

GAMMACAN INTERNATIONAL INC
Form 424B3
August 20, 2007

Reg. No. 333-145026

Filed pursuant to Rule 424(b)(3)

16,583,753 Shares

Common Stock

This is an offering (the "*Offering*") of up to an aggregate of 16,583,753 shares (the "*Shares*") of common stock, \$0.0001 par value, of GammaCan International, Inc., a Delaware corporation ("*we*", "*us*", or "*GammaCan*"), by the selling stockholders named in this prospectus (the "*Selling Stockholders*"). Of the Shares, 16,250,000 Shares are issuable upon the exercise of warrants (the "*Private Placement Warrants*") issued by us in a private placement (the "*Private Placement*") of securities exempt from the registration requirements of the Securities Act of 1933, as amended (the "*Securities Act*"), in February 2007, and 250,000 Shares are issuable upon the exercise of warrants (the "*Consulting Warrants*") and, together with the Private Placement Warrants, the "*Warrants*") issued by us to consultants in June 2007 in a transaction exempt from the registration requirements of the Securities Act.

Our common stock is quoted on the OTC Bulletin Board (the "*OTCBB*") under the symbol "*GCAN.OB*". On July 24, 2007, the closing sales price of our common stock on the OTCBB was \$0.48 per share.

See "**Risk Factors**" beginning on page 7 for a discussion of factors that you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

We will receive no proceeds from the sale of the Shares sold by the Selling Stockholders.

The date of this prospectus is August 13, 2007.

TABLE OF CONTENTS

	Page
<u>Prospectus Summary</u>	3
<u>The Offering</u>	5
<u>Summary Consolidated Financial Data of Gammacan International, Inc.</u>	6
<u>Risk Factors</u>	7
<u>Special Note Regarding Forward-Looking Statements</u>	16
<u>Use of Proceeds</u>	17
<u>Dividend Policy</u>	17
<u>Capitalization</u>	18
<u>Selected Consolidated Financial Data</u>	19
<u>Management's Discussion and Analysis and Plan of Operations</u>	20
<u>Business</u>	29
<u>Market Price for the Common Stock</u>	42
<u>Management</u>	43
<u>Certain Relationships and Related Party Transactions</u>	51
<u>Principal and Management Stockholders</u>	52
<u>Selling Stockholders</u>	54
<u>Description Of Capital Stock</u>	57
<u>Shares Eligible For Future Sale</u>	59
<u>Plan Of Distribution</u>	61
<u>Legal Matters</u>	63
<u>Experts</u>	63
<u>Where You Can Find More Information</u>	63

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information that you should consider before investing in our common stock. You should carefully read the entire prospectus, especially the risks of investing in our common stock discussed under “Risk Factors”. Unless we state otherwