PROCESSES and LICENSED SERVICES.

1.18 "PATENT RIGHTS" shall mean all of the following M.I.T. intellectual property:

- a. the United States patents listed in Appendix A;
- b. the United States patent applications listed in Appendix A, and divisionals, continuations and claims of continuation-in-part applications which shall be directed to subject matter specifically described in such patent applications, and the resulting patents;
- c. any patents resulting from reissues or reexaminations of the United States patents described in a. and b. above;

- d. the Foreign patents listed in Appendix A;
- e. the Foreign parent applications listed in Appendix A, and divisionals, continuations and claims of continuation-in-part applications which shall be directed to subject matter specifically described in such Foreign patent applications, and the resulting patents;
- f. Foreign patent applications filed after the EFFECTIVE DATE in the countries listed in Appendix B and divisionals, continuations and claims of continuation in-part applications which shall be directed to subject matter specifically described in such patent applications, and the resulting patents; and
- 9. any Foreign patents, resulting from equivalent Foreign procedures to United States reissues and reexaminations of the Foreign patents described in d., e. and f. above.

1.19 "PROGRAM" shall mean the computer program(s), "NULLGSC" and "FOCUSGSC" and related documentation, if any described in Appendix C (hereinafter the "M.I.T. COPYRIGHTED PROGRAM"), and shall also include ADAPTATIONS, DERIVATIVE WORKS and TRANSLATIONS. PROGRAM may be protected by both PATENT RIGHTS and COPYRIGHTS,

1.20 "SUBLICENSEE" shall mean an entity which has the right to i) make or have made and sell LICENSED PRODUCTS or ii) make or have made and lease LICENSED PRODUCTS.

1.21 "TRANSLATION" shall mean a translation of the PROGRAM into another language.

2-GRANT  
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2.1 M.I.T. hereby grants to LICENSEE the right and license for FIELD OF USE ONE, FIELD OF USE TWO, and FIELD OF USE THREE to practice under the PATENT RIGHTS and, to the extent not prohibited by other patents, to make, have made, use, lease, sell and import LICENSED PRODUCTS and to practice the LICENSED PROCESSES, and to perform LICENSED SERVICES until the expiration of the last to expire of the, PATENT RIGHTS, unless this Agreement shall be sooner terminated according to the terms hereof.

2.2 M.I.T. hereby grants to LICENSEE the following rights and licenses for FIELD OF USE ONE, FIELD OF USE TWO, and FIELD OF USE THREE to the end of the term for which the COPYRIGHT shall be granted, unless this Agreement shall be sooner terminated:

- a. to use and reproduce the PROGRAM;
- b. to create DERIVATIVE WORKS; and
- c. to lease, transfer and sublicense the PROGRAM to END-USERS through the normal channels of distribution; and

2.3 In order to establish a period of exclusivity for LICENSEE, M.I.T. hereby agrees that it shall not grant any other license to the PATENT RIGHTS for

the EXCLUSIVE FIELDS OF USE, and also that it shall not grant any other license to the COPYRIGHT for the EXCLUSIVE FIELDS OF USE, subject only to Paragraphs 2.5 and 2.6 and to the royalty-free, nonexclusive license rights of the United States Government pursuant to 48 CFR 52.227-14 (Civilian Agencies) and DFARS 252.227-7013 (Defense Agencies) during the period of time commencing with the EFFECTIVE DATE and terminating with the first to occur of:

- (a) the expiration of ten (10) years after the first commercial sale of a LICENSED PRODUCT or first commercial use of a LICENSED PROCESS or the first commercial performance of a LICENSED SERVICE; or
- (b) the expiration of twelve (12) years after the EFFECTIVE DATE of this Agreement.

2.4 At the end of the exclusive period, the license granted hereunder shall become nonexclusive and shall extend to the end of the term or terms for which any PATENT RIGHTS or COPYRIGHT are granted, unless sooner terminated as hereinafter provided. The period of exclusivity may be extended with the written consent of M.I.T., on a field of use basis, which consent shall not unreasonably be withheld, provided that LICENSEE is a licensee in good standing, owing no fees, royalties or any other monies to M.I.T., and having met all the diligence milestones pertaining to the particular field of use in which an extension of the period of exclusivity is under consideration.

2.5 M.I.T. reserves the right to practice under the PATENT RIGHTS for its own noncommercial research purposes.

2.6 M.I.T. reserves the right to use the PROGRAM, to use and create DERIVATIVE WORKS of the PROGRAM and to distribute the PROGRAM and M.I.T.-created DERIVATIVE WORKS to third parties for noncommercial research purposes.

2.7 LICENSEE agrees that LICENSED PRODUCTS leased or sold in the United States shall be manufactured substantially in the United States.

2.8 In order to encourage and facilitate the development of LICENSED PRODUCTS, LICENSED PROCESSES, and LICENSED SERVICES M.I.T. agrees to perform the work described in the Technology Transfer Agreement attached to this license as ADDENDUM A.

2.9 LICENSEE shall have the right to enter into sublicensing agreements for the rights, privileges and licenses granted hereunder only during the exclusive period of this Agreement, and with the following restrictions:

- a) Such sublicenses may extend past the expiration date of the exclusive period of this Agreement, or upon the termination of LICENSEE's exclusive rights in a particular field of use, pursuant to paragraphs 3.6, 3.7, and 3.8, but any exclusivity of such sublicenses shall expire upon the expiration of LICENSEE's exclusivity,
- b) Upon any termination of this Agreement, sublicensees' rights shall also terminate, subject to Paragraph 13.6 hereof.

- c) LICENSEE may not grant sublicenses which perrmit further sublicensing of the INTELLECTUAL PROPERTY RIGHTS without the express written permission of M.I.T.,
- d) LICENSEE may not grant the rights to make, lease or sell LICENSED PRODUCTS to MEDICAL SERVICES PROVIDERS.

2.10 LICENSEE agrees that any sublicenses granted by it shall provide that the obligations to M.I.T. of Articles 2, 5, 7, 8, 9, 10, 12, 13, and 15 of this Agreement shall be binding upon the sublicensee as if it were a party to this Agreement. LICENSEE further agrees to attach copies of these Articles to sublicense agreements.

