

GAMMACAN INTERNATIONAL INC  
Form 10KSB  
December 28, 2007

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-KSB**

(Mark One)

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

**For the Fiscal Year Ended September 30, 2007**

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

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

**Commission file number: 0-32835**

**GAMMACAN INTERNATIONAL, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**33-0956433**

(IRS Employer Identification  
No.)

**Kiryat Ono Mall**

**Azorim Center A**

**39 Jerusalem St.,**

**55423 Kiryat Ono, Israel**

(Address of principal executive offices)

**972 3 7382616**

(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Exchange Act: Common Stock, \$0.0001 par value

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

---

---

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) Yes  No

State issuer's revenues for its most recent fiscal year \$0.00

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of a specified date within the past 60 days. As of December 24, 2007: \$14,940,899 (37,352,248 shares at \$0.40 per share).

State the number of shares outstanding of each of the registrant's classes of common equity, as of the latest practicable date: 44,958,917 shares issued and outstanding as of December 24, 2007.

GAMMACAN INTERNATIONAL, INC.

FORM 10-KSB

TABLE OF CONTENTS

<u>PART I</u>	1
<u>ITEM 1 - BUSINESS</u>	1
<u>ITEM 1A - RISK FACTORS</u>	22
<u>ITEM 2 - PROPERTIES</u>	35
<u>ITEM 3 - LEGAL PROCEEDINGS</u>	35
<u>ITEM 4 - SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.</u>	35
<u>PART II</u>	36
<u>ITEM 5 - MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS</u>	36
<u>ITEM 6 - MANAGEMENT'S DISCUSSION AND ANALYSIS AND PLAN OF OPERATION</u>	40
<u>ITEM 7 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	F-1 - F-32
<u>ITEM 8 - CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	48
<u>ITEM 8A - CONTROLS AND PROCEDURES</u>	48
<u>ITEM 8B - OTHER INFORMATION</u>	48
<u>PART III</u>	55
<u>ITEM 10 - EXECUTIVE COMPENSATION</u>	55
<u>ITEM 11 - SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	61
<u>ITEM 12 - CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u>	63
<u>ITEM 13 - EXHIBITS</u>	65
<u>ITEM 14 - PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	67

---

**PART I**

**ITEM 1 - BUSINESS**

*This Annual Report on Form 10-KSB (including the section regarding Management's Discussion and Analysis of Financial Condition and Results of Operations) contains forward-looking statements regarding our business, financial condition, results of operations and prospects. Words such as expects, anticipates, intends, plans, believes, seeks, estimates and similar expressions or variations of words are intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this Annual Report on Form 10-KSB. Additionally, statements concerning future matters are forward-looking statements.*

Although forward-looking statements in this Annual Report on Form 10-KSB reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under the heading *Risks Related to Our Business* below, as well as those discussed elsewhere in this Annual Report on Form 10-KSB. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-KSB. We file reports with the Securities and Exchange Commission (the *Commission*). We make available on our website under Investor Information/SEC Filings, free of charge, our annual reports on Form 10-KSB, quarterly reports on Form 10-QSB, current reports on Form 8-K and amendments to those reports as soon as reasonably practicable after we electronically file such materials with or furnish them to the SEC. Our website address is [www.gammacan.com](http://www.gammacan.com). You can also read and copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. You can obtain additional information about the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an internet site ([www.sec.gov](http://www.sec.gov)) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Annual Report on Form 10-KSB. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this Annual Report, which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

As used in this Annual Report, the terms *we*, *us*, *our*, and *GammaCan* mean GammaCan International, Inc. and our subsidiary, GammaCan, Ltd., unless otherwise indicated.

All dollar amounts refer to US dollars, unless otherwise indicated. Throughout this document we use IgG to refer to intravenous immunoglobulin therapy, unless otherwise indicated. Others in the industry use abbreviations such as IVIG or IVIg when referring to intravenous immunoglobulin therapy.

## DESCRIPTION OF BUSINESS

### General

We are a life science company focused on the development of immunotherapy and related approaches to treat cancer. To date, we have focused on the use of intravenous immunoglobulins, or *IgGs*, derived from human plasma to treat melanoma, and other cancers. We believe that *IgGs* may be the basis for safer, more effective and efficient cancer treatment as a mono-therapy, a combination therapy and as an adjuvant therapy. Our business objective is to become a recognized leader in the development of immunotherapy and related approaches to treat cancer.

***IgG-based Technology:*** Based on our research, *IgG*-derived from human plasma has anti-cancer properties. These properties appear to be the result of the immunomodulatory effects of *IgGs*, as well as the direct effects of certain antibody populations present in *IgG* fractions. We have demonstrated a reduction in metastatic lesions and an improved survival rate in mice injected with human sarcoma or human melanoma cells when the animals were treated with *IgGs*. There is also clinical evidence suggesting that *IgG*-based therapy is efficacious in human cancers, including melanoma. Also, *IgGs* have been found to dramatically reduce the white blood cell count in chronic lymphocytic leukemia.

In addition, we recognize that *IgG*-based therapies possess the following unique advantages as a result of more than thirty years of clinical experience and manufacturing know-how pertaining to the treatment of immune deficiencies and autoimmune diseases:

*Superior product safety* - *IgGs* are *safe* and *non-toxic*; and

*Minimal manufacturing risk* the manufacturing process for *IgGs* is well established and optimized due to the numerous products that have been developed from human plasma to date.

As a result, we are pursuing the development of *IgG*-based technology to develop therapies for the treatment of melanoma, as well as therapies directed toward disrupting the blood supply to cancers, referred to as anti-angiogenesis.

***Melanoma:*** The incidence of melanoma, despite new developments in other cancers, continues to increase with little or no therapeutic progress in the last ten years. Our lead product candidate, VitiGam , is a first-in-class anti-cancer immunotherapy derived entirely from the plasma of donors with vitiligo, a benign autoimmune skin condition affecting up to two percent of the general population. We have demonstrated that plasma from individuals with vitiligo contains anti-melanoma activities. Based on this, we are developing VitiGam to initially address Stage III and Stage IV melanoma and possibly earlier stages of melanoma at a future time.

In June 2007, we completed a non-FDA Phase II clinical trial designed to test the safety and efficacy of standard *IgG* (collected and manufactured from general population donors, which may have included donors with vitiligo) in patients with prostate cancer, colon cancer and melanoma. In this trial, no serious untoward effects of *IgGs* were noted. In one patient with melanoma, the cancer remained stable or improved over eight cycles of therapy (approximately ten months).

In addition to the pre-clinical evidence we have accumulated using vitiligo-derived plasma, the above observations provide further validation for our plan to develop VitiGam .

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

We plan to file an Investigational New Drug Application, or *IND*, for VitiGam in the near future. We believe that the FDA is well acquainted with IgG-based therapies and their safety profiles resulting from a long history of regulatory approvals of IgG-based products.

In addition to VitiGam, we are also developing the following:

*Next generation (recombinant) VitiGam* - VitiGam is currently manufactured as a mixture that largely consists of IgG molecules (antibodies of the IgG type). We anticipate that within this mixture, only a subset of IgG molecules will be responsible for the biological activity of VitiGam. Next generation VitiGam will be composed of *only the IgGs required to exert the anti-melanoma effect*, thereby creating a more effective compound. Identifying the relevant IgGs may also permit cost reductions; and

*Cancer vaccines based on VitiGam* - An off-the-shelf cancer vaccine is considered a silver bullet in cancer therapy. We anticipate that based on our evolving understanding of the specific IgG molecules responsible for the biological activity of VitiGam, we may be in a position to identify the corresponding antigens that may be used to develop melanoma cancer vaccines.

**Anti-angiogenesis:** We are developing additional novel IgG-based therapies for cancer and other diseases. These therapies are based on the disruption of the blood supply to cells. Our scientists have shown that several mechanisms may be involved in mediating the anti-cancer effects of IgG-based immunotherapies. Angiogenesis is one of a number of well known pathways to deprive cells from their blood supply.

In June 2007, we announced the discovery of proprietary IgG sub-fractions, in human plasma, which contain potent anti-angiogenic properties. These sub-fractions may be used for treatment of disorders resulting from neovascularization (the formation of new blood vessels or angiogenesis).

We have established a pre-clinical development program to define and characterize these anti-angiogenic anti-cancer fractions and to test their biological activity in animal models. We believe that successfully developed therapies derived from our novel IgG sub-fractions have the potential to address multi-billion dollar markets. For example, Avastin®, also known as *Bevacizumab*, counteracts VEGF, a growth factor which stimulates neovascularization, and is used to treat colon and other cancers. Sales for Avastin® in 2006 were in excess of \$2 billion.

**Intellectual Property:** We own a significant portfolio of patents and patent applications covering our technologies and are aggressively protecting these technology developments on a worldwide basis. In addition, in August 2007, VitiGam received Orphan Drug Status in the U.S. for Stage IIB to Stage IV metastatic melanoma. We are currently applying for Orphan Drug Designation in the European Union ( *E.U.* ) and its member states. Orphan Drug Status is granted by the U.S. and European regulatory authorities to promote the development of drugs for diseases affecting less than 200,000 people and in the E.U. for diseases affecting less than 5 cases per 10,000 people. In the U.S., Orphan Drug Status provides market exclusivity for a seven year period as well as other regulatory and income tax advantages. In the E.U. Orphan Drug Designation, if granted, will provide us with market exclusivity for ten years, certain fee reductions, protocol assistance (scientific advice), and various other E.U. and member state-specific incentives.

**In-licensing and Acquisitions:** We are continuously evaluating in-licensing and/or acquisition opportunities to broaden our product portfolio and technology base.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

**Management:** We are led by a highly-experienced management team knowledgeable in immunotherapy for the treatment of cancer. Our management team has access to our internationally recognized Scientific Advisory Board whose members are thought-leaders in their respective areas. Our subsidiary's Chief Scientist, Professor Yehuda Shoenfeld, M.D., FRCP, is a world-recognized immunologist and the innovator primarily responsible for much of our IgG-based technology development and know-how.

### 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. We engaged in several business models and acquisition plans, until in June 2004, approximately 27% of our then outstanding shares of common stock was acquired by Zeev Bronfeld and Vered Caplan in a private transaction. Shortly thereafter, on August 14, 2004 we raised approximately \$900,000 in a private placement, and, pursuant to an agreement for the purchase and sale of intellectual property between our newly formed Israeli subsidiary, GammaCan, Ltd., and ARP Biomed, Ltd. ( *ARP* ), our subsidiary completed the purchase and sale of ARP's intellectual property on August 17, 2004 in consideration for the issuance to ARP of 12.5% of the outstanding shares of our subsidiary. As a result, we became the owner of 87.5% of our subsidiary which in turn owns all of the aforementioned intellectual property consisting of IgG research and development, patents and other intellectual property. At the same time, we also made a loan of \$800,000 from the proceeds of the private placement to the subsidiary to finance its new business. On August 19, 2004, we changed our name to GammaCan International, Inc.

On December 13, 2007, we entered into a Share Purchase Agreement made as of November 26, 2007 with ARP. The Share Purchase Agreement provides that, subject to fulfillment of certain closing conditions, including the receipt of an Israeli tax ruling, ARP will sell to us 12.5% of the issued and outstanding shares of our subsidiary such that at closing we will own 100% of the issued and outstanding shares of our subsidiary. In consideration for such sale, we agreed to issue to ARP, at closing, 2,697,535 shares of our common stock, a warrant to acquire 1,123,973 shares of our common stock and an additional warrant to acquire 449,589 shares of our common stock. Both warrants are exercisable for five years at an exercise price equal to the average last sales price of our common stock during the sixty trading days prior to November 26, 2007. The warrants are subject to adjustment for, among other things, stock splits, stock dividends, distributions and reclassifications. In the case of the warrant to acquire 1,123,973 shares, if there is a change of control (as defined therein), then subject to certain restrictions, the warrant shall be deemed exercised in full and no exercise price shall be payable by the holder. The securities (and underlying securities) to be issued under the Share Purchase Agreement will also be subject to a separate lock up agreement and registration rights agreement upon issuance.

In connection with the Share Purchase Agreement, ARP and our subsidiary agreed to enter into an amendment of the agreement for the purchase and sale of intellectual property from ARP, which amendment specifically delineates clarity of title and related issues to certain intellectual property sold under the original agreement.

### Background

#### Current Approaches to Cancer Therapy

Cancer is a malignant condition which starts in a cell of a specific organ in the body. If left untreated, the cancer will grow in size, affect the organ, and ultimately spread (metastasize) to other organs throughout the body where it will also grow and affect the vital function of the organs to which it has spread. Malignant cancers are ultimately terminal because they affect vital organ function. The rate at which these events occur depends on the natural course of the specific cancer, host factors such as the general health of the patient, his or her age, the ability of his or her immune system to deal with the cancer, and other factors.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

In general and whenever possible, primary cancers are surgically removed, particularly if the tumor has not spread beyond the site where it originated. In most cases excision will be curative if the cancer has not spread (e.g. such is the case with early stage melanomas). For some cases, adjuvant chemo and/or radiation therapy may be indicated, even when the primary tumor does not appear to have spread elsewhere. Once the cancer has spread beyond its primary site, a variety of therapeutic options are available depending on the location and extent of metastases and the natural history of the cancer. Patient factors also play a role. Therapeutic options can be one or more of the following:

Further surgical removal;

Chemotherapy the use of drugs designed to destroy cancer cells;

Radiotherapy the use of radiation to kill the cancer. Radiation may be administered externally (e.g. x-ray) or via a drug that targets the cancer (brachytherapy);

Hormonal therapy Some cancers are hormone-sensitive (e.g. prostate and breast);

Immunotherapy the use of drugs such as antibodies or cancer vaccines that attack the cancer immunologically; and

Combinations of any of the above.

More recently, the use of antibodies plus chemotherapy has emerged as a promising approach to treat cancers.

### **Use of Immunotherapy in Cancer Treatment**

Cancer develops from a single abnormal cell. Most individuals immune systems recognize the cancer cell as a foreign invader and destroy it. Under certain conditions, however, when the individual's immune system is inadequate or when the cancerous cell fools the immune system into treating the cell as normal tissue, the cancerous cell will multiply unchecked and over time cancer will develop. Because of the importance of the immune system in protecting against cancer in the natural state, there has been extensive research dedicated to enlisting immunological approaches to treat cancer. These may be summarized as follows:

#### *Immunoglobulin or Antibody-Based Treatments*

Antibodies are plasma-derived proteins (also called immunoglobulins) that bind or interact with one specific (unique) target. The body synthesizes antibodies to destroy and eliminate any cell or organism that bears (expresses) the target to which the immunoglobulin is specific. After the antibodies have bound to their targets, immune cells (B and T cells and macrophages) effect the destruction of the target cell and remove the debris.

Scientists have harnessed the body's tools and are now able to make antibodies against virtually any target. Antibodies are manufactured outside the body, usually in cell lines, in large manufacturing plants. These antibodies are generally monoclonal - and may affect the cancer in a variety of ways:



A monoclonal antibody may attack the tumor cell itself. An example of such a drug is Herceptin trastuzumab (it binds to the HER-2 receptor which is over-expressed in cancerous breast tissue), used in the treatment of certain patients with breast cancer;

The antibody may react against a substance that is secreted by the tumor to enhance its own cancerous capabilities (for example to stimulate the formation of new blood vessels). Avastin bevacizumab (it targets VEGF, a growth factor that stimulates blood vessel formation or angiogenesis), used to treat colon and other cancers, is an example of such a drug;

The antibody may attack a target central to the modulation of the immune system. Although there are no approved therapies available for cancer, there are several products in late stage development including anti-CTLA4 antibodies (Antegren natalizumab targets a receptor in the Integrin family and is approved for the treatment of multiple sclerosis).

We are developing immunoglobulin or antibody-based therapies. We use more than one antibody, which we understand enhances our product vis-à-vis the others discussed above. Moreover, we harvest IgG from human donors, which we think makes our IgG-based therapy safer than others. Our donors are considered healthy and are extensively screened for possible diseases or contaminants.

Immunoglobulins are also used in combination with chemotherapeutic drugs as an adjuvant therapy. We are active in developing this approach as well.

#### *Cell-Based Therapies*

There are two basic approaches to this therapy. The first involves harvesting the patient's own immune or other cells, manipulating them outside the body and then returning them to the patient as an anti-cancer therapy. A second approach involves taking established immune or other cells and giving them to a cancer patient. Clinical and commercial development of cell-based therapies has been challenging and there are no commercial products in the market at present.

#### *Tumor Vaccinations*

This is the use of tumor extracts or other substances related to the tumor to induce the patient's immune system to act against the tumor. Such vaccines would work in a manner similar to any other vaccine (e.g. rubella, varicella) except that the target is an internal invader, the cancer, rather than an external pathogen such as a virus. To date, only two cancer vaccines are commercially available (Melacine, sold by GlaxoSmithKline in Canada to treat melanoma and Merck's Gardasil® human papilloma virus vaccine to prevent cervical cancer). We are also pursuing novel ways to leverage our knowledge of the immune system, IgG biology, and the cellular immune response in order to develop cancer vaccines.

#### *Immune Modulators*

Small stretches of nucleic acids have been shown to be *immunostimulatory*. These molecules affect the innate immune response by means of so called pattern recognition receptors. Several therapies based on this concept are in clinical development.

**Stage III and Stage IV Melanoma**

Melanoma is a serious skin cancer that originates from the transformation (e.g., conversion from normal cells to cancerous cells) of melanocytes, the skin's pigment (melanin) producing cells. In 2002, the American Joint Committee on Cancer (AJCC) published a revised staging system for melanoma comprising five different stages of the degree of the disease (Stages 0 through IV).

Current therapies for melanoma, especially those available for the treatment of Stage III and Stage IV metastatic melanoma, are unsatisfactory. Chemotherapy, with or without the addition of biologics, have improved survival only slightly, if at all, and the overall prognosis in these patients is poor. Interferon (IFN), interleukin-2 (IL-2) and dacarbazine are the most commonly prescribed therapeutics for the treatment of Stage III and Stage IV melanoma. Their efficacy is moderate and these drugs are plagued by significant side effects. Newer therapies, including monoclonal antibodies and vaccines, are still in development stage. Accordingly, new approaches for the treatment of melanoma are being actively pursued and metastatic melanoma remains a major unmet medical need.

According to the American Cancer Society (ACS):

there were 62,160 new cases of melanoma diagnosed in the U.S. during 2006; and

the incidence of melanoma in the U.S. has doubled since 1973 and has doubled around the world as well.

If recognized early, melanoma is curable by surgery alone. Most new cases are, in fact, cured surgically. For Stage 0, simple excision is 100% effective. For Stage I melanoma, surgery is also almost 100% effective.

Melanoma can be a particularly aggressive cancer. Although melanoma accounts for only 4% of all skin cancers, it accounts for 80% of all skin cancer deaths. Once the disease has spread, the prognosis worsens dramatically. There have been no significant advances in improving the survival of patients with advanced melanoma (Stages II to IV) in the ten last years and limited success in improving their quality of life. We are committed to developing better and safer immune-mediated approaches to treat melanoma and other cancers.

We believe that the U.S. melanoma market will continue to grow significantly in the next few years as a result of:

ozone depletion;

increased exposure to the sun; and

population growth in the sunbelt.

Market researchers estimate the number of melanoma cases will grow from 731,000 cases in 2004 to over 1,000,000 cases in 2010.

According to Navigant Consulting, the worldwide melanoma market is expected to double from \$265 million in 2004 to over \$600 million in 2009. Experts estimate that it will exceed \$1 billion in 2010. The U.S. accounts for close to 50% of the worldwide melanoma market.

### **Intravenous Immunoglobulin (IgG)**

Intravenous immunoglobulins are manufactured from human plasma. More than 12 million liters of source plasma are collected annually in the U.S. Virtually all this plasma is collected from paid donors.

The plasma industry has existed for more than 50 years and has developed substantial experience and know-how in methods to attract, recruit and retain donors. The industry recruits individuals to donate plasma for the manufacture of standard plasma products as well as other individuals who agree to be immunized prior to the donation of plasma for the production of specific immunoglobulin preparations (e.g., rabies immune globulin, Rh immune globulin, hepatitis B immune globulin, etc.). This also includes recruiting specific patients whose plasma contains commercially valuable constituents, particularly for use as control reagents in the diagnostic field and for research (e.g., patients with anti-mitochondrial antibodies, patients with various hyperglobulinemic syndromes, etc.).

Plasma for manufacture into *plasma derivatives* is collected by *plasmapheresis*. This is a process where the donor is connected to a machine for about 40 minutes. The machine extracts plasma, and returns the blood's cellular components to the donor automatically. Plasma collected by this approach is termed *source plasma*. On average, about 800 to 850 mls of plasma are harvested per donation. Donors may donate twice per week and are monitored with an FDA-mandated series of tests with every donation which includes a plasma protein determination and testing for transmissible diseases. There is substantial literature going back more than 30 years indicating that regular plasmapheresis donors suffer no ill effects from this activity.

### **Strategy**

Our business objective is to become a recognized leader in the development of immunotherapy and related approaches to treat cancer. We intend to pursue our objective by implementing the following key strategies:

#### **Market Introduction of VitiGam Through Its Designation as an Orphan Drug**

In August of 2007, we received Orphan Drug Status by the FDA VitiGam for the treatment of Stage IIB to Stage IV metastatic melanoma. Orphan Drug Status is granted by the FDA to promote the development of drugs for diseases affecting fewer than 200,000 people in the U.S. Orphan Drug Status provides us with the following:

seven year period of market exclusivity;

waiver of fees required for FDA filings and registrations; and

tax incentives for up to 50% of clinical development costs.

We are currently also applying for Orphan Drug Designation for VitiGam for Stage IIB to Stage IV metastatic melanoma in the E.U. and its member states. Similar to the FDA, the European Medicines Agency ( *EMA* ) grants Orphan Drug Designation to promote the development of drugs for diseases with a prevalence of fewer than 5 cases per 10,000 inhabitants. If granted, Orphan Drug Designation would provide us with the following:

ten year period of market exclusivity;

fee reductions;

protocol assistance (scientific advice); and

European Community and member state specific incentives.

**Leverage Our Capabilities in Order to Bring to Market Novel and Improved Cancer Therapy Products**

We intend to leverage our IgG-based technology, the expertise of our development team, and the expertise of GammaCan's research and development partner, Sheba Hospital in Tel Ha Shomer, and Professor Yehuda Shoenfeld, M.D., F.R.C.P., a world renowned immunologist.

**Leverage Our Research and Development Efforts to Attract Collaborative Partners to Assist Us**

We intend to utilize our research and development efforts to attract collaborative partners with expertise in, and resources necessary for, clinical trials and manufacturing. By entering into collaborative arrangements, we anticipate that we will gain access to sales, marketing, and other resources to expedite commercialization of our product candidates.

**Continue to Leverage Our Technology to Develop Additional Products**

We intend to build upon our technology to develop the following:

*Next generation (recombinant) VitiGam* - VitiGam is currently manufactured as a mixture that largely consists of IgG molecules (antibodies of the IgG type). We anticipate that within this mixture, only a subset of IgG molecules will be responsible for the biological activity of VitiGam. Next generation VitiGam will be composed of *only the IgGs required to exert the anti-melanoma effect*, thereby creating a more effective compound. Identifying the relevant IgGs may also permit cost reductions;

*Cancer vaccines based on VitiGam* - An off-the-shelf cancer vaccine is considered a silver bullet in cancer therapy. We anticipate that based on our evolving understanding of the specific IgG molecules responsible for the biological activity of VitiGam, we may be in a position to identify the corresponding antigens that may be used to develop melanoma cancer vaccines; and

*Anti-angiogenesis* - We are developing additional novel IgG-based therapies for cancer and other diseases. These therapies are based on the disruption of the blood supply to cells. Our scientists have shown that several mechanisms may be involved in mediating the anti-cancer effects of IgG-based immunotherapies. Angiogenesis is one of a number of well known pathways to deprive cells of their blood supply.

## Research and Development Program

### Foundational Research

Prior to our acquisition of ARP intellectual property by us, ARP scientists conducted extensive pre-clinical research to test the effectiveness of IgG immunotherapy in treating cancer. They have employed mouse models of various types of cancers as well as various types of human cancers introduced into these mice. They have investigated the effectiveness of IgG treatment at various stages of disease progression, using alternative dosages and routes of administration. These pre-clinical and preliminary experiments have shown that IgG treatment prevents metastases and tumor recurrence for a broad spectrum of cancers with few or no side effects.

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 IgG representing 1% (20 milligrams per kilogram body weight) of the standard IgG dosage. These experiments suggest that IgG treatment could be affordably administered as a preventive measure. IgG 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). IgG has also been shown to be effective when administered as a whole molecule or as a fraction.

### Product Development

Our near term focus is to demonstrate efficacy of IgG-based cancer immunotherapy in human clinical trials. Efficacy is the ability of a drug or other treatments to produce the desired result when taken by its intended users. If ultimately proven to be successful, and we can provide no assurance that it will be, we could be well-positioned to enter into a licensing agreement with one or more major pharmaceutical partners for late stage clinical development and/or commercial market development and sales.

IgG 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 the safety and determine the maximum tolerated dose, or MTD. Phase II studies are designed to determine preliminary efficacy and establish dosing. Phase III studies are conducted to demonstrate therapeutic efficacy in a statistically significant manner at the levels of optimal dose, method or route of delivery into the body, and the schedule of administration. Once clinical trials are completed successfully, products may receive regulatory approval. See *Business Government Regulation* .

