

GAMMACAN INTERNATIONAL INC
Form 8-K
September 01, 2004

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **August 17, 2004**

GAMMACAN INTERNATIONAL, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

33-0956433

(State of Incorporation)

(I.R.S. Employer Identification No.)

Suite 1500, 800 West Pender Street, Vancouver B.C. Canada, V6C 2V6

(Address of Principal Executive Offices) (Zip Code)

(780) 708-0495

(Registrant's telephone number, including area code)

San Jose International, Inc.

(Former Name)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.01 Completion of Acquisition or Disposition of Assets

Introduction

Pursuant to an agreement for purchase and sale of intellectual property between our subsidiary, Gammacan, Ltd., and ARP Biomed, Ltd. ("ARP") previously disclosed in our current report on Form 8-K filed on June 22, 2004, we fulfilled the subject conditions in that agreement and completed the purchase and sale of the intellectual property on August 17, 2004. As a result, we now own all of ARP's rights and interests in the intellectual property assets (the "Intellectual Property") consisting of intravenous immunoglobulin ("IVIG") research and development, patents and other intellectual property, which appears to hold promising potential for the clinical treatment for various cancer types. In consideration for acquiring the Intellectual Property, we have issued to ARP 12.5% of the common shares of Gammacan, Ltd., leaving us with an 87.5% controlling interest in Gammacan, Ltd.. We also loaned

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\$800,000 to Gammacan, Ltd., which will be utilized to commence clinical trials, to conduct further research and development utilizing the Intellectual Property, and for general working capital purposes.

DESCRIPTION OF BUSINESS

As used in this current report, the terms "we", "us", "our", and "Gammacan" mean Gammacan International, Inc. and our wholly-owned subsidiary, Gammacan, Ltd., unless otherwise indicated.

All dollar amounts refer to US dollars unless otherwise indicated.

Corporate History

We were incorporated under the laws of the state of Delaware on October 6, 1998 under the name of San Jose International, Inc. Our fiscal year end is September 30. Our shares of Common Stock are quoted in the United States on the National Association of Securities Dealers Over the Counter Bulletin Board (the "OTCBB"). On August 19, 2004, we changed the name of our company to Gammacan International, Inc. in the State of Delaware. Our name change became effective on the OTCBB on August 24, 2004 and our new trading symbol is "GCAN".

Initially, our business plan was to focus on the business of marketing and selling custom-designed Spanish colonial doors, windows, frames and related door hardware. We were planning to sell our products to the home building industry. During the fourth quarter of our last fiscal year, it became apparent that we could not readily attract additional financing for our proposed business. We currently have minimal assets and no capital resources to proceed with our business plan. These circumstances have significantly impacted our ability to develop a successful business plan around these products. As an alternative, we undertook initiatives to identify alternative businesses that may be more receptive to the financial markets and more likely to achieve profitable operations.

During our first quarter ended December 31, 2003, we identified a promising business prospect focused on the seismic acquisition business located in Western Canada and agreed in principal to acquire all of the shares of two Alberta based companies. However, on April 20, 2004, we decided to terminate our efforts to pursue this proposed acquisition, because it appeared we would not be successful in obtaining the necessary financing on a timely basis.

Recent Developments

On June 21, 2004, we announced that we signed an agreement with ARP of Israel to acquire all of ARP's interest in the Intellectual Property. The Intellectual Property being acquired includes patents in the United States and certain other countries, pending patents in other countries, know-how, trial protocols, manuscripts, and certain material contracts.

On August 13, 2004, we completed a private placement of 1,224,998 units of our securities for gross proceeds of \$918,750. Each unit consists of one common share in our company and one share purchase warrant, which entitles the

holder to purchase an additional common share for \$1.50 on or before August 13, 2005.

On August 17, 2004, we completed the acquisition of the Intellectual Property through Gammacan, Ltd., a subsidiary we created specifically for this purpose. As consideration for the Intellectual Property, we issued 12.5% of the shares of Gammacan, Ltd. with a deemed value of \$100,000 to ARP. As a result, we currently own the remaining 87.5% of the shares of Gammacan, Ltd. In addition, we also made a loan of

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\$800,000 to Gammacan, Ltd., which we expect will conduct further research and development utilizing the Intellectual Property and commence clinical trials.

Business Subsequent to the Acquisition of the Intellectual Property

With the acquisition of the Intellectual Property, we plan to focus on the commercialization of an anti-cancer immunotherapy that appears to be effective in reducing the metastatic spread of a wide range of cancers. Our proposed treatment will be based on intravenous immunoglobulin or IVIG, a safe, non-toxic human plasma-based product, currently used to treat a variety of immune deficiencies and autoimmune diseases, and replace the antibodies in people who are unable to produce them. Antibodies are a naturally occurring, disease fighting protein or compound produced by healthy people. Intravenous implies the direct injection or delivery, via certain equipment, into the patient's bloodstream. In preliminary studies, IVIG appears to boost and strengthen cancer patient's immune systems or antibody levels, which may be successful in fighting cancer. Although there can be no assurance, many experts currently view IVIG as a promising future alternative to today's standard chemotherapy.

Current Cancer Statistics

Cancer is a disease of the body's cells. Cells in all the tissues and organs of the body constantly grow and divide to replace old and damaged cells and maintain the health of the body. Normally, all cells divide and reproduce themselves in an orderly and controlled manner. In cancer, however, some cells keep dividing without proper control, forming a lump (which is called a primary tumour). In leukaemia, or cancer of the blood, too many white blood cells are produced.

Sometimes cancer cells break away from a tumour and travel to other parts of the body through the bloodstream or lymphatic system. The lymphatic system is a network of fine channels - called lymph vessels - which run throughout the body and are part of the body's protection against infection and cancer. When the cancer cells reach other parts of the body they may settle and start to develop into new tumours. These are known as secondary cancers/tumors or metastases.

There are approximately 2.5 million cases of cancer diagnosed each year in the Western world alone. Primary tumors, while still localized, can be treated through surgery and radiation. However, cancers tend to metastasize, or spread, and form secondary tumors in other locations throughout the body. Most existing therapeutics or treatments fail because the cancer has metastasized and formed multiple tumors. At present, nearly 40% of cancer victims with operable tumors ultimately succumb to metastatic or spreading cancer following surgery. Frequently, metastasis is triggered by the surgical operation itself. During the course of surgery, malignant cells may become dislodged from the tumor mass and enter the circulatory system thus increasing the chance of spreading cancer.

The extent to which metastases occur varies with the type of primary tumor. Melanoma or skin cancer, breast cancer, lung cancer, colon cancer and prostate cancer are among the types of cancer that frequently metastasize or spread. When metastasis takes place, the secondary tumors may form at a number of sites in the body. Lungs, liver, brain and bone are the most common sites of secondary tumors.

Cancer therapeutics represents a major pharmaceutical market with \$12 billion to \$13 billion in worldwide sales in 2001. Between 1995 and 2000, the market grew at an average annual rate of 15 to 20%. Our management believes that average annual growth is forecast to be 8 to 10% through 2015. Despite the large number of patients and the high medical need for effective treatments, the cancer drug market is ranked only eighth in terms of drug sales. This corresponds to 4.0% of the total worldwide

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pharmaceutical market of \$248 billion. In comparison, the 2001 worldwide drug market for cardiovascular diseases totaled \$49 billion (representing 19.5% of the total worldwide pharmaceutical market), central nervous system diseases \$41 billion (representing 16.5% of the total worldwide pharmaceutical market), and alimentary/metabolism diseases \$38 billion (representing 15.3% of the total worldwide pharmaceutical market). The reason for the relatively small size of the cancer treatment market is believed to be primarily due to the lack of effective, safe treatments.

Current Cancer Treatments

Current cancer treatments include surgery, radiation, and chemotherapy. These treatments can be ineffective because they are either unable to target cancer cells throughout the body or they give rise to serious and life-threatening side effects. Consequently, the medical community is still a long way from winning the war on cancer. Companies which can provide winning anti-cancer drugs that at least partially overcome the limitations of current cancer treatments are likely to be well received by the medical establishment and to achieve a leadership position in the cancer drug market.