2.11 LICENSEE agrees to forward to M.I.T. a copy of any and all sublicense agreements promptly upon execution by the parties.

2.12 LICENSEE shall not receive from SUBLICENSEES anything of value in lieu of cash payments in consideration for any sublicense under this Agreement, without the express prior written permission of M.I.T.

2.13 The license granted hereunder shall not be construed to confer any rights upon LICENSEE by implication, estoppel or otherwise as to any technology not specifically set forth in Appendix A hereof

### 3 - DUE DILIGENCE

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3.1 LICENSEE shall use its best efforts to bring one or more LICENSED PRODUCTS, LICENSED PROCESSES, or LICENSED SERVICES to market through a thorough, vigorous and diligent program for exploitation of the INTELLECTUAL PROPERTY RIGHTS and to continue active, diligent marketing efforts for one or more LICENSED PRODUCTS, LICENSED PROCESSES or LICENSED SERVICES throughout the. life of this Agreement.

3.2 LICENSEE shall raise a minimum of (Confidential Treatment Requested) Dollars toward the development of LICENSED PRODUCTS, LICENSED PROCESSES or LICENSED SERVICES according to the following schedule:

- (a) (Confidential Treatment Requested) Dollars on or before January 1, 1998.
- (b) An additional(Confidential Treatment Requested) Dollars on or before June 30, 1998.
- (c) An additional(Confidential Treatment Requested) Dollars on or before January 1, 2000.

3.3 (a) In addition, pertaining to FIELD OF USE ONE, LICENSEE shall adhere to the following milestone:

As soon as possible, but in all events on or before June 30, 1999 LICENSEE shall apply for FDA approval for commercial sale of a LICENSED PRODUCT in FIELD OF USE ONE, and/or for FDA approval for the commercial use of

a LICENSED PROCESS or commercial performance of a LICENSED SERVICE in FIELD OF USE ONE.

(b) In addition, pertaining to FIELD OF USE TWO, LICENSEE shall adhere to the following milestone:

As soon as possible, but in all events on or before June 30, 2001 LICENSEE shall apply for FDA approval for commercial sale of a LICENSED PRODUCT in FIELD OF USE TWO, and/or for FDA approval for the commercial use of a LICENSED PROCESS or commercial performance of a LICENSED SERVICE in FIELD OF USE TWO.

(c) In addition, pertaining to FIELD OF USE THREE, LICENSEE shall adhere to the following milestone:

As soon as possible, but in all events on or before June 30, 2002 LICENSEE shall apply for FDA approval for commercial sale of a LICENSED PRODUCT in FIELD OF USE THREE, and/or for FDA approval for the commercial use of a LICENSED PROCESS or commercial performance of a LICENSED SERVICE in FIELD OF USE THREE.

3.4 LICENSEE shall make sales of LICENSED PRODUCTS in FIELD OF USE ONE according to the following schedule:

1998	at least 1 unit
1999	at least 5 units
2000	at least (Confidential Treatment Requested) units
2001 and each year there after	at least (Confidential Treatment Requested) units

3.5 Failure to comply with any of paragraphs 3.2 (a), (b) or (c) shall be grounds for for M.I.T. to terminate this license pursuant to paragraph 13.3 hereof, M.I.T. to terminate this license pursuant to paragraph 13.3 hereof,

3.6 Failure to comply with paragraph 3.3 (a) or paragraph 3.4 shall be grounds to remove FIELD OF USE ONE from the definition of "EXCLUSIVE FIELDS OF USE", thereby terminating LICENSEE's exclusive rights to FIELD OF USE ONE. Under these circumstances, LICENSEE explicitly retains non-exclusive rights to FIELD OF USE ONE.

3.7 Failure to comply with paragraph 3.3 (b) shall be grounds to remove FIELD OF USE TWO from the definition of "EXCLUSIVE FIELDS OF USE", thereby terminating LICENSEE's exclusive rights to FIELD OF USE TWO. Under these circumstances, LICENSEE explicitly retains non-exclusive rights to FIELD OF USE TWO.

3.8 Failure to comply with paragraph 3.3 (c) shall be grounds to remove FIELD OF USE THREE from the definition of "EXCLUSIVE FIELDS OF USE", thereby terminating LICENSEE's exclusive rights to FIELD OF USE THREE. Under these circumstances, LICENSEE explicitly retains non-exclusive rights to FIELD OF USE THREE.

4 - ROYALTIES  
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4.1 For the rights, privileges and license granted hereunder, LICENSEE shall pay royalties to M.I.T. in the manner hereinafter provided to the end of the term of the PATENT RIGHTS or until this Agreement shall be terminated:

- (a) License Maintenance Fees of (Confidential Treatment Requested) Dollars per year payable on January 1, 1998 and on January 1, 1999; provided, however, that Running Royalties subsequently due on NET SALES for each said year, if any, shall be creditable against the License Maintenance Fee for said year. License Maintenance Fees paid in excess of Running Royalties shall not be creditable to Running Royalties for future years.
- (b) License Maintenance Fees of (Confidential Treatment Requested) Dollars per year payable on January 1, 2000 and on January 1, 2001 provided, however, that Running Royalties subsequently due on NET SALES for each said year, if any, shall be creditable against the License Maintenance Fee for said year, License Maintenance Fees paid in excess of Running Royalties shall not be creditable to Running Royalties for future years.
- (c) License Maintenance Fees of (Confidential Treatment Requested) Dollars per year payable on January 1, 2002 and on January 1 of each year thereafter; provided, however, " License Maintenance Fees may be credited to Running Royalties subsequently due on NET SALES for each said year, if any. License Maintenance Fees paid in excess of Running Royalties shall not be creditable to Running Royalties for future years.
- (d) (i) Running Royalties in an amount equal to (Confidential Treatment Requested) percent of NET SALES of the LICENSED PRODUCTS, leased or sold by and/or for LICENSEE and/or its SUBLICENSEES for LICENSED PRODUCTS which are either made or leased or sold in a country in which there is a valid, issued claim of a patent described in either APPENDICES A or B.  
  