We are pursuing the development of IgG-based technology to develop therapies for the treatment of melanoma, as well as therapies directed toward disrupting the blood supply to cancers, referred to as anti-angiogenesis therapies.

Our lead product candidate, VitiGam , is a first-in-class anti-cancer immunotherapy derived entirely from the plasma of donors with vitiligo, a benign autoimmune skin condition affecting up to two percent of the general population. We have demonstrated that plasma from individuals with vitiligo contains anti-melanoma activities. Based on this, we are developing VitiGam to initially address Stage III and Stage IV melanoma and possibly earlier stages of melanoma at a future time.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

In June 2007, we completed a non-FDA Phase II clinical trial designed to test the safety and efficacy of standard IgG (collected and manufactured from general population donors, which may have included donors with vitiligo) in patients with prostate cancer, colon cancer and melanoma. In this trial, no serious untoward effects of IgGs were noted. In one patient with melanoma, the cancer remained stable or improved over eight cycles of therapy (approximately ten months).

In addition to the pre-clinical evidence we have accumulated using vitiligo-derived plasma, the above observations provide further validation for our plan to develop VitiGam .

We plan to file an Investigational New Drug Application, or *IND*, for VitiGam in the near future with the intent to conduct a Phase I/II trial to evaluate VitiGam in patients with Stage III and IV melanoma. We estimate that the costs of this Phase I/II will be substantial and the timing of initiation of the Phase I/II trials will be based on several major factors, including our ability to attract sufficient financing on acceptable terms.

We are developing additional novel IgG-based therapies for cancer and other diseases. These therapies are based on the disruption of the blood supply to cells. Our scientists have shown that several mechanisms may be involved in mediating the anti-cancer effects of IgG-based immunotherapies. Angiogenesis is one of a number of well known pathways to deprive cells of their blood supply.

In June 2007, we announced the discovery of proprietary IgG sub-fractions which contain potent anti-angiogenic properties. These sub-fractions may be used for treatment of disorders resulting from neovascularization (the formation of new blood vessels or angiogenesis).

We have established a pre-clinical development program to define and characterize these anti-angiogenic anti-cancer fractions and to test their biological activity in animal models. We believe that successfully developed therapies derived from our novel IgG sub-fractions have the potential to address multi-billion dollar markets. For example, Avastin®, also known as *Bevacizumab*, counteracts VEGF, a growth factor which stimulates neovascularization, and is used to treat colon and other cancers. Sales for Avastin® in 2006 were in excess of \$2 billion.

We are also contemplating conducting additional clinical trials to test new formulations and/or combinations of IgG-based immunotherapies and to test these formulations and/or methods for different cancers at different stages of disease progression with varying dosages and routes of administration. To achieve this, we may elect to partner with a pharmaceutical company to conduct these further clinical trials, in order to attain broad-based regulatory approval.

We expect that it will take a number of years to receive final approval and registration of our IgG preparation for commercial use as an anti-cancer agent. Our strategy is to collaborate with a suitable partner to support late stage (Phase III) clinical development, registration and/or sales for our IgG-based cancer products.

We have spent approximately \$2.7 million through September 30, 2007 on our research and development.

### **Raw Materials**

IgGs are manufactured from human plasma. More than 12 million liters of source plasma are collected annually in the U.S. Virtually all this plasma is collected from paid donors. The U.S. supplies the majority of the plasma needed for the in excess of \$6 billion plasma-derivatives market worldwide. The largest producers of IgG are CSL-Behring, a subsidiary of CSL LTD., Baxter Bioscience, a business of Baxter International Inc., and Talecris Biotherapeutics, Inc. (formerly the plasma business of Bayer A.G.'s Biological Products business unit). In addition, there are numerous smaller suppliers serving the market. We generally depend upon a limited number of suppliers for our IgGs. Although alternative sources of supply for these materials are generally available, we could incur significant costs and disruptions in changing suppliers. The termination of our relationship with our suppliers or the failure of these suppliers to meet our requirements for raw materials on a timely and cost-effective basis could materially adversely affect our business, prospects, financial condition and results of operations.

## Patents and Licenses

To the best of our knowledge, we are the only entity to own issued patents covering the use of IgG-based therapies for the treatment of cancer. We have been issued two U.S. patents that cover the use of basic IgG to treat cancers.

*U.S. Patent 5,562,902, Immunotherapeutic Method of Treating Cancerous Disease by Administration of Intravenous Immunoglobulin* claims the use of intravenous IgG or fragments to inhibit melanoma metastasis. The claims further recite the intracavitary and subcutaneous administration of intravenous IgG or fragments to inhibit tumor metastasis. The patent was issued on October 8, 1996.

*U.S. Patent 5,965,130, Immunotherapeutic Method of Treating Cancerous Disease by Administration of Gamma Globulins* claims the use of 2g/kg bodyweight/month to inhibit the growth of a primary tumor or metastases. The claims further recite the intracavitary and subcutaneous administration of intravenous IgG or fragments to inhibit tumor metastasis. The patent was issued on October 12, 1999.

In December 2006, we filed two Continuations in Part ( *CIPs* ) to these patents. The first CIP is titled *Administration of Gamma Globulins to Treat Metastatic Melanoma* and builds on the pre-clinical work conducted at GammaCan and substantiates these findings with data from our non-FDA clinical trials. The second CIP is titled *Administration of Gamma Globulins to Treat Cancer* and provides experimental data supporting the use of IgG-based therapy for colorectal cancers.

Consistent with a strategy to seek protection in key markets worldwide, we have been issued or are prosecuting national counterparts to our issued U.S. patents.

We have filed two additional U.S. patent applications that cover both composition of matter and methods for using IgG manufactured from donors with Vitiligo (VitiGam ) and its use in melanoma. The prosecution of these and related patents is taking place in the U.S. and worldwide.

We have also filed one additional U.S. patent application covering novel IgG sub-fractions with potent anti-angiogenic properties. In June 2007, we discovered that IgGs contain sub-fractions with potent anti-angiogenic properties which may have application in disorders of neovascularization (the formation of new blood vessels), including cancer and other diseases. We anticipate that this discovery may be developed into broad-based cancer therapies and other therapies that address non-cancer disorders.

We have also filed a patent application for the utilization of IgG therapy as a potential treatment of Avian Influenza.

Our patent strategy is as follows:

Aggressively protect all current and future technological developments to assure strong and broad protection by filing patents and/or continuations in part as appropriate;

Protect technological developments at various levels, in a complementary manner, including the base technology, as well as specific applications of the technology; and

Establish comprehensive coverage in the U.S. and in all relevant foreign markets in anticipation of future commercialization opportunities.

We believe that our success will depend in part on our ability to obtain patent protection for our intellectual property. Our patent coverage includes a wide range of matters including but not limited to: a novel method of administering to a mammal a preparation of IgG for inhibiting tumor metastasis, for treating primary tumors, and for a broad spectrum of cancerous diseases. Our patents will both expire in November 2014.

We believe anyone selling IgG 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. Our policy is 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 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 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 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. Although we have conducted freedom of use patent searches, 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 effect 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.

### **Partnerships and Collaborative Arrangements**

We anticipate that we will enter into strategic relationships for plasma collection and for the manufacture of VitiGam . There is considerable specialized expertise associated with the collection and manufacture (fractionation) of plasma products. There are also significant expenses, capital expenditures and infrastructure involved in the manufacture of plasma. We believe that working together with strategic partners will expedite product formulation, production and approval.

On December 13, 2005, our subsidiary, GammaCan Ltd., entered into a Research and Licensing Agreement (the *Research and Licensing Agreement* ) with Tel Ha Shomer Medical Research Infrastructure and Services LTD. ( *THM* ), pursuant to which our subsidiary agreed to provide THM with \$200,000 in funding for THM to conduct a research project relating to the mechanism of action for intravenous IgG, hyper-immune intravenous IgG and use of intravenous IgG as an anti-cancer treatment. To date, our subsidiary paid a total of \$200,000 to THM under this agreement. Pursuant to the Research and Licensing Agreement, THM has granted our subsidiary an exclusive worldwide license to any resulting technology and know-how as described in the above mentioned agreement.

On December 23, 2007, our subsidiary entered into an Amendment of the Research and Licensing Agreement (the *Amendment* ) with THM. The Amendment reduces the license fees payable under the Research and Licensing Agreement and clarifies, among other things, the nature of research activities pursuant to the Research and Licensing Agreement. Further, the research period under the Research and Licensing Agreement has been extended for a two year period, commencing January 1, 2007, and the research funding for this period totals \$500,000.

In connection with this Amendment, we will issue to THM a five year warrant to acquire 500,000 shares of our common stock exercisable, commencing December 31, 2008, at \$0.40 per share. In addition, within 30 days of the acceptance by the FDA of each new IND application that results from work pursuant to a research project (excluding INDs pertaining to VitiGam ), we will issue to THM a warrant to acquire 250,000 shares of our common stock at an exercise price equal to the closing price of our common stock on the date of issuance of such warrant. The warrants are subject to adjustment for, among other things, stock splits, stock dividends, distributions and reclassifications.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

In October 2006, we entered into a strategic agreement with Life Therapeutics, Inc. ( *Life* ) for the purpose of collecting source plasma from individuals with Vitiligo. Under the agreement, Life will be responsible for the collection, storage, quality control, import/export, delivery, and supply of plasma to us in such amounts as required to complete Phase I and Phase II clinical trials for VitiGam . Life is a U.S./Australian company that specializes in niche therapeutic hyperimmune products. Life currently operates 13 plasma collection centers in eight American states and has considerable experience recruiting and collecting hard to find plasma donors . Life is headquartered in Atlanta, Georgia and operates facilities in the U.S. and in Australia. In the event that Life, for any reason, fails to provide us with its total required plasma for the timely initiation and completion of Phase I and Phase II clinical testing for VitiGam , we will have the unrestricted right to acquire plasma from other sources. We recognize the importance of having access to sufficient plasma for the clinical development of VitiGam as well as for commercial sale. Life and GammaCan have been approved for a \$1 million dollar grant for VitiGam s Phase I and Phase II clinical program by the BIRD Foundation, an Israeli Government non-profit organization that promotes U.S./Israeli joint programs.

On September 6, 2007, we entered into an agreement for the purchase and sale of blood plasma with DCI Management Group, LLC ( *DCI* ). Under the terms of the agreement, DCI will collect plasma from vitiligo donors at DCI operated FDA-approved, IQPP certified donor centers for the manufacture of VitiGam . The entry into this agreement is part of our revised strategy to assure a continued and uninterrupted supply of Vitiligo plasma for the clinical development and long-term commercial sale of VitiGam as we gear up to submit an Investigational New Drug Application (IND) for VitiGam .

We have engaged INC Research to assist us in conducting our clinical trials. INC Research is a therapeutically focused contract research organization engaged in conducting global Phase I - Phase IV clinical development programs in therapeutic areas including oncology. INC Research is headquartered in Raleigh, North Carolina and has 24 offices with a presence in 36 locations worldwide.

We have also engaged BioSolutions Services, LLC ( *BioSolutions* ) for various projects to assist us with the commercialization of our anti-cancer immunotherapy to treat metastatic cancer. The first project relates to regulatory consulting services to be provided by BioSolutions in connection with the application for an IND with the FDA for VitiGam .

### **Government Regulation**

#### **The Drug and Therapeutic Product Development Process**

The FDA requires that pharmaceutical and certain other therapeutic products undergo significant clinical experimentation and clinical testing prior to their marketing or introduction to the general public. Clinical testing, known as *clinical trials* or *clinical studies*, is either conducted internally by life science, pharmaceutical, or biotechnology companies or is conducted on behalf of these companies by contract research organizations.

The process of conducting clinical studies is highly regulated by the FDA, as well as by other governmental and professional bodies. Below we describe the principal framework in which clinical studies are conducted, as well as describe a number of the parties involved in these studies.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

*Protocols.* Before commencing human clinical studies, the sponsor of a new drug or therapeutic product must submit an investigational new drug application, or IND, to the FDA. The application contains what is known in the industry as a *protocol*. A protocol is the blueprint for each drug study. The protocol sets forth, among other things, the following:

who must be recruited as qualified participants;

how often to administer the drug or product;

what tests to perform on the participants; and

what dosage of the drug or amount of the product to give to the participants.

*Institutional Review Board.* An institutional review board is an independent committee of professionals and lay persons which reviews clinical research studies involving human beings and is required to adhere to guidelines issued by the FDA. The institutional review board does not report to the FDA, but its records are audited by the FDA. Its members are not appointed by the FDA. All clinical studies must be approved by an institutional review board. The institutional review board's role is to protect the rights of the participants in the clinical studies. It approves the protocols to be used, the advertisements which the company or contract research organization conducting the study proposes to use to recruit participants, and the form of consent which the participants will be required to sign prior to their participation in the clinical studies.

*Clinical Trials.* Human clinical studies or testing of a potential product are generally done in three stages known as Phase I through Phase III testing. The names of the phases are derived from the regulations of the FDA. Generally, there are multiple studies conducted in each phase.

*Phase I.* Phase I studies involve testing a drug or product on a limited number of healthy participants, typically 24 to 100 people at a time. Phase I studies determine a product's basic safety and how the product is absorbed by, and eliminated from, the body. This phase lasts an average of six months to a year;

*Phase II.* Phase II trials involve testing up to 200 participants at a time who may suffer from the targeted disease or condition. Phase II testing typically lasts an average of one to two years. In Phase II, the drug is tested to determine its safety and effectiveness for treating a specific illness or condition. Phase II testing also involves determining acceptable dosage levels of the drug. If Phase II studies show that a new drug has an acceptable range of safety risks and probable effectiveness, a company will continue to review the substance in Phase III studies.

*Phase III.* Phase III studies involve testing large numbers of participants, typically several hundred to several thousand persons. The purpose is to verify effectiveness and long-term safety on a large scale. These studies generally last two to three years. Phase III studies are conducted at multiple locations or sites. Like the other phases, Phase III requires the site to keep detailed records of data collected and procedures performed.

*New Drug Approval.* The results of the clinical trials are submitted to the FDA as part of a new drug application ( *NDA* ). Following the completion of Phase III studies, assuming the sponsor of a potential product in the United States believes it has sufficient information to support the safety and effectiveness of its product, it submits an NDA to the FDA requesting that the product be approved for marketing. The application is a comprehensive, multi-volume filing that includes the results of all clinical studies, information about the drug's composition, and the sponsor's plans for producing, packaging and labeling the product. The FDA's review of an application can take a few months to many years, with the average review lasting 18 months. Once approved, drugs and other products may be marketed in the United States, subject to any conditions imposed by the FDA.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

*Phase IV.* The FDA may require that the sponsor conduct additional clinical trials following new drug approval. The purpose of these trials, known as Phase IV studies, is to monitor long-term risks and benefits, study different dosage levels or evaluate safety and effectiveness. In recent years, the FDA has increased its reliance on these trials. Phase IV studies usually involve thousands of participants. Phase IV studies also may be initiated by the company sponsoring the new drug to gain broader market value for an approved drug. For example, large-scale trials may also be used to prove effectiveness and safety of new forms of drug delivery for approved drugs. Examples may be using an inhalation spray versus taking tablets or a sustained-release form of medication versus capsules taken multiple times per day.

*Biologics License Application.* Once clinical trials are completed and the results tabulated and analyzed, a Biologics License Application ( *BLA* ) is submitted to the FDA. The application presents to FDA reviewers the entire history or the whole story of the drug product including animal studies/human studies, manufacturing, and labeling/medical claims. Before the FDA applies its scientific technical expertise to the review of the application, it will decide if the application gets a priority review or a standard review . This classification determines the review timeframe. A priority review is for a drug that appears to represent an advance over available therapy, whereas, a standard review is for a drug that appears to have therapeutic qualities similar to those of an already marketed product. Generally, an advisory committee (the Oncology Drug Advisory Committee, ODAC) will review the BLA and make a recommendation to the FDA. This outside advice is sought so that the FDA will have the benefit of wider expert input. The FDA usually agrees with advisory committee decisions but they are not binding.

The FDA takes action on the BLA after their review is complete. There are three possible actions to be taken by the review team:

**Approved** This indicates to a company that it may now market in the U.S.;

**Not Approved** This tells a company that the product may not be marketed in the U.S. and is accompanied by a detailed explanation as to why; or

**Approvable** This indicates that the FDA is prepared to approve the application upon the satisfaction of certain conditions. These drug products may not be legally marketed until the deficiencies have been satisfied, as well as any other requirements that may be imposed by the FDA.

The drug approval process is time-consuming, involves substantial expenditures of resources, and depends upon a number of factors, including the severity of the illness in question, the availability of alternative treatments, and the risks and benefits demonstrated in the clinical trials.

*Orphan Drug Act.* The Orphan Drug Act provides incentives to develop and market drugs ( *Orphan Drugs* ) for rare disease conditions in the United States. A drug that receives Orphan Drug designation and is the first product to receive FDA marketing approval for its product claim is entitled to a seven-year exclusive marketing period in the United States for that product claim. A drug which is considered by the FDA to be different than such FDA-approved Orphan Drug is not barred from sale in the United States during such exclusive marketing period even if it receives approval for the same claim. We can provide no assurance that the Orphan Drug Act's provisions will be the same at the time of the approval, if any, of our products.

*Orphan Drug Designation.* The E.U. offers a range of incentives to encourage the development of orphan drugs for rare disease conditions in the E.U and its member states. A drug that receives orphan drug designation and is the first product to receive EMEA marketing approval for its product claim is entitled to a ten-year exclusive marketing period in the E.U and its member states for that product claim. A drug which is considered by the EMEA to be different than such EMEA-approved orphan drug is not barred from sale in the E.U and its member states during such exclusive marketing period even if it receives approval for the same claim. We can provide no assurance that the above provisions will be the same at the time of the approval, if any, of our products.

### **Other Regulations**

Various federal and state laws, regulations, and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import, export, use, and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research are applicable to our activities. They include, among others, the United States Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Occupational Safety and Health Act, the National Environmental Policy Act, the Toxic Substances Control Act, and Resources Conservation and Recovery Act, national restrictions on technology transfer, import, export, and customs regulations, and other present and possible future local, state, or federal regulation. The extent of governmental regulation which might result from future legislation or administrative action cannot be accurately predicted.

### **Competition**

#### **Competition in General**

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. We can provide 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 effect on our business, prospects, financial condition and results of operations. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants.

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

#### **Competition for VitiGam**

We anticipate VitiGam to be a competitive anti-melanoma drug because of its anticipated efficacy and safety profile. Treatment options for Stage III and Stage IV melanoma comprise three drugs from major drug classes as follows:

**Antineoplastics** Antineoplastics include chemotherapeutics (alkylating agents, antimetabolites and antimetotic agents) that are administered intravenously or orally. Generally speaking, they have significant toxicity associated with severe side effects to the patient. Antineoplastics are typically used to treat Stage IV melanoma.

**Immunomodulators** Substances that suppress, stimulate or boost the immune system. These have some efficacy (10% to 20%), with side effects that are moderate compared to antineoplastics.

**Vaccines** Preparations that aim at coaxing the patient's immune system to mount an immune response against the tumor.

Because of the paucity of safe and effective therapies to treat late stage melanomas, so called off-label use of drugs is common and physicians typically use antineoplastics approved for other cancers in treating melanoma.

Antineoplastics and immunomodulators account for 80% of the treatment for Stage III and Stage IV melanoma. Interferon (IFN), interleukin-2 (IL-2) and dacarbazine are the most commonly prescribed therapeutics in these categories.

Schering Corporation's INTRON® A (Interferon alfa-2b, recombinant) dominates the melanoma market with a 46% market share;

Chiron's PROLEUKIN® (aldesleukin, recombinant human interleukin-2, rhIL-2) commands approximately 28% of the total melanoma market; and

Bayer's DITC DOME (dacarbazine, alkylating agent) accounts for 9%.

The majority of the remaining 17% of the market is comprised of a group of antineoplastics that are sold by Bristol Myers Squibb, Daiichi, Eli Lilly, and Roche. GlaxoSmithKline is currently the only company selling a melanoma vaccine.

#### **Scientific Advisory Board**

We maintain a scientific advisory board consisting of internationally recognized scientists who advise us on scientific and technical aspects of our business. The scientific advisory board meets periodically to review specific projects and to assess the value of new technologies and developments to us. In addition, individual members of the scientific advisory board meet with us periodically to provide advice in particular areas of expertise. The scientific advisory board consists of the following members, information with respect to whom is set forth below: David Sidransky; Richard Spritz, M.D.; Yoseff Yarden M.D., Ph D.; Lynn M. Schuchter M.D.; and Pearl E. Grimes M.D.

*David Sidransky, M.D.* Dr. Sidransky is the Director of the Head and Neck Cancer Research Division at Johns Hopkins University School of Medicine. In addition, he is Professor of Oncology, Otolaryngology-Head and Neck Surgery, Cellular & Molecular Medicine, Urology, Genetics, and Pathology at Johns Hopkins University and Hospital. Dr. Sidransky is certified in Internal Medicine and Medical Oncology by the American Board of Medicine. He has served as a Director of Imclone since January 2004. He is a founder of several private biotechnology companies and has served on the scientific advisory boards of many private and public companies including MedImmune, Telik, Roche and Amgen. He was formerly on the Board of Scientific Counselors at the NIDCR and is currently a member of the Recombinant DNA Advisory Committee at the National Institute of Health (NIH). Dr. Sidransky is a member of numerous editorial boards. He has over 250 peer-reviewed publications, has contributed more than 40 cancer reviews, and also has numerous issued biotechnology patents. He has been the recipient of many awards and honors, including the 1997 Sarstedt International Prize from the German Society of Clinical Chemistry, the 1998 Alton Ochsner Award Relating To Smoking and Health by the American College of Chest Physicians, and the 2004 Hinda and Richard Rosenthal Award from the American Association of Cancer Research.

*Richard Spritz, M.D.* Dr. Spritz is the Director Human Medical Genetics Program and Professor of Pediatrics, Biochemistry and Molecular Genetics at the University of Colorado Health Science Center. Prior to his tenure at the University of Colorado, Dr. Spritz served as Professor of Medical Genetics and Pediatrics at the University of Wisconsin. Among his numerous accomplishments, Dr. Spritz sits on the Medical Advisory Board of Vitiligo Support International, is a member of the Council of the PanAmerican Pigment Cell Society, and has chaired a number of NIH Committees. He has for many years served on various national research advisory committees and for the March of Dimes Birth Defects Foundation. He has published over 170 peer-reviewed papers and receives ongoing research support from the NIH, specifically for studies of the genetics of human pigmentation and autoimmune disorders. Dr. Spritz holds an M.D. from Pennsylvania State University, was a Resident in Pediatrics at the Children's Hospital of Philadelphia, and was a Fellow in Human Genetics at the Yale University School of Medicine. Dr. Spritz has received many honors and awards, including the first Annual Research Award from the Society for Pediatric Dermatology, the Vitiligo and Melanocyte Biology Research Achievement Award from the American Skin Association, the Tanioku Memorial Lectureship from the Japanese Society for Investigative Dermatology, and the Alumni Fellow Medal from Pennsylvania State University.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

*Yoseff Yarden M.D., Ph.D.* Dr. Yarden is professor in the Department of Biological Regulation at the Weizmann Institute of Science in Rehovot. He received his B.Sc. in Biology and Geology (cum laude) at the Hebrew University in Jerusalem in 1979, and his Ph.D. at the Weizmann Institute in 1985. Dr. Yarden's research career has been devoted to understanding the role of the EGFR family of growth-factor receptors and EGF-like growth factors in human cancers. He has been involved in many crucial developments in this field, including isolating the EGFR, isolating several neuregulins, establishing the pivotal role of receptor dimerization in transmembrane signaling, understanding the role of HER2 in signal transduction and tumor development, and resolving the process of ligand-induced degradation of oncogenic receptors.

*Lynn M. Schuchter M.D.* Dr. Schuchter is Director of the Abramson Cancer Center at the University of Pennsylvania and is a world renowned hematologist and oncologist. Her published research and focus of investigative clinical trial activity is melanoma and breast cancer. Dr. Schuchter's research has led to the development of leading-edge approaches to melanoma therapy.

*Pearl E. Grimes M.D.* Dr. Grimes is nationally and internationally recognized for her work on pigmentary disorders. She lectures worldwide on pigmentary disorders including Vitiligo, Melasma, and post-inflammatory hyperpigmentation. Dr. Grimes is the past Assistant Editor of the Journal of the American Academy of Dermatology, and has served on the Editorial Board of the Journal of Clinical Dermatology, Practical Dermatology, and Skin & Allergy News. Dr. Grimes is presently a contributing editor to Cosmetic Dermatology. As founder of The Vitiligo and Pigmentation Institute of Southern California and its ongoing research program, Dr. Grimes' mission is to provide cutting edge therapies to patients suffering from Vitiligo and other pigmentary disorders. She has authored over 100 publications and abstracts and is a member of: The American Academy of Dermatology; the American Society of Dermatological Surgery; the American Dermatological Association; Society of Investigative Dermatology; Dermatology Foundation; and the International Pigment Cell Society. Dr. Grimes is a graduate of Washington University in St. Louis, Missouri and completed her Dermatology Residency at Howard University Hospital in Washington, D.C.

### **Employees**

We have been successful in retaining the experienced personnel involved in our research and development program. In addition, we believe we have successfully recruited clinical/regulatory, quality assurance and other personnel needed to advance through clinical studies or have engaged the services of experts in the field for these requirements. As of September 30, 2007, we employed eight individuals and engaged the services of several consultants. Of our employees, three were senior management, three were engaged in research and development work, and the remaining in administration work.