The alternative to the traditional cancer treatments is the use of various immunotherapies. Current efforts to deliver effective cancer immunotherapies generally fall into three categories: cytokines, monoclonal antibodies and vaccines. Cytokines are medical drugs that stimulate the immune system during infections. Drug developers have hoped that the same factors that fight infections could be used to combat cancer cells. Several have been approved for commercial use, but they are generally limited in their application.

Many companies are involved in developing monoclonal antibodies, which are designed to bind to specific cancer cells and target them for destruction by the immune system. These products are generally more developed, in terms of market use and acceptance, than cytokines and several have significant sales. The monoclonal antibody products realizing significant sales generally have limited or few side effects.

Cancer vaccines rely on the administration of tumor antigens to elicit an immune response that remains after the vaccine itself has disappeared. Most cancer vaccine products currently being developed require the harvesting and processing of tumor cells to make custom vaccines for each patient. Though this approach has shown promise in clinical trials, scaling-up manufacture is likely to be problematic, and these vaccines are generally considered to be a number of years away from commercial use.

Chemotherapy

Chemotherapy is the use of anti-cancer drugs to destroy cancer cells. There are over 50 different chemotherapy drugs and some are given on their own, but often several drugs may be combined. The type of chemotherapy treatment given for a particular cancer depends on many things, the type of disease, where in the body it started, what the cancer cells look like under the microscope and whether they have spread to other parts of the body.

Chemotherapy is currently the standard treatment for cancer that has or may have metastasized or spread. Chemotherapy is a systemic treatment, usually administered intravenously, but can be administered a number of ways, intended to kill cancer/tumor cells, which have spread to multiple sites. However, chemotherapy may also kill healthy dividing cells and consequently, may cause serious side effects. These side effects may include a weakening of a patient's immune system, and reduction in number of white blood cells which are necessary to combat bacterial

infections, inhibition or slowing of bone marrow cell growth, which also may be accompanied with slow down in the production of red blood cells or anemia, the inability to form blood clots, diarrhea, nausea and hair loss. Generally, these side effects

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are temporary in nature, but most patients experience a significant degree of discomfort, and can be long term in some cases.

Chemotherapy can fail to completely eradicate micro-metastases, or the spreading of very small cancer tumors, already residing in remote organs (lung, liver, bone marrow or brain), especially when treatment is discontinued due to patients' inability to tolerate its side effects. If the cancer is not completely eradicated, it will likely continue to grow.

The need for an effective, non-toxic treatment to inhibit spreading cancers is widely recognized and numerous researchers, biotechnology and pharmaceutical companies are seeking alternatives to chemotherapy drugs. The potential for a large receptive commercial market exists for a successful approach to inhibiting spreading cancers without causing serious side effects.

IVIG or Intravenous Immunoglobulin

Our proposed immunotherapy product, if ultimately proven to be successful on a regulatory and commercial basis, aims to harness the body's immune system, or its natural defense mechanism to destroy cancer cells.

Immunoglobulin or IVIG is a type of protein found in human blood that helps to fight off harmful bacteria, viruses and other germs. IVIG is a blood plasma-derived product containing protective antibodies normally present in the blood of healthy individuals. IVIG is used to replace the antibodies in people who are unable to produce them, thereby restoring an almost normal immune response and helping to prevent or reduce the severity of certain infections. It is widely used in the treatment of certain autoimmune diseases. Extensive use over a period of years has demonstrated that IVIG therapy is a safe, non-toxic therapy with virtually no side effects.

Currently, approximately twenty companies produce IVIG products, achieving worldwide sales of about \$500 million annually. These companies manage pools of 1,000 to 20,000 blood donors who are carefully screened prior to being allowed to give blood. This donated plasma is also extensively tested for pathogens prior to use. It is this donated blood plasma that is used to manufacture IVIG, and through the combining the blood plasma of many individual donors, it is believed that the resulting combination provides superior therapy than IVIG from one individual exclusively.

The largest producers of IVIG for the U.S. market are ZLB Bioplasma (a subsidiary of the Australian blood products company, CSL Ltd.), Alpha Therapeutics, Baxter Healthcare, Bayer Biological Products and Aventis Behring.

IVIG products became commercially available in the early 1980's. There are six indications or uses approved by the U.S. Food and Drug Administration (the "FDA"), but IVIG is also used to treat over seventy other "off-label" conditions supported by a consensus of expert opinion, mostly primary immune deficiencies or autoimmune neuromuscular disorders. Between 40% and 50% of IVIG prescriptions are written for off-label indications. Patients receiving IVIG therapy for primary immune deficiencies usually receive the therapy for life, while patients receiving IVIG therapy for autoimmune disorders receive the therapy intermittently over a period of months, and sometimes years, depending on their condition.

IVIG is generally considered to be an expensive therapy, because it is a natural product manufactured from whole human blood. A typical dose may consist of five consecutive days of intravenous

administration of 2 grams per kilogram of patients' body weight. The price of one gram of IVIG has recently ranged from \$18 to \$25 on the wholesale level. For a 150 pound (68.2 kilogram) individual, this translates into a price of between \$2,455 and \$3,410 for a full two gram per kilogram body-weight round of treatment. The cost of administration in a hospital, is also considerable and the total cost for a round of treatment can thus range from \$8,500 to \$20,000 per treatment.

Pre-Clinical and Preliminary Experiments

ARP's scientists have already conducted certain animal experiments to test the effectiveness of IVIG immunotherapy in treating cancer, and investigated the effectiveness of IVIG treatment at various stages of disease progression with varying dosages and routes of administration. They have made preliminary progress in understanding the mechanisms under which IVIG appears to fight cancer.

While these experiments showed promising results, they are preliminary. Use of IVIG in a commercial setting would be subject to much further substantial and significant testing, and subject to certain clinical trials required by the FDA and similar regulatory bodies in other countries.

At this stage however, there can be no assurance that IVIG will evolve into a successful commercial product, gain acceptance for general use or use as a replacement for existing therapeutic products, or even be approved for use by the regulatory authorities.

These early experiments have shown that IVIG treatment appears to reduce metastases and tumor recurrence for a broad spectrum of cancers, with virtually no side effects. However, much more testing must be completed. IVIG also appears to show promise to increase the chances for long term recovery by preventing the return and spread of cancer. These preliminary experiments have also indicated that IVIG therapy holds promise as an effective anti-cancer treatment at much lower doses than is commonly used for treating immune deficiencies. This would serve to make the treatment more affordable and may enable IVIG immunotherapy to be used as a cancer prevention measure in high risk populations.

In these preliminary experiments, IVIG also appears to be effective when administered intravenously, or through several other methods of delivery into the patient's body. Alternative routes of administration could dramatically improve ease-of-use, lower the delivered price of treatments, and enable the treatment of additional conditions.

Intellectual Property

Our success will depend in part on our ability to obtain patent protection for our Intellectual Property. Subsequent to our acquisition of the Intellectual Property from ARP, we enjoy the patented protection of IVIG for treating solid tumors through two major U.S. patents (#5,562,902 and #5,965,130), and additional U.S. and international patent applications. The latest US patent was registered in October 1999. Patent coverage includes a wide range of issues such as: a novel method of administering to a mammal a preparation of IVIG for inhibiting tumor metastasis or spreading, for treating primary tumors, and for a broad spectrum of cancerous diseases. The IVIG preparation to be administered according to this invention may contain intact or fragmented immunoglobulin molecules. The preparation may be administered intravenously, directly under the skin or subcutaneous routes, directly into a cavity (such as an organ or stomach), either as a sole agent or in combination with other agents or methods, which are commonly used for cancer treatment. We believe anyone selling IVIG for treatment of cancer is subject to these patents.

However, the validity and breadth of claims in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. No assurance can be given that any patents based on pending patent applications or any future patent applications by us will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of the patents that have been or may be issued to us will be held valid if subsequently challenged or that others will not claim rights in or ownership of the patents and other proprietary rights held or licensed by us. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our technology or design around any patents that have been or may be issued to us. Since patent applications in the United States are maintained in secrecy for the initial period of time following filing, we also cannot be certain that others did not first file applications for inventions covered by our pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements. It has not been, but is now our intended policy to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, board of directors, technical review board and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements will provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific limited circumstances. We also will commence to require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements will generally provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as the exclusive property of our company. There can be no assurance, however, that all persons who we desire to sign such agreements will sign, or if they do, that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or unpatentable know-how will not otherwise become known or be independently developed by competitors.