(ii) Running Royalties in an amount equal to (Confidential Treatment Requested) percent of NET SALES of LICENSED SERVICES performed by and/or for LICENSEE and/or its SUBLICENSEES and/or 'authorized MEDICAL SERVICE PROVIDERS, utilizing LICENSED PRODUCTS which are either made or leased or sold in a country in which there is a valid, issued claim of. a patent described in either APPENDICES A, or B.
- (e) (i) Running Royalties in an amount equal to (Confidential Treatment Requested) percent of NET SALES of the LICENSED PRODUCTS, leased or sold by and/or for LICENSEE and/or its SUBLICENSEES for LICENSED PRODUCTS which are neither made nor leased nor sold in a country in which there is a valid, issued claim of a patent described in either APPENDICES A or B, but which utilize the COPYRIGHT and/or practice or ran the PROGRAM, as described in APPENDIX C.  
  
(ii) Running Royalties in an amount equal to (Confidential Treatment Requested) percent of NET SALES of LICENSED SERVICES performed by and/or for LICENSEE and/or its SUBLICENSEES and/or authorized MEDICAL SERVICE PROVIDERS, Utilizing LICENSED PRODUCTS which are neither made nor leased nor sold in a country in which there is a valid, issued claim of a patent described in either APPENDICES A or B, but which utilize the COPYRIGHT and/or practice or run the PROGRAM, as described in APPENDIX C.

- (f) Running Royalties in an amount equal to (Confidential Treatment Requested) percent of NET SALES of the PROGRAM delivered to END-USERS if the PROGRAM is sold separately from the LICENSED PRODUCTS.
- (g) (Confidential Treatment Requested) Percent of MILESTONE PAYMENTS received by LICENSEE.
- (h) (Confidential Treatment Requested) Percent of lump sum type payments received by LICENSEE from its SUBLICENSEES in consideration for a grant by LICENSEE to a SUBLICENSEE to practice under the INTELLECTUAL PROPERTY RIGHTS, including, explicitly, the right to make, sell, and lease LICENSED PRODUCTS, without a substantial and essentially simultaneous grant by LICENSEE to the SUBLICENSEE of LICENSEE-owned technology.
- (i) (Confidential Treatment Requested) Percent of lump sum type payments received by LICENSEE from its SUBLICENSEES in consideration for a grant by LICENSEE to a SUBLICENSEE to practice under the INTELLECTUAL PROPERTY RIGHTS, including, explicitly, the right to make, sell, and lease LICENSED PRODUCTS, with a substantial and essentially simultaneous grant by LICENSEE to the SUBLICENSEE of LICENSEE-owned technology.
- (j) (Confidential Treatment Requested) Percent of lump sum type payments received by LICENSEE from its MEDICAL SERVICE PROVIDERS in consideration for a fully paid up license and/or authorization to practice LICENSED PROCESSES and perform LICENSED SERVICES, with no further reporting required from the MEDICAL SERVICE PROVIDER to LICENSEE concerning its practice of LICENSED PROCESSES or performance of LICENSED SERVICES.
- (k) If OTHER REVENUE is greater than NET SALES, then Running Royalties in an amount equal to (Confidential Treatment Requested) percent of OTHER REVENUE.
- (l) If OTHER REVENUE is less than NET SALES, then Running Royalties in an amount equal to (Confidential Treatment Requested) percent of OTHER REVENUE.

4.2 All payments due hereunder shall be paid in full, without deduction of taxes or other fees which may be imposed by any government and which shall be paid by LICENSEE.

4.3 No multiple royalties shall be payable because any LICENSED PRODUCT, its manufacture, use, lease or sale are or shall be covered by more than one PATENT RIGHTS patent application or COPYRIGHT or PATENT RIGHTS patent licensed under this Agreement.

4.4 No multiple royalties shall be payable because any LICENSED PROCESS of LICENSED SERVICE, its use, practice, or performance is covered by more than one PATENT RIGHTS patent application or COPYRIGHT or PATENT RIGHTS patent licensed under this Agreement.

4.5 Royalty payments shall be paid in United States dollars in Cambridge, Massachusetts, or at such other place as M.I.T. may reasonably designate consistent with the laws and regulations controlling in any foreign country. If any currency conversion shall be required in connection with the payment of royalties hereunder, such conversion shall be made by using the

exchange rate prevailing at the Chase Manhattan Bank (N.A.) on the last business day of the calendar quarterly reporting period to which such royalty payments relate.

5 - REPORTS AND RECORDS  
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5.1 LICENSEE shall keep full, true and accurate books of account containing all particulars that may be necessary for the purpose of showing the amounts payable to M.I.T. hereunder. Said books of account shall be kept at LICENSEE's principal place of business or the principal place of business of the appropriate division of LICENSEE to which this Agreement relates. Said books and the supporting data shall be open at all reasonable times for five (5) years following the end of the calendar year to which they pertain, to the inspection of M.I.T. or its agents for the purpose of verifying LICENSEE's royalty statement or compliance in other respects with this Agreement, Should such inspection lead to the discovery of a greater than Ten Perceric (1070) discrepancy in reporting to M.I.T.'s detriment, LICENSEE agrees to pay die reasonable cost of such inspection.

5.2 LICENSEE shall deliver to M.I.T. true and accurate reports, giving such particulars of the business conducted by LICENSEE and its sublicensees under this Agreement as shall be pertinent to diligence under Article 3 and royalty accounting hereunder.

- a. before the first commercial sale of a LICENSED PRODUCT or LICENSED SERVICE, annually, on January 31 of each year; and
- b. after the first commercial sale of a LICENSED PRODUCT or LICENSED SERVICE, quarterly, within sixty (60) days after March 31, June 30, September 30 and December 31, of each year.

These reports shall include at least the following

- a. money raised pursuant to paragraph 3.2.
- b. number of LICENSED PRODUCTS manufactured, leased and sold by and/or for LICENSEE and all SUBLICENSEES;
- c. accounting for all LICENSED SERVICES sold by and/or for LICENSEE and all SUBLICENSEES and all MEDICAL SERVICE PROVIDERS;
- d. accounting for NET SALES, noting the deductions and credits applicable as provided in Paragraphs 1.16 and 6.3, accounting for OTHER REVENUE;
- e. Running Royalties due under Paragraph 4.1 (d), (e), and (f);
- f. payments on MILESTONE PAYMENTS due under Paragraph 4.1 (g);
- g. Share of lump sum type payment received from SUBLICENSEES and from MEDICAL SERVICE PROVIDERS due under Paragraph 4.1 (h), (i) and (j);
- h. payments on OTHER REVENUE due under paragraphs 4.1 (k) and (1);



- i. total royalties due; and
- j. names and addresses of all SUBLICENSEES of LICENSEE and of all authorized MEDICAL SERVICE PROVIDERS.

5.3 With each such report submitted, LICENSEE shall pay to M.I.T. the royalties due and payable under this Agreement. If no royalties shall be due, LICENSEE shall so report.

5.4 On or before the ninetieth (90th) day following the close of LICENSEE's fiscal year, LICENSEE shall provide M.I.T. with LICENSEE's certified financial statements for the preceding fiscal year including, at a minimum, a Balance Sheet and an Operating Statement.

5.5 The royalty payments set forth in this Agreement and amounts due under Article 6 shall, if overdue, bear interest until payment at a per annum rate two percent (2%) above the prime rate in effect at the Chase Manhattan Bank (N.A.) on the due date. The payment of such interest shall not foreclose M.I.T. from exercising any other rights it may have as a consequence of the lateness of any payment.

#### 6 - PATENT PROSECUTION

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6.1 M.I.T. have the administrative responsibility to apply for, seek prompt issuance of, and maintain during the term of this Agreement the PATENT RIGHTS in the United States and in the foreign countries listed in Appendices A and B hereto. Appendix B may be amended by verbal agreement of both parties, such agreement to be confirmed in writing within ten (10) days. The prosecution, filing and maintenance of all PATENT RIGHTS patents and applications shall be the primary responsibility of M.I.T.; provided, however, LICENSEE shall have reasonable opportunities to advise M.I.T. and shall cooperate with M.I.T. in such prosecution, filing and maintenance.

6.2 Payment of all fees and costs relating to the filing, prosecution, and maintenance of the PATENT RIGHTS incurred after the date of this Agreement shall be the responsibility of LICENSEE. M.I.T. is not financially obliged to maintain and prosecute patents.

6.3 M.I.T. agrees that LICENSEE may take a cumulative life of license credit for expenditures on the PATENT RIGHTS, such credit not to exceed (Confidential Treatment Requested) Dollars and to be taken according to the following schedule:

- a) LICENSEE may credit their above referenced patent prosecution and maintenance expenditures incurred in a given calendar year against up to one half of License Maintenance Fees due the following January 1 under paragraphs, 4.1 (a), (b), and (c).
- b) In the event that Running Royalties exceed the License Maintenance Fee for a given year, and LICENSEE owes M.I.T. Running Royalties in addition to the License Maintenance Fee already paid, then LICENSEE may use their patent prosecution and maintenance credit against up to one half of the Running Royalties due paragraphs 4.1 (d), (e) and (f).

7 - INFRINGEMENT  
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7.1 LICENSEE shall inform M.I.T. promptly in writing of any alleged infringement of the INTELLECTUAL PROPERTY RIGHTS by a third party of which it becomes aware and of any available evidence thereof. M.I.T. shall inform LICENSEE promptly in writing of any alleged infringement of the INTELLECTUAL PROPERTY RIGHTS by a third party of which it becomes aware and of any available evidence thereof. Within ten (10) business days of such notice the parties shall confer to determine how best to proceed.

7.2 During the term of this Agreement, M.I.T. shall have the right, but shall not be obligated, to prosecute at its own expense all infringements of the INTELLECTUAL PROPERTY RIGHTS and, in furtherance of such right, LICENSEE hereby agrees that M.I.T. may include LICENSEE as a party plaintiff in any such suit, without expense to LICENSEE. The total cost of any such infringement action commenced or defended solely by M.I.T. shall be borne by M.I.T. and M.I.T. shall keep any recovery or damages for past infringement derived therefrom.

7.3 If within six (6) months after having been notified of any alleged infringement, M.I.T. shall have been unsuccessful in persuading the alleged infringer to desist and shall not have brought and shall not be diligently prosecuting an infringement action, or if M.I.T. shall notify LICENSEE at any time prior thereto of its intention not to bring suit against any alleged infringer for the EXCLUSIVE FIELDS OF USE, then, and in those events only, LICENSEE shall have the right, but shall not be obligated, to prosecute at its own expense any infringement of the INTELLECTUAL PROPERTY RIGHTS for the EXCLUSIVE FIELDS OF USE, and LICENSEE may, for such purposes, use the name of M.I.T. as party plaintiff; provided, however, that such right to bring such an infringement action shall remain in effect only for so long as the license granted herein remains exclusive. No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of M.I.T., which consent shall not unreasonably be withheld. LICENSEE shall indemnify M.I.T. against any order for costs that may be made against M.I.T. in such proceedings.

7.4 In the event that LICENSEE shall undertake the enforcement and/or defense of the INTELLECTUAL PROPERTY RIGHTS by litigation, LICENSEE may withhold up to (Confidential Treatment Requested) percent of the payments otherwise thereafter due M.I.T. under Article 4 hereunder and apply the same toward reimbursement of up to half of LICENSEE's expenses, including reasonable attorneys' fees, in connection therewith. Any recovery of damages by LICENSEE for each such suit shall be applied first in satisfaction of any unreimbursed expenses and legal fees of LICENSEE relating to such suit, and next toward reimbursement of M.I.T. for any payments under Article 4 past due or withheld and applied pursuant to this Article 7. The balance remaining from any such recovery shall be divided so that the percentage of the recovery due M.I.T. is calculated by creating a fraction,

the numerator of which is the amount of royalties withheld, and denominator of which is the cost of litigation paid by LICENSEE, but in no event shall such sum be less than (Confidential Treatment Requested) Percent of the net recovery.