### **Facilities**

Our principal executive offices are located in approximately 1337 square feet of office space in Kiryat Ono, Israel. The lease commenced on August 10, 2006 and lasts for a period of 36 months. The aggregate annual base rental for this space is \$26,827. Since June 8, 2006, we have been leasing a suite in New York for the use of our CEO. The lease agreement was renewed on June 6, 2007 for a period of 12 months and the aggregate annual base rental for this space is \$24,000. We believe that our existing facilities are suitable and adequate to meet our current business requirements. In the event that we should require additional or alternative facilities, we believe that such facilities can be obtained on short notice at competitive rates.



## Legal Proceedings

We are not a party to any material legal proceedings.

## ITEM 1A RISK FACTORS

*An investment in our common stock involves a high degree of risk. You should consider carefully the following information about these risks, together with the other information contained in this prospectus before buying shares of our common stock. Our business, prospects, financial condition, and results of operations may be materially and adversely affected as a result of any of the following risks. The trading of our common stock could decline as a result of any of these risks. You could lose all or part of your investment in our common stock. Some of the statements in Risk Factors are forward looking statements. See Special Note Regarding Forward Looking Statements .*

### Risks Related to Our Business

**There is substantial doubt as to our ability to continue as a going concern.**

Our financial statements were prepared on the assumption that we will continue as a going concern. We estimate that our cash reserves will be sufficient to permit us to continue at our anticipated level of operations for a minimum four months from the date of this Annual Report. During 2008, we plan to increase research and development, product development, and administrative expenses relating to our business, including expenses related to research and development related to our IgG technology. We intend to use our cash reserves, as well as other funds in the event that they shall be available on commercially reasonable terms, to finance these activities and other activities described herein, although we can provide no assurance that these additional funds will be available in the amounts or at the times we may require. If sufficient capital is not available, we would likely be required to scale back or terminate our research and development efforts. See *Risk Factors We will need additional capital in order to satisfy our business objectives .*

**As we have a limited operating history, investors may not have a sufficient history on which to base an investment decision.**

Although we were incorporated in 1998, we acquired our operating subsidiary in August 2004 and are in the development stage. Accordingly, we have a limited operating history upon which investors may evaluate our prospects for success. Investors must consider the risks and difficulties frequently encountered by early stage companies, particularly in rapidly evolving markets such as the life science industry. Such risks include, without limitation, the following:

competition;

need for acceptance of products;

ability to anticipate and adapt to a competitive market and rapid technological developments;

amount and timing of operating costs and capital expenditures relating to expansion of our business, operations, and infrastructure; and

dependence upon key personnel.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

We cannot be certain our strategy will be successful or that we will successfully address these risks. In the event that we do not successfully address these risks, our business, prospects, financial condition, and results of operations could be materially and adversely affected. Information regarding all of our past operations can be found in our reports and registration statements that have been previously filed with the Securities and Exchange Commission.

### **We are a development stage company with a history of losses and can provide no assurance as to our future operating results.**

We are a development stage company with no revenues from our contemplated principal business activity. Consequently, we have incurred net losses and negative cash flows since inception. We currently have no product revenues, and may not succeed in developing or commercializing any products which will generate product or licensing revenues. We do not expect to have any products on the market for several years. In addition, development of our product candidates requires a process of pre-clinical and clinical testing, during which our products could fail. We may not be able to enter into agreements with one or more companies experienced in the manufacturing and marketing of therapeutic drugs and, to the extent that we are unable to do so, we will not be able to market our product candidates. Eventual profitability will depend on our success in developing, manufacturing, and marketing our product candidates. As of September 30, 2007 and 2006, we had working capital of \$3,177,967 and \$222,133, respectively, and stockholders' equity of \$3,200,838 and \$259,190, respectively. We generated no revenues to date. For the period from our inception on October 6, 1998 through September 30, 2007 we incurred net losses of \$(8,956,187). For the years ended September 30, 2007 and 2006, we incurred net losses of \$(5,178,774), and \$(2,064,795), respectively. We may never achieve profitability and expect to incur net losses in the foreseeable future. See *Management's Discussion and Analysis of Financial Condition and Results of Operations*.

### **At present, our success depends solely on the successful commercialization of IgG-based therapies for our proposed use as a cancer therapy alternative.**

The successful commercialization of IgG-based cancer immunotherapies is crucial for our success. Our proposed products and their potential applications are in an early stage of clinical and manufacturing/process development and face a variety of risks and uncertainties. Principally, these risks include the following:

future clinical trial results may show that IgG based therapy is not well tolerated by recipients at its effective doses or is not efficacious as compared to placebo;

future clinical trial results may be inconsistent with ARP's previous preliminary testing results and data from our earlier studies may be inconsistent with clinical data;

even if our IgG-based therapies are shown to be safe and effective for their intended purposes, we may face significant or unforeseen difficulties in obtaining or manufacturing sufficient quantities or at reasonable prices;

our ability to complete the development and commercialization of IgG-based therapies 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, IgGs on a worldwide basis;

even if our IgG-based products are successfully developed, commercially produced and receive all necessary regulatory approvals, there is no guarantee that there will be market acceptance of the products; and

our competitors may develop therapeutics or other treatments which are superior to, 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 IgG products for some other reason, it would likely seriously harm our business.

**We can provide no assurance of the successful and timely development of our new products.**

Our product candidates are at various stages of research and development. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. Our success will depend on our ability to achieve scientific and technological advances and to translate such advances into reliable, commercially competitive products on a timely basis. Products that we have developed and may in the future develop are not likely to be commercially available for some time. The proposed development schedules for our products may be affected by a variety of factors, including technological difficulties, proprietary technology of others, and changes in governmental regulation, many of which will not be within our control. Any delay in the development, introduction, or marketing of our products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of our projects, the nature of technology involved, and the other factors, described elsewhere in Risk Factors, there can be no assurance that we will be able to complete successfully the development or marketing of any new products.

**We will need additional capital in order to satisfy our business objectives.**

To date, we have financed our operations principally through offerings of securities exempt from the registration requirements of the Securities Act. We believe that our available resources and cash flow will be sufficient to meet our anticipated working capital needs for a minimum of four months from the date of this Annual Report. We estimate that we will require substantial additional financing at various intervals in order to continue our research and development programs, including significant requirements for operating expenses including intellectual property protection and enforcement, for pursuit of regulatory approvals, and for commercialization of our products. We can provide no assurance that additional funding will be available on a timely basis, on terms acceptable to us, or at all. In the event that 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

effects of commercialization activities and facility expansions if and as required.

If we cannot secure adequate financing when needed, we may be required to delay, scale back or eliminate one or more of our research and development programs or to enter into license or other arrangements with third parties to commercialize products or technologies that we would otherwise seek to develop ourselves and commercialize ourselves. In such event, our business, prospects, financial condition, and results of operations may be adversely affected as we may be required to scale-back, eliminate, or delay development efforts or product introductions or enter into royalty, sales or other agreements with third parties in order to commercialize our products.

**In the future, we may rely upon our collaborative agreements with large pharmaceutical companies.**

In the future, we may rely heavily on collaborative agreements with large pharmaceutical companies, governments, or other parties for our revenues. Our inability to obtain any one or more of these agreements, on commercially reasonable terms, or at all, or to circumvent the need for any such agreement, could cause significant delays and cost increases and materially affect our ability to develop and commercialize our product candidates. Some of our programs may require the use of multiple proprietary technologies, especially patented drugs. Obtaining licenses for these technologies may require us to make cumulative royalty payments or other payments to several third parties, potentially reducing amounts paid to us or making the cost of our products commercially prohibitive. Manufacturing of drug products may also require licensing technologies and intellectual property from third parties.

**We rely upon patents to protect our technology. We may be unable to protect our intellectual property rights and we may be liable for infringing the intellectual property rights of others.**

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies, including IgG technologies. We currently hold several patents and pending patent applications in the United States and corresponding patents and patent applications filed in certain other countries covering IgG. Further, we intend to rely on a combination of trade secrets and non-disclosure, and other contractual agreements and technical measures to protect our rights in our technology. We intend to depend upon confidentiality agreements with our officers, directors, employees, consultants, and subcontractors, as well as collaborative partners, to maintain the proprietary nature of our technology. These measures may not afford us sufficient or complete protection, and others may independently develop technology similar to ours, otherwise avoid our confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition, and results of operations. We believe that our technology is not subject to any infringement actions based upon the patents of any third parties; however, our technology may in the future be found to infringe upon the rights of others. Others may assert infringement claims against us, and if we should be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, our ability to continue to use our technology or the licensed technology could be materially restricted or prohibited. If this event occurs, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Licenses or royalty agreements required in order for us to use this technology may not be available on terms acceptable to us, or at all. These claims could result in litigation, which could materially adversely affect our business, prospects, financial condition, and results of operations.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

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 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. See *Business Patents and Licenses* .

### **We can provide no assurance that our products will obtain regulatory approval or that the results of clinical studies will be favorable.**

The testing, marketing and manufacturing of any of our products will require the approval of the FDA. We cannot predict with any certainty the amount of time necessary to obtain such FDA approvals and whether any such approvals will ultimately be granted. In any event, review and approval by the FDA is anticipated to take a number of years. Preclinical and clinical trials may reveal that one or more of our products are ineffective or unsafe, in which event further development of such products could be seriously delayed or terminated. Moreover, obtaining approval for certain products may require the testing on human subjects of substances whose effects on humans are not fully understood or documented. Delays in obtaining FDA or any other necessary regulatory approvals of any proposed product and failure to receive such approvals would have an adverse effect on the product's potential commercial success and on our business, prospects, financial condition, and results of operations. In addition, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts which arise after development has been completed and regulatory approvals have been obtained. In this event we may be required to withdraw such product from the market. To the extent that our success will depend on any regulatory approvals from governmental authorities outside of the United States which perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist. See *Business Governmental Regulation* .

**If our products are commercialized, we may be subject to product liability claims.**

The testing, marketing, and sale of pharmaceutical products entail inherent risks. If we succeed in developing new pharmaceutical products, the sale of such products may expose us to potential liability resulting from the use of such products. Such liability might result from claims made directly by consumers or by pharmaceutical companies or others selling such products. While we may seek to obtain product liability insurance, there can be no assurance that we will be able to obtain such insurance or, if obtained, that such insurance can be acquired in amounts sufficient to protect us against such potential liability or at a reasonable cost. We do not currently maintain product liability insurance.

**As we have no sales, marketing, and distribution capabilities, we will be required to either develop such capabilities or to outsource these activities to third parties.**

We currently have no sales, marketing or distribution capabilities. In order to succeed, we ultimately will be required to either develop such capabilities or to outsource these activities to third parties. We can provide no assurance that third parties will be interested in acting as our outsourced sales, marketing, and distribution arms on a timely basis, on commercially reasonable terms, or at all. If we are unable to establish sales, marketing, or distribution capabilities either by developing our own organization or by entering into agreements with others, we may be unable to successfully sell any products that we are able to begin to commercialize, which would have a material adverse effect upon our business, prospects, financial condition, and results of operations. Further, in the event that we are required to outsource these functions on disadvantageous terms, we may be required to pay a relatively large portion of our net revenue to these organizations, which would have a material adverse effect upon our business, prospects, financial condition, and results of operations.

**We have no prior experience manufacturing our products.**

We currently lack the resources to manufacture any of our product candidates on a large scale. Our ability to conduct clinical trials and commercialize our product candidates will depend, in part, on our ability to manufacture our products, either directly or, as currently intended, through contract manufacturers, at a competitive cost and in accordance with current Good Manufacturing Practices ( *cGMP* ) and other regulatory requirements. We anticipate that we will be required to depend on contract manufacturers or collaborative partners for the manufacturing of our product candidates for preclinical studies and clinical trials and intend to use contract manufacturers to produce any products we may eventually commercialize. If we are not able to obtain contract manufacturing on commercially reasonable terms, we may not be able to conduct or complete clinical trials or commercialize our product candidates. We have identified multiple suppliers for most if not all of the components of our drug product candidates, although we can provide no assurance that these components will be available when needed on commercially reasonable terms.

In order to succeed, we ultimately will be required to either develop such manufacturing capabilities or to outsource manufacturing on a long-term basis to third parties. We can provide no assurance that third parties will be interested in manufacturing our products on a timely basis, on commercially reasonable terms, or at all. If we are unable to establish manufacturing capabilities either by developing our own organization or by entering into agreements with others, we may be unable to commercialize our products, which would have a material adverse effect upon our business, prospects, financial condition, and results of operations. Further, in the event that we are required to outsource these functions on disadvantageous terms, we may be required to pay a relatively large portion of our net revenue to these organizations, which would have a material adverse effect upon our business, prospects, financial condition, and results of operations.

**We have limited experience in conducting clinical trials.**

Clinical trials must meet FDA and foreign regulatory requirements. We have limited experience in designing, conducting and managing the preclinical studies and clinical trials necessary to obtain regulatory approval for our product candidates in any country. We may encounter problems in clinical trials that may cause us or the FDA or foreign regulatory agencies to delay, suspend or terminate our clinical trials at any phase. These problems could include the possibility that we may not be able to conduct clinical trials at our preferred sites, enroll a sufficient number of patients for our clinical trials at one or more sites or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, we, the FDA or foreign regulatory agencies may suspend clinical trials at any time if we or they believe the subjects participating in the trials are being exposed to unacceptable health risks or if we or they find deficiencies in the clinical trial process or conduct of the investigation. If clinical trials of any of the product candidates fail, we will not be able to market the product candidate which is the subject of the failed clinical trials. The FDA and foreign regulatory agencies could also require additional clinical trials, which would result in increased costs and significant development delays. Our failure to adequately demonstrate the safety and effectiveness of a pharmaceutical product candidate under development could delay or prevent regulatory approval of the product candidate and could have a material adverse effect on our business, prospects, financial condition, and results of operations.

**We are dependent upon third party suppliers of our raw materials.**

We are dependent on outside vendors for our entire supply of IgG. While we believe that there are numerous sources of supply available, if the third party suppliers were to cease production or otherwise fail to supply us with quality IgG in sufficient quantities on a timely basis 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 materially adversely affected.

**We have limited senior management resources and may be required to obtain more resources to manage our growth.**

We expect the expansion of our business to place a significant strain on our limited managerial, operational, and financial resources. We will be required to expand our operational and financial systems significantly and to expand, train, and manage our work force in order to manage the expansion of our operations. Our failure to fully integrate our new employees into our operations could have a material adverse effect on our business, prospects, financial condition, and results of operations. Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from

other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human, and other resources than we have. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, our business, prospects, financial condition, and results of operations will be materially adversely affected. See *Management's Discussion and Analysis of Financial Condition and Results of Operations*, *Business Strategy*, and *Business Employees*.

**We depend upon our senior management and skilled personnel and their loss or unavailability could put us at a competitive disadvantage.**

We currently depend upon the efforts and abilities of our senior executives, as well as the services of several key consultants and other key personnel. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition, and results of operations. 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. Our inability to attract and retain qualified skilled personnel would have a material adverse effect on our business, prospects, financial condition, and results of operations.

**Because we will not pay cash dividends, investors may have to sell shares in order to realize their investment.**

We have not paid any cash dividends on our common stock and do not intend to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, for reinvestment in the development and expansion of our business. Any credit agreements which we may enter into with institutional lenders or otherwise may restrict our ability to pay dividends. Whether we pay cash dividends in the future will be at the discretion of our board of directors and will be dependent upon our financial condition, results of operations, capital requirements, and any other factors that the board of directors decides is relevant. See *Dividend Policy* and *Description of Securities - Common Stock*.

**Fulfilling our obligations incident to being a public company will be expensive and time consuming.**

As a public company, the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, requires us to implement additional corporate governance practices and adhere to a variety of reporting requirements and complex accounting rules. Compliance with these public company obligations increases our legal and financial compliance costs and places significant additional demands on our finance and accounting staff and on our financial, accounting and information systems.

In particular, as a public company, our management will be required to conduct an annual evaluation of our internal controls over financial reporting and include a report of management on our internal controls in our annual reports on Form 10-KSB. Under current rules, we will be subject to this requirement beginning with our annual report on Form 10-KSB for our fiscal year ending September 30, 2008. In addition, we will be required to have our independent public accounting firm attest to and report on management's assessment of the effectiveness of our internal controls over financial reporting. Under current rules, we will be subject to this requirement beginning with our annual report on Form 10-KSB for our fiscal year ending September 30, 2009. If we are unable to conclude that we have effective internal controls over financial reporting or, if our independent auditors are unable to provide us with an attestation and an unqualified report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.



**Risks Related to our Industry**

**The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.**

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed products could become obsolete before we recoup any portion of our related research and development and commercialization expenses. These industries are highly competitive, and this competition comes both from biotechnology firms and from major pharmaceutical and chemical companies. Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our products from universities and other research institutions and compete with others in acquiring technology from such universities and institutions. In addition, certain of our products may be subject to competition from products developed using other technologies. See *Business Competition* .

**The industry in which we operate is highly competitive.**

Numerous well-known companies, which have substantially greater capital, research and development capabilities and experience than we have, are presently engaged in research and development efforts with respect to our target indications. By virtue of having or introducing competitive products on the market before us, these entities may gain a competitive advantage. Further, future technological developments may render some or all of our current or future products noncompetitive or obsolete, and we may not be able to make the enhancements to our products necessary to compete successfully with newly emerging technologies. If we are unable to successfully compete in our chosen markets, our business prospects, financial condition, and results of operations would be materially adversely affected. See *Business Competition* .

**The government regulatory approval process is time consuming and expensive.**

To date, we have not submitted a marketing application for any product candidate to the FDA or any foreign regulatory agency, and none of our product candidates have been approved for commercialization in any country. Prior to commercialization, each product candidate will be subject to an extensive and lengthy governmental regulatory approval process in the United States and in other countries. We may not be able to obtain regulatory approval for any product candidate we develop or, even if approval is obtained, the labeling for such products may place restrictions on their use that could materially impact the marketability and profitability of the product subject to such restrictions. We have limited experience in designing, conducting and managing the clinical testing necessary to obtain such regulatory approval. Satisfaction of these regulatory requirements, which includes satisfying the FDA and foreign regulatory authorities that the product is both safe and effective for its intended therapeutic uses, typically takes several years depending upon the type, complexity and novelty of the product and requires the expenditure of substantial resources.

**Any manufacturer to produce our products will be required to comply with extensive government regulation.**

Before we can begin to commercially manufacture any of our product candidates, we must either secure manufacturing in an approved manufacturing facility or obtain regulatory approval of our own manufacturing facility and processes. In addition, the manufacturing of our product candidates must comply with cGMP and/or other requirements of the FDA and requirements by regulatory agencies in other countries. These requirements govern, among other things, quality control and documentation procedures. We or any third-party manufacturer of our product candidates, may not be able to comply with these requirements, which would prevent us from selling such products. Material changes to the manufacturing processes of our products after approvals have been granted are also subject to review and approval by the FDA or other regulatory agencies.

**The commercial success of any newly-introduced pharmaceutical product depends in part upon the ability of patients to obtain adequate reimbursement.**

If we succeed in bringing our product candidates to market, they may not be considered cost-effective, and coverage and adequate payments may not be available or may not be sufficient to allow us to sell our products on a competitive basis. In both the United States and elsewhere, sales of medical products, diagnostics, and therapeutics are dependent, in part, on the availability of reimbursement from third party payors, such as health maintenance organizations and other private insurance plans and governmental programs such as Medicare. Third party payors are increasingly challenging the prices charged for pharmaceutical products and services. We anticipate that our business will be affected by the efforts of government and third party payors to contain or reduce the cost of health care through various means. In the United States, there have been and will continue to be a number of federal and state proposals to implement government controls on pricing. Similar government pricing controls exist in varying degrees in other countries. In addition, the emphasis on managed care in the United States has increased and will continue to increase the pressure on the pricing of pharmaceutical products. We cannot predict whether any legislative or regulatory proposals will be adopted or the effect these proposals or managed care efforts may have on our business.

**Risks Related to our Common Stock**

**As the market price of our common stock may fluctuate significantly, this may make it difficult for you to sell your shares of common stock when you want or at prices you find attractive.**

The price of our common stock is quoted on the OTCBB and constantly changes. In recent years, the stock market in general has experienced extreme price and volume fluctuations. We expect that the market price of our common stock will continue to fluctuate. These fluctuations may result from a variety of factors, many of which are beyond our control. These factors include:

quarterly variations in our operating results;

operating results that vary from the expectations of management, securities analysts and investors;

changes in expectations as to our business, prospects, financial condition, and results of operations;

announcements by us, our partners or our competitors regarding material developments;

the operating and securities price performance of other companies that investors believe are comparable to us;

future sales of our equity or equity-related securities;

changes in general conditions in our industry and in the economy, the financial markets and the domestic or international political situation;

fluctuations in oil and gas prices;

departures of key personnel; and

regulatory considerations.

As a result of these fluctuations, you may experience difficulty selling shares of our common stock when desired or at acceptable prices.

**Future sales of common stock or the issuance of securities senior to our common stock or convertible into, or exchangeable or exercisable for, our common stock could materially adversely affect the trading price of our common stock, and our ability to raise funds in new equity offerings.**

Future sales of substantial amounts of our common stock or other equity-related securities in the public market or privately, or the perception that such sales could occur, could adversely affect prevailing trading prices of our common stock and could impair our ability to raise capital through future offerings of equity or other equity-related securities. We can make no prediction as to the effect, if any, that future sales of shares of our common stock or equity-related securities, or the availability of shares of common stock for future sale, will have on the trading price of our common stock.

**Our common stock is deemed to be a penny stock, which may make it more difficult for investors to sell their shares due to suitability requirements.**

The SEC has adopted regulations that generally define penny stock to be an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. The market price of our common stock is currently less than \$5.00 per share and therefore is a penny stock according to SEC rules. This designation requires any broker or dealer selling these securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell our common stock and may affect the ability of investors hereunder to sell their shares.

You should be aware that, according to the SEC, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include:

Control of the market for the security by one or a few broker-dealers;

Boiler room practices involving high-pressure sales tactics;

Manipulation of prices through prearranged matching of purchases and sales;

The release of misleading information;

Excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and

Dumping of securities by broker-dealers after prices have been manipulated to a desired level, which hurts the price of the stock and causes investors to suffer loss.

We are aware of the abuses that have occurred in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, we will strive within the confines of practical limitations to prevent such abuses with respect to our common stock.

**Future sales of our common stock by our existing stockholders could adversely affect our stock price.**

The market price of our common stock could decline as a result of sales of a large number of shares of our common stock in the market, or the perception that these sales could occur. These sales also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Currently, we have outstanding 44,958,917 shares of common stock. Of these shares, 33,780,421 shares, are freely tradable. Giving effect to the exercise in full of all of our outstanding warrants and options, we would have outstanding 70,021,475 shares of common stock.

Some of our stockholders, holding approximately 1,333,332 shares of common stock, have the right, subject to a number of conditions and limitations, to include their shares in registration statements relating to our securities. By exercising their registration rights and causing a large number of shares to be registered and sold in the public market, these holders may cause the market price of the common stock to fall. In addition, any demand to include these shares in our registration statements could have an adverse effect on our ability to raise needed capital. In connection with our private placement which closed on February 26, 2007, directors, officers, employees, consultants and certain stockholders beneficially owning in the aggregate 16,030,013 shares of common stock, agreed to restrict their ability to dispose of their shares of common stock or common stock equivalents until the first anniversary of the effective date of the initial registration statement that was filed pursuant to such private placement.

**Our issuance of warrants and options to investors, employees and consultants and the registration rights for the underlying shares of common stock may have a negative effect on the trading prices of our common stock as well as a dilutive effect.**

We have issued and may continue to issue warrants and options at or below the current market price. As of September 30, 2007, we had outstanding 25,062,558 warrants and options (5,917,775 for the year ended September 30, 2006). In addition to the dilutive effect of a large number of shares and a low exercise price for the warrants and options, there is a potential that a large number of underlying shares may be sold in the open market at any given time, which could place downward pressure on the trading of our common stock.

**Risks Related to Conducting Business in Israel**

**We are affected by the political, economic, and military risks of locating our principal operations in Israel.**

Our operations are located in the State of Israel, and we are directly affected by political, economic, and military conditions in that country. Since December 1987, the State of Israel has experienced severe civil unrest primarily in the areas that have been under its control since 1967. No prediction can be made as to whether these problems will be resolved. Our business, prospects, financial condition, and results of operations could be materially adversely affected if major hostilities involving Israel should occur or if trade between Israel and its current trading partners is interrupted or curtailed.

All adult male permanent residents of Israel under the age of 51, unless exempt, may be required to perform between 14 and 40 days of military reserve duty annually. Additionally, all such residents are subject to being called to active duty at any time under emergency circumstances. Some of our officers, directors, and employees currently are obligated to perform annual military reserve duty. We can provide no assurance that such requirements will not have a material adverse effect on our business, prospects, financial condition, and results of operations in the future, particularly if emergency circumstances occur.

**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 judgment and civil liabilities against our officers, directors, experts and agents.**

Some 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 some of 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.

**ITEM 2 - PROPERTIES**

Our principal executive offices are located in approximately 1337 square feet of office space in Kiryat Ono, Israel. The lease commenced on August 10, 2006 and lasts for a period of 36 months. The aggregate annual base rental for this space is \$26,827.

We are leasing a suite in New York City since June 8, 2006 for the use of our CEO. The lease agreement was renewed on June 6, 2007 for a period of 12 months and the aggregate annual base rental for this space is \$24,000

We believe that our existing facilities are suitable and adequate to meet our current business requirements.