Our success will also depend in part on our ability to commercialize our technology without infringing the proprietary rights of others. We have not conducted freedom of use patent searches and no assurance can be given that patents do not exist or could not be filed which would have an adverse affect on our ability to market our technology or maintain our competitive position with respect to our technology. If our technology components, products, processes or other subject matter are claimed under other existing United States or foreign patents or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our technology. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed technology or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse affect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease our development and commercialization of our technology.

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Research and Development

Foundational Research

Scientists have conducted extensive pre-clinical research to test the effectiveness of IVIG immunotherapy in treating cancer. They have employed mice models of various types of cancers as well as various types of human cancers

introduced into immune deficient (SCID) mice. They have investigated the effectiveness of IVIG treatment at various stages of disease progression, using alternative dosage and routes of administration. These pre-clinical and preliminary experiments have shown that IVIG treatment prevents metastases and tumor recurrence for a broad spectrum of cancers with little or no side effects.

IVIG treatment was shown to work in conjunction with surgery to provide long term recovery. While surgery provides an effective short term mechanism for treating localized cancer tumors, IVIG treatment was shown to increase the chances of long term recovery by preventing the return or spread of the cancer. Parallel studies conducted in melanoma, carcinomas and sarcomas confirm these results.

Scientists conducted a series of experiments in which mice were inoculated in the foot pad with cancerous cells which formed tumors. When the tumor grew to a size of 1 cm³ the inoculated leg was amputated. These experiments parallel the surgical removal of primary tumor in human patients. Post-amputation, IVIG therapy was administered and the recurrence of metastases at the amputation site and in the lungs was significantly reduced. Experiments conducted with human cancer cells implanted in immune suppressed SCID mice have shown similar when treated with IVIG.

Most pre-clinical experiments were conducted using a standard dosage of 2.0 grams per kilogram body weight. Additional experiments have shown that our proposed therapy is effective with low doses of IVIG representing 1% (20 milligrams per kilogram body weight) of the standard IVIG dosage. These experiments suggest that

IVIG treatment could be affordably administered as a preventative measure. IVIG has been shown in mice experiments to be effective when administered subcutaneously, intravenously, or through intra-cavitary injection. The option of alternative routes of administration dramatically improves ease-of-use and enables the treatment of previously untreatable conditions such as intra-peritoneal spread (i.e. ovarian carcinoma). IVIG has also been shown to be effective when administered as a whole molecule or as a fraction.

Product Development

Our initial focus over the next several years is to demonstrate efficacy of IVIG cancer immunotherapy in human clinical trials. Efficacy is the ability of a drug or other treatment to produce the desired result when taken by its intended users. If ultimately proven to be successful, and there can be no assurance that it will be, we could be well-positioned to enter a licensing agreement with a major pharmaceutical partner for commercial market development and sales.

IVIG immunotherapy will require regulatory approval before being commercially marketed for human therapeutic use. Clinical trials generally include three phases that together may take several years to complete. Phase I clinical studies (toxicity trials) are primarily conducted to establish safety. Phase II studies are designed to determine preliminary efficacy. Phase III studies are conducted to optimize therapeutic efficacy in a statistically significant manner at the levels of optimal dose, method of delivery into the body or route, and schedule of administration. Once clinical trials are completed successfully, products may receive regulatory approval.

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Since IVIG is an established, safe therapy, we will not be required to conduct Phase I studies. We plan to begin enrolling patients within the next six months for a Phase II study using IVIG immunotherapy as an adjunct treatment for a wide range of cancers. Phase II clinical trials will be conducted at two or more medical centers in Israel. It is expected to take six months to enroll patients. We are planning on including several different cancers in the trial, some of which metastasize and progress quickly, so statistically significant preliminary results may be available after one year. We will continue to monitor patients for at least two years. If successful or promising, and at this preliminary stage there is no assurance they will be, results of these clinical trials will be used to enter into discussions with a major pharmaceutical partner to work with us to potentially commercialize the products.

Employees

During the next 12 months, we plan to function with a small management staff. During this time, we will focus on managing Phase II clinical trials and establishing preliminary relationships with potential commercial partners. Our employees include Mr. David Stephens, the Chief Executive Officer of our company, Dr. Dan J. Gelvan, the Chief Executive Officer of Gammacan, Ltd., Ms. Tovi Ben Zeev, the Chief Financial Officer of Gammacan, Ltd., and Professor Yehuda Shoenfeld, M.D., the Chief Scientist of Gammacan, Ltd. The positions of Chief Financial Officer and Chief Scientist of Gammacan, Ltd. will initially be on a part-time basis and will become full-time positions as activities expand in over the next 12 months. We also plan to hire additional administrative staff as needed as well as a Director of Clinical Trials.

Competition

Competition in the area of biomedical and pharmaceutical research and development is intense and significantly depends on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. Our competitors include major pharmaceutical, medical products, chemical and specialized biotechnology companies, many of which have financial, technical and marketing resources significantly greater than ours. In addition, many biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with ours. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint ventures. We are aware of certain other products manufactured or under development by competitors that are used for the treatment of the diseases and health conditions that we have targeted for product development. There can be no assurance that developments by others will not render our technology obsolete or noncompetitive, that we will be able to keep pace with new technological developments or that our technology will be able to supplant established products and methodologies in the therapeutic areas that are targeted by us. The foregoing factors could have a material adverse affect on our business, financial condition and results of operations. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with our company in recruiting and retaining highly qualified scientific personnel and consultants.

Competition within this sector itself is increasing, so we will encounter competition from existing firms that offer competitive solutions in the cancer treatment solutions. These competitive companies could develop products that are superior to, or have greater market acceptance, than the products being developed by our company. We will have to compete against other biotechnology and pharmaceutical

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companies with greater market recognition and greater financial, marketing and other resources.

Our competition will be determined in part by the potential indications for which our technology is developed and ultimately approved by regulatory authorities. In addition, the first product to reach the market in a therapeutic or preventive area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our potential corporate partners, can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market are expected to be important competitive factors. Our competitive position will also depend on our ability to attract and retain qualified scientific and other personnel, develop effective proprietary products, develop and implement production and marketing plans, obtain and maintain patent protection and secure adequate capital resources. We expect our technology, if approved for sale, to compete primarily on the basis of product efficacy, safety, patient convenience, reliability, value and patent position.

Government Regulations and Supervision

We will be using and developing biotechnology and pharmaceutical products for use in treating human diseases. We will be directly affected by governmental regulations from the United States Food and Drug Administration (the "FDA") for these products.

The FDA regulates clinical development and marketing approval of all medical products intended for human use. The laws and regulations of the FDA place the burden of proof of safety and efficacy on the manufacture of the product. This agency possesses extensive experience with its regulatory mechanisms and applies them to all products, with differing statutes for various categories of products. Other countries have comparable regulatory agencies to the FDA, although the specific regulations may differ substantially.

The principal activities which must be completed prior to obtaining approval for marketing in the United States are as follows:

- a) *Pre-clinical Studies.* Pre-clinical studies are conducted in animals to test pharmacology, efficacy and toxicology and to do manufacturing and formulation work based on *in vivo* results.
- b) *Phase I Clinical Trials.* Phase I clinical trials consist of testing a product in a small number of humans for its safety (toxicity), dose tolerance and pharmacokinetic properties.
- c) *Phase II Clinical Trials.* Phase II clinical trials usually involve a larger patient population than is required for Phase I trials and are conducted to evaluate the effectiveness of a product in patients having the disease or medical condition for which the product is indicated. These trials also serve to identify possible common short-term side effects and risks in a larger group of patients.
- d) *Phase III Clinical Trials.* Phase III clinical trials involve conducting tests in an expanded patient population at geographically dispersed test sites (i.e. multi-centre trials) in a controlled and/or uncontrolled environment to establish clinical safety and effectiveness. These trials also generate information from which the overall benefit-risk relationship relating to the drug can be determined and provide a basis for drug labeling.

Since IVIG is an established, safe therapy, we will not be required to conduct Pre-Clinical and Phase I Clinical Trials. Two key factors that influence the rate of progression of the remaining clinical trials are the rate at which patients can be recruited to participate in the research program, and whether effective

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treatments are currently available for the disease the drug is intended to treat. Patient recruitment is largely dependent upon the incidence and severity of the disease and the alternative treatments available. Regulatory agencies can demand more patients and longer exposure if they deem it prudent, so as to better assess the relative safety compared with the long-term efficacy of the drug.