7.5 In the event that a declaratory judgment action alleging invalidity or noninfringement of any of the INTELLECTUAL PROPERTY RIGHTS shall be brought against LICENSEE, M.I.T., at its option, shall have the right, within thirty (30) days after commencement of such action, to intervene and take over the sole defense of the action at its own expense.

7.6 In any infringement suit as either party may institute to enforce the PATENT RIGHTS pursuant to this Agreement, the other party hereto shall, at the request and expense of the party initiating, such suit, cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like.

7.7 LICENSEE, during the exclusive period of this Agreement, shall have the sole right in accordance with the terms and conditions herein to sublicense any alleged infringer for the EXCLUSIVE FIELDS OF USE for future use of the INTELLECTUAL PROPERTY RIGHTS. Any upfront fees as part of such a sublicense shall be shared equally between LICENSEE and M.I.T.; other royalties shall be treated per Article 4.

#### PRODUCT LIABILITY

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8.1 LICENSEE shall at all times during the term of this Agreement and thereafter, indemnify, defend and hold M.I.T., its trustees, directors, officers, employees and affiliates, harmless against all claims, proceedings, demands and liabilities of any kind whatsoever, including legal expenses and reasonable attorneys' fees, arising out of the death of or injury to any person or persons or out of any damage to property, resulting from the production, manufacture, sale, use, lease, consumption or advertisement of the LICENSED PRODUCT(s) and/or LICENSED PROCESS (es) or arising from any obligation of LICENSEE hereunder.

8.2 LICENSEE shall obtain and carry in full force and effect commercial general liability insurance which shall protect LICENSEE and M.I.T. with respect to events covered by Paragraph 8.1 above. Such insurance shall be written by a reputable insurance company authorized to do business in the Commonwealth of Massachusetts, shall list M.I.T. as an additional named insured thereunder, shall be endorsed to include product liability coverage and shall require thirty (30) days written notice to be given to M.I.T. prior to any cancellation or any change thereof. The limits of such insurance shall not be less than (Confidential Treatment Requested) Dollars per occurrence with an aggregate of (Confidential Treatment Requested) Dollars for personal injury or death, and (Confidential Treatment Requested) Dollars per occurrence with an aggregate of (Confidential Treatment Requested) Dollars for property damage. LICENSEE shall provide M.I.T. with Certificates of Insurance evidencing the same.

8.3 EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, M.I.T., ITS TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES, AND AFFILIATES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF PATENT RIGHTS CLAIMS, ISSUED OR PENDING, AND TO THE COPYRIGHT AND THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY M.I.T. THAT THE PRACTICE BY LICENSEE OF THE LICENSE GRANTED HEREUNDER SHALL NOT INFRINGE THE PATENT RIGHTS OR THE COPYRIGHT OF ANY THIRD PARTY. IN NO EVENT SHALL M.I.T., ITS TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES AND AFFILIATES BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING ECONOMIC DAMAGE OR INJURY TO PROPERTY AND LOST PROFITS, REGARDLESS OF WHETHER M.I.T. SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF TIM FOREGOING.

9 - EXPORT CONTROL

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LICENSEE acknowledges that it is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities (including the Arms Export Control Act, as amended and the United States Department of Commerce Export Administration Regulations). The transfer of such items may require a license from the cognizant agency of the United States Government and/or written assurances by LICENSEE that LICENSEE shall not export data or commodities to certain foreign countries without prior approval of such agency. M.I.T. neither represents that a license shall not be required nor that, if required, it shall be issued.

10 - NON-USE OF NAMES.

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LICENSEE shall not use the names or trademarks of the Massachusetts Institute of Technology or Lincoln Laboratory, nor any adaptation thereof, nor the names of any of their employees, in any advertising, promotional or sales literature without prior written consent obtained from M.I.T., or said employee, in each case, except that LICENSEE may state that it is licensed by M.I.T. under one or more of the patents and/or applications comprising the PATENT RIGHTS, and that it has a license to the COPYRIGHT.

11 - ASSIGNMENT

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This Agreement is not assignable and any attempt to do so shall be void.

12 - DISPUTE RESOLUTION

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12.1 Except for the right of either party to apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm, any and all claims, disputes or controversies arising under, out of, or in connection with the Agreement, including any dispute relating to patent validity or infringement, which the parties shall be unable to resolve within sixty (60) days shall be mediated in good faith. The party raising such dispute shall promptly advise the other party of such claim, dispute or controversy in a writing which describes in reasonable detail the nature of such dispute. By not later than five (5) business days after the recipient has received such notice of dispute, each party shall have selected for itself a representative who shall have the authority to bind such party, and shall additionally have advised the other party in writing of the name and title of such representative. By not later than ten (10) business days after the date of such notice of dispute, the party against whom harm the dispute shall be raised shall select a mediation firm in the Boston area and such representatives shall schedule a date with such firm for a mediation hearing. The parties shall enter into good faith mediation and shall share the costs equally. If the representatives of the parties have not been able to resolve the dispute within fifteen (15) business days after such mediation hearing, then any and all claims, disputes or controversies arising, under, out of, or in connection with this Agreement, including any dispute relating to patent validity or infringement, shall be resolved by final and binding arbitration in Boston, Massachusetts under the rules of the American Arbitration Association, or the Patent Arbitration Rules if applicable, then obtaining. The arbitrators shall have no power to add to, subtract from or modify any of the terms or conditions of this Agreement, nor to award punitive damages. Any award rendered in such arbitration may be enforced by either party in either the courts of the Commonwealth of Massachusetts or in the United States District Court for the District of Massachusetts, to whose jurisdiction for such purposes M.I.T. and LICENSEE each hereby irrevocably consents and submits.

12.2 Notwithstanding the foregoing, nothing in this Article shall be construed to waive any rights or timely performance of any obligations existing under this Agreement.