**ITEM 3 - LEGAL PROCEEDINGS**

From time to time we may become subject to litigation incidental to our business. We are not currently a party to any material legal proceedings.

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

Stockholders at the Annual Meeting of Stockholders held on September 10, 2007 took the following six actions:

Approved the election of five directors.

<b>Name of Nominee</b>	<b>Number of Votes For</b>	<b>Number of Votes Against</b>
Yair Aloni	24,298,298	17,350
Steven Katz	24,277,248	38,400
Shmuel Levi*	24,298,098	17,550
Josef Neuhaus	24,299,706	15,942
Albert Passner	24,298,456	17,192

\* On October 30, 2007, Mr. Levi resigned from our board of directors and our audit and compensation committees. His vacancy was filled by Mr. DeMedio.

Approved an amendment to our Certificate of Incorporation to increase the number of our authorized shares of common stock from 100,000,000 to 200,000,000 by a vote of 23,913,623 shares for, 145,875 shares against and 256,150 shares abstaining.

Approved an amendment to our Certificate of Incorporation to classify 20,000,000 shares of our preferred stock as blank check preferred by a vote of 23,715,714 shares for, 164,137 shares against and 435,797 shares abstaining.

Approved an amendment to our Certificate of Incorporation to indemnify our directors and officers to the fullest extent permitted by Delaware law by a vote of 24,204,521 shares for, 101,670 shares against and 9,457 shares abstaining.

Approved an amendment to our Certificate of Incorporation to limit the liability of our directors by a vote of 24,094,136 shares for, 193,320 shares against and 28,192 shares abstaining.

Approved the ratification of the appointment of Kesselman & Kesselman, certified public accountants (Isr.), a member of PriceWaterhouseCoopers International Limited, as our independent auditor of the financial statements for the year ended September 30, 2007 by a vote of 24,232,898 shares for, 76,550 shares against and 6,200 shares abstaining.

**PART II**

**ITEM 5 - MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**

**Market Price for our Common Stock**

Our common stock is quoted on the OTC Bulletin Board (the *OTCBB*) under the symbol *GCAN.OB*. The quarterly high and low reported sales prices for our common stock as quoted on the OTCBB for the periods indicated are as follows:

	<u>High</u>	<u>Low</u>
<b>Year Ended September 30, 2006</b>		
Three Months Ended December 31, 2005	\$1.75	\$1.01
Three Months Ended March 31, 2006	\$1.72	\$1.05
Three Months Ended June 30, 2006	\$1.69	\$0.71
Three Months Ended September 30, 2006	\$1.20	\$0.53
<b>Year Ended September 30, 2007</b>		
Three Months Ended December 31, 2006	\$0.70	\$0.35
Three Months Ended March 31, 2007	\$0.68	\$0.37
Three Months Ended June 30, 2007	\$0.70	\$0.45
Three Months Ended September 30, 2007	\$0.79	\$0.40

The foregoing quotations were provided by Yahoo finance and the quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

The last reported sale price per share of common stock as quoted on the OTCBB was \$0.40 on December 24, 2007. As of such date, we had 44,958,917 shares of common stock outstanding. Based on information available from our registrar and transfer agent, we estimate that we had approximately 49 stockholders of record on December 24, 2007.

**Dividend Policy**

We have never paid any cash dividends on our capital stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain future earnings to fund ongoing operations and future capital requirements of our business. Any future determination to pay cash dividends will be at the discretion of our board and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as our board deems relevant.

**Recent Sales of Unregistered Securities**

During the year ended September 30, 2007, we issued unregistered securities to the persons, as described below. We believe that each transaction was exempt from the registration requirements of the Securities Act of 1933, as amended, by virtue of Section 4(2) thereof and/or Rule 506 of Regulation D promulgated thereunder. All recipients had adequate access, through their relationships with us, to information about us.

On October 12, 2006, we granted options to purchase up to 50,000 shares of our common stock at an exercise price of \$0.65 to a then new member of our Scientific Advisory Board.

On October 18, 2006 we entered into a Strategic Alliance Agreement with UTEK Corporation ( *UTEK* ), pursuant to which UTEK would assist us in identifying technology acquisition opportunities. As consideration for the services being provided to us by UTEK, we issued UTEK an aggregate of 171,432 shares of our common stock which vested in 12 equal monthly instalments of 14,286 shares each.

On November 13, 2006, we granted options to purchase up to 150,000 shares of our common stock under our 2004 Stock Option Plan at an exercise price of \$0.45 to each of Steven Katz and Albert Passner, our then two new additions to our board of directors.

On December 5, 2006, we granted options to purchase up to 50,000 shares of our common stock under our 2004 Stock Option Plan at an exercise price of \$0.50 to a then new member of our Scientific Advisory Board.

On January 30, 2007, we granted warrants to purchase 434,783 shares of our common stock exercisable for five years at an exercise price of \$0.45 to our regulatory consultant.

On February 15, 2007, we granted options to purchase up to 100,000 shares of our common stock under our 2004 Stock Option Plan at an exercise price of \$0.45 to an employee.

On February 26, 2007, we granted options to purchase 2,340,000 shares of our common stock at an exercise price of \$0.53 to our directors, officers, employees and consultants. Of the options granted, 865,000 were granted under the 2004 Stock Option Plan and 1,475,000 were granted under the 2007 Stock Option Plan.

On February 27, 2007, we completed a private placement for the sale of 16,250,000 units at a purchase price of \$0.40 per unit, for total consideration of \$6,500,000. Each unit consisted of one share of common stock and one share purchase warrant. Each warrant entitles the holder to purchase one share of common stock for a period of five years at an exercise price of \$0.48 per share. In connection with the private placement, T.R. Winston & Company, LLC acted as placement agent and received aggregate commissions of \$487,500.



## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

On March 22, 2007, we granted warrants to purchase 350,000 shares of our common stock exercisable for five years at an exercise price of \$0.53 to a consultant.

On May 15, 2007, we prepaid the principal amount of a convertible note issued on November 20, 2006, in the amount of \$350,000. The accumulated interest on the principal amount, in the amount of \$13,501, was converted into 33,753 shares of our common stock.

On May 17, 2007, we granted options to purchase 2,790,000 shares of our common stock under the 2007 Stock Option Plan at an exercise price of \$0.61 to our directors, officers and employees. These options were issued upon the surrender and cancellation by each of such directors, officers and employees of options, exercisable for an aggregate of 2,780,000 shares of our common stock at exercise prices ranging from \$0.93 to \$1.37, which were granted previously.

On May 17, 2007, we granted options to purchase 20,000 of our common stock under the 2007 Stock Option Plan to an employee at an exercise price of \$0.61 per share.

On June 1, 2007, we entered into a services agreement with ROI Group, LLC, pursuant to which we issued them 50,000 shares of our common stock and consulting warrants exercisable for an aggregate of 62,500 shares of common stock at an exercise price of \$0.75 which vested on August 31, 2007, 62,500 shares of common stock at an exercise price of \$0.90 which vested on November 30, 2007, 62,500 shares of common stock at an exercise price of \$1.10 which vest on February 28, 2008 and 62,500 shares of common stock at an exercise price of \$1.25 which vest on May 31, 2008. The warrants are exercisable from their respective date of vesting through February 27, 2014.

### **Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

We did not purchase any of our shares of common stock or other securities during the year ended September 30, 2007.

### **Securities Authorized for Issuance under Equity Compensation Plans**

The following table sets forth information with respect to our 2004 Employees and Consultants Stock Option Plan ( *2004 Stock Option Plan* ) and our 2007 Global Share Option Plan ( *2007 Stock Option Plan* ) as of September 30, 2007:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weight-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
	(a)	(b)	(c)
Equity Compensation Plans Approved By Security Holders			
Equity Compensation Plans Not Approved By Security Holders	5,800,000 <sup>(1)</sup>	\$0.58	4,200,000 <sup>(2)</sup>
<b>TOTAL</b>			

---

1. Represents 1,515,000 shares of our common stock issuable upon exercise of options granted under our 2004 Stock Option Plan and 4,285,000 shares of our common stock issuable upon exercise of options granted under our 2007 Stock Option Plan.

2. Represents up to 3,485,000 shares of our common stock authorized for issuance under our 2004 Stock Option Plan and up to 715,000 shares of our common stock authorized for issuance under our 2007 Stock Option Plan.

**ITEM 6 - MANAGEMENT'S DISCUSSION AND ANALYSIS AND PLAN OF OPERATION**

We are a development stage company and currently have no revenue from operations. Other than existing cash reserves and our intellectual property we have no significant assets, tangible or intangible. Presently, we do not have sufficient cash resources to meet our requirements in the twelve months following October 1, 2007 and we expect to seek to raise additional funds during that time period. There can be no assurance that we will raise additional funds on a timely basis, on terms acceptable to us or at all and 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.

**Plan of Operation**

**Short Term Business Plan**

We are a life science company focused on the development of immunotherapy and related approaches to treat cancer. Until recently, we have focused on the use of intravenous immunoglobulins, or *IgGs*, derived from human plasma to treat melanoma, prostate, and colon cancers. We believe that IgG therapy may be the basis of a more effective and efficient cancer treatment both as a mono or a combination therapy as well as for adjuvant cancer treatments (IgGs used in concert with other proprietary pharmaceuticals). Our business objective is to become a recognized leader in the development of immunotherapy including IgG-based therapies and related approaches to treat cancer.

IgG-based 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 are conducted primarily to establish safety and determine the maximum tolerated dose, or *MTD*. Phase II studies are designed to determine preliminary efficacy and establish dosing. Phase III studies are conducted to demonstrate therapeutic efficacy in a statistically significant number of patients, at an optimal dose level, method or route of delivery into the body, and a schedule of administration. Once clinical trials are successfully completed, products may receive regulatory approval.

We are pursuing the development of IgG-based technology to develop therapies for the treatment of melanoma, as well as therapies directed toward disrupting the blood supply to cancers, referred to as anti-angiogenesis.

**Melanoma:** Our lead product candidate, VitiGam, is a first-in-class anti-cancer immunotherapy derived entirely from the plasma of donors with vitiligo, a benign autoimmune skin condition affecting up to two percent of the general population. We have demonstrated that plasma from individuals with vitiligo contains anti-melanoma activities. Based on this, we are developing VitiGam to initially address Stage III and Stage IV melanoma and possibly earlier stages of melanoma at a future time.

In June 2007, we completed a non-FDA Phase II clinical trial designed to test the safety and efficacy of standard IgG (collected and manufactured from general population donors, which may have included donors with vitiligo) in patients with prostate cancer, colon cancer and melanoma. In this trial, no serious untoward effects of IgGs were noted. In one patient with melanoma, the cancer remained stable or improved over eight cycles of therapy (approximately ten months).

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

In addition to the pre-clinical evidence we have accumulated using vitiligo-derived plasma, the above observations provide further validation for our plan to develop VitiGam .

We plan to file an Investigational New Drug Application, or *IND*, for VitiGam in the near future. We believe that the FDA is well acquainted with IgG-based therapies and their safety profiles resulting from a long history of regulatory approvals of IgG-based products.

In addition to VitiGam , we are also developing the following:

*Next generation (recombinant) VitiGam* - VitiGam is currently manufactured as a mixture that largely consists of IgG molecules (antibodies of the IgG type). We anticipate that within this mixture, only a subset of IgG molecules will be responsible for the biological activity of VitiGam .

Next generation VitiGam will be composed of *only the IgGs required to exert the anti-melanoma effect*, thereby creating a more effective compound. Identifying the relevant IgGs may also permit cost reductions; and

*Cancer vaccines based on VitiGam* - An off-the-shelf cancer vaccine is considered a silver bullet in cancer therapy. We anticipate that based on our evolving understanding of the specific IgG molecules responsible for the biological activity of VitiGam , we may be in a position to identify the corresponding antigens that may be used to develop melanoma cancer vaccines.

**Anti-angiogenesis:** We are developing additional novel IgG-based therapies for cancer and other diseases. These therapies are based on the disruption of the blood supply to cells. Our scientists have shown that several mechanisms may be involved in mediating the anti-cancer effects of IgG-based immunotherapies. Angiogenesis is one of a number of well known pathways to deprive cells of their blood supply.

In June 2007, we announced the discovery of proprietary IgG sub-fractions in human plasma, which contain potent anti-angiogenic properties. These sub-fractions may be used for treatment of disorders resulting from neovascularization (the formation of new blood vessels or angiogenesis).

We have established a pre-clinical development program to define and characterize these anti-angiogenic anti-cancer fractions and to test their biological activity in animal models. We believe that successfully developed therapies derived from our novel IgG sub-fractions have the potential to address multi-billion dollar markets. For example, Avastin®, also known as *bevacizumab*, counteracts VEGF, a growth factor which stimulates neovascularization, and is used to treat colon and other cancers. Sales for Avastin® in 2006 were in excess of \$2 billion.

We are also contemplating conducting additional clinical trials to test new formulations and/or combinations of IgG-based immunotherapy candidates and to test these formulations and/or methods for different cancers at different stages of disease progression with varying dosages and routes of administration. To achieve this, we may elect to partner with a pharmaceutical company to conduct these further clinical trials, although there can be no assurance that we will locate a pharmaceutical company able, or willing, to partner with us on terms commercially acceptable to us, in order to attain broad-based regulatory approval.

Although there can be no assurance that the FDA will approve VitiGam<sup>®</sup>, or any other IgG immunotherapy candidate, we expect that, at a minimum, it will take a number of years to receive final approval and registration for commercial use as an anti-cancer agent. Our strategy is to collaborate with a suitable partner, although there can be no assurance that we will locate a suitable partner, to support late stage (Phase III) clinical development, registration and/or sales for our IgG-based cancer products.

### **Long Term Business Strategy**

If our IgG-based cancer immunotherapy candidates show significant promise in clinical trials, and at this preliminary stage there can be no assurance that any such immunotherapy candidates will show significant promise, we plan to ultimately seek a strategic commercial partner, or partners, with extensive experience in the development, commercialization, and marketing of cancer drugs and/or other infused therapeutic proteins, although there can be no assurance that we will locate a strategic commercial partner or partners on terms commercially acceptable to us. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) to ensure regulatory approvals and registrations in the appropriate territories in a timely manner. We further anticipate that the partner, or partners, would be responsible for sales and marketing of our IgG-based immunotherapies in certain agreed upon territories. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post-marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. Any future strategic partner, or partners, may also provide capital and expertise that would enable the partnership to develop new formulations of IgG cancer immunotherapy suitable for patients at different stages of disease progression as well as IgG derivatives. Under certain circumstances, we may determine to develop one or more of our IgG-based cancer immunotherapies on our own, either worldwide or in select territories.

### **Other Research and Development Plans**

In addition to conducting early-stage clinical trials, we plan to conduct pre-clinical research to accomplish the following:

Further deepen and broaden our understanding of the biology of our IgG products in cancer;

Develop alternative delivery systems and determine the optimal dosage for different patient groups;

Investigate alternative sources of immunoglobulin other than human plasma;

Develop novel IgG-based therapies; and

Develop successor products.

Our plan is to patent any successful inventions resulting from our future research activities and to exploit any other means that may exist to protect our future IgG anti-cancer therapies in the commercial markets; although at this early stage there can be no assurance that there will be any successful inventions resulting from such research activities.

#### **Other Strategic Plans**

In addition to developing our own IgG-based anti-cancer therapies drug portfolio, we are, on an on-going basis, considering in-licensing and other means of obtaining additional lead molecules of technologies to complement and/or expand our current product portfolio. Our goal is to create a well-balanced product portfolio that includes lead molecules in different stages of development and addresses different medical needs.

#### **Critical accounting policies and estimates**

Management's discussion and analysis of the financial condition and results of operations is based upon the consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, expenses and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates and judgments. We base our estimates on various factors, including historical experience that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other resources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

#### **Going concern assumption**

The accompanying financial statements have been prepared assuming that we will continue as a going concern. We have net losses for the period from inception (October 6, 1998) through September 30, 2007 of \$8,956,187, as well as negative cash flow from operating activities. Presently we do not have sufficient cash resources to meet our requirements in the twelve months following October 1, 2007. These factors raise substantial doubt about our ability to continue as a going concern. Management is in the process of evaluating various financing alternatives as we will need to finance future research and development activities and general and administrative expenses through fund-raising in the public or private equity markets. Although there is no assurance that we will be successful with those initiatives, management is confident that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders.

The financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. Our continuation as a going concern is dependent on our ability to obtain additional financing as may be required and ultimately to attain profitability.

### **Valuation of options and warrants**

We granted options to purchase shares of our common stock to employees and consultants and issued warrants in connection with fund-raising.

Until September 30, 2006, we accounted for employee stock based compensation in accordance with Accounting Principles Board Opinion No. 25 *Accounting for Stock Issued to Employees* ( *APB 25* ) and related interpretations. In accordance with FAS 123 *Accounting for Stock-Based Compensation* ( *FAS 123* ), we disclosed pro-forma data assuming we had accounted for employee stock option grants using the fair value-based method defined in FAS 123.

Effective October 1, 2006, we adopted the revised Statement of Financial Accounting Standards No. 123, *Share-Based Payment* ( *FAS 123R* ), which addresses the accounting for share-based payment transactions in which we obtain employee services in exchange for (a) equity instruments of the Company or (b) liabilities that are based on the fair value of our equity instruments or that may be settled by the issuance of such equity instruments. FAS 123R eliminates the ability to account for employee share-based payment transactions using APB 25, and requires instead that such transactions be accounted for using the grant-date fair value based method.

The fair value of each stock option grant was estimated at the date of grant using a Black-Scholes option pricing model. The volatility is based on a historical volatility, by statistical analysis of the weekly share price for past periods. The expected term is the length of time until the expected dates of exercising the options, based on estimated data regarding employees' exercise behavior.

FAS 123R applies to all awards granted or modified after the Statement's effective date. In addition, compensation cost for the unvested portion of previously granted awards that remain outstanding on the Statement's effective date is recognized on or after the effective date, as the related services are rendered, based on the awards' grant-date fair value as previously calculated for the pro-forma disclosure under FAS 123.

We applied the modified prospective application transition method, as permitted by the Statement. Under such transition method, upon the adoption of FAS 123R, our financial statements for periods prior to the effective date of the Statement are not restated.

We account for equity instruments issued to third party service providers (non-employees) in accordance with the fair value based on an option-pricing model, pursuant to the guidance in EITF 96-18 *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*. The fair value of the options granted is revalued over the related service periods and recognized using the accelerated method.

### **Deferred income taxes**

Deferred taxes are determined utilizing the assets and liabilities method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Deferred tax balances are computed using the tax rates expected to be in effect when those differences reverse. A valuation allowance in respect of deferred tax assets is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have provided a full valuation allowance with respect to our deferred tax assets.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

Regarding our Israeli subsidiary, Gammacon Ltd, paragraph 9(f) of FAS 109, *Accounting for Income Taxes*, prohibits the recognition of deferred tax liabilities or assets that arise from differences between the financial reporting and tax bases of assets and liabilities that are measured from the local currency into dollars using historical exchange rates, and that result from changes in exchange rates or indexing for tax purposes. Consequently, the above mentioned differences were not reflected in the computation of deferred tax assets and liabilities.

### Results of Operations

The following table summarizes certain statement of operations data for the Company for the year ended September 30, 2007 and 2006 (in US\$):

<b>Operating Data:</b>	<b>Year ended</b>	
	<b>September 30, 2007</b>	<b>September 30, 2006</b>
Research and development costs	\$ 1,198,004	\$ 802,254
General and administrative expenses	4,090,163	1,263,070
Financial income, net	(110,771)	(29,151)
Loss before tax on income	5,177,396	2,036,173
Taxes on income	1,378	28,622
Net loss for the period	\$ (5,178,774)	\$ (2,064,795)
Loss per common share basic and diluted	\$ (0.14)	\$ (0.07)
Weighted average common shares outstanding	38,043,043	28,052,065

### Research and development costs

Research and development expenses are the costs incurred in the process of our pre-clinical and our clinical trials. Clinical trial and pre-clinical expenses include regulatory consultant compensation and fees, research expenses, purchase of plasma, the cost of manufacturing IgG and payments to medical centers for patient recruitment and treatment.

During the year ended September 30, 2007 and September 30, 2006, the research and development expenses included, among others, the cost of IgG used in the clinical trials and research work, payments to medical centers and research labs for clinical trial and pre-clinical trial work, regulatory and scientific consultant compensation, costs related to the maintenance of our registered patents, costs related to the filings of patent applications as well as salaries and related expenses of research and development staff.

During the year ended September 30, 2007, the research and development expenses totaled \$1,198,004 compared to \$802,254 during the year ended September 30, 2006. The increase is related to the pre-clinical, assay development and regulatory work in preparation for the VitiGam FDA clinical trial as well as stock-based compensation expenses. The research and development costs include stock based compensation costs, which during the year ended September 30, 2007 totaled \$166,147 as compared to \$33,440 during the year ended September 30, 2006. This increase is attributable to the implementation of FAS123R since October 1, 2006.



**General and administrative expenses**

The general and administrative expense includes the salaries and related expenses of our management, consulting costs, legal and professional fees, travel costs, business development costs, insurance expenses and other general costs.

For the year ended September 30, 2007, general and administrative expenses totaled \$4,090,163 compared to \$1,263,070 for the year ended September 30, 2006. Costs incurred for general and administrative activities in the year ended September 30, 2007 reflect an increase in the number of employees as compared to the year ended September 30, 2006, from five to eight as well as additional professional, legal and consulting expenses and an increase in general expenses such as office and maintenance expenses. During the year ended September 30, 2007, as part of the general and administrative expenses, we incurred \$1,580,963 of compensation expenses due to the implementation of FAS 123R related to stock options granted to employees. During the year ended September 30, 2006, we accounted for employee stock based compensation in accordance with APB 25 and incurred \$163,517 of costs. Additional costs in the year ended September 30, 2007 included \$474,087 related to the fair value of options, warrants and shares issued to consultants during the period, with no similar costs being incurred in the year ended September 30, 2006.

**Financial income/expense, net**

During the year ended September 30, 2007 and 2006, we generated interest income on available cash and cash equivalents balance as well as bank charges. During the year ended September 30, 2007, we incurred financial expenses related to a convertible promissory note, issued on November 20, 2006, in the total amount of \$13,501.

**Liquidity and Capital Resources**

Through September 30, 2007, we incurred losses in an aggregate amount of \$9,011,687. We have financed our operations from the private placements of equity and debt financing. Through September 30, 2007, we raised a total of \$9,538,553, net of transaction cost, through private placements of equity. We anticipate that additional financing will be through similar sources. As of September 30, 2007, we have \$4,048,583 of available cash, most of which is deposited in short term, interest bearing, bank deposits. We do not have material financing commitments.

Our financing activities for the year ended September 30, 2007 included the following:

On November 20, 2006, we issued a convertible promissory note, in the principal amount of \$350,000, which bore interest at 8% payable on maturity of the note and with a maturity date of November 20, 2007. On May 15, 2007, we prepaid the principal amount of \$350,000. The accumulated interest in the amount of \$13,501 was converted into 33,753 shares of our common stock.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

On February 27, 2007, we completed a private placement for the sale of 16,250,000 units at a purchase price of \$0.40 per unit for total consideration of \$6,500,000. Each unit consisted of one share of common stock and one share purchase warrant. Each share purchase warrant entitles the holder to purchase one share of common stock for a period of five years at an exercise price of \$0.48.

On February 27, 2007, we reduced the exercise price of 333,333 and 1,333,334 warrants issued to investors on October 31, 2005 and December 20, 2005 respectively, from \$1.00 and \$1.20, respectively, to \$0.55.

### Off Balance Sheet Arrangements

We have no off-balance sheet arrangements.

### Planned Expenditures

The estimated expenses referenced herein are in accordance with our business plan. As our 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 twelve months following October 1, 2007 are as follows:

Category	Amount
Research & Development	\$ 5,309,000
General & Administrative Expenses	2,824,000
Finance Income, net	(105,000)
Total	<u>\$ 8,028,000</u>

As previously indicated, we are planning to file an IND with the FDA for VitiGam . Our ability to proceed with this IND application as well as the commencement of the related clinical trial is dependent on several major factors including the ability to attract sufficient financing on terms acceptable to us.