The results of the pre-clinical tests and clinical trials are submitted to the FDA in the form of a biologic license application for marketing approval. The testing and approval process is likely to require substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. Additional animal studies or clinical trials may be requested during the FDA review period that may delay marketing approval. After FDA approval for the initial indications, further clinical trials may be necessary to gain approval for the use of the product for additional indications. The FDA requires that adverse affects be reported to the FDA and may also require post-marketing testing to monitor for adverse affects, which can involve significant expense.

The growth in this industry over the last several decades has been accompanied by growth in the extent and complexity of the FDA statutes and regulations, and of the intensity of the FDA's regulations of the development, manufacturing, distribution, marketing, promotion, advertising and use of regulated products. In the last decade, the FDA legal and regulatory obstacles to product commercialization and the penalties of non-compliance have been pivotal factors in the success or failure of companies in our industry. This is particularly true for small, emerging companies developing biopharmaceuticals and other biotechnology products.

Risk Factors

Much of the information included in this current report includes or is based upon estimates, projections or other "forward looking statements". Such forward looking statements include any projections or estimates made by us and our management in connection with our business operations. While these forward-looking statements, and any assumptions upon which they are based, are made in good faith and reflect our current judgment regarding the direction of our business, actual results will almost always vary, sometimes materially, from any estimates, predictions, projections, assumptions or other future performance suggested herein.

Such estimates, projections or other "forward looking statements" involve various risks and uncertainties as outlined below. We caution the reader that important factors in some cases have affected and, in the future, could materially affect actual results and cause actual results to differ materially from the results expressed in any such estimates, projections or other "forward looking statements".

Our common shares are considered speculative during the development of our new business operations. Prospective investors should consider carefully the risk factors set out below.

Our Company has a limited operating history.

Our company has a limited operating history and must be considered in the development stage. Our company's operations will be subject to all the risks inherent in the establishment of a developing enterprise and the uncertainties arising from the absence of a significant operating history. No assurance can be given that we may be able to operate on a profitable basis.

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At present, our success depends solely on the successful commercialization of IVIG for our proposed use as a cancer therapy alternative.

The successful commercialization of IVIG is crucial for our success. This proposed product and its potential application is in an early stage of clinical and manufacturing/process development. It faces a variety of risks and uncertainties. Principally, these risks include the following:

- ◆ future clinical trial results may show that IVIG at effective doses is not well tolerated by the recipients or not efficacious as compared to placebo.
- ◆ future clinical trial results may be inconsistent with ARP's previous preliminary testing results. Data from our earlier studies may be inconsistent with clinical data.
- ◆ even if IVIG is shown to be safe and effective for its intended purpose, we may face significant or unforeseen difficulties in obtaining/manufacturing sufficient quantities at or at reasonable prices.
- ◆ our ability to complete the development and commercialization of IVIG for our intended use is significantly dependent upon our ability to obtain and maintain experienced and committed partners to assist us with obtaining clinical and regulatory approvals for, and the manufacturing, marketing and distribution of IVIG on a worldwide basis.

- ◆ even if IVIG products are successfully developed, commercially produced and receive all necessary regulatory approvals, there is no guarantee that there will be market acceptance.
- ◆ our competitors may develop therapeutics or other treatments which are superior or less costly than our own with the result that our products, even if they are successfully developed, manufactured and approved, may not generate significant revenues

If we are unsuccessful in dealing with any of these risks, or if we are unable to successfully commercialize our IVIG products for some other reason, it would likely seriously harm our business.

We may require significant additional financing before our products may be marketed.

We raised an aggregate of \$918,750 in a private placement of our securities in August of 2004 and we anticipate that this amount will only be sufficient to fund our proposed operations for 5 months. Accordingly, our ability to continue develop and, if warranted, commercialize our proposed IVIG products, will be dependent upon our ability to raise significant additional financing. If we are unable to obtain such financing, we will not be able to fully develop and commercialize our technology. Our future capital requirements will depend upon many factors, including:

- continued scientific progress in our research and development programs;
- costs and timing of conducting clinical trials and seeking regulatory approvals and patent prosecutions;
- competing technological and market developments;
- our ability to establish additional collaborative relationships; and
- the effect of commercialization activities and facility expansions if and as required.

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We have limited financial resources and to date, no cash flow from operations and we are dependent for funds on our ability to sell our common shares, primarily on a private placement basis. There can be no assurance that we will be able to obtain financing on that basis in light of factors such as the market demand for our securities, the state of financial markets generally and other relevant factors. The method of financing employed by us to date results in increased dilution to the existing shareholders each time a private placement is conducted.

Our success depends on our ability to attract and retain collaborative partners over whom we have limited control.

Our business will likely depend on our ability to enter into arrangements with corporate and academic collaborators relating to the testing, manufacturing, marketing and commercialization of our products. If successful, we are intending to license or sublicense that property to others. We are planning to try to have our partners assume the obligation to manufacture, market and distribute the resulting products. Consequently, our success depends upon our partners' ability to perform these tasks. There can be no assurance that we will be able to establish necessary arrangements on favorable terms, or at all, or that collaborative agreements will be successful.

Our success depends on our ability to protect our proprietary rights and operate without infringing upon the proprietary rights of others.

We plan to continue to protect the technology that we consider important to the development of our business by filing United States and selected foreign patent applications. We currently hold several patents and pending patent applications in the United States and corresponding patents and patent applications filed in certain other countries over IVIG and its proposed use in cancer therapeutics.

The patent position of biopharmaceutical and biotechnology firms, is generally uncertain and involves complex legal and factual questions. We do not know whether any of our current or future patent applications will result in the issuance of any patents. Even issued patents may be challenged, invalidated or circumvented. Patents may not provide a competitive advantage or afford protection against competitors with similar technology. Competitors or potential competitors may have filed applications for, or may have received patents and may obtain additional and proprietary rights to compounds or processes used by or competitive with ours. In addition, laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States or Canada.

Patent litigation is becoming widespread in the biotechnology industry and we cannot predict how this will affect our efforts to form strategic alliances, conduct clinical testing or manufacture and market any products under development. If challenged, our patents may not be held valid. We could also become involved in interference proceedings in connection with one or more of our patents or patent applications to determine priority of invention. If we become involved in any litigation, interference or other administrative proceedings, we will likely incur substantial expenses and the efforts of our technical and management personnel will be significantly diverted. In addition, an adverse determination could subject us to significant liabilities or require us to seek licenses that may not be available on favorable terms, if at all. We may be restricted or prevented from manufacturing and selling our products in the event of an adverse determination in a judicial or administrative proceeding or if we fail to obtain necessary licenses.

Our commercial success will also depend significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Patent applications are, in many cases, maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature

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frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications are filed. In the event of infringement or violation of another party's patent, we may be prevented from pursuing product development or commercialization.

In addition to patents, we are planning to rely on trade secrets and proprietary know-how to protect our intellectual property. We are planning to require our employees, consultants, outside scientific collaborators and sponsored researchers and other advisors to enter into confidentiality agreements. These agreements may not provide meaningful protection or adequate remedies in the event of unauthorized use or disclosure of our proprietary information. In addition, it is possible that third parties could independently develop proprietary information and techniques substantially similar to ours or otherwise gain access to our trade secrets.

We may not be able to obtain regulatory approvals that will be necessary to commercialize our products.

The manufacture and sale of therapeutic products in the United States and Canada is governed by a variety of statutes and regulations in both countries. These laws govern the development, testing, manufacture, safety, efficacy, record keeping, labelling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. If our products are ultimately marketed abroad, they would also be subject to extensive regulation by foreign governments. There can be no assurance that we will be able to obtain the required regulatory approvals or comply with the applicable regulatory requirements for any of our IVIG products in development. If we are unable to obtain necessary regulatory approvals, we may not be able to commercialize our products.