13 - TERMINATION

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13.1 If LICENSEE shall cease to carry on its business, this Agreement shall terminate upon notice by M.I.T.

13.2 Should LICENSEE fail to make any payment whatsoever due and payable to M.I.T. hereunder, M.I.T. shall have the right to terminate this Agreement effective on thirty (30) days' notice, unless LICENSEE shall make all such payments to M.I.T. within said thirty (30) day period. Upon the expiration of the thirty (30) day period, if LICENSEE shall not have made all such payments to M.I.T., the rights, privileges and license granted hereunder shall automatically terminate.

13.3 Upon any material breach or default of this Agreement by LICENSEE (including, but not limited to, breach or default under Paragraph 3.3), other than those occurrences set out in Paragraphs 13.1 and 13.2 hereinabove, which shall always take precedence in that order over any material breach or default referred to in this Paragraph 13.3, M.I.T. shall have the right to terminate this Agreement and the rights, privileges and license granted hereunder effective on ninety (90) days' notice to LICENSEE. Such termination shall become automatically effective unless LICENSEE shall have cured any such material breach or default prior to the expiration of the ninety (90) day period.

13.4 LICENSEE shall have the right to terminate this Agreement at any time on six (6) months' notice to M.I.T., and upon payment of all amounts due M.I.T. through the effective date of the termination.

13.5 Upon termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination; and Articles 1, 8, 9, 10, 12, 13.5, 13.6, and 15 shall survive any such termination. LICENSEE and any SUBLICENSEE thereof may, however, after the effective date of such termination, sell all LICENSED PRODUCTS, and complete LICENSED PRODUCTS in the process of manufacture at the time of such termination and sell the same, provided that LICENSEE shall make the payments to M.I.T. as required by Article 4 of this Agreement and shall submit the reports required by Article 5 hereof.

13.6 Upon termination of this agreement for any reason:

- a. LICENSEE shall provide M.I.T. with written assurance that the original and all copies of the PROGRAM and DERIVATIVE, WORKS in its possession or control have been destroyed, except that, upon prior written authorization from M.I.T., LICENSEE may retain a copy for archival purposes; and
- b. the rights of END-USERS to use the PROGRAM shall continue, provided that any END-USER leasing or sublicensing the PROGRAM and not then in default shall obtain a lease or sublicense directly from M.I.T. under reasonable terms and conditions, which shall, at a minimum, include, indemnification of M.I.T. and proof of adequate insurance.

13.7 Upon termination of this Agreement for any reason, any SUBLICENSEE not then in default shall have the right to seek a license from M.I.T. M.I.T. agrees to negotiate such licenses in good faith under reasonable terms and conditions, which, shall, at a minimum, include indemnification of M.I.T. and proof of adequate insurance.

13.8 Upon termination of this Agreement for any reason, any MEDICAL SERVICE PROVIDER shall have the right to seek a license from M.I.T. to continue practicing the LICENSED PROCESSES and or performing the LICENSED SERVICES. M.I.T. agrees to negotiate such licenses in good faith under reasonable terms and conditions, which shall, at a minimum, include indemnification of M.I.T. and proof of adequate insurance.

14 - PAYMENTS, NOTICES  
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& OTHER COMMUNICATIONS  
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Any payment, notice or other communication pursuant to this Agreement shall be sufficiently made or given on the date of mailing if sent to such party by certified first class mail, return receipt requested, postage prepaid, addressed to it at its address below or as it shall designate, by written notice given to the other party:

In the case of M.I.T.:

Director  
Technology Licensing Office  
Massachusetts Institute of Technology  
Room E32-300  
Cambridge, Massachusetts 02139

In the case of LICENSEE:

John Mon  
General Manager  
Cheung Laboratories  
10220-1 Old Columbia Road  
Columbia, NO 21046-1705

15-MISCELLANEOUS PROVISIONS  
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15.1 All disputes arising out of or related to this Agreement, or the performance, enforcement, breach or termination hereof, and any remedies relating thereto, shall be construed, governed, interpreted and applied in accordance with the laws of the Commonwealth of Massachusetts, U.S.A., except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted.

15.2 The parties hereto acknowledge that this Agreement sets forth the entire Agreement, and understanding of the parties hereto as to the subject matter hereof, and shall not be subject to any change or modification except by the execution of a written instrument signed by the parties.

15.3 The provisions of this Agreement are severable, and in the event that any provisions of this Agreement shall be determined to be invalid or unenforceable under any controlling body of the law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions hereof.

15.4 LICENSEE agrees to mark the LICENSED PRODUCTS sold in the United States with all applicable United States patent numbers. All LICENSED PRODUCTS shipped to or sold in other countries shall be marked in such a manner as to conform with the parent laws and practice of the country of manufacture or sale.

15.5 The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party.

IN WITNESS WHEREOF, the parties have duly executed this Agreement the day and year Set forth below.

MASSACHUSETTS INSTITUTE OF  
TECHNOLOGY

By /s/Lita Nelsen

-----  
Name Lita L. Nelsen  
  
Title Director Technology  
Licensing Office  
Date October 17, 1997

CHEUNG LABORATORIES, INC.

By /s/Augustine Y. Cheung

-----  
Name Augustine Y. Cheung  
  
Title Chairman  
Date October 24, 1997



APPENDIX A

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PATENT RIGHTS ON THE EFFECTIVE DATE

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UNITED STATES PATENT RIGHTS

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M.I.T. Case No. 5493L

U.S. Patent No. 5,251,645, Issued October 12, 1993

"Adaptive Nulling Hyperthermia Array"

By Alan Fenn

M.I.T. Case No. 5672L

U.S. Patent Number 5,441,532, Issued August 15, 1995

"Adaptive Focusing and Nulling Hyperthermia Annular and Monopole Phased Array

Applicators"

By Alan Fenn

M.I.T. Case No. 6512L

U.S.P.N. 5,540,737, Issued July 30, 1996

"Minimally Invasive Monopole Phased Array Hyperthermia Applicators For Treating

Breast Carcinomas"