ITEM 7 - FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

TABLE OF CONTENTS

	<b>Page</b>
<u>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM - Report of Kesselman &amp; Kesselman</u>	F-2
<u>REPORT OF INDEPENDENT AUDITORS - Report of Armando C. Ibarra</u>	F-3
<b>CONSOLIDATED FINANCIAL STATEMENTS:</b>	
<u>Balance sheets</u>	F-4
<u>Statements of operations</u>	F-5
<u>Statements of changes in stockholders' equity</u>	F-6
<u>Statements of cash flows</u>	F-7
<u>Notes to financial statements</u>	F-8-F-32

**Kesselman & Kesselman**  
Certified Public Accountants (Isr.)  
Trade Tower, 25 Hamered Street  
Tel Aviv 68125 Israel  
P.O Box 452 Tel Aviv 61003  
Telephone +972-3-7954555  
Facsimile +972-3-7954556

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders of  
GammaCan International, Inc.  
(A Development Stage Company)

We have audited the accompanying consolidated balance sheets of GammaCan International, Inc. (A Development Stage Company) and its subsidiary (the *Company*) as of September 30, 2007 and 2006, and the related consolidated statements of operations, changes in stockholders equity and cash flows for each of the two years then ended and cumulatively, for the period from October 1, 2003 to September 30, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We did not audit the cumulative totals of the Company for the period from October 6, 1998 (date of incorporation) to September 30, 2003, which totals reflect a deficit of \$15,640 accumulated during the development stage. Those cumulative totals were audited by other independent auditors, whose report, dated November 17, 2003, expressed an unqualified opinion on the cumulative amounts but included an emphasis of a matter. Our opinion, insofar as it relates to amounts included for that period is based on the report of the other independent auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based upon our audits and the report of the other independent auditors, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of September 30, 2007 and 2006, and the consolidated results of their operations and their cash flows for each of the years then ended and cumulatively, for the period from October 1, 2003 to September 30, 2007, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1m to the financial statements, effective October 1, 2006 the Company changed its method of accounting for stock-based payment to conform with FASB Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-based Payment*.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has net losses for the period from inception (October 6, 1998) through September 30, 2007 of \$8,956,187 and presently the Company does not have sufficient cash resources to meet its requirements in the twelve months following October 1, 2007. These reasons raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1a. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Kesselman & Kesselman

Tel Aviv, Israel  
December 28, 2007

**ARMANDO C. IBARRA**  
Certified Public Accountants  
A Professional Corporation

Armando C. Ibarra, C.P.A.  
Armando Ibarra, Jr., C.P.A., JD

Members of the California Society of Certified Public Accountants  
Members of the American Institute of Certified Public Accountants  
Members of the Better Business Bureau since 1997

**INDEPENDENT AUDITORS' REPORT**

To the Board of Directors of  
San Jose International, Inc.  
(A Development Stage Company)

We have audited the statements of operations, changes in stockholders' equity and cash flows for the period from October 6, 1998 (date of inception) through September 30, 2003 of San Jose International, Inc. (A Development Stage Company). These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of San Jose International, Inc. for the period from October 6, 1998 (date of inception) through September 30, 2003 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has had significant losses since inception. This condition raises substantial doubt as to its ability to continue as a going concern. Management's plans regarding those matters are also described in Note 1. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

*/s/ Armando C. Ibarra, CPA-APC*

---

*Armando C. Ibarra, CPA-APC*

November 17, 2003  
Chula Vista, California

371 E Street, Chula Vista, CA 91910 Tel: (619) 422-1348 Fax: (619) 422-1465

## GAMMACAN INTERNATIONAL, INC.

(A Development Stage Company)

## CONSOLIDATED BALANCE SHEETS

	September 30	
	2007	2006
<b>Assets</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 4,048,583	\$ 538,738
Prepaid expenses	9,851	
Other	47,271	12,494
<b>T o t a l current assets</b>	<b>4,105,705</b>	<b>551,232</b>
<b>FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT (Note 2)</b>	<b>49,281</b>	<b>21,071</b>
<b>LONG TERM DEPOSITS (Note 3)</b>	<b>18,590</b>	<b>22,270</b>
<b>PROPERTY AND EQUIPMENT, NET (Note 4)</b>	<b>26,338</b>	<b>25,247</b>
<b>T o t a l assets</b>	<b>\$ 4,199,914</b>	<b>\$ 619,820</b>
<b>Liabilities and stockholders equity</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 797,515	\$ 279,857
Payroll and related accruals	130,223	49,242
<b>T o t a l current liabilities</b>	<b>927,738</b>	<b>329,099</b>
<b>LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT (Note 2)</b>	<b>71,338</b>	<b>31,531</b>
<b>COMMITMENTS (Note 5)</b>		
<b>STOCKHOLDERS EQUITY:</b>		
Preferred stock, \$0.0001 par value (20,000,000 shares authorized; none issued and outstanding)		
Common stock, \$0.0001 par value (100,000,000 authorized shares; 44,958,917 and 28,453,732 shares issued and outstanding as of September 30, 2007 and 2006, respectively)	4,495	2,845
Additional paid-in capital	8,968,930	3,172,284
Warrants	3,203,600	861,474
Deficit accumulated during the development stage	(8,956,187)	(3,777,413)
Services not yet rendered	(20,000)	
<b>T o t a l stockholders equity</b>	<b>3,200,838</b>	<b>259,190</b>
<b>T o t a l liabilities and stockholders equity</b>	<b>\$ 4,199,914</b>	<b>\$ 619,820</b>

The accompanying notes are an integral part of the financial statements.

## GAMMACAN INTERNATIONAL, INC.

(A Development Stage Company)

## CONSOLIDATED STATEMENTS OF OPERATIONS

(US \$, except share data)

	Year ended September 30		Period from October 6, 1998* to September 30 2007
	2007	2006	
<b>RESEARCH AND DEVELOPMENT COSTS</b> (Note 10)	\$ 1,198,004	\$ 802,254	\$ 2,713,178
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b> (Note 11)	4,090,163	1,263,070	6,378,874
<b>OPERATING LOSS</b>	5,288,167	2,065,324	9,092,052
<b>FINANCIAL INCOME</b>	(152,088)	(44,130)	(216,921)
<b>FINANCIAL EXPENSES</b>	41,317	14,979	63,431
<b>LOSS BEFORE TAXES ON INCOME</b>	5,177,396	2,036,173	8,938,562
<b>TAXES ON INCOME</b> (Note 9)	1,378	28,622	30,000
<b>LOSS FROM OPERATIONS OF THE COMPANY AND ITS CONSOLIDATED SUBSIDIARY</b>	5,178,774	2,064,795	8,968,562
<b>MINORITY SHARE IN LOSSES OF A SUBSIDIARY</b>			(12,375)
<b>NET LOSS FOR THE PERIOD</b>	\$ (5,178,774)	\$ (2,064,795)	\$ (8,956,187)
<b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>	\$ (0.14)	\$ (0.07)	
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES USED IN COMPUTING BASIC AND DILUTED LOSS PER COMMON SHARE</b>	38,043,043	28,052,065	

\* Incorporation date, see Note 1a.

The accompanying notes are an integral part of the financial statements.

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)  
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
(US \$, except share data)

	Number of Shares	Common Stock Amount	Warrants	Additional paid-in capital	Deficit accumulated during the development stage	Services not yet rendered	Total
<b>Changes during the period from October 6, 1998 (date of incorporation) to September 30, 2004</b>							
Common stock and warrants issued for cash	57,506,498	\$ 5,750	\$ 139,494	\$ 782,141	\$	\$	\$ 927,385
Contributed capital				7,025			7,025
Cancellation of shares at June 8, 2004	(32,284,988)	(3,228)		3,228			
Gain on issuance of subsidiary stock to third party				86,625			86,625
Stock based compensation				62,600			62,600
Net loss					(514,086)		(514,086)
<b>Balance at September 30, 2004</b>	<b>25,221,510</b>	<b>2,522</b>	<b>139,494</b>	<b>941,619</b>	<b>(514,086)</b>		<b>569,549</b>
Common stock and warrants issued for cash on November 11, 2004, net of issuance costs	978,000	97	367,892	766,630			1,134,619
Common stock and warrants issued for cash on January 25, 2005, net of issuance costs	32,000	3	12,037	24,760			36,800
Issuance of warrants to consultants				34,592			34,592
Net loss					(1,198,532)		(1,198,532)
<b>Balance at September 30, 2005</b>	<b>26,231,510</b>	<b>2,622</b>	<b>519,423</b>	<b>1,767,601</b>	<b>(1,712,618)</b>		<b>577,028</b>
Common stock and warrants issued for cash on October 31, 2005, net of issuance costs	666,666	67	72,410	365,670			438,147
Common stock and warrants issued for cash on December 20, 2005, net of issuance costs	1,555,556	156	269,641	804,998			1,074,795
Options issued to employees and directors				163,517			163,517
Options and warrants issued to non-employees				70,498			70,498
Net loss					(2,064,795)		(2,064,795)
<b>Balance at September 30, 2006</b>	<b>28,453,732</b>	<b>2,845</b>	<b>861,474</b>	<b>3,172,284</b>	<b>(3,777,413)</b>		<b>259,190</b>
Common stock and warrants issued for cash on February 27, 2007, net of issuance costs	16,250,000	1,625	2,231,459	3,652,640			5,885,724
Common stock issued as part of the prepayment of the convertible promissory note*	33,753	3		13,498			13,501
Amendment of warrants exercise price			110,667	(110,667)			
Stock based compensation expenses:							
Common stock issued for services	221,432	22		149,978			150,000
Services not yet rendered **						(20,000)	(20,000)
Options issued to employees and directors				1,713,169			1,713,169
Options and warrants issued to non-employees				378,028			378,028
Net loss					(5,178,774)		(5,234,274)
<b>Balance at September 30, 2007</b>	<b>44,958,917</b>	<b>\$ 4,495</b>	<b>\$ 3,203,600</b>	<b>\$ 8,968,930</b>	<b>\$ (8,956,187)</b>	<b>\$ (20,000)</b>	<b>\$ 3,200,838</b>

\* See Note 6

\*\* See Note 8(v)

The accompanying notes are an integral part of the financial statements.





## GAMMACAN INTERNATIONAL, INC.

(A Development Stage Company)  
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended September 30		Period from October 6, 1998* to September 30, 2007
	2007	2006	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss for the period	\$ (5,178,774)	\$ (2,064,795)	\$ (8,956,187)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation	8,311	4,299	15,203
Exchange differences on long term deposits	310	(48)	262
Common stock issued for services	143,501		146,501
Minority share in losses of a subsidiary			(12,375)
Write off of in process research and development			100,000
Employees and consultants stock based compensation expenses	2,091,197	196,957	2,385,346
Increase in liability for employee rights upon retirement	39,807	17,806	71,338
Changes in operating assets and liabilities:			
Decrease (increase) in prepaid expenses	(9,851)	6,416	(9,851)
Decrease (increase) in other current assets	(29,592)	9,535	(45,611)
Increase in current liabilities	598,639	155,065	926,738
Net cash used in operating activities	(2,336,452)	(1,674,765)	(5,378,636)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Increase in long term deposits	(1,815)	(17,019)	(20,512)
Funds in respect of employee rights upon retirement	(28,210)	(13,543)	(49,281)
Purchase of property and equipment	(9,402)	(19,277)	(41,541)
Net cash used in investing activities	(39,427)	(49,839)	(111,334)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Issuance of common stock and warrants net of issuance costs	5,885,724	1,550,000	9,538,553
Net cash provided by financing activities	5,885,724	1,550,000	9,538,553
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>3,509,845</b>	<b>(174,604)</b>	<b>4,048,583</b>
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>538,738</b>	<b>713,342</b>	
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 4,048,583</b>	<b>\$ 538,738</b>	<b>\$ 4,048,583</b>

Supplemental information on financing activities not involving cash flow issuance costs paid by a grant of warrants to third parties who assisted in securing subscription agreements totaled \$37,058 for the year ended September 30, 2006.

\* Incorporation date, see Note 1a.

The accompanying notes are an integral part of the financial statements.



**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES:**

**a. General:**

GammaCan International, Inc. (A Development Stage Company) was incorporated on October 6, 1998, under the laws of the State of Delaware, under the name of San Jose International, Inc. Unless the context indicates otherwise, references to the *Company* refer to GammaCan International, Inc. and its Israeli subsidiary, GammaCan Ltd (the *Subsidiary*).

The Company is engaged in research and development in the biotechnology field and is considered a development stage company in accordance with Statement of Financial Accounting Standard ( *SFAS* ) No. 7 *Accounting and Reporting by Development Stage Enterprises* .

The Company's lead product candidate, VitiGam , is an anti-cancer immunotherapy derived entirely from the plasma of donors with vitiligo, a benign skin condition affecting up to 2% of the general population. The Company is developing VitiGam to treat melanoma. The Company has demonstrated that plasma from individuals with vitiligo contains anti-melanoma activities, and the Company is seeking to develop VitiGam for the treatment of Stage III and Stage IV melanoma.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company has net losses for the period from inception (October 6, 1998) through September 30, 2007 of \$8,956,187, as well as negative cash flow from operating activities. Presently, the Company does not have sufficient cash resources to meet its requirements in the twelve months following October 1, 2007. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management is in the process of evaluating various financing alternatives as the Company will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that the Company will be successful with those initiatives, management is confident that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders.

These financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent on its ability to obtain additional financing as may be required and ultimately to attain profitability.

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

**b. Accounting principles**

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ( *U.S. GAAP* ).

**c. Use of estimates in the preparation of financial statements**

The preparation of the financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the financial statement date and the reported expenses during the reporting periods. Actual results could differ from those estimates.

**d. Functional currency**

The currency of the primary economic environment in which the operations of the Company are conducted is the U.S. dollar ( \$ or *dollar* ).

Most of the Company's research and development costs are incurred in dollars. A significant part of the Company's capital expenditures and most of its financing is in dollars. Thus, the functional currency of the Company is the dollar.

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in foreign currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For foreign transactions and other items reflected in the statements of operations, the following exchange rates are used: (1) for transactions exchange rates at transaction dates or average rates and (2) for other items (derived from non-monetary balance sheet items such as depreciation) historical exchange rates. The resulting transaction gains or losses are carried to financial income or expenses, as appropriate.

**e. Principles of consolidation**

The consolidated financial statements include the accounts of GammaCan International, Inc. and its Israeli subsidiary GammaCan Ltd. All material inter-company transactions and balances have been eliminated in consolidation.

**f. Property and equipment**

Property and equipment are recorded at cost and depreciated by the straight-line method over the estimated useful lives of the assets.

Annual rates of depreciation are as follows:

	%
Computers and peripheral equipment	33
Office furniture and equipment	6-15

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

**g. Deferred taxes**

Deferred taxes are determined utilizing the assets and liabilities method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Deferred tax balances are computed using the tax rates expected to be in effect when those differences reverse. A valuation allowance in respect of deferred tax assets is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company has provided a full valuation allowance with respect to its deferred tax assets.

Regarding the Subsidiary, paragraph 9(f) of FAS 109, *Accounting for Income Taxes*, prohibits the recognition of deferred tax liabilities or assets that arise from differences between the financial reporting and tax bases of assets and liabilities that are measured from the local currency into dollars using historical exchange rates, and that result from changes in exchange rates or indexing for tax purposes. Consequently, the abovementioned differences were not reflected in the computation of deferred tax assets and liabilities.

**h. Research and development**

Research and development costs are expensed as incurred.

Acquisition of in process research and development and the costs of registration of patents that have not yet reached technological feasibility, have no alternative future use, are expensed as incurred.

**i. Cash equivalents**

The Company considers all short term, highly liquid investments, which include short-term deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash, to be cash equivalents.

**j. Comprehensive loss**

The Company has no other comprehensive loss components other than net loss for the reported periods.

**k. Loss per share**

Basic and diluted net losses per share of common stock are computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period. Outstanding stock options and warrants have been excluded from the calculation of the diluted loss per share because all such securities are anti-dilutive for all periods presented. The total number of common stock options and warrants excluded from the calculation of diluted net loss was 25,062,558 for the year ended September 30, 2007 (5,917,775 for the year ended September 30, 2006).

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

**l. Impairment in value of long-lived assets**

The Company reviews long-lived assets, to be held and used, for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. In the event the sum of the expected future cash flows (undiscounted and without interest charges) of the long-lived assets is less than the carrying amount of such assets, an impairment loss would be recognized, and the assets are written down to their estimated fair values.

**m. Stock based compensation**

Until September 30, 2006, the Company accounted for employees' share-based payment under the intrinsic value model in accordance with Accounting Principles Board Opinion No. 25 - *Accounting for Stock Issued to Employees* ( *APB 25* ) and related interpretations. In accordance with Statement of Financial Accounting Standards No. 123 - *Accounting for Stock-Based Compensation* ( *FAS 123* ), as amended by Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure* , the Company disclosed pro forma information, assuming the Company had accounted for employees' share-based payments using the fair value-based method defined in FAS 123.

Effective October 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-based Payment* ( *FAS 123(R)* ). FAS 123(R) supersedes APB 25 and related interpretations and amends Statement of Financial Accounting Standards No. 95, *Statement of Cash Flows* ( *FAS 95* ). FAS 123(R) requires awards classified as equity awards be accounted for using the grant-date fair value method. The fair value of share-based payment transactions is recognized as expense over the requisite service period, net of estimated forfeitures. The Company estimated forfeitures based on historical experience and anticipated future conditions.

In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 ( *SAB 107* ). SAB 107 provides supplemental implementation guidance on FAS 123(R), including guidance on valuation methods, inventory capitalization of share-based compensation cost, income statement effects, disclosures and other issues. SAB 107 requires share-based payment to be classified in the same expense line items as cash compensation. The Company has applied the provisions of SAB 107 in its adoption of FAS 123(R).

The Company elected to recognize compensation cost for an award with only service conditions that has a graded vesting schedule using the accelerated method based on multiple option award approach.

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

FAS 123(R) applies to all awards granted or modified after the Statement's effective date. In addition, compensation cost for the unvested portion of previously granted awards that remain outstanding on the Statement's effective date shall be recognized on or after the effective date, as the related services are rendered, based on the awards' grant-date fair value as previously calculated for the pro-forma disclosure under FAS 123.

The Company elected to adopt the modified prospective application transition method, as permitted by the Statement. Under such transition method, upon the adoption of FAS 123(R), the Company's financial statements for periods prior to the effective date of the Statement are not restated.

Costs incurred in respect of stock based compensation for years ended September 30, 2007 and 2006 were \$1,713,169 and \$163,517, respectively.

The Company accounts for equity instruments issued to third party service providers (non-employees) in accordance with the fair value based on an option-pricing model or when more reliability is based on the fair value of the services received, pursuant to the guidance in EITF 96-18 *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*. The fair value of the options granted is revalued over the related service periods and recognized using the accelerated method.

The Company recorded stock compensation of \$508,028 and \$33,440 during the years ended September 2007 and 2006 respectively, related to consulting services.

The following table illustrates the pro-forma effect on net loss and loss per common share assuming the Company had applied the fair value recognition provisions of FAS 123 to its stock-based employee compensation:

	<b>Year ended September 30 2006</b>
	<u>                    </u>
Net loss as reported	\$ (2,064,795)
Add back: Stock based employee compensation expense included in net loss as reported	163,517
Deduct: pro forma stock based employee compensation expense determined under fair value method for all awards	(1,107,201)
Recognize the reversal of the pro forma stock based employee compensation expense determined under fair value method due to forfeiture of awards granted to employees	<u>79,676</u>
Pro forma net loss	<u>\$ (2,928,803)</u>
Net loss per common share:	
Basic and diluted loss per shares - as reported	<u>\$ (0.07)</u>
Basic and diluted loss per shares - pro forma	<u>\$ (0.10)</u>



**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

The fair value of each option grant is estimated on the date of grant using the Black Scholes option-pricing model with the following weighted average assumptions:

	For options granted in year ended September 30	
	2007	2006
Expected option life (years)	5.47-7.88	7.85
Expected stock price volatility	85.0%-89.9%	80.0%-85.1%
Risk free interest rate	4.23%-4.68%	4.5%
Expected dividend yield	0.0%	0.0%

**n. Newly issued and recently adopted accounting pronouncements:**

- 1) In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* ( *SAB 108* ), which provides interpretive guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. SAB 108 is effective for fiscal years ending after November 15, 2006 (September 30, 2007 for the Company). The Company adopted SAB 108 in these financial statements and accordingly, follows SAB 108 requirements when quantifying financial statement misstatements. The adoption of SAB No.108 did not result in corrections of the Company's financial statements.
- 2) In July 2006, the FASB issued FASB Interpretation No. 48 *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement 109* ( *FIN 48* ). FIN 48 prescribes a comprehensive model for recognizing, measuring and presenting in the financial statements tax positions taken or expected to be taken on a tax return. This Interpretation also provides guidance on derecognition, classification, interest and penalties and disclosure requirements for uncertain tax positions. FIN 48 is effective for fiscal years beginning on or after December 15, 2006 (October 1, 2007, for the Company). The provisions of FIN 48 shall be applied to all tax positions upon initial adoption of this Interpretation. Only tax positions that meet the more likely than not recognition threshold at the effective date may be recognized or continue to be recognized upon adoption of this Interpretation. The cumulative effects, if any, of applying this Interpretation will be recorded as an adjustment to retained earnings. The Company is currently assessing this standard effect on its financial statements in future periods.
- 3) In September 2006, the FASB issued Statement of Financial Accounting Standard No. 157, *Fair Value Measurements* ( *FAS 157* ). FAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. FAS 157 will apply whenever another standard requires (or permits) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value to any new circumstances. FAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years (October 1, 2008, for the Company). The Company is currently assessing this standard effect on its financial statements in future periods.

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

- 4) In February 2007, FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. This standard permits companies to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. This statement will be effective for fiscal years beginning on or after November 15, 2007 (October 1, 2008, for the Company). The Company is currently evaluating the impact that the adoption of SFAS 159 will have on its consolidated financial statements.
- 5) In June 2007, the Emerging Issues Task Force ( EITF ) issued EITF 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-3 ). EITF 07-3 addresses the diversity which exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. The EITF concluded that an entity will defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-3 is effective for interim or annual reporting periods in fiscal years beginning after December 15, 2007 (October 1, 2008 for the Company). The Company is currently evaluating the impact of adopting EITF 07-03 on its financial statements and results of operations.
- 6) In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* ( SFAS 141(R) ). SFAS 141(R) expands the definition of a business and a business combination, requires the fair value of the purchase price of an acquisition, including the issuance of equity securities to be determined on the acquisition date, requires that all assets, liabilities, contingent consideration, contingencies and in-process research and development costs of an acquired business be recorded at fair value at the acquisition date, requires that acquisition costs generally be expensed as incurred, requires that restructuring costs generally be expensed in periods subsequent to the acquisition date, and requires changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period to impact income tax expense. SFAS 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008 (October 1, 2009 for the Company). Early application is prohibited. The Company is currently evaluating the impact SFAS 141(R) will have on its consolidated financial statements.

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

- 7) In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51* ( *SFAS 160* ). SFAS 160 amends ARB 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. An ownership interest in subsidiaries held by parties other than the parent should be presented in the consolidated statement of financial position within equity, but separate from the parent's equity. SFAS 160 requires that changes in a parent's ownership interest while the parent retains its controlling financial interest in its subsidiary should be accounted for similarly as equity transactions. When a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary should be initially measured at fair value, with any gain or loss recognized in earnings. SFAS 160 requires consolidated net income to be reported at amounts that include the amounts attributable to both the parent and the noncontrolling interest. It also requires disclosure, on the face of the consolidated income statement, of the amounts of consolidated net income attributable to the parent and to the noncontrolling interests. SFAS 160 is effective for fiscal years (including interim periods within those fiscal years) beginning on or after December 15, 2008 (October 1, 2009 for the Company). Earlier adoption is prohibited. The statement shall be applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for the presentation and disclosure requirement which shall be applied retrospectively for all periods presented. The Company is currently evaluating the impact SFAS 160 will have on its consolidated financial statements.
- 8) In December 2007, the FASB ratified *EITF Issue No. 07-01, Accounting for Collaborative Arrangements* ( *EITF 07-01* ). EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-01 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-01 is effective for fiscal years beginning after December 15, 2008 (October 1, 2009 for the Company). The Company is currently evaluating the impact EITF 07-01 will have on its consolidated financial statements.

**o. Reclassifications**

Certain figures in respect of prior years have been reclassified to conform to the prior year presentation.

F-15

---

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 2 - EMPLOYEE RIGHTS UPON RETIREMENT**

- a.** Israeli labor laws and agreements require payment of severance pay upon dismissal of an employee or upon termination of employment in certain other circumstances. The Subsidiary's severance pay liability to its employees, mainly based upon length of service and the latest monthly salary (one month's salary for each year worked), is reflected by the balance sheet accrual under the liability for employee rights upon retirement. The Company records the liability as if it was payable at each balance sheet date on an undiscounted basis. The liability is partly funded by purchase of insurance policies. The amounts funded are included in the balance sheet as funds in respect of employee rights upon retirement. The policies are the Company's assets and under labor agreements, subject to certain limitations, they may be transferred to the ownership of the beneficiary employees.
- b.** The severance pay expenses for the years ended September 30, 2007 and 2006, were \$39,807 and \$17,806 respectively.
- c.** Cash flow information regarding the Company's liability for employee rights upon retirement:
- 1) The Company expects to contribute to the insurance policies \$23,000 in respect of severance pay for the year ended September 30, 2008.
  - 2) Due to the relatively young age of the Company's employees, benefit payments to employees reaching retirement age in the next 10 years, are not material. The amounts were determined based on the employees current salary rates and the number of service years that will accumulate upon their retirement date. These amounts do not include amounts that might be paid to employees who will cease working for the Subsidiary before their normal retirement age.

**NOTE 3 LONG TERM DEPOSITS**

	September 30	
	2007	2006
Bank Deposits (1)	\$ 11,723	\$ 12,034
Deposits in respect of vehicles lease agreements (2)	6,867	10,236
	18,590	22,270

(1) See also Note 5a

(2) See also Note 5b

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 4 PROPERTY AND EQUIPMENT, Net**

- a. Composition of property and equipment, grouped by major classifications, is as follows:

	September 30	
	2007	2006
Cost:		
Office furniture and equipment	\$ 24,316	\$ 14,287
Computers and peripheral equipment	17,225	17,852
	41,541	32,139
Less - accumulated depreciation	15,203	6,892
	\$ 26,338	\$ 25,247

- b. Depreciation expense totaled \$8,311 and \$4,299 in the years ended September 30, 2007 and 2006, respectively.

**NOTE 5 COMMITMENTS:**

- a. On May 18, 2006, the Subsidiary entered into a new lease agreement for its new office facilities, in Israel, which commenced on August 10, 2006. The new lease agreement is for a period of 36 months with an option to renew the lease for an additional 36 month period. The monthly lease payment is \$2,236. The future lease payments under the lease are \$26,827 and \$22,356 for the years ending September 30, 2008 and 2009 respectively.

As security for its obligation under this lease agreement the Company provided a bank guarantee in an amount equal to six monthly lease payments, which is secured by a long term bank deposit (See also Note 3).

On June 8, 2006, the Company entered into a lease agreement for the office facilities, in the United States, it currently occupies. The lease agreement was for a period of 12 months with an automatic option to renew for another 60 days at the same monthly rate plus an increase of 14.83%. The monthly lease payment was \$1,800. On June 6, 2007, the Company renewed the lease agreement for a period of 12 months. The current monthly lease payments is \$2,000. The future lease payments under this lease are \$16,000 for the year ending September 30, 2008.

Rental expenses, for all office facilities used by the Company, for the years ended September 30, 2007 and 2006 were \$43,219 and \$18,307, respectively.

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 5 COMMITMENTS** (continued):

- b.** The Subsidiary has entered into operating lease agreements for vehicles used by its employees for a period of 3 years. The lease expenses for the years ended September 30, 2007 and 2006 were approximately \$45,766 and \$39,328, respectively. The future lease payments under the lease agreement are \$28,443 and \$4,990 for the years ending September 30, 2008, and 2009 respectively.
- c.** On December 13, 2005, the Subsidiary entered into a Research and Licensing Agreement with Tel Hashomer Medical Research Infrastructure and Services LTD. ( *THM* and *THM Agreement* ), pursuant to which the Subsidiary provided THM with \$200,000 in funding for THM to conduct a research project relating to the mechanism of action for IVIg, hyper-immune IVIg and use of IVIg as an anti-cancer treatment. As of September 30, 2007, the Company paid its obligation under the contract. According to the THM Agreement, THM granted the Subsidiary an exclusive worldwide license to any resulting technology and know-how as described in the above mentioned agreement. See Note 13d in connection with an amendment to the THM Agreement.
- d.** On January 30, 2007, the Subsidiary entered into a Master Services Agreement with BioSolutions Services, LLC ( *BioSolutions* ), an outside party, pursuant to which the Subsidiary will from time-to-time engage BioSolutions for various projects to assist it with the commercialization of its anti-cancer immunotherapy to treat metastatic cancer. The services to be performed under the Master Services Agreement will be specified in separate work orders, which will set forth the scope of the work, schedule and costs.

Work Order # 1 relates to regulatory consulting services to be provided by BioSolutions in connection with the application for an IND with the US FDA for VitiGam . As compensation for the services, the Subsidiary agreed to pay BioSolutions a cash fee of between \$170,000 to \$290,000 based on several factors. The Company issued to BioSolutions a warrant to purchase 434,783 shares of its common stock at a purchase price of \$0.45 per share vesting as follows: (1) 33% upon signature of a definitive agreement with an IVIg manufacturer, (2) 33% upon the IND filing and (3) 34% when the IND has been approved by the FDA (See also Note 8m).

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 5 COMMITMENTS** (continued):

- e. On February 1, 2007, the Subsidiary entered into a Cooperation and Project Funding Agreement with Israel-U.S. Binational Industrial Research and Development (the *BIRD Foundation*) and Life Therapeutics (*Life*), pursuant to which the BIRD Foundation will provide the Subsidiary and Life with funding of the lesser of \$1,000,000 or 50% of expenditures on the development of an anti-cancer immunotherapy to treatment for metastatic cancer (the *Project*), which funding will be repaid to the BIRD Foundation if the development work goes beyond a Phase II clinical trial. The repayment of the funding will be due within twelve months following the completion of the Project in an amount equal to the total funding linked to the US Consumer Price Index.
- f. On September 6, 2007, the Subsidiary entered into an Agreement for the Purchase of Blood Plasma with DCI Management Group, LLC (*DCI*). Under the terms of the agreement, DCI will collect plasma from vitiligo donors at DCI operated FDA-approved, IQPP certified donor centers for the manufacture of VitiGam.

**NOTE 6 CONVERTIBLE PROMISSORY NOTE:**

On November 20, 2006, the Company issued a convertible promissory note, in a principal amount of \$350,000, which bore annual interest at 8% payable on maturity of the note with a maturity date of November 20, 2007. On May 15, 2007 (the *Prepayment Date*) the Company repaid the principal amount of the note and issued 33,753 shares of its common stock in exchange for the accrued interest on the principal amount to that date.

As of the date of issuance, the hybrid instrument was bifurcated into an option and a host debt contract. The fair value assigned to the option, determined using Black Scholes option-pricing model, was \$109,075. As of the Prepayment Date, the fair value allocated to the option, estimated by using the Black Scholes option-pricing model was \$93,273. The value was based on the following assumptions: dividend yield of 0%; expected volatility of 87%; risk-free interest rates of 5.0%; and expected lives of 0.52 years.

**NOTE 7 STOCK HOLDERS EQUITY:**

The Company's shares are traded on the Over-The-Counter Bulletin Board.

The following are capital stock transactions that took place during the years ended September 30, 2007 and 2006:

- a. On October 31, 2005, the Company entered into a subscription agreement for the sale of 666,666 units at a purchase price of \$0.75 per unit for total consideration of \$500,000. Each unit consisted of one share of the Company's common stock and one common stock purchase warrant. Each warrant entitles the holder to purchase half a share of common stock exercisable for three years at an exercise price of at \$1.00 per share.

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 7 STOCK HOLDERS EQUITY** (continued):

In connection with the subscription agreement, the Company paid a \$50,000 cash fee to a third party which assisted in securing the agreement and issued a three year warrant to acquire 66,666 shares of common stock exercisable at \$1.50 per share.

The consideration was allocated to the shares and warrants issued based on relative fair value. The value allocated to the warrants estimated by using the Black Scholes option-pricing model is \$72,410 and was based on the following assumptions: dividend yield of 0%; expected volatility of 80%; risk-free interest rates of 4.4%; and expected lives of 3 years.

- b.** On December 20, 2005, the Company entered into a subscription agreement for the sale of 1,333,334 units at a purchase price of \$0.75 per unit for total consideration of \$1,000,000. Each unit consisted of one share of the Company's common stock and one common stock purchase warrant. Each warrant entitles the holder to purchase one share of common stock exercisable for three years at an exercise price of \$1.20 per share.

In connection with the subscription agreement the Company paid a \$100,000 cash fee to third parties who assisted in securing the agreement, as well as issued warrants to purchase 133,332 shares of common stock exercisable for three years. Warrants exercisable for 66,666 shares of common stock are exercisable at \$1.25 per share, and warrants exercisable for 66,666 shares of common stock are exercisable at \$1.50 per share.

The consideration was allocated to the shares and warrants issued based on relative fair value. The value allocated to all warrants estimated by using the Black Scholes option-pricing model is \$235,527 and was based on the following assumptions: dividend yield of 0%; expected volatility of 81%; risk-free interest rates of 4.4%; and expected lives of 3 years.

- c.** On December 20, 2005, the Company entered into a subscription agreement for the sale of 222,222 units at a purchase price of \$0.90 per unit for a total consideration of \$200,000. Each unit consisted of one share of the Company's common stock and one common stock purchase warrant. Each warrant entitles the holder to purchase half a share of common stock exercisable for three years at an exercise price of \$1.15 per share.

The consideration was allocated to the shares and warrants issued based on relative fair value. The value allocated to all warrants estimated by using the Black Scholes option-pricing model is \$34,114 and was based on the following assumptions: dividend yield of 0%; expected volatility of 81%; risk-free interest rates of 4.4%; and expected lives of 3 years.

- d.** On February 27, 2007, the Company completed a private placement for the sale of 16,250,000 units at a purchase price of \$0.40 per unit for total consideration of \$6,500,000. Each unit consisted of one share of common stock and one share purchase warrant. Each warrant entitles the holder to purchase one share of common stock for a period of five years at an exercise price of \$0.48. The consideration was allocated to the shares and warrants issued based on relative fair value. The fair value, net transaction costs allocated to the warrants is \$2,231,459, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 89%; risk-free interest rates of 4.63%; and expected lives of 5 years. Transaction costs of \$614,275 were paid.



**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 7 STOCK HOLDERS EQUITY** (continued):

- e. On February 27, 2007, the exercise price of 1,333,334 warrants was reduced to \$0.55. The warrants were issued on December 20, 2005 as part of a subscription agreement for the sale of 1,333,334 units at a purchase price of \$0.75 per unit for total consideration of \$1,000,000. The increase in the fair value of the warrants is charged in the Statement of Changes in Stockholders' Equity against the additional paid-in capital.
- f. On February 27, 2007, the exercise price of 333,333 warrants was reduced to \$0.55. The warrants were issued on October 31, 2005 as part of a subscription agreement for the sale of 666,666 units at a purchase price of \$0.75 per unit for a total consideration of \$500,000. The increase in the fair value of the warrants is charged in the Statement of Changes in Stockholders' Equity against the additional paid-in capital.
- g. On May 15, 2007, the Company issued 33,753 shares of its common stock in exchange for the interest accumulated on the principal amount of a convertible promissory note issued by the Company on November 20, 2006. See also Note 6.
- h. As to shares issued as part of stock based compensation plan see Note 8.

**NOTE 8 STOCK BASED COMPENSATION:**

On August 17, 2004, the Company's board of directors adopted the 2004 Employees and Consultants Stock Option Plan (the *2004 Stock Option Plan*).

On February 26, 2007, the Company's board of directors adopted the 2007 Global Share Option Plan (the *2007 Stock Option Plan*).

Under both plans 10,000,000 shares have been reserved for the grant of options, which may be issued at the discretion of the Company's board of directors from time to time. Under these plans, each option is exercisable into one share of common stock of the Company.

The options may be exercised after vesting and in accordance with vesting schedules which will be determined by the board of directors for each grant. The maximum term of the options is 10 years.

The fair value of each stock option grant is estimated at the date of grant using a Black Scholes option pricing model. The volatility is based on a historical volatility, by statistical analysis of the weekly share price for past periods. The expected term is the length of time until the expected dates of exercising the options, based on estimated data regarding employees' exercise behavior.

In connection with the completion on February 27, 2007 of a private placement by the Company (See Note 7d), the officers, directors, and employees holding a total of 5,600,000 options, agreed to restrictions on resale of the shares underlying the options until the first anniversary of the effective date of the initial registration statement that was filed pursuant to the private placement.

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 8 STOCK BASED COMPENSATION** (continued):

The following are stock options and warrants transactions made during the years ended September 30, 2007 and 2006, (See Note 13 as to grants of stock options subsequent to September 30, 2007):

- a.** On October 6, 2005, 350,000 options were granted to an employee under the 2004 Stock Option Plan at an exercise price of \$0.93 per share which was equivalent to 90% of the traded market price on the date of grant. Compensation costs calculated in accordance with APB 25 totaled \$35,000. The fair value of these options on the date of grant is \$283,262 using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 80%; risk-free interest rates of 4.5%; and expected lives of 7.59 years. These options were cancelled on May 17, 2007 (See also Note 8s).
- b.** On October 20, 2005, 30,000 options were granted to an employee under the 2004 Stock Option Plan at an exercise price of \$1.35 per share which was equivalent to the traded market price on the date of grant. The fair value of the above options on the date of grant is \$32,637 using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 85%; risk-free interest rates of 4.5%; and expected lives of 7.85 years. These options were cancelled on May 17, 2007 (See also Note 8s).
- c.** On December 21, 2005, 250,000 options were granted to an employee under the 2004 Stock Option Plan. at an exercise price of \$1.34 per share which was equivalent to the traded market price on the date of grant. The fair value of these options on the date of the grant, is \$269,449 using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 85%; risk-free interest rates of 4.5%; and expected lives of 7.85 years. These options were cancelled on May 17, 2007 (See also Note 8s).
- d.** On January 12, 2006, 50,000 options were granted to an employee under the 2004 Stock Option Plan at an exercise price of \$1.10 per share which was equivalent to the traded market price on the date of grant. The fair value of these options on the date of the grant, is \$44,163 using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 85%; risk-free interest rates of 4.5%; and expected lives of 7.85 years.
- e.** On March 15, 2006, 50,000 options were granted to a director under the 2004 Stock Option Plan at an exercise price of \$1.37 per share which was equivalent to the traded market price on the date of grant. The fair value of these options on the date of grant is \$54,712 using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 84%; risk-free interest rates of 4.5%; and expected lives of 7.85 years. These options were cancelled on May 17, 2007 (See also Note 8s).

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 8 STOCK BASED COMPENSATION** (continued):

- f.** On April 17, 2006, 1,400,000 stock options were granted to the then new CEO under the 2004 Stock Option Plan at an exercise price of \$1.29 per share which was equivalent to 90% of the average closing price of the common stock of the Company on the 30 days immediately preceding the date of grant. Compensation costs calculated in accordance with APB 25 totaled \$434,000. The fair value of these options on the date of grant is \$1,832,296 using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 83%; risk-free interest rates of 4.5%; and expected lives of 7.85 years. These options were cancelled on May 17, 2007 (See also Note 8s).
- g.** On May 4, 2006, 500,000 (100,000 for each of its five board members) options were granted under the 2004 Stock Option Plan at an exercise price of \$1.29 per share which was equivalent to 90% of the average closing price of the common stock of the Company on the 30 days immediately preceding the date of grant. Compensation costs calculated in accordance with APB 25 totaled \$105,000. The fair value of these options on the date of grant is \$605,909 using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 82%; risk-free interest rates of 4.5%; and expected lives of 7.85 years. These option were cancelled on May 17, 2007 (See also Note 8s).
- h.** During September 2006, 50,000 options were forfeited due to the departure of a scientific advisor. Expenses in respect of options forfeited due to non-performance were reversed.
- i.** On October 12, 2006, 50,000 options were granted under the 2004 Stock Option Plan to a then new member of the Scientific Advisory Board, an outside party, at an exercise price of \$0.65 per share, which was equivalent to the traded market price on the date of grant. These options vest according to the following vesting schedule:

  - 1) On the first anniversary of the grant date, 25% of the options vest;
  - 2) On the last day of each of the 36 months following the first anniversary of the grant date, the remaining options vest in equal monthly installments.

The fair value of these options as of September 30, 2007 is \$14,849, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 85%; risk-free interest rates of 4.23%; and expected lives of 5.47 years.

- j.** On October 18, 2006 the Company entered into a Strategic Alliance Agreement with UTEK Corporation ( *UTEK* ), pursuant to which UTEK would assist the Company in identifying technology acquisition opportunities. In consideration for the services being provided to the Company by UTEK, the Company agreed to pay UTEK \$120,000. The Company had the option of paying UTEK \$10,000 per month in cash and instead issued UTEK an aggregate of 171,432 shares of common stock of the Company which vest in 12 equal monthly instalments of 14,286 shares each.

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 8 - STOCK BASED COMPENSATION** (continued):

**k.** On November 13, 2006, 150,000 options were granted under the 2004 Stock Option Plan to each of the Company's two board members who joined the Board of Directors on November 6, 2006 (totaling 300,000 options). The options are exercisable at \$0.45 per share (equivalent to the traded market price on the date of grant), in accordance with the following vesting schedule:

- 1) On the first anniversary commencing the grant date, 25% of the options vest;
- 2) On the last day of each of the 36 months following the first anniversary of the grant date, the remaining options vest in equal monthly installments.

The fair value of these options on the date of grant is \$111,859, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0%; expected volatility of 90%; risk-free interest rates of 4.65%; and expected lives of 7.88 years.

**l.** On December 5, 2006, 50,000 options were granted under the 2004 Stock Option Plan to a then new member of the Scientific Advisory Board, an outside party. The options are exercisable at \$0.50 per share (equivalent to the traded market price on the date of grant) in accordance with the following vesting schedule:

- 1) On the first anniversary commencing the grant date, 25% of the options vest;
- 2) On the last day of each of the 36 months following the first anniversary of the grant date, the remaining options vest in equal monthly installments.

The fair value of these options as of September 30, 2007 is \$15,789, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 85%; risk-free interest rates of 4.23%; and expected lives of 5.47 years.

**m.** On January 30, 2007, warrants to acquire 434,783 shares of common stock of the Company were granted to an outside consultant. The warrants are exercisable for a period of five years at an exercise price of \$0.45 per share. Since the warrants only vest if certain performance conditions are met (See also Note 5d), no compensation was recorded this period.

**n.** On February 15, 2007, 100,000 options were granted under the 2004 Stock Option Plan to an employee. The options are exercisable at \$0.45 per share, (equivalent to the traded market price on the date of grant) in accordance with the following vesting schedule:

- 1) On the first anniversary commencing the grant date, 25% of the options vest;
- 2) On the last day of each of the 36 months following the first anniversary of the grant date, the remaining options vest in equal monthly installments.

The fair value of these options on the date of grant is \$34,244, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 90%; risk-free interest rates of 4.68%; and expected lives of 5.91 years.

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 8 - STOCK BASED COMPENSATION** (continued):

- o.** On February 26, 2007, 785,000 and 400,000 options were granted under the 2004 Stock Option Plan and the 2007 Stock Option Plan, respectively. The options were granted to directors, officers and employees. The options are exercisable at \$0.53 per share (equivalent to the traded market price on the date of grant) with one third vesting on each of the first, second and third anniversaries of the grant date. The fair value of these options on the date of grant is \$412,685, using Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 89%; risk-free interest rates of 4.62%; and expected lives of 5.89 years.
- p.** On February 26, 2007, 80,000 options were granted under the 2004 Stock Option Plan to the Subsidiary's Chief Scientist and a consultant, both outside parties. The options are exercisable at \$0.53 per share (equivalent to the traded market price on the date of grant) with one third vesting on each of the first, second and third anniversaries of the grant date. The fair value of these options as of September 30, 2007 is \$24,936, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 85%; risk-free interest rates of 4.23%; and expected lives of 5.47 years.
- q.** On February 26, 2007, 1,075,000 options were granted under the 2007 Stock Option Plan to the Chairman of the Board in his capacity as an outside consultant. The options are exercisable at \$0.53 per share (equivalent to the traded market price on the date of grant) with one third vesting on each of the first, second and third anniversaries of the grant date. The fair value of these options as of September 30, 2007 is \$335,080, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 85%; risk-free interest rates of 4.23%; and expected lives of 5.47 years.
- r.** On March 22, 2007, warrants to purchase 350,000 shares of common stock were granted to an outside consultant. The warrants are exercisable for five years at an exercise price of \$0.53. The fair value of these warrants on the date of grant is \$179,470, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 89%; risk-free interest rates of 4.62%; and expected lives of 5 years.
- s.** On May 17, 2007, 2,790,000 options were granted under the 2007 Stock Option Plan at an exercise price of \$0.61, which was the fair market value at the close of business on May 16, 2007, to directors, officers and employees of the Company (total 9 individuals), upon the surrender and cancellation by each of such directors, officers and employees of options, exercisable for an aggregate 2,780,000 shares of common stock which were granted previously. The additional fair value added due to the replacement of these options is \$177,881, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 87%; risk-free interest rates of 4.68%; and expected lives of 5.80 years.

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 8 - STOCK BASED COMPENSATION** (continued):

- t.** On May 17, 2007, 20,000 options were granted to an employee under the 2007 Stock Option Plan at an exercise price of \$0.61 per share with one third vesting on each of the first, second and third anniversary of the date of grant. The fair value of these options on the date of grant is \$9,096, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 87%; risk-free interest rates of 4.68%; and expected lives of 5.80 years.
- u.** On May 21, 2007, two Subsidiary directors resigned from their positions and as part of accepting their resignation, the Board of Directors extended the term of all options granted to them (350,000 in total for both) until May 20, 2010. The fair value of the unvested portion of the 350,000 options as of that date, held by these directors, is \$98,423, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 87%; risk-free interest rates of 4.68%; and expected lives of 3 years.
- v.** On June 1, 2007, the Company entered into a Service Agreement with ROI Group, LLC ( *ROI* ), pursuant to which ROI is to provide investor relations services for a period of one year. In consideration for the services being provided to the Company, the Company pays a monthly retainer of \$9,500. In addition, the Company issued 50,000 fully vested shares of common stock of the Company and warrants to acquire 250,000 shares of common stock.

The warrants will expire on February 27, 2014 and are exercisable into 62,500 shares of common stock at an exercise price of \$0.75 which vested on August 31, 2007, 62,500 shares of common stock at an exercise price of \$0.90 which vested on November 30, 2007, 62,500 shares of common stock at an exercise price of \$1.10 which vest on February 28, 2008 and 62,500 shares of common stock at an exercise price of \$1.25 which vest on May 31, 2008.

The Company has valued the shares issued to ROI based on the market value of the shares of the Company on the date of issuance, which was \$0.60. The value of the shares issued assigned to services not yet rendered through September 30, 2007 are presented as a separate line item (contra-equity). The fair value of these warrants is \$72,511, using the Black Scholes option-pricing model and was based on the following assumptions: dividend yield of 0% for all years; expected volatility of 85%; risk-free interest rates of 4.23%; and expected lives of 6.42 years.

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 8 - STOCK BASED COMPENSATION** (continued):

A summary of the status of the stock options granted to employees and directors as of September 30, 2007, and changes during the year ended on this date, is presented below:

	Year ended September 30			
	2007		2006	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
	\$	\$		\$
<b>For options granted to Employees and Directors:</b>				
Options outstanding at beginning of year	2,830,000	\$ 1.24	350,000	\$ 1.17
Changes during the year:				
Granted at market price	4,395,000	0.57	380,000	1.31
Granted at an exercise price less than market price			2,250,000	1.23
Forfeited	(2,780,000)	1.24	(150,000)	1.20
Options outstanding at end of year	4,445,000	0.58	2,830,000	1.24
Options exercisable at end of year	812,458		82,292	
Weighted average fair value of options granted during the year	\$ 0.49		\$ 1.19	

The following table presents summary information concerning the options outstanding as of September 30, 2007:

Range of exercise prices \$	Number outstanding	Weighted average remaining contractual life Years	Weighted average exercise price \$	Aggregate intrinsic value \$
0.45 to 0.61	4,395,000	9.53	0.57	28,000
0.93 to 1.37	50,000	8.00	1.10	
	4,445,000	9.51	0.58	28,000

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 8 - STOCK BASED COMPENSATION** (continued):

The following table presents summary information concerning the options exercisable as of September 30, 2007:

Range of exercise prices \$	Number exercisable	Weighted average remaining contractual life Years	Weighted average exercise price \$	Aggregate intrinsic value \$
0.45 to 0.61	788,500	9.63	0.61	
0.93 to 1.37	23,958	8.00	1.10	
	<u>812,458</u>	<u>9.58</u>	<u>0.61</u>	

Unrecognized compensation as determined under FAS 123R as of September 30, 2007 totaled \$1,254,999, to be recorded over the next 41 months.

A summary of the status of the stock options granted to non-employees as of September 30, 2007, and changes during the year ended on this date, is presented below:

	Year ended September 30			
	2007		2006	
	Number of options	Weighted average exercise price \$	Number of options	Weighted average exercise price \$
<b>For options granted to Non-Employees:</b>				
Options outstanding at beginning of year	100,000	1.15	150,000	1.15
Changes during the year:				
Granted at market price	1,255,000	0.53		
Forfeited			50,000	1.15
Expired				
Options outstanding at end of year	<u>1,355,000</u>	<u>0.58</u>	<u>100,000</u>	<u>1.15</u>
Options exercisable at end of year	89,583		37,500	
Weighted average fair value of options granted during the year	<u>\$ 0.31</u>			



**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 9 - TAXES ON INCOME:****a. Deferred income taxes:**

	September 30	
	2007	2006
In respect of:		
Net operating loss carryforward	\$ 1,102,725	\$ 431,165
Research and development expenses	215,522	145,840
Start-up costs		142,932
Other	11,036	6,209
Less - Valuation allowance	(1,329,283)	(726,146)
	\$ 1,000,000	\$ 1,000,000
Net deferred tax assets	\$ 1,000,000	\$ 1,000,000

Realization of deferred tax assets is dependent upon sufficient future taxable income during the period that deductible temporary differences and carryforwards are expected to be available to reduce taxable income. As the achievement of required future taxable income is uncertain, the Company recorded a full valuation allowance.

**b. Corporate taxation in the U.S.**

Taxes on income included in the consolidated statements of operations represent current taxes due to taxable income of the US Company.

The applicable corporate tax rate for the Company is 22%.

**c. Corporate taxation in Israel**

The Subsidiary is taxed in accordance with Israeli tax laws. Under the Income Tax (Inflationary Adjustments) Law, 1985, results for tax purposes are measured in real terms, in accordance with the changes in the Israeli consumer price index ( *CPI* ).

The regular corporate tax rate in Israel for 2007 is 29%. The corporate tax rates for 2008 and thereafter are as follows: 2008 27%, 2009 26% and for 2010 and thereafter 25%.

As of September 30, 2007, the Subsidiary has an accumulated tax loss carryforward of approximately \$3,348,267 (September 30, 2006 approximately - \$1,724,661). Under Israeli tax laws, carryforward tax losses are linked to the Israeli CPI. The Israeli loss carryforwards have no expiration date.

**d. Reconciliation of the theoretical tax expense to actual tax expense**

The main reconciling items, between the statutory tax rate of the Company and the effective rate are the non deductible expenses and the provision of the valuation allowance in respect of the Company's deferred income tax asset (see above).

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 10 - RESEARCH AND DEVELOPMENT COSTS:**

	Year ended September 30	
	2007	2006
Clinical trials	\$ 370,066	\$ 390,717
Consulting fees	248,460	142,404
Salaries and related expenses	400,705	155,116
Costs for registration of patents	144,698	79,982
Compensation costs in respect of warrants granted to consultants	33,941	33,440
Other	134	595
	\$ 1,198,004	\$ 802,254

**NOTE 11 - GENERAL AND ADMINISTRATIVE EXPENSES**

	Year ended September 30	
	2007	2006
Payroll and related expenses	\$ 2,141,555	\$ 567,785
Consulting fees	945,643	83,113
Travel costs	152,243	99,417
Professional services	361,155	247,132
Insurance	69,501	57,481
Business development	212,299	94,786
Other	207,767	113,356
	\$ 4,090,163	\$ 1,263,070

**NOTE 12 - RELATED PARTIES - TRANSACTIONS:**

- a. On March 1, 2005, the Company entered into an agreement appointing a principal shareholder as Vice President of Business Development, in consideration of a salary of \$4,000 per month, commencing February 2005 and ended July 2, 2005. Effective July 2, 2005, this individual served as the CEO of the Subsidiary and as acting CEO of the Company, devoting approximately 70% of her time to the affairs of the Company for a monthly salary of \$6,475. On April 15, 2006, this individual resigned from her position as the acting CEO of the Company, and continued as the CEO of the Subsidiary. Payroll and related expenses in respect of this individual for the years ended September 30, 2007 and 2006 was \$111,841 and \$111,609, respectively (see also Notes 12d and 13b).

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 12 - RELATED PARTIES TRANSACTIONS** (continued):

- b.** On April 16, 2006, the Company entered into an employment agreement with its then new CEO pursuant to which the CEO will serve as CEO of the Company, effective April 15, 2006. Under the agreement, the CEO is entitled to an annual salary of \$200,000 and an annual bonus of up to \$200,000 upon achieving certain objectives. Pursuant to a separate agreement between the Company and the CEO, the Company agreed to indemnify the CEO for substantially all liabilities he may incur as a result of his employment by or service to the Company. Payroll and related expenses, including stock based compensation expenses, in respect of the CEO for the years ended September 30, 2007 and 2006 was \$1,205,028 and \$593,641, respectively.
- c.** On October 31, 2006, the Company entered into a consulting agreement with Steven Katz & Associates, Inc., ( *SKA* ), a company wholly-owned by the Company's Chairman of the Board and President, engaging it as a consultant. For the year ended September 30, 2007 the Company incurred a total of \$466,070 of consulting fees and a total of \$158,953 of stock based compensation expenses in respect of the services provided by SKA.
- d.** On May 22, 2007, the CEO of the Subsidiary was appointed as VP of Corporate Development of the Company. On the same date, the CEO of the Company assumed the position of CEO of the Company's Subsidiary.

**NOTE 13 SUBSEQUENT EVENTS:**

- a.** On October 30, 2007, a director of the Company resigned from his positions as member of the Company's Board of Directors, Audit Committee and Compensation Committee and Chairman of the Audit Committee. The departing director will continue to serve the Company as a consultant. The Company also amended the departing director's option agreements so that his 225,000 options previously granted to him will continue to vest and be exercisable under the terms of such agreements.

In connection with the foregoing resignation, on October 30, 2007, a new director was appointed to fill the vacancy on the Company's Board of Directors and was additionally appointed to the Company's Audit Committee and Compensation Committee. In connection with the appointment, the Company granted the new director options to purchase a total of 225,000 shares of its common stock under the 2007 Stock Option Plan at an exercise price of \$0.41 per share, one third vesting on each of the first, second and third anniversaries of the new director's appointment. Further, the Company entered into its standard form of indemnification agreement with the new director.

- b.** On November 30, 2007, the employment agreement with the related party serving as the VP of Corporate Development was terminated. Subsequently a consulting agreement was entered into between the Company and the related party pursuant to which the related party will perform certain consulting services as requested from time to time by the Company and will be compensated based on hours worked.

**GAMMACAN INTERNATIONAL, INC.**  
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 13 SUBSEQUENT EVENTS** (continued):

- c. On December 13, 2007, the Company entered into a Share Purchase Agreement made as of November 26, 2007 with ARP Biomed, Ltd. ( *ARP* ). The Share Purchase Agreement provides that subject to fulfillment of certain closing conditions, including the receipt of an Israeli tax ruling, ARP will sell to the Company 12.5% of the issued and outstanding shares of our Subsidiary such that at closing the Company will own 100% of the issued and outstanding shares of our Subsidiary. In consideration for such sale, the Company agreed to issue to ARP, at closing, 2,697,535 shares of its common stock, a warrant to acquire 1,123,973 shares of its common stock and an additional warrant to acquire 449,589 shares of its common stock.

In connection with the Share Purchase Agreement, ARP and our Subsidiary agreed to enter into an amendment of the agreement for the purchase and sale of intellectual property from ARP, which amendment specifically delineates clarity of title and related issues to certain intellectual property sold under the original agreement.

A member of our board of directors, is the Chief Executive Officer of ARP and the Chief Scientist of the Subsidiary, is an advisor to ARP.

- d. On December 23, 2007, the Subsidiary entered into an Amendment to the THM Agreement (the *Amendment* ) with THM. The Amendment reduces the license fees payable under the THM Agreement and clarifies, among other things, the nature of research activities pursuant to the THM Agreement. Further, the research period under the THM Agreement has been extended for a two year period, commencing January 1, 2007, and the research funding for this period totals \$500,000.

In connection with this Amendment, the Company will issue to THM a five year warrant to acquire 500,000 shares of the Company's common stock exercisable, commencing December 31, 2008, at \$0.40 per share. Pursuant to certain conditions, the Company will issue to THM an additional warrant to acquire 250,000 shares of its common stock.

F-32

---

**ITEM 8 - CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None

**ITEM 8A CONTROLS AND PROCEDURES**

**Evaluation of disclosure controls and procedures.**

An evaluation was performed under the supervision and with the participation of our management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on management's evaluation as of the end of the period covered by this Annual Report, our Chief Executive Officer and Chief Financial Officer concluded that as of the end of the period covered by this report, our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the *Exchange Act*)) were effective in ensuring that the information required to be disclosed by us in the reports that we file under the Exchange Act is gathered, analyzed and disclosed with adequate timeliness, accuracy and completeness.

**Changes in internal controls.**

There were no changes in our internal controls over financial reporting, that occurred during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 8B OTHER INFORMATION**

Amendment of Research and Licensing Agreement

The following disclosure would have otherwise been filed on Form 8-K under the heading Item 1.01 Entry into a Material Definitive Agreement. and Item 3.02 Unregistered Sales of Equity Securities.

On December 23, 2007, our subsidiary, GammaCan Ltd., entered into an Amendment of the Research and Licensing Agreement (the *Amendment*) with Tel Ha Shomer-Medical Research Infrastructure and Services LTD. ( *THM* ) originally entered into on December 13, 2005 (the *Research and Licensing Agreement* ). The Amendment reduces the license fees payable under the Research and Licensing Agreement and clarifies, among other things, the nature of research activities pursuant to the Research and Licensing Agreement. Further, the research period under the Research and Licensing Agreement has been extended for a two year period, commencing January 1, 2007, and the research funding for this period totals \$500,000.

In connection with this Amendment, we will issue to THM a five year warrant to acquire 500,000 shares of our common stock exercisable, commencing December 31, 2008, at \$0.40 per share. In addition, within 30 days of the acceptance by the FDA of each new IND application that results from work pursuant to a research project (excluding INDs pertaining to VitiGam ), we will issue to THM a warrant to acquire 250,000 shares of our common stock at an exercise price equal to the

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

closing price of our common stock on the date of issuance of such warrant. The warrants are subject to adjustment for, among other things, stock splits, stock dividends, distributions and reclassifications.

The foregoing description is a summary and is qualified in its entirety by the transaction documents attached as exhibits hereto and incorporated by reference herein.

### Amendment of Certificate of Incorporation

The following disclosure would have otherwise been filed on Form 8-K under the heading Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

On December 27, 2007, we filed with the Secretary of State of the State of Delaware, a Certificate of Amendment to our Certificate of Incorporation. Pursuant to the proposals to amend our Certificate of Incorporation approved at our Annual Meeting of Stockholders held on September 10, 2007, our Certificate of Incorporation has been amended in the following respects:

the number of our authorized shares of common stock has been increased from 100,000,000 to 200,000,000;

20,000,000 shares of our preferred stock have been classified as blank check preferred ;

a provision providing for the indemnification of our directors and officers to the fullest extent permitted by Delaware law has been added; and

a provision for the limitation of liability of our directors has been added.

The foregoing description is a summary and is qualified in its entirety by the Certificate of Amendment attached as an exhibit hereto and incorporated by reference herein.

**PART III****ITEM 9 - DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT**

Set forth below is certain information with respect to the individuals who are our directors, executive officers and significant employees.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Steven Katz	59	Chairman of the Board of Directors and President
Patrick Schnegelsberg	44	Chief Executive Officer
Albert Passner	69	Director
Yair Aloni <sup>(2)</sup>	58	Director
David DeMedio <sup>(1) (2)</sup>	36	Director
Josef Neuhaus <sup>(1) (2)</sup>	44	Director
Chaime Orlev <sup>(3)</sup>	37	Chief Financial Officer and Treasurer
Prof. Yehuda Shoenfeld, M.D. FRCP.	57	Chief Scientist of GammaCan, Ltd.

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) On November 15, 2007, Mr. Orlev tendered his resignation and has agreed to stay on in his current position at our request until no later than February 28, 2008.

**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 significant 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.

**Mr. Steven Katz** has served as our Chairman of the Board since November 2006 and since May 2007 has served as President. Mr. Katz has been, since 1982, President of Steven Katz & Associates, Inc., a health care and technology-based management consulting firm specializing in strategic planning, corporate development, new product planning, technology licensing, and structuring and securing various forms of financing. From January 2000 to October 2001, he was President and Chief Operating Officer of Senesco Technologies, Inc., an American Stock Exchange company engaged in the identification and development of proprietary gene technology with application to human, animal and plant systems. He was a co-founder and Executive Vice President, from 1983 to 1984, of S.K.Y. Polymers, Inc., a biomaterials company. Prior thereto, Mr. Katz was Vice President and General Manager of a non-banking division of Citicorp and from 1976 to 1981 held various senior management positions at National Patent Development Corporation, including President of three subsidiaries. He had been employed by Revlon, Inc. in 1975 and Price Waterhouse & Co. from 1969 to 1974. Mr. Katz received a Bachelors of Business Administration degree in Accounting from the City College of New York (CCNY) in 1969. He is presently a member of the Board of Directors of several private companies and the following publicly-held corporations: USA Technologies, Inc. (NASDAQ: USAT); NaturalNano, Inc. (OTCBB: NNAN); and Health Systems Solutions, Inc. (OTCBB: HSSO).

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

**Mr. Patrick Schnegelsberg** has served as our Chief Executive Officer since April 2006. Prior to joining us from April 2005 to April 2006, he served as Director of Investment Banking for Global Capital Markets Group (GCMG), an independent investment bank known internationally for advising on mergers and acquisitions and crafting innovative financial and strategic solutions for clients globally, with offices in New York and Sydney, Australia. Prior to GCMG Mr. Schnegelsberg served as Director of Investment Banking at Rodman & Renshaw from March 2004 to April 2005. In this position, he led M&A and private transactions for a host of significant companies in Life Sciences. Prior to entering investment banking, from March 2002 to March 2004, Mr. Schnegelsberg acted as a buy-side analyst and portfolio manager for Mehta Partners, a leading healthcare-focused hedge fund. He joined Mehta Partners after having worked for several years in the consulting industry with tenures at Booz Allen Hamilton's New York healthcare practice and at Boston-based Global Prior Art, where he founded and fostered the growth of the Company's Life Sciences practice and intellectual property practice. The client roster included top tier pharmaceutical and biotechnology companies as well as some of the top U.S. and EU IP law firms. Mr. Schnegelsberg graduated from Harvard Medical School and performed his Ph.D. thesis research in the laboratory of Dr. Rudolf Jaenisch at the Whitehead Institute/M.I.T. He published his first peer-reviewed paper as an undergraduate and since then his work has been published in peer reviewed journals including *Cell* and *Nature*.

**Mr. Yair Aloni** has served as our director since August 2004. He has more than 25 years of experience as a senior executive of a number of companies. Since 1996, Mr. Aloni has been the managing director of Megafil Ltd., an Israeli company specializing in international trading and consulting. From 2003 to 2005, he served as the Chief Executive Officer of Solidimension Ltd., a private company specializing in 3D printers. From 1997 to 2003, Mr. Aloni served as the Chief Executive Officer of Avnan Yazamut Ltd., a company involved in investing in hi-tech, biotechnology and electronics companies. Prior to 1997, Mr. Aloni was an executive or senior manager at several electronic and auto parts companies. Mr. Aloni currently serves on the board of the following publicly-held corporation: Global Energy, Inc. (OTCBB: GEYI).

**Mr. David DeMedio** has served as our director since October 2007. He currently serves as Chief Financial Officer of USA Technologies, Inc. (NASDAQ: USAT), a provider of wireless networking, cashless transactions, asset monitoring and energy management products, and has held this position since April 2005. Since joining USA Technologies in March 1999, Mr. DeMedio has held various positions including Vice President-Financial & Data Services, interim Chief Financial Officer, Director of Network and Financial Services, and Controller. Prior to joining USA Technologies, Mr. DeMedio was employed by Elko, Fischer, Cunnane and Associates, LLC as a supervisor of its accounting and auditing and consulting practice. Prior thereto, Mr. DeMedio held various accounting positions with Intelligent Electronics, Inc. Mr. DeMedio graduated with a Bachelor of Science in Business Administration from Shippensburg University and is a Certified Public Accountant.



## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

**Mr. Josef Neuhaus** has served as our director since March 2006. Mr. Neuhaus has been an independent consultant since 2004 and brings extensive experience as a senior executive in a number of companies. From August 2006 to February 2007, Mr. Neuhaus served as Chief Financial Officer, Treasurer and Secretary of Advanced Technology Acquisition Corp. (AMEX: AXC). Prior to that, between August 2005 and February 2006, Mr. Neuhaus served as Chief Financial Officer of Axis Mobile Ltd. (LSE: AXIS.L). From March 2003 to November, 2003, he served as CEO of RoadEye FLR G.P. and Managing Director of Gintec Active Safety Ltd., both private companies dealing with collision avoidance systems. During 2002, Mr. Neuhaus took a sabbatical year to complete an Executive M.B.A. From 2000 to 2001, Mr. Neuhaus was the CFO of PassCall Advanced Technologies LTD., a start-up dealing with wireless Internet. From 1998 to 2000 he was Acting Managing Director and CFO of ITA (International Tourist Attractions) Ltd. a private company initiating and building tourist attractions. From 1995 to 1998 he served as the CFO of ICTS International NV (NASDAQ: ICTS). Prior to 1995, Mr. Neuhaus was a senior auditor at Somekh Chaikin (KPMG in Israel). Mr. Neuhaus received both his M.B.A and B.A. in Accounting and Economics at the Tel Aviv University. He is an Israeli CPA. Mr. Neuhaus currently serves on the board of the following publicly-held corporation: Global Energy, Inc. (OTCBB: GEYI).

**Mr. Albert Passner** has served as our director since November 2006. He has been for more than five years a consultant in the fields of physics and engineering following an illustrious career at Lucent/AT&T Bell Labs of more than thirty years. Among his many achievements with Lucent were: the development of ultra-low noise amplifiers used to measure transistor noise; the design of the world's most powerful pulsed electromagnet; the production of a positron plasma in the laboratory; the production of the first transverse laser in semi-conductor thin film, and the demonstration that stellar images could be corrected in real time using an electronically deformed mirror. Mr. Passner has authored and co-authored more than fifty publications. Between August 2004 and December 2006, Mr. Passner served as director of Nanoscience Technologies, Inc. (OTCBB: NANS) and between June 2006 and March 2007, Mr. Passner served as director of USA Technologies, Inc. (NASDAQ: USAT). Prior to Lucent /AT&T Bell Labs, Mr. Passner served as an engineer at RCA from 1961 to 1963 and a member of the staff at the Princeton-Penn Accelerator in Princeton, N.J. from 1963 to 1969. He received a B.S. in Physics from the City College of New York in 1960 and an M.S. in Physics from New York University in 1966.

**Mr. Chaime Orlev** has served as our Chief Financial Officer since October 2005. He is a certified public accountant in Israel and prior to joining us, from September 2004 to September 2005, Mr. Orlev acted as Chief Financial Officer for Solel Solar Systems, an Israeli-based company specializing in the development, manufacturing and marketing of solar energy systems and related equipment, as well as coatings for different substrates. From April 2001 to August 2004 Mr. Orlev was the Vice President, Finance and Chief Financial Officer of Huntleigh, a provider of airport services to carriers. From 1999 to 2001 he served as Financial Controller and Acting Chief Financial Officer for ICTS International N.V. (NASDAQ:ICTS).

**Prof. Yehuda Shoenfeld, M.D. FRCP.** has served as Chief Scientist of our subsidiary since August 2004. He is one of Israel's most prominent physicians and scientists in the field of immunology. He heads the Department of Internal Medicine at Israel's largest hospital, Sheba Medical Center at Tel Ha Shomer. Professor Shoenfeld also heads the Research Center for Autoimmune Diseases at Sheba Medical Center and is a Professor of Medicine in Tel Aviv University and the 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. Fifty eight of his publications relate to intravenous IgG, of which seven focus on intravenous IgG as a treatment for cancer. Prof. Shoenfeld also serves as editor of several medical journals and as scientific consultant to a number of biotechnology companies. He received the prestigious Carol Nachman Award for Rheumatology in 2004 for outstanding innovative research work and the EULAR (European Union Congress of Rheumatology) Prize in 2005.

### **Board of Directors and Officers**

There are no agreements with respect to the election of directors. Each director is elected for a period of one year at our annual meeting of stockholders and serves until the next such meeting and until his or her successor is duly elected. The board of directors may also appoint additional directors up to the maximum number permitted under our by-laws. A director so chosen or appointed will hold office until the next annual meeting of stockholders.

There have been no events under any bankruptcy act, no criminal proceedings and no judgments, injunctions, orders or decrees material to the evaluation of the ability and integrity of any director, executive officer, or control person of the Company during the past five years.

### **Board Meeting Attendance**

During the year ended September 30, 2007, our board held 10 meetings and took actions by written consent on 26 occasions. No incumbent director of the meeting attended fewer than 75% of the aggregate of: (i) the total number of meetings of the board (during the period for which such director served as a director); and (ii) the total number of meetings held by all committees of the board on which such director served (during the period for which such director served on such committees). Board members are encouraged to attend our annual meetings of stockholders.

### **Committees**

On January 11, 2005, we established an Audit Committee and a Compensation Committee.

#### **Audit Committee**

The Audit Committee is responsible for the following:

- reviewing the results of the audit engagement with the independent auditors;
- identifying irregularities in the management of our business, and suggesting an appropriate course of action;
- reviewing the adequacy, scope, and results of the internal accounting controls and procedures;
- reviewing the degree of independence of the auditors, as well as the nature and scope of our relationship with our independent auditors;
- reviewing the auditors' fees; and
- recommending the engagement of auditors to the full board of directors.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

A charter has been adopted to govern the Audit Committee. A copy of the charter is available on our website located at [www.gammacan.com](http://www.gammacan.com). The Audit Committee members are Messrs. Josef Neuhaus (Chairman) and David DeMedio, each of whom has no other affiliation with us and is independent as defined under Rule 4200(a)(15) of the Nasdaq Marketplace Rules, even though such definition does not currently apply to us because we are not listed on Nasdaq. Each has also been determined by the board to be an audit committee financial expert as defined by the SEC.

### **Compensation Committee**

The Compensation Committee determines the salaries and incentive compensation of our executive officers, subject to outstanding employment agreements and provides recommendations for the salaries and incentive compensation of its other employees and consultants. Its members are Yair Aloni (Chairman), David DeMedio, and Josef Neuhaus. A charter has been adopted to govern the Compensation Committee. A copy of the charter is available on our website located at [www.gammacan.com](http://www.gammacan.com).

Our compensation programs are intended to enable the attraction, motivation, reward, and retention of the management talent required to achieve corporate objectives and thereby increase stockholder value. The Committee's policy has been to provide incentives to our senior management to achieve both short-term and long-term objectives and to reward exceptional performance and contributions to the development of our business. To attain these objectives, the executive compensation program may include a competitive base salary, cash incentive bonuses, and stock-based compensation.

### **Relationship of Compensation to Performance and Compensation of Executive Officers**

The Compensation Committee annually establishes, subject to the approval of our Board and any applicable employment agreement, the salaries that will be paid to our executive officers during the year. In setting salaries, the Committee takes into account several factors, including the following:

competitive compensation data;

the extent to which an individual may participate in the stock plans which may be maintained by us; and

qualitative factors bearing on an individual's experience, responsibilities, management and leadership abilities, and job performance.

### **Nomination of Directors**

Our board has not established a nominating committee because the board believes that it is unnecessary in light of our size and the fact that a majority of our five board members are independent. Our board does not utilize a nominating committee charter. In the event that vacancies on our board of directors arise, the board considers potential candidates for director, which may come to the attention of the board through current directors, professional executive search firms, stockholders or other persons. The board will consider candidates recommended by stockholders if the names and qualifications of such candidates are submitted in writing in accordance with the notice provisions for stockholder proposals to our corporate secretary at Gammacan International, Inc. Kiryat Ono Mall, Azorim Center A, 39 Jerusalem Street, 55423 Kiryat Ono, Israel. The board will consider properly submitted stockholder nominations for candidates for the board in the same manner as it evaluates other nominees. Following verification of the stockholder status of persons proposing candidates, recommendations are aggregated and considered by the board and the materials provided by a stockholder to the corporate secretary for consideration of a nominee for director are forwarded to the board. All candidates are evaluated at meetings of the board. In evaluating such nominations, the board seeks to achieve the appropriate balance of industry and business knowledge and experience in light of the function and needs of the board. The board considers candidates with excellent decision-making ability, business experience, personal integrity and reputation.

**Section 16(a) Beneficial Ownership Reporting Compliance**

Based solely upon a review of Forms 3, 4 and 5, and amendments thereto, furnished to us during fiscal year 2007, we believe that during fiscal year 2007, other than as set forth below, our executive officers, directors and all persons who own more than ten percent of a registered class of our equity securities complied with all Section 16(a) filing requirements except with respect to late filings of Form 4 of Patrick Schnegelsberg, Josef Neuhaus, Yair Aloni, Chaime Orlev, and Shmuel Levi.

**Code of Ethics**

We have adopted a Code of Ethics for our officers, directors and employees. A copy of the Code of Ethics is located at our website at [www.gammacan.com](http://www.gammacan.com).

**Part III****ITEM 10 - EXECUTIVE COMPENSATION****Summary Compensation Table**

The following table sets forth the compensation earned during the years ended September 30, 2007 and 2006 by our President and Chairman of the Board, Chief Executive Officer, our Chief Financial Officer and former Vice President of Corporate Development (the *Named Executive Officers*):

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation	All Other Compensation	Total
	(1)	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)	(\$)
Steven Katz, President and Chairman of Board <sup>(8)</sup>	2007	466,070 <sup>(9)</sup>	Nil	Nil	119,450	Nil	Nil	Nil	585,520
	2006	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Patrick Schnegelsberg, Chief Executive Officer <sup>(10)</sup>	2007	212,170	Nil	Nil	992,858	Nil	Nil	Nil	1,205,028
	2006	99,084	Nil	Nil	494,557	Nil	Nil	Nil	593,641
Vered Caplan, Former Vice President of Corporate Development <sup>(11)</sup>	2007	82,113	Nil	Nil	Nil	Nil	Nil	29,727	111,841
	2006	82,113	Nil	Nil	Nil	Nil	Nil	29,496	111,609
Chaime Orlev, Chief Financial Officer <sup>(12)</sup>	2007	94,055	Nil	Nil	121,662	Nil	Nil	25,568	241,285
	2006	74,868	Nil	Nil	174,887	Nil	Nil	21,175	270,930

- 
- (1) The information is provided for each fiscal year which begins on October 1 and ends on September 30.
- (2) No bonus awards were made to the Named Executive Officers in the fiscal years ended September 30, 2007 and 2006.
- (3) No stock awards were granted to the Named Executive Officers in the fiscal years ended September 30, 2007 and 2006.
- (4) The amounts reflect the compensation expense in accordance with FAS 123(R) of these option awards. The assumptions used to determine the fair value of the option awards for fiscal years ended September 30, 2007 and 2006 are set forth in Note 8 of our audited consolidated financial statements included in our Form 10-KSB for fiscal year ended September, 2007. Our Named Executive Officers will not realize the value of these awards in cash unless and until these awards are exercised and the underlying shares subsequently sold.
- (5) We do not have a non-equity incentive compensation plan.
- (6) We do not have a deferred non-qualified compensation plan.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

- (7) See All Other Compensation Table below.
- (8) Mr. Katz was appointed Chairman of the Board on November 6, 2006 and President on May 22, 2007
- (9) Pursuant to an agreement between the Company and Steven Katz & Associates, Inc. ( SKA ), a company wholly-owned by Steven Katz, we pay SKA consulting fees for consulting services provided. The amount includes \$216,635 paid to SKA and \$249,435 accrued but not yet paid as of September 30, 2007.
- (10) Mr. Schnegelsberg was appointed Chief Executive Officer on April 16, 2006 and served as Chief Executive Officer of our subsidiary, GammaCan Ltd, from May 22, 2007.
- (11) Ms. Caplan served as acting Chief Executive Officer from July 2, 2005 until April 15, 2006 and served as Chief Executive Officer of our subsidiary, GammaCan Ltd, from July 2, 2005 until May 22, 2007. From May 22, 2007 until November 30, 2007, Ms. Caplan served as our Vice President of Corporate Development. As of November 30, 2007 Ms. Caplan is no longer employed by the Company.
- (12) Mr. Orlev was appointed Chief Financial Officer on October 6, 2005. On November 15, 2007, Mr. Orlev tendered his resignation and has agreed to stay on in his current position at our request until no later than February 28, 2008.

**All Other Compensation Table**

All Other Compensation amounts in the Summary Compensation Table consist of the following:

<b>Name</b>	<b>Year</b>	<b>Automobile Related Expenses (\$)</b>	<b>Manager s Insurance * (\$)</b>	<b>Education Fund* (\$)</b>	<b>Total (\$)</b>
Vered Caplan	2007	15,063	11,129	3,535	29,727
	2006	15,225	11,129	3,142	29,496
Chaime Orlev	2007	9,285	12,748	3,535	25,568
	2006	7,886	10,147	3,142	21,175

---

\* Manager s insurance and education funds are customary benefits provided to employees based in Israel. Manager s insurance is a combination of severance savings (in accordance with Israeli law), defined contribution tax-qualified pension savings and disability insurance premiums. An Education fund is a savings fund of pre-tax contributions to be used after a specified period of time for educational or other permitted purposes.

**Outstanding Equity Awards at Fiscal Year-End**

The following table sets forth information concerning stock options and stock awards held by the Named Executive Officers as of September 30, 2007.

Name	Option Awards					Stock Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock Held That Have Not Vested (\$)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)
Steven Katz, President and Chairman	Nil	150,000 <sup>(1)</sup>	Nil	\$0.45	11/06/16	Nil	Nil	Nil	Nil
Patrick Schnegelsberg CEO	Nil	1,150,000 <sup>(2)</sup>	Nil	\$0.53	02/25/17	Nil	Nil	Nil	Nil
Chaime Orlev, CFO	Nil	250,000 <sup>(3)</sup>	Nil	\$0.53	02/25/17	Nil	Nil	Nil	Nil
Vered Caplan Former Vice President of Corporate Development	400,000 <sup>(4)</sup>	1,100,000 <sup>(4)</sup>	Nil	\$0.61	05/16/17	Nil	Nil	Nil	Nil
	Nil	300,000 <sup>(5)</sup>	Nil	\$0.53	02/25/17	Nil	Nil	Nil	Nil
	150,000 <sup>(6)</sup>	150,000 <sup>(6)</sup>	Nil	\$0.61	05/16/17	Nil	Nil	Nil	Nil

- (1) On November 7, 2006, Mr. Katz was granted options under the 2004 Stock Option Plan to purchase 150,000 shares of our common stock at an exercise price of \$0.45 per share. These options are exercisable with respect to 37,500 shares on November 7, 2007 and the remaining in equal installments on the last day of each month for 36 months thereafter.
- (2) On February 26, 2007, Mr. Katz was granted options under the 2007 Stock Option Plan to purchase 1,150,000 shares of our common stock at an exercise price of \$0.53 per share, one third of which vest on each of the first, second and third anniversaries of the grant date.
- (3) On February 26, 2007, Mr. Schnegelsberg was granted options under the 2007 Stock Option Plan to purchase 250,000 shares of our common stock at an exercise price of \$0.53, one third of which vest on each of the first, second and third anniversaries of the grant date.
- (4) On May 17, 2007, the grant of options to Mr. Schnegelsberg under the 2004 Stock Option Plan to purchase 1,400,000 shares of our common stock at an exercise price of \$1.29 per share was cancelled. On the same day, Mr. Schnegelsberg was granted options under the 2007 Stock Option Plan to purchase 1,500,000 shares of our common stock at an exercise price of \$0.61 per share. These options are exercisable with respect to 400,000 on the grant date and the remaining 1,100,000 in two equal installments on the first and second anniversary of the grant date.
- (5) On February 26, 2007, Mr. Orlev was granted options to purchase 300,000 shares of our common stock at an exercise price of \$0.53, one third of which vest on each of the first, second and third anniversaries of the grant date.
- (6) On May 17, 2007, the grant of options to Mr. Orlev under the 2004 Stock Option Plan to purchase 350,000 shares of our common stock at an exercise price of \$0.93 per share was cancelled. On the same day, Mr. Orlev was granted options under the 2007 Stock Option Plan to purchase 300,000 shares of our common stock at an exercise price of \$0.61. These options are exercisable with respect to 150,000 on

the grant date and the remaining 150,000 in two equal installments on the first and second anniversaries of the grant date.



## Stock Option Plans

### 2004 Employees and Consultants Stock Option Plan

On August 17, 2004, our board adopted the 2004 Employees and Consultants Stock Option Plan in order to attract and retain quality personnel. Under the 2004 Plan, 5,000,000 shares have been reserved for the grant of options by the board. As of September 30, 2007, options with respect to 1,515,000 shares have been granted under the 2004 Stock Option Plan.

### 2007 Global Share Option Plan

On February 26, 2007, our board adopted the 2007 Global Share Option Plan in order to attract and retain quality personnel. Under the 2007 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. As of September 30, 2007, options exercisable for an aggregate of 4,285,000 shares have been granted.

## Employment and Consulting Agreements

On August 17, 2004, our subsidiary, GammaCan, Ltd. entered into a consultancy agreement with Professor Yehuda Shoenfeld, M.D., providing for a monthly compensation of 22,685 NIS (approximately \$5,300 as of the date hereof) for his services as the Chief Scientist of GammaCan, Ltd. Either Prof. Shoenfeld or GammaCan, Ltd. may terminate the agreement without cause, for any reason, with 30 days notice.

On March 1, 2005, GammaCan, Ltd. entered into an employment agreement with Vered Caplan for her to be Vice President of Business Development and provide at least 20 hours of service per week for a salary of \$4,000 per month. She was appointed as acting Chief Executive Officer of both the Company and its subsidiary, effective July 2, 2005 at a salary of \$6,475 per month. Ms. Caplan has devoted approximately 70% of her business time during the period to the affairs of both companies. She resigned from her position as our acting Chief Executive Officer, effective April 15, 2006. As of May 22, 2007, Ms. Caplan became our Vice President of Corporate Development and commencing with this appointment, Ms. Caplan ceased her service as Chief Executive Officer of our subsidiary. As of November 30, 2007, Ms. Caplan is no longer employed by the Company. We subsequently entered into a consulting agreement with Ms. Caplan whereby she will perform certain consulting services as requested from time to time by us and will be compensated based on hours worked.

On September 6, 2005, GammaCan, Ltd. entered into an employment agreement with Chaime Orlev pursuant to which he has served as Chief Financial Officer of the Company and its subsidiary since October 6, 2005. He received a salary pursuant to the agreement of 25,000 NIS per month (approximately US\$5,800, as of the date hereof), which was increased on April 16, 2006 to \$6,500 per month. His salary was subsequently increased on October 24, 2007 to \$8,333 effective from April 1, 2007. The agreement provided for the grant of 350,000 of our stock options at an exercise price of \$0.93 per share. On May 17, 2007, these options were cancelled and surrendered for options to purchase 300,000 shares of our common stock at an exercise price of \$0.61. These options are exercisable with respect to 150,000 on the grant date and the remaining 150,000 in two equal installments on the first and second anniversary of the grant date. Previously, on February 26, 2007, Mr. Orlev was granted options to purchase 300,000 shares of our common stock at an exercise price of \$0.53, one third of which vest on each of the first, second and third anniversaries of the grant date. The agreement further provided for the provision of a company car and manager's insurance as well as the maintenance of an education fund.

On April 16, 2006, we entered into an agreement with Patrick Schnegelsberg employing him as our Chief Executive Officer. The agreement provides for an annual salary of \$200,000 and an annual bonus of up to \$200,000 upon achieving certain objectives. The agreement provided for the grant of 1,400,000 stock options at an exercise price of \$1.29 per share. On May 17, 2007, these options were cancelled and surrendered for options to purchase 1,500,000 shares of our common stock at an exercise price of \$0.61. These options are exercisable with respect to 400,000 on the grant date and the remaining 1,100,000 in two equal installments on the first and second anniversary of the grant date. Previously on February 26, 2007, Mr. Schnegelsberg was granted options to purchase 250,000 shares of our common stock at an exercise price of \$0.53, one third of which vest on each of the first, second and third anniversaries of the grant date. If we terminate Mr. Schegelsberg's employment without cause, he shall continue to be entitled to his compensation under the employment agreement during the advance notice of termination period which is 45 days during the first year of employment, 90 days during the second year of employment and 180 days thereafter.

On October 31, 2006, we entered into a consulting agreement with Steven Katz & Associates, Inc., ( SKA ), a company wholly-owned by Steven Katz, the Company's Chairman of the Board and President, engaging it as a consultant at a fee of \$345 per hour.

On December 20, 2007, we entered into an indemnification agreement with our directors and officers which supersedes any indemnification agreements previously entered into with such individuals.

### **Director Compensation**

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. Effective October 1, 2006, each outside director is entitled to receive as remuneration for his or her service as a member of the board a sum equal to US\$8,000 per annum, to be paid quarterly and shortly after the close of each quarter. Effective as of October 1, 2007, this amount was increased to \$12,000. The board of directors may award special remuneration to any director undertaking any special services on behalf of us 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.

Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

The following table sets forth director compensation for the year ended September 30, 2007.

Name of Director	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation	All Other Compensation (\$)	Total (\$)
Yair Aloni	\$8,000	Nil	\$ 78,564 <sup>(1)</sup>	Nil	Nil	Nil	\$ 86,564
Steven Katz <sup>(2)</sup>	Nil	Nil	\$ 39,503 <sup>(1)</sup>	Nil	Nil	Nil	\$ 39,503
Shmuel Levi <sup>(3)</sup>	\$8,000	Nil	\$ 78,564 <sup>(1)</sup>	Nil	Nil	Nil	\$ 86,564
Josef Neuhaus	\$8,000	Nil	\$ 89,502 <sup>(1)</sup>	Nil	Nil	Nil	\$ 97,502
Albert Passner	\$8,000	Nil	\$ 39,503 <sup>(1)</sup>	Nil	Nil	Nil	\$ 47,503

- 
- (1) The amounts reflect the compensation expense in accordance with FAS 123(R) of these option awards. The assumptions used to determine the fair value of the option awards are set forth in Note 8 of our audited consolidated financial statements included in this Form 10-KSB. Our directors will not realize the value of these awards in cash unless and until these awards are exercised and the underlying shares subsequently sold.
- (2) Please refer to the summary compensation table for executive compensation with respect to the named individual.
- (3) On October 30, 2007, Mr. Levi resigned from our board of directors and our audit and compensation committees. His vacancy was filled by Mr. DeMedio.

**ITEM 11- SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The following table sets forth certain information regarding beneficial ownership of our common stock as of September 30, 2007 by (i) by each person who is known by us to own beneficially more than 5% of our common stock, (ii) by each of the Named Executive Officers and (iv) by all our directors and executive officers as a group. On such date, we had 44,958,917 shares of common stock outstanding.

As used in the table below and elsewhere in this Annual Report on Form 10-KSB, the term *beneficial ownership* with respect to a security consists of sole or shared voting power, including the power to vote or direct the vote and/or sole or shared investment power, including the power to dispose or direct the disposition, with respect to the security through any contract, arrangement, understanding, relationship, or otherwise, including a right to acquire such power(s) during the next 60 days following September 30, 2007.

Name and address of Beneficial Owner	Number of Shares	Percentage of Shares Beneficially Owned
Andrew Lessman 430 Parkson Rd. Henderson, NV	7,666,668 <sup>(1)(16)</sup>	15.7
MM&B Holdings, a California general partnership 23622 Calabassas Road Calabassas, California	5,293,334 <sup>(2)(16)</sup>	11.2
Zeev Bronfeld 6 Uri St. Tel Aviv, Israel	3,900,006	8.7
Vered Caplan 69 Deganya St. Pardes Hanna Karkur, Israel	3,900,006	8.7
JMG Triton Offshore Fund Ltd 11601 Wilshire Blvd., Suite 2180 Los Angeles, CA 90025	3,000,000 <sup>(3)(16)</sup>	6.5
JMG Capital Partners LP 11601 Wilshire Blvd., Suite 2180 Los Angeles, CA 90025	3,000,000 <sup>(3)(16)</sup>	6.5
Ram Capital Group LLC 1974 Sproul Road, Suite 204 Broomall, PA 19008	2,500,000 <sup>(4)(16)</sup>	5.4

Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

Bristol Investment Fund Ltd 10990 Wilshire Blvd., Suite 1410 Los Angeles, CA 90024	2,394,800 <sup>(4)(16)</sup>	5.2
Yair Aloni <sup>(5)</sup> 12A Shabazy St. Tel Aviv, Israel	310,005 <sup>(6)</sup>	*
Steven Katz <sup>(5)(7)</sup> 20 Rebel Run Drive East Brunswick NJ 08816	37,500 <sup>(9)</sup>	*
Josef Neuhaus <sup>(5)</sup> 45 Eliezer Yafeh St. Ra'anana, Israel	15,000 <sup>(10)</sup>	*
Albert Passner <sup>(5)</sup> 3 Disbrow Court East Brunswick, NJ 08816	37,500 <sup>(9)</sup>	*
Shmuel Levi <sup>(11)</sup> 14 Hanita St. Naharia, Israel	30,000 <sup>(12)</sup>	*
Patrick Schnegelsberg <sup>(7)</sup> 100 John St. 2901 New York, NY	400,000 <sup>(13)</sup>	*
Chaime Orlev <sup>(7)</sup> 10 Hameyasdim St. Kiryat-Ono, Israel	150,000 <sup>(14)</sup>	*
Prof. Yehuda Shoenfeld, M.D. <sup>(8)</sup> 26 Sapir St. Ramat Gan, Israel	699,996	1.6
All current Executive Officers and Directors as a group (eight persons)	1,680,001 <sup>(15)</sup>	3.7

\* Less than 1%

- (1) Includes 3,833,334 shares of common stock issuable upon the exercise of warrants beneficially owned by the referenced entity.
- (2) Includes 2,500,000 shares of common stock issuable upon the exercise of warrants beneficially owned by the referenced entity.
- (3) Includes 1,500,000 shares of common stock issuable upon the exercise of warrants beneficially owned by the referenced entity.
- (4) Includes 1,250,000 shares of common stock issuable upon the exercise of warrants beneficially owned by the referenced entity.
- (5) Indicates Director.
- (6) Includes 30,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (7) Indicates Officer.
- (8) The referenced individual serves as our subsidiary's Chief Scientist and for the purposes of this table only is considered an executive officer.
- (9) Consists of 37,500 shares of common stock issuable upon the exercise of outstanding stock options.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

- (10) Consists of 15,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (11) The referenced individual resigned from our board of directors and our audit and compensation committees on October 30, 2007. His vacancy was filled by Mr. DeMedio.
- (12) Consists of 30,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (13) Consists of 400,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (14) Consists of 150,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (15) Includes 700,000 shares of common stock issuable upon the exercise of outstanding stock options.
- (16) Notwithstanding the inclusion of warrants beneficially owned by the referenced entity in the beneficial ownership calculation, the warrants provide that the holder of the warrants shall not have the right to exercise any portion of the warrants, and we shall not effect any exercise of such warrants, to the extent that after giving effect to such issuance after exercise such holder of the warrants, together with his, her or its affiliates, would beneficially own in excess of 4.99% of the number of shares of common stock outstanding immediately after giving effect to such issuance. Such 4.99% limitation may be waived by each holder upon not less than 61 days prior notice to change such limitation to 9.99% of the number of shares of common stock outstanding immediately after giving effect to such issuance.

**ITEM 12 - 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 required to be disclosed pursuant to Item 404 of Regulation S-B.

Our policy is to enter into transactions with related parties on terms that, on the whole, are no less favorable than those available from unaffiliated third parties. Based on our experience in the business sectors in which we operate and the terms of our transactions with unaffiliated third parties, we believe that all of the transactions described below met this policy standard at the time they occurred.

On December 13, 2007, we entered into a Share Purchase Agreement made as of November 26, 2007 with ARP. The Share Purchase Agreement provides that, subject to fulfillment of certain closing conditions, including the receipt of an Israeli tax ruling, ARP will sell to us 12.5% of the issued and outstanding shares of our subsidiary such that at closing we will own 100% of the issued and outstanding shares of our subsidiary. In consideration for such sale, we agreed to issue to ARP, at closing, 2,697,535 shares of our common stock, a warrant to acquire 1,123,973 shares of our common stock and an additional warrant to acquire 449,589 shares of our common stock. Both warrants are exercisable for five years at an exercise price

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

equal to the average last sales price of our common stock during the sixty trading days prior to November 26, 2007. The warrants are subject to adjustment for, among other things, stock splits, stock dividends, distributions and reclassifications. In the case of the warrant to acquire 1,123,973 shares, if there is a change of control (as defined therein), then subject to certain restrictions, the warrant shall be deemed exercised in full and no exercise price shall be payable by the holder. The securities (and underlying securities) to be issued under the Share Purchase Agreement will also be subject to a separate lock up agreement and registration rights agreement upon issuance.

In connection with the Share Purchase Agreement, ARP and our subsidiary agreed to enter into an amendment of the agreement for the purchase and sale of intellectual property from ARP, which amendment specifically delineates clarity of title and related issues to certain intellectual property sold under the original agreement.

Mr. Yair Aloni, a member of our board of directors, is the Chief Executive Officer of ARP and Professor Yehuda Shoenfeld, M.D., our Chief Scientist of our subsidiary, is an advisor to ARP.

See Employment and Consultancy Agreements above for information as to the agreements with our employees and consultants.



## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

### ITEM 13 EXHIBITS

#### Exhibits:

Number	Exhibit
3.1	Certificate of Incorporation, incorporated by reference to the Registration Statement on Form 10-SB filed with the Commission on June 4, 2001.
3.2	Certificate of Amendment to Certificate of Incorporation dated May 28, 2004 incorporated by reference to Current Report on Form 8-K filed with the Commission on June 8, 2004.
3.3	Certificate of Amendment to Certificate of Incorporation dated August 19, 2004 incorporated by reference to Current Report on Form 8-K filed with the Commission on August 27, 2004.
3.4	Certificate of Amendment to Certificate of Incorporation dated December 27, 2007.*
3.5	By-Laws, incorporated by reference to the Registration Statement on Form 10-SB filed with the Commission on June 4, 2001.
4.1	2004 Employees and Consultants Stock Compensation Plan, incorporated by reference to Current Report on Form 8-K filed with the Commission on September 1, 2004.
4.2	2007 Global Share Option Plan.*
10.1	Sale of Intellectual Property Agreement dated as of June 11, 2004 between GammaCan, Ltd. and ARP Biomed, Ltd., incorporated by reference to Current Report on Form 8-K filed with the Commission on June 22, 2004.
10.2	Services Agreement dated August 17, 2004 between GammaCan, Ltd. and Prof. Yehuda Shoenfeld, M.D., incorporated by reference to Current Report on Form 8-K filed with the Commission on September 1, 2004.
10.3	Consulting agreement between GammaCan Ltd. and PBD Ltd., dated as of November 4, 2004, incorporated by reference to Form 8-K dated as of November 4, 2004
10.4	Employment Agreement between GammaCan, Ltd. and Vered Caplan, dated as of June 21, 2005, incorporated by reference to Current Report on Form 8-K filed with the Commission on June 27, 2005.
10.5	Employment Agreement between GammaCan, Ltd. and Chaime Orlev, dated as of September 6, 2005, incorporated by reference to Current Report on Form 8-K filed with the Commission on September 12, 2005.
10.6	Research and Licensing Agreement dated December 13, 2005 between Gammacan Ltd and Tel Hashomer Medical Research Infrastructure and Services Ltd., incorporated by reference to Current Report on Form 8-K filed with the Commission on December 19, 2005.
10.7	Employment Agreement between GammaCan, Ltd. and Patrick Schnegelsberg, dated as of April 16, 2006, incorporated by reference to Current Report on Form 8-K filed with the Commission on April 19, 2006.
10.9	8% Convertible Promissory Note issued November 20, 2006 incorporated by reference to Current Report on Form 8-K filed with the Commission on November 22, 2006.
10.10	Form of Securities Purchase Agreement from the private placement that closed on February 27, 2007 incorporated by reference to Current Report on Form 8-K filed with the Commission on March 1, 2007.
10.11	Form of Stock Purchase Warrant from the private placement that closed on February 27, 2007 incorporated by reference to Current Report on Form 8-K filed with the Commission on March 1, 2007.
10.12	Form of Lock Up Agreement from the private placement that closed on February 27, 2007 incorporated by reference to Current Report on Form 8-K filed with the Commission on March 1, 2007.
10.13	Form of Registration Rights Agreement from the private placement that closed on February 27, 2007 incorporated by reference to Current Report on Form 8-K filed with the Commission on March 1, 2007.

## Edgar Filing: GAMMACAN INTERNATIONAL INC - Form 10KSB

- 10.14 Agreement for the Purchase and Sale of Blood Plasma between GammaCan Ltd. and DCI Management Group, LLC incorporated by reference to Current Report on Form 8-K filed with the Commission on October 5, 2007.
- 10.15 Form of Indemnification Agreement between GammaCan International, Inc. and its directors and officers.\*
- 10.16 Share Purchase Agreement made as of November 26, 2007 between GammaCan International, Inc. and ARP BioMed, Ltd. incorporated by reference to Current Report on Form 8-K filed with the Commission on December 19, 2007.
- 10.17 Form of Amendment to Sale of Intellectual Property Agreement effective as of November 26, 2007 between GammaCan, Ltd. and ARP BioMed, Ltd. incorporated by reference to Current Report on Form 8-K filed with the Commission on December 19, 2007.
- 10.18 Form of Warrant to be issued to ARP BioMed, Ltd. under the Share Purchase Agreement incorporated by reference to Current Report on Form 8-K filed with the Commission on December 19, 2007.
- 10.19 Form of Additional Warrant to be issued to ARP BioMed, Ltd. under the Share Purchase Agreement incorporated by reference to Current Report on Form 8-K filed with the Commission on December 19, 2007.
- 10.20 Form of Registration Rights Agreement made as of November 26, 2007 between ARP BioMed, Ltd. and GammaCan International, Inc. incorporated by reference to Current Report on Form 8-K filed with the Commission on December 19, 2007.
- 10.21 Form of Lock-Up Agreement made as of November 26, 2007 between ARP BioMed, Ltd. and GammaCan International, Inc. incorporated by reference to Current Report on Form 8-K filed with the Commission on December 19, 2007.
- 10.22 Form of Amendment to Research and Licensing Agreement effective as of December 23, 2007 between GammaCan Ltd. and Tel Ha Shomer Medical Research Infrastructure and Services Ltd.+
- 14 Code of Ethics incorporated by reference to Form 10KSB for the year ended September 30, 2007 filed with the Commission on January 13, 2005.
- 21.1 List of Subsidiaries.\*
- 31.1 Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.\*
- 31.2 Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d 14(a), promulgated under the Securities and Exchange Act of 1934, as amended.\*
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).\*
- 32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).\*

\* Filed herewith

+ We have requested confidential treatment with respect to this exhibit. In the event that the Commission should deny such request in whole or in part, such exhibit or the relevant portions thereof shall be filed by amendment to this Annual Report on Form 10-KSB.

**ITEM 14 - PRINCIPAL ACCOUNTANT FEES AND SERVICES**

We incurred the following fees to Kesselman & Kesselman, certified public accountants (Isr.), a member of PriceWaterhouse Coopers International Limited, for services rendered during the fiscal year ended September 30, 2007 and 2006:

<u>Summary:</u>	<u>2007</u>	<u>2006</u>
Audit fees <sup>(1)</sup>	\$95,000	\$74,000
Audit related fees <sup>(2)</sup>	\$18,400	
Tax fees <sup>(3)</sup>	\$ 5,500	\$ 5,000
Other fees		

- 
- (1) Amount represents fees paid for professional services for the audit of our consolidated annual financial statements and review of our interim consolidated financial statements included in quarterly reports and services that are normally provided by Kesselman & Kesselman in connection with statutory and regulatory filings or engagements.
- (2) Amount represents fees paid for professional services for assurance and related services by Kesselman & Kesselman that are reasonably related to the performance of the audit or review of our financial statements and are not reported under item (1).
- (3) Amount represents fees paid for professional services for tax compliance and tax advice.

**SIGNATURES**

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

**GAMMACAN INTERNATIONAL, INC.**

/s/ PATRICK SCHNEGELSBERG

---

Patrick Schnegelsberg,  
Chief Executive Officer  
(principal executive officer)

/s/ CHAIME ORLEV

---

Chaime Orlev,  
Chief Financial Officer  
(principal accounting officer)

Date: December 28, 2007

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities as on December 28, 2007.

/s/ STEVEN KATZ

---

Steven Katz,  
Chairman of the Board

/s/ ALBERT PASSNER

---

Albert Passner,  
Director

/s/ YAIR ALONI

---

Yair Aloni,  
Director

/s/ DAVID DEMEDIO

---

David DeMedio,  
Director

/s/ JOSEF NEUHAUS

---

Josef Neuhaus,  
Director