The IVIG products currently under development will require significant clinical testing and investment of significant funds prior to commercialization. Securing regulatory approval requires us to submit extensive clinical data and supporting information for each indication to establish the product's efficacy. The process of completing these processes is likely to take a number of years. Any delay in obtaining approvals may:

- adversely affect the successful commercialization of our product(s) that we develop

- diminish any competitive advantages that we may obtain
- adversely affect our receipt of revenues or royalties

Additionally, if we fail to comply with applicable regulatory requirements at any stage during the regulatory process, we may be subject to sanctions, including fines, suspensions, product recalls, production suspensions, civil penalties and criminal prosecution, among other actions.

Even if we are able to commercialize our products, our products may not gain market acceptance.

Whether or not any our products gain market acceptance among the medical community in general, as well as the degree of market acceptance of any of our products, will depend on a number of factors, including:

- establishment and demonstration of clinical usefulness and safety
- cost-effectiveness of the products

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- their potential advantage over alternative products
- reimbursement policies of governments and third-party payors
- marketing and distribution support for the products

The success of other products in our market segment in establishing the market, their pricing, their clinical usefulness or other potential advantages or disadvantages, will very likely have a major impact on the success of our product. If our products do not achieve significant market acceptance, our business, financial condition and results of operations will be harmed. In addition, third-party payors such as government health administration authorities, managed care providers and private health insurers are increasingly challenging the price and examining the cost effectiveness of medical products and services. If these third-party payors fail to provide adequate coverage for our products, the market acceptance of the products may be adversely affected.

Competition in our targeted markets is intense and developments by other companies could render our products or technologies non-competitive.

The biotechnology industry is highly competitive and subject to significant and rapid technological change. Developments by other companies within the industry could render our products or technologies non-competitive. Some of these products may be more effective or have an entirely different approach or means of accomplishing the desired effect than our products. We expect technological competition from biotechnology companies and academic research institutions to increase over time.

Many competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. Our competitors may succeed in developing products earlier and obtaining regulatory approvals and patent protection for such products more rapidly than we can.

Our lack of commercial manufacturing experience means that we will have to incur substantial costs to develop manufacturing facilities or contract with third parties over whom we have limited control to develop our products.

In order to be successful, our products must be manufactured and/or obtained in commercial quantities in compliance with regulatory requirements and at acceptable costs. We do not have facilities to commercially manufacture our

products under development and we must initially obtain the small amounts of products we require for clinical studies from contract manufacturing companies. In order to manufacture our products in commercial quantities, we will need to develop manufacturing facilities or contract with third parties to manufacture our products. We may not be able to develop or otherwise secure access to appropriate facilities and manufacturing contracts with third parties may not be available to us on favorable terms, if at all.

Our lack of marketing and sales experience means that we must rely on the efforts of others to commercialize our products.

We do not have a marketing, sales or distribution capability. We intend to enter into arrangements with third parties to market and sell most of our products. We may not be able to enter into marketing and sales arrangements with others on favorable terms, if at all. To the extent that we enter into marketing and sales arrangements with other companies, our revenues will depend on the efforts of others and which efforts may not be successful. If we are unable to enter into satisfactory third-party arrangements, then we

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must develop a marketing and sales force, which may need to be substantial in size, in order to achieve commercial success for any product. We may not successfully develop or obtain the necessary marketing and sales experience or have sufficient resources to do so. If we fail to establish successful marketing and sales capabilities or to enter into successful marketing arrangements with third parties, our business, financial condition and results of operations will be materially adversely affected.

Our development programs and future products subject us to the risk of product liability claims for which we may not be able to obtain adequate insurance coverage.

Human therapeutic products involve the risk of product liability claims and associated adverse publicity. Currently, our principal risks relate to participants in our clinical trials who may become ill or suffer unintended consequences from our IVIG therapeutic. If we ultimately are successful in commercializing a product, claims might be made directly by consumers, healthcare providers or by pharmaceutical companies or others selling or using our products. There can be no assurance that we will be able to obtain or maintain sufficient and affordable insurance coverage for any of these claims and, without sufficient coverage, any claim brought against us could have a materially adverse effect on our business, financial condition or results of operations.

Our business may be harmed if we cannot obtain sufficient quantities of raw materials.

We will be dependent on outside vendors for our entire supply of IVIG. If the third party suppliers were to cease production or otherwise fail to supply us with quality IVIG and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products, and to conduct testing and clinical trials would be adversely affected.

If we are unable to enroll sufficient patients and clinical investigators to complete our clinical trials, our development programs could be delayed or terminated.

The rate of completion of our clinical trials, and those of our collaborators, is significantly dependent upon the rate of enrollment of patients and clinical investigators. Patient enrollment is a function of many factors, including:

- efforts of the sponsor and clinical sites involved to facilitate timely enrollment
- patient referral practices of physicians

- design of the protocol
- eligibility criteria for the study in question
- perceived risks and benefits of the drug under study
- the size of the patient population
- availability of competing therapies
- availability of clinical trial sites
- proximity of and access by patients to clinical sites

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We may have difficulty obtaining sufficient patient enrollment or clinician participation to conduct our clinical trials as planned, and we may need to expend substantial additional funds to obtain access to resources or delay or modify our plans significantly. These considerations may lead us to consider the termination of ongoing clinical trials or development of a product for a particular indication.

Our collaborations with scientific advisors and academic institutions may be subject to restriction and change.

We plan on working with scientific advisors and academic collaborators who will assist us in our ongoing research and development efforts. These scientists will not be our employees and may have other commitments that limit their availability to us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, although we plan on our scientific advisors and academic collaborators signing non-disclosure agreements, it is possible that valuable proprietary knowledge may become publicly known which would compromise our competitive advantage.

We are subject to intense competition for skilled personnel and the loss of key personnel or the inability to attract and retain additional personnel could impair our ability to conduct our operations.

We will be highly dependent on the principal members of our management and scientific staff, especially Dr. Dan J. Gelvan, the Chief Executive Officer of Gammacan, Ltd., and Professor Yehuda Shoenfeld, M.D., the Chief Scientist of Gammacan, Ltd. The loss of whose services might adversely impact the achievement of our objectives and the continuation of existing collaborations. In addition, recruiting and retaining qualified scientific personnel to perform future research and development work will be critical to our success. There is currently a shortage of employees with expertise in our areas of research and clinical and regulatory affairs, and this shortage is likely to continue. Competition for skilled personnel is intense and turnover rates are high. Our ability to attract and retain qualified personnel may be limited.

"Penny Stock" Rules may restrict the market for the Company's shares

Our shares of common stock are subject to rules promulgated by the Securities and Exchange Commission relating to "penny stocks," which apply to companies whose shares are not traded on a national stock exchange or on the NASDAQ system, trade at less than \$5.00 per share, or who do not meet certain other financial requirements specified by the Securities and Exchange Commission. These rules require brokers who sell "penny stocks" to persons other than established customers and "accredited investors" to complete certain documentation, make suitability inquiries of investors, and provide investors with certain information concerning the risks of trading in the such penny stocks. These rules may discourage or restrict the ability of brokers to sell our shares of common stock and may affect the

secondary market for our shares of common stock. These rules could also hamper our ability to raise funds in the primary market for our shares of common stock.

Our share price will likely become highly volatile.

Factors such as announcements of technological innovations, new commercial products, patents, the development of technologies (by us or others), results of clinical studies, regulatory actions, publications, financial results or public concern over the safety of our products or other related products and other factors could have a significant effect on the market price of our common shares.

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Our Principal Research and Development Facilities are Located in Israel, which Has Historically Experienced Military and Political Unrest.

Our principal research and development facilities are located in Israel. As a result, we are directly influenced by the political, economic and military conditions affecting Israel. Any major hostilities involving Israel, or the interruption or curtailment of trade between Israel and its present trading partners, could significantly harm our business, operating results and financial condition.

Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors and, since September 2000, involving the Palestinian population, and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel and companies based in Israel. Acts of random terrorism periodically occur which could affect our operations or personnel. In addition, Israeli-based companies and companies doing business with Israel, have been the subject of an economic boycott by members of the Arab League and certain other predominantly Muslim countries since Israel's establishment. Although Israel has entered into various agreements with certain Arab countries and the Palestinian Authority, and various declarations have been signed in connection with efforts to resolve some of the economic and political problems in the Middle East, the Company cannot predict whether or in what manner these problems will be resolved. Also, since the end of September 2000, there has been a marked increase in the level of terrorism in Israel, which has significantly damaged both the Israeli economy and levels of foreign and local investment.