By Alan Fenn

M.I.T. Case No. 7615L

"Adaptive Nulling And Focusing, Hyperthermia Phased Arrays

For Activating Thermosensitive, Liposomes For Targeted Delivery Of Drugs To Deep

Human Tissues"

by Alan J. Fenn

FOREIGN PATENT RIGHTS

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M.I.T. CaseNo. 7615L

Pending Applications in Great Britain, Germany and Canada

"Minimally Invasive Monopole Phased Array Hyperthermia Applicators For Treating

Breast Carcinomas

By Alan Fenn

APPENDIX C  
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M.I.T. COPYRIGHTED SOFTWARE  
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MIT. Case No. 7299LS  
"NULLGSC"  
By Alan Fenn

MIT. Case No. 7298LS  
"FOCUSGSC"  
By Alan Fenn

ADDENDUM A

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MASSACHUSETTS INSTITUTE OF TECHNOLOGY  
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TECHNOLOGY TRANSFER AGREEMENT  
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This Agreement is made and entered into this 24th day of October, 1997, (the "Effective Date") by and between CHEUNG LABORATORIES, INC., a corporation duly organized under the laws of Maryland and having its principal office at 10220-I Old Columbia Road, Columbia, MD 21046-1705 (hereinafter referred to as "LICENSEE") and the MASSACHUSETTS INSTITUTE OF TECHNOLOGY, a corporation duly organized and existing under the laws of the Commonwealth of Massachusetts and having its principal office at 77 Massachusetts Avenue, Cambridge, Massachusetts 02139, U.S.A. (hereinafter referred to as "M.I.T."), and relates to the transfer of existing technology in conjunction with a license granted by M.I.T. to LICENSEE on the 24th day of October, 1997 for the Patent Rights to M.I.T. Case No. 5493L, "Adaptive Hyperthermia System," by Alan J. Penn, and M.I.T. Case No. 5672L, "Non-Invasive Monopole Hyperthermia Array for Brain Tumor Heating," by Alan J. Fenn, and M.I.T. Case No. 6512L "Minimally Invasive Monopole Phased Array Hyperthermia Applicators for Treating Carcinoma," by Alan J. Fenn and M.I.T. Case No. 7615L, "Adaptive Nulling And Focusing Hyperthermia Phased Arrays For Activating Thermosensitive Liposomes For Targeted Delivery Of Drugs To Deep Human Tissues," by Alan J. Fenn (hereinafter the "Rights Granted").

WHEREAS, M.I.T. and LICENSEE recognize that the effective development of the licensed Rights Granted requires the INVENTOR (as later defined herein) to provide technical assistance to the LICENSEE to facilitate the transfer of existing licensed technology; and

WHEREAS, this Agreement defines the terms and conditions under which Alan J. Fenn (hereinafter referred to as the "INVENTOR"), a researcher employed by M.I.T. and the INVENTOR of M.I.T. Case Numbers 5493L, 5672L, 6512L, and M.I.T. Case No. 7615L, shall provide technical assistance to LICENSEE relating to said M.I.T. Cases (hereinafter referred to as the "TRANSFER PROGRAM").

NOW, THEREFORE, the parties hereto agree as follows:

1. FIELD AND SCOPE OF THE TRANSFER PROGRAM:

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The field of the TRANSFER PROGRAM is defined by the Work Statement attached hereto as Attachment A. The TRANSFER PROGRAM may include site visits to LICENSEE's facilities, and consultation by telephone. M.I.T. agrees to use reasonable efforts to make available to the LICENSEE technical assistance by the INVENTOR.

2. DURATION

The TRANSFER PROGRAM shall begin on the Effective Date and terminate one (1) year later on \_\_\_\_\_ unless sooner terminated at will by LICENSEE notifying M.I.T. in writing Thirty (30) days before it wishes to terminate the TRANSFER PROGRAM. M.I.T. may terminate the TRANSFER PROGRAM if circumstances beyond M.I.T.'s control shall preclude continuation. The TRANSFER PROGRAM may be extended by mutual written consent. The scheduling of days shall be by mutual agreement between LICENSEE and the INVENTOR with the schedule designed to minimize impact on other Lincoln Laboratory commitments. The total number of days shall be at LICENSEE's request, within the limits for each INVENTOR listed below.

INVENTOR SCHEDULED TIME AVAILABLE

Alan Fenn Not more than Ten (10) days within Twelve (12) months from the Effective Date.

3. REIMBURSEMENT:

The LICENSEE agrees to reimburse M.I.T. for:

- (a) each work day or part thereof spent traveling to or from or working on the TRANSFER PROGRAM either at M.I.T Lincoln Laboratory or at LICENSEE's facilities, in accordance with the following per them schedule:

Table with 3 columns: INVENTOR, PER DIEM, THEREAFTER. Row 1: Alan Fenn, (Confidential Treatment Requested) subject to change, Increased by amount of all pay raises and overhead increases.

- (b) the traveling expense of the INVENTOR in accordance with normal M.I.T. Lincoln Laboratory Travel rules; and
(c) an administrative fee of (Confidential Treatment Requested) percent of the above reimbursable costs.

4. PAYMENT:

Payments shall be made to M.I.T. within thirty (30) days of LICENSEE's receipt of invoice.

5. NON-USE OF NAMES

LICENSEE shall not use the names or trademarks of the Massachusetts Institute of Technology, nor any adaptation thereof, nor the names of any of its employees, in any advertising, promotional or sales literature without prior written consent obtained from M.I.T., and said employee, in each case, except that LICENSEE may state that it is licensed by M.I.T. under one or more of the patents and/or applications comprising the PATENT RIGHTS.

6. LIMITATION OF LIABILITY

LICENSEE AGREES THAT ALL TECHNICAL ASSISTANCE PROVIDED UNDER THE TRANSFER PROGRAM IS MADE WITHOUT WARRANTY OF ANY KIND EXPRESS OR IMPLIED. Neither M.I.T. nor any INVENTOR shall have any liability whatsoever to LICENSEE or any third party in regard to the TRANSFER PROGRAM, including, but not limited to, technical assistance, and know-how, and LICENSEE shall indemnify M.I.T. for any and all liability of any kind which M.I.T. may incur in regard thereto.