In addition, certain of our officers and employees may be obligated to perform annual reserve duty in the Israel Defense Forces and are subject to being called up for active military duty at any time. All Israeli male citizens who have served in the army are subject to an obligation to perform reserve duty until they are between 45 and 54 years old, depending upon the nature of their military service.

Indemnification of Directors, Officers and Others

Our by-laws contain provisions with respect to the indemnification of our officers and directors against all expenses (including, without limitation, attorneys' fees, judgments, fines, settlements, and other amounts actually and reasonably incurred in connection with any proceeding arising by reason of the fact that the person is one of our officers or directors) incurred by an officer or director in defending any such proceeding to the maximum extent permitted by Delaware law.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of our company under Delaware law or otherwise, we have been advised the opinion of the Securities and Exchange Commission is that such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable.

Because some of our officers and directors are located in non-U.S. jurisdictions, you may have no effective recourse against the management for misconduct and may not be able to enforce judgement and civil liabilities against our officers, directors, experts and agents.

All of our directors and officers are nationals and/or residents of countries other than the United States, and all or a substantial portion of their assets are located outside the United States. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against our officers or directors, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any U.S. state.

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There is a possibility you may experience future dilution of the shares.

Our constating documents authorize the issuance of 100,000,000 shares of common stock, each with a par value of \$0.0001. In the event that we are required to issue any additional shares or enter into private placements to raise financing through the sale of equity securities, investors' interests in our company will be diluted and investors may suffer dilution in their net book value per share depending on the price at which such securities are sold. If we issue any such additional shares, such issuance also will cause a reduction in the proportionate ownership and voting power of all other shareholders. Further, any such issuance may result in a change in our control.

Anti-Takeover Provisions

We do not currently have a shareholder rights plan or any anti-takeover provisions in our By-laws. Without any anti-takeover provisions, there is no deterrent for a take-over of our company, which may result in a change in our management and directors.

PLAN OF OPERATIONS

We currently have no revenue from operations, we are in a start-up phase with our existing assets and we have no significant assets, tangible or intangible. There can be no assurance that we will generate revenues in the future, or that we will be able to operate profitably in the future, if at all. We have incurred net losses in each fiscal year since inception of our operations.

Our initial focus over the next several years is to demonstrate efficacy of IVIG cancer immunotherapy in human clinical trials. Efficacy is the ability of a drug or other treatment to produce the desired result when taken by its intended users. If ultimately proven to be successful, and there can be no assurance that it will be, we could be well-positioned to enter a licensing agreement with a major pharmaceutical partner for commercial market development and sales.

We plan to begin enrolling patients within the first two quarters following closing, for a Phase II study using IVIG immunotherapy as an adjunct treatment for a wide range of cancers. Since IVIG is an established, safe therapy, we will not be required to conduct Phase I studies. Phase II clinical trials will be conducted at two or three medical centers in Israel. It is expected to take six months to enroll patients. We are planning on including several different cancers in the trial, some of which metastasize and progress quickly, so statistically significant preliminary results may be available after one year. We will continue to monitor patients for at least two years. If successful or promising, and at this preliminary stage there is no assurance they will be, results of these clinical trials will be used to enter into discussions with a major pharmaceutical partner to work with us to potentially commercialize the products.

We estimate that it will take about thirty months to complete Phase III trials and receive regulatory approval to market IVIG immunotherapy. In 2007, when we anticipate IVIG immunotherapy may be available commercially for treating cancer, provided that the trials are successful, clinical trial results and applications for the products will be published.

These studies will enable physicians to study and ultimately prescribe IVIG therapy for a range of specific cancers. Subsequent post-marketing studies would then also be conducted to further evaluate efficacy for different population groups and different stages of disease progression.

We are also planning to conduct additional clinical trials to test new formulations of IVIG and to test IVIG immunotherapies for different cancers at different stages of disease progression with varying dosages and routes of administration. Our goal is to partner with a pharmaceutical company to conduct

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these further Phase II and Phase III trials, in order to attain broad-based regulatory approval.

Long Term Business Strategy

As noted previously, if IVIG shows significant promise through clinical trials, we plan to ultimately seek a strategic commercial partner with extensive experience commercializing and marketing cancer drugs. It is envisaged that the partner would be responsible to ensure that regulatory approvals are achieved in a timely manner and that our IVIG immunotherapies penetrate the cancer market rapidly following FDA approval. This planned strategic partnership could provide a marketing and sales infrastructure for our products as well as financial and operational support for global trials and other FDA requirements concerning future clinical development. Our future pharmaceutical partner could also provide capital and expertise that would enable the partnership to develop new formulations of IVIG cancer immunotherapy suitable for patients at different stages of disease progression.

We also plan to establish a close relationship with at least one producer of IVIG products to co-develop new product formulations and to provide us with IVIG for further pre-clinical testing and clinical trials. There is considerable expertise involved in producing IVIG and significant expense and infrastructure involved in collecting and testing blood. Working together with a partner in the industry will expedite new product formulation, production and ensure a safe standardized product.

Other Research and Development Plans

In addition to conducting early-stage clinical trials, we plan to conduct research to develop alternative delivery systems, to determine the optimal dosage for different patient groups and to investigate alternative sources of immunoglobulin other than human plasma. We plan to conduct research to isolate the fraction of IVIG, which is responsible for its anti-metastasis effects and to develop a synthetic version of IVIG. These formulations will be suitable for:

- Low-dose, preventative therapy for disease-free, high-risk individuals,
- Strong dose for use in conjunction with surgery and other cancer treatments, and
- Maintenance dose for use to prevent recurrence of cancer growth.

Our plan is to patent any successful inventions resulting from our further research activities.

Planned Expenditures

The estimate expenses referenced herein are in accordance with the business plan. As the technology is still in the development stage, it can be expected that there will be changes in some budgetary items. Our planned expenditures for the next 12 months include:

Category	Amount
<u>Research & Development</u>	
	\$70,000
Salaries	\$200,000
Contract	\$400,000
Clinical Trials	\$20,000
Patents and IP	\$120,000
Other	
<u>Marketing</u>	
	\$140,000
Salaries	\$160,000
Other	
<u>General & Administrative Expenses</u>	
	\$150,000
Salaries	\$40,000
Consultants	\$50,000
Travel	\$180,000
Professional fees	\$200,000
Office and other	
Total	\$1,730,000

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We are also considering expanding and accelerating our planned clinical trials program for IVIG. Ultimately, such a change may enable our company to commercialize the product sooner if the trials prove to be successful. If we decide to adjust our program, we anticipate that our related clinical trial costs over the next 12 months would increase by approximately \$1 million. The decision to proceed will be based on several major factors, one of which is the ability of our company to attract sufficient financing on acceptable terms.

DESCRIPTION OF PROPERTY

During the quarter ended June 30, 2004, we relocated our operations to Suite 1500, 800 West Pender Street, Vancouver, B.C. Canada, V6C 2V6. We occupy less than 100 square feet on a rent free basis.

We plan to relocate and establish office and laboratory facilities of approximately 150 square meters (1,700 square feet) within six months and to add another 250 square meters of space in 2006 or 2007 as the Company grows. During an initial period, the Company plans to rent small offices.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Principal Stockholders

The following table sets forth, as of August 25, 2004, certain information with respect to the beneficial ownership of our common stock by each stockholder known by us to be the beneficial owner of more than 5% of our common

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stock, as well as by each of our current directors and executive officers. Each person has sole voting and investment power with respect to the shares of common stock, except as otherwise indicated. Beneficial ownership consists of a direct interest in the shares of common stock, except as otherwise indicated.

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Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership ⁽¹⁾	Percentage of Class ⁽¹⁾
Yair Aloni Director of our company 12A Shabazy St. Tel Aviv, Israel	280,005 common shares	1.11%
Yehuda Shoenfeld Chief Scientist of Gammacan, Ltd. 26 Sapir St. Ramat Gen Israel	699,996 common shares	2.78%
David Stephens Chief Executive Officer and a director of our company 9830 72th St. Edmonton, A.B. T6A 2W1 Canada	135,000 common shares (2)	0.54%
Zeev Bronfeld 6 Uri St. Tel Aviv, Israel	3,900,006 common shares	15.46%
Vered Caplan 69 Deganyq St. Pares Hanna Karkur Israel	3,900,006 common shares	15.46%
L.H. Osterloh 1305 1090 West Georgia St. Vancouver, B.C. V6E 3V7 Canada	1,650,000 common shares	6.54%
Vantech Securities Ltd. 1305 1090 West Georgia St. Vancouver, B.C. V6E 3V7 Canada	1,650,000 common shares	6.54%
Directors and Executive Officers as a Group	1,115,001 common shares	4.42%

(1) Based on 25,221,510 shares of common stock issued and outstanding as of August 25, 2004. Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws

where applicable. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock subject to options or warrants currently exercisable, or exercisable within 60 days, are deemed outstanding for purposes of computing the percentage ownership of the person holding such option or warrants, but are not deemed outstanding for purposes of computing the percentage ownership of any other person.

(2) These 135,000 shares of common stock are owned by 669477 Alberta, Ltd., a company owned by Mr. David Stephens.

DIRECTORS AND EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

As at August 25, 2004, our directors and executive officers, their ages, positions held, and duration of such, are as follows:

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Name	Position Held with our Company	Age	Date First Elected or Appointed
David Stephens	President, Chief Executive Officer and Director of our company	48	June 21, 2004
Shmuel Levi	Director of our company and Gammacan, Ltd.	54	Director of our company and Gammacan, Ltd. since August 17, 2004
Yair Aloni	Director of our company and Gammacan, Ltd.	54	Director of our company and Gammacan, Ltd. since August 17, 2004
Dr. Dan J. Gelvan	Chief Executive Officer of Gammacan, Ltd.	40	August 17, 2004
Tovi Ben Zeev	Chief Financial Officer of Gammacan, Ltd.	52	August 17, 2004
Miriam Sani	Director of Gammacan, Ltd.	42	May 20, 2004
Prof. Yehuda Shoenfeld, M.D.	Chief Scientist of Gammacan, Ltd.	56	August 17, 2004

Business Experience

The following is a brief account of the education and business experience during at least the past five years of each director, executive officer and key employee, indicating the principal occupation during that period, and the name and principal business of the organization in which such occupation and employment were carried out.

David Stephens

Mr. Stephens is the President, Chief Executive Officer and a director of our company. From 1999 to 2004, Mr. Stephens has been self-employed as an independent business consultant. Mr. Stephens provides consulting services in the areas of finance, operations and regulatory disclosure. He has provided services to a number of public and private companies conducting business in telecommunications, hydrocarbon exploration and services, and biotechnology. From late 1995 to 1999 he was the Chief Financial Officer of Telelink Communications Corp. and the President of its manufacturing division. Telelink was a public company listed on the CDNX exchange in Canada and provided national wireless paging services and paging infrastructure equipment. From 1992 to 1995 he was the President, Chief Executive Officer and Chief Financial Officer of the Novatel finance companies, owned by the Government of the Province of Alberta, which provided startup financing for the US cellular industry. Prior to 1992, he served as the Chief Financial Officer for several publicly listed local financial institutions, and emerging technology companies. Mr. Stephens is also an officer and director of Descorp, Inc., a US domestic reporting company that is not currently listed on any exchange.

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Mr. Yair Aloni

Mr. Aloni is a director of our company and our subsidiary, Gammacan, Ltd. He brings over 25 years experience as a senior executive in a number of companies. From 2002 to present, he has served as the Chief Executive Officer of Solidimension Ltd., a private company specializing in 3D printers. From 1996 to 2002, Mr. Aloni served as the Chief Executive Officer of Avnan Yazamut Ltd., a company involved in the investments in companies in the fields of high technology, biotechnology and electronics. Prior to 1996, Mr. Aloni worked as an executive or senior manager of several electronic and auto parts companies. Mr. Aloni graduated from the Technion, Israel Institute of Technology in 1980 with a specialization in Management and Marketing for Managers.

Mr. Shmuel Levi

Mr. Levi is also a director of our company and our subsidiary, Gammacan, Ltd. He has held senior level financial management positions for over 28 years, for major organizations, high tech and start-up companies in Israel. These include serving as the Chief Financial Officer of Rafael Group from 1996 to 1999, the Corporate Finance Manager of Strauss Group from 1991 to 1996 and a Senior Vice President for Finance of North Hills Israel Ltd. For the last 5 years, Mr. Levi concentrated in high-tech and start-up companies using his expertise in performing due diligence, fundraising, public offerings and structuring financial and legal transactions. From 2003 to 2004, he acted as the Chief Financial Officer of Pluristem Life Systems, Inc., a biotechnology company whose shares are quoted on the NASD Over the Counter Bulletin Board. Mr. Levi received a M.Sc. and B.Sc. in Economics and Management from the Technion, Israel Institute of Technology in 1976.

Dr. Dan J. Gelvan

Dr. Gelvan is the Chief Executive Officer of our subsidiary, Gammacan, Ltd. He is an experienced life science executive who brings to us an unique combination of operational and strategic management. Over the past 6 years, Dr. Gelvan founded and managed ZetiQ Technologies Ltd. an industry leader in cell-based high-throughput screening for novel anti-cancer drugs. Under Dr. Gelvan's management, ZetiQ Technologies Ltd. initiated collaborative research projects with a number of leading pharmaceutical and biotechnology companies and successfully discovered a number of new lead compounds. For the two year period prior to founding ZetiQ Technologies Ltd., Dr. Gelvan held a number of strategic and business development positions in Clal (Israel) Ltd, one of Israel's largest holding conglomerates. Dr. Gelvan is a member of Israel's National Committee for Biotechnology, and holds a Ph.D. in Business Economics from Roskilde University in Denmark as well as a BA and MA (*cum laude*) in economics from the Hebrew University of Jerusalem.

Ms. Tovi Ben-Zeev

Ms. Ben-Zeev is the Chief Financial Officer of our subsidiary, Gammacan, Ltd. She brings 25 years of senior level financial experience to Gammacan. Ms. Ben-Zeev is a Certified Public Accountant in Israel and holds an MBA from Rutgers University of New Jersey. She also holds an M.Sc. in Physical Chemistry from Bar Ilan University in Israel. Before her appointment as the Chief Financial Officer of Gammacan, Ltd., Ms. Ben-Zeev was the Chief Financial Officer of Zikit Ltd. from 1987 to 1993, a leading Israeli textile processor whose shares are listed on the Tel-Aviv Stock Exchange. From 1997 to 1999, she acted as the Chief Financial Officer and Chief Operating Officer of Sensotech Ltd., a developer of intelligent safety systems. From 1999 to 2001, she acted as the Chief Financial Officer and Chief

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Operating Officer of Eldan Electronic Instruments Ltd., a leading representative of a number of medical devices and life science companies.

Ms. Miri Sani

Ms. Sani is a director of our subsidiary, Gammacan, Ltd. Since 2003, she has been an independent consultant specializing in clinical trials and regulatory affairs related to the bio-pharmaceutical industry. She focuses her advice and services on bio-pharmaceutical research and development programs, related regulatory affairs, and has recently completed several clinical trials and regulatory affairs programs for emerging medical and biotech companies. From 1999 to 2003, she acted as the Vice President of Regulatory Affairs and Clinical Studies for MTRE, a company specializing in various medical treatments. Ms. Sani received her Masters Degree in Biotechnology and Food Engineering from the Technion, Israel Institute of Technology in 1998.

Prof. Yehuda Shoenfeld, M.D.

Prof. Shoenfeld is the Chief Scientist of our subsidiary, Gammacan, Ltd. He is one of Israel's leading physicians and scientists in the field of immunology. Since 1989, Prof. Shoenfeld has lead the Department of Internal Medicine "B", and the Research Center for Autoimmune Diseases at the Sheba Medical Center, Israel's largest hospital. In 1990, Dr. Shoenfeld was appointed a Professor of Medicine at Tel Aviv University and incumbent of the Laura Schwartz-Kipp Chair for Autoimmunity. He is the author of more than 1,000 scientific papers and more than 40 scientific books.

Committees of the Board

We do not have an audit or compensation committee at this time. Our entire board of directors will operate as the audit committee until such time when an audit committee is appointed.

Family Relationships

There are no family relationships between any of our directors or executive officers.

Involvement in Certain Legal Proceedings

Other than as discussed below, none of our directors, executive officers, promoters or control persons have been involved in any of the following events during the past five years:

1. any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offences);

3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities; or

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4. being found by a court of competent jurisdiction (in a civil action), the Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated.

EXECUTIVE COMPENSATION

The following table summarizes the compensation of Christopher Greenwood, the former President and director of our company, during the last three fiscal years ended September 30, 2001, 2002, and 2003. No other officers or directors received annual compensation in excess of \$100,000 during the most recently completed fiscal year.

Name and Principal Position	Year	Annual Compensation			Long Term Compensation		Pay-outs
		Salary	Bonus	Other Annual Compensation	Securities Under Options/SAR's Granted	Restricted Shares or Restricted Share Units	LTIP Pay-outs
Christopher Greenwood ⁽¹⁾ Former President & Director	2003	Nil	\$Nil	Nil	Nil	Nil	Nil
	2002	Nil	\$Nil	Nil	Nil	Nil	Nil
	2001	Nil	\$Nil	Nil	Nil	Nil	Nil

(1)

Mr. Christopher Greenwood resigned as our President and director on June 21, 2004.

Employment/Consulting Agreements

On August 17, 2004, we entered into a written employment agreement with Dr. Dan J. Gelvan, who currently serves as the Chief Executive Officer of our subsidiary, Gammacan, Ltd. Dr. Gelvan will receive a monthly salary of \$8,000 for the first three months of his services and will receive a monthly salary of \$9,250 thereafter. Dr. Gelvan will also be entitled to receive options under the 2004 Employees and Consultant Stock Option Plan to purchase up to 1,400,000 common shares of our company at the exercise price of \$1.30 per share. Either Dr. Gelvan or our company may terminate the employment agreement with Dr. Gelvan without cause, for any reason whatsoever, with 30 days notice within the first year of the his engagement and with 90 days prior written notice thereafter.

On August 17, 2004, we also entered into a written employment agreement with Ms. Tovi Ben Zeev, who currently serves as the Chief Financial Officer of our subsidiary, Gammacan, Ltd. Ms. Ben Zeev will receive a monthly salary of \$1,300 for her services as the Chief Financial Officer of Gammacan, Ltd. Ms. Ben Zeev will also be entitled to receive options under the 2004 Employees and Consultant Stock Option Plan to purchase up to 50,000 common shares of our company at the exercise price of \$1.30 per share. Either Ms. Ben Zeev or our company may terminate the employment agreement with Ms. Ben Zeev without cause, for any reason whatsoever, with 30 days notice.

On August 17, 2004, we entered into a services agreement with Professor Yehuda Shoenfeld, M.D., who will serve as the Chief Scientist of our subsidiary, Gammacan, Ltd., commencing on September 1, 2004. Prof. Shoenfeld will receive a monthly compensation in the amount of 22,685 NIS (New Israel Shekels), or approximately \$5,000 USD, for his services as the Chief Scientist of Gammacan, Ltd. Either Prof.

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Shoenfeld or our company may terminate the services agreement with Prof. Shoenfeld without cause, for any reason whatsoever, with 30 days notice.

We do not have any material bonus or profit sharing plans pursuant to which cash or non-cash compensation is or may be paid to our directors or executive officers. When a compensation committee of our board of directors is created, arrangements and plans to provide pension, retirement or similar benefits for directors or executive officers will be decided upon by the compensation committee.

Stock Option Plan

On August 17, 2004, our board of directors adopted the 2004 Employees and Consultants Stock Option Plan in order to attract and retain quality personnel. Under the 2004 Employees and Consultants Stock Option Plan, 5,000,000 shares have been reserved for the grant of options, which may be issued at the discretion of our board of directors from time to time.

Stock Options/SAR Grants

There were no grants of stock options or stock appreciation rights to any officers, directors, consultants or employees of our company during the fiscal year ended September 30, 2003. On August 17, 2004, we granted options to Dr. Dan J. Gelvan under the 2004 Employees and Consultants Stock Option Plan to allow Dr. Gelvan to purchase up to 1,400,000 common shares of our company at an exercise price of \$1.30 per share. On the same date, we also granted options to Ms. Tovi Ben Zeev under the 2004 Employees and Consultants Stock Option Plan to allow Ms. Ben Zeev to purchase up to 50,000 common shares of our company at an exercise price of \$1.30 per share. The options granted to Dr. Gelvan and Ms. Ben Zeev are exercisable until August 17, 2014.

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

The following table sets forth, for Mr. Christopher Greenwood, who served as the President and the sole director of our company until June 21, 2004, stock options exercised during fiscal year ended September 30, 2003 and the fiscal year-end value of unexercised options:

Name	Shares Acquired on Exercise (#)	Value Realized (\$)	Number of Securities Underlying Unexercised Options/SARs at September 30, 2003 Exercisable/Unexercisable	Value of Unexercised In-the-Money Options at September 30, 2003 Exercisable/Unexercisable
Christopher Greenwood ⁽¹⁾ President	Nil	Nil	Nil	Nil

(1)

Mr. Christopher Greenwood resigned as our President and director on June 21, 2004.

Directors Compensation

We reimburse our directors for expenses incurred in connection with attending board meetings but did not pay director's fees or other cash compensation for services rendered as a director in the year ended September 30, 2003.

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Other than the 2004 Employees and Consultants Stock Option Plan, we have no formal plan for compensating our directors for their service in their capacity as directors, although in the future, such directors are expected to receive compensation in addition to options to purchase shares of common stock as awarded under the 2004 Employees and Consultants Stock Option Plan. Directors are entitled to reimbursement for reasonable travel and other out-of-pocket expenses incurred in connection with attendance at meetings of our board of directors. The board of directors may award special remuneration to any director undertaking any special services on behalf of our company other than services ordinarily required of a director. Other than indicated in this annual report, no director received and/or accrued any compensation for his or her services as a director, including committee participation and/or special assignments.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Except as otherwise indicated below, we have not been a party to any transaction, proposed transaction, or series of transactions in which the amount involved exceeds \$60,000, and in which, to its knowledge, any of its directors, officers, five percent beneficial security holder, or any member of the immediate family of the foregoing persons has had or will have a direct or indirect material interest:

Mr. Yair Aloni, a director of our company, and Professor Yehuda Shoenfeld, M.D., the Chief Scientist of our subsidiary, Gammacan, Ltd., are authorized signatories of ARP Biomed Ltd. for the Intellectual Property Purchase and Sale Agreement we entered into with ARP Biomed Ltd. on June 11, 2004.

Item 9.01 Financial Statements and Exhibits.

Financial Statements

Not Applicable.

Exhibits

Copies of the following documents are included as exhibits to this report pursuant to Item 601 of Regulation S-B.

SEC Ref. No. Title of Document

(3) Articles of Incorporation, By-laws

3.1 Articles of Incorporation (incorporated by reference from our Form 10-SB Registration Statement, filed June 4, 2001).

3.2 Bylaws (incorporated by reference from our Form 10-SB Registration Statement, filed June 4, 2001).

3.3 Certificate of Amendment of Certificate of Incorporation, dated April 23, 2004 (incorporated by reference from our Form 8-K Current Report, filed June 8, 2003).

(10) Material Contracts

10.1 Sale of Intellectual Property Agreement dated June 11, 2004 between Gammacan, Ltd. and ARP Biomed, Ltd. (incorporated by reference from our Form 8-K Current Report, filed June 22, 2004).

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10.2 Capital Note dated August 17, 2004 issued by Gammacan, Ltd. to San Jose International, Inc. for repayment of \$800,000 loan.

10.3 Employment Agreement dated August 17, 2004 between Gammacan Ltd. and Dr. Dan J. Gelvan.

10.4 Employment Agreement dated August 17, 2004 between Gammacan Ltd. and Ms. Tovi Ben Zeev.

10.5 Services Agreement dated August 17, 2004 between Gammacan, Ltd. and Prof. Yehuda Shoenfeld, M.D.

10.6J004 Employees and Consultants Stock Compensation Plan.

(21) Subsidiaries

21.1 Gammacan, Ltd.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GAMMACAN INTERNATIONAL, INC.

Date: August 31, 2004

/s/ David Stephens

David Stephens, President and Director