7. NOTICES:

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Any payment, notice or other communication pursuant to this Agreement shall be sufficiently made or given on the date of mailing if sent to such party by certified first class mail, postage prepaid, addressed to it at its address below or as it shall designate by written notice given to the other party:

In the case of M.I.T.:

Director  
Technology Licensing Office  
Massachusetts Institute of Technology  
Room E32-300  
Cambridge, Massachusetts 02139

In the case of LICENSEE:

please advise

John Mon  
Cheung Laboratories, Inc.  
10220-1 Old Columbia Road  
Columbia, MD 21046-1705

Agreed to for;

MASSACHUSETTS INSTITUTE  
OF TECHNOLOGY

CHEUNG LABORATORIES, INC.

By: /s/Lita L. Nelsen  
-----  
Name: LITA L. NELSEN, DIRECTOR  
Title: TECHNOLOGY LICENSING OFFICE  
Date: Oct. 17, 1997

By: /s/Augustine Y. Cheung  
-----  
Name: Augustine Y. Cheung  
Title: Chairman  
Date: Oct. 24, 1997

ATTACHMENT A  
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WORK STATEMENT

Alan Fenn will assist Cheung Laboratories with technical questions and assist in any engineering aspects of clinical trials including visits to sites where clinical trials are being conducted.

Agreed to for;

MASSACHUSETTS INSTITUTE  
OF TECHNOLOGY

CHEUNG LABORATORIES, INC.

By: /s/Lita L. Nelsen  
-----

By: /s/Augustine Y. Cheung  
-----

Name: LITA L. NELSEN, DIRECTOR  
Title: TECHNOLOGY LICENSING OFFICE  
Date: Oct. 17, 1997

Name: Augustine Y. Cheung  
Title: Chairman  
Date: Oct. 24, 1997

November 25,1997

Dr. Fred Sterzer, President  
MMTC, Inc.  
12 Roszel Road, Suite A-203  
Princeton, NJ 08540

RE: Amendment to the License Agreement between MMTC, Inc. ("MMTC ") and Cheung Laboratories, Inc. ("CLI") dated August 23, 1996 as extended April 11, 1997.

Dear Dr. Sterzer:

Based upon our conversations and prior negotiations, I understand that MMTC has agreed to amend the above referenced License Agreement as follows:

a. The "Licensed Patents" listed in Appendix I shall include U.S. Patent 5,149,198 dated September 22, 1992 (Sterzer - Temperature-Measuring Microwave Radiometer Apparatus) and 5,688,050 dated November 17, 1997 (Sterzer - Temperature-Measuring Microwave Radiometer Apparatus) (the "New Patents"). The parties agree that any CLI rights to the New Patents will be limited to the "Field", as defined in the Agreement. In order to maintain rights to the New Patents, CLI must fund research and development work by MMTC in an amount of (Confidential Treatment Requested) per month commencing December 1, 1997. Such research and development work will initially consist of incorporating the radiometer technology into the balloon catheter device. If such work is completed within a one year period, then the funded research and development work may be used, upon the mutual agreement of MMTC and CLI, for additional phantom studies or animal studies to demonstrate the validity of the technology. If CLI funds such research and development activities for 12 months, its rights to the New Patents shall be the same as its rights to other Licensed Patents and its research and development funding obligation shall cease.

b. Section 3.2 is amended to read as follows:

3.2 CLI shall meet the following development milestones by the specified date:

- (i) to file Investigational Device Exemption (IDE) within 2 months after completion of necessary animal safety data from the animal study performed at Montefiore Medical Center, however no later than June 30, 1998; or
- (ii) to commence a clinical safety trial with not less than ten (10) patients (or as required by FDA) within 60 days upon receipt of IDE approval from the FDA and upon the investigator receiving Internal Review Board (IRB) approval as required by his medical facility, however no later than July, 31, 1998; thereafter
- (iii) to commence clinical efficacy trial within 60 days upon receipt of further IDE approval to do such and approval by the investigational site's IRB to do such, however no later than October 31, 1998.

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c. Section 9.2(iii) is replaced in the entirety and to read as follows:

9.2(iii) CLI shall purchase product liability insurance for the protection of MMTC, its directors, officers, agents and employees, that, in the absolute and unreviewable discretion of MMTC, is satisfactory to MMTC in the amount of not less than (Confidential Treatment Requested) for product liability. CLI shall have said product liability coverage in effect prior to the first human patient being treated with the herein technology of this agreement. This representation is a condition precedent to the effectiveness of this Agreement. Liability should cover long-term complaints by patients after the treatment and on other personnel involved directly or indirectly with operations of the equipment, even if the agreement is no longer in force.

d. Section 12.6 is replaced in the entirety and to read as follows: Section 12.6 CLI shall raise by public/or private offering of its stock (Confidential Treatment Requested) in funds by March 31,1998. If CLI does not realize or obtain the (Confidential Treatment Requested) in funds by said date, MMTC shall at its option, terminate this agreement and shall be allowed to retain any and all funds received by MMTC from CLI. The registration statements or prospectuses or any other papers written in connection with such public/or private offering shall not refer by name to MMTC or any of its directors, officers, agents, or employees unless agreed to by MMTC.

The foregoing sets forth your understanding of the extensions and amendments to

the Agreement, please countersign this letter in the space provided below.

CHEUNG LABORATORIES, INC.

MMTC, INC.

By /s/Spencer J. Volk

By /s/Fred Sterzer

-----  
Spencer J. Volk, President  
November 25, 1997

-----  
Fred Sterzer, President



CONSENT OF INDEPENDENT AUDITORS

We hereby consent to the inclusion in Form 10-KA for the fiscal year ended September 30, 1998 of our report dated November 18, 1998 except for footnote 5 which is dated November 29, 1999 relating to the financial statements of Celsion Corporation.

/s/ Stegman & Co.

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Baltimore, Maryland  
November 29, 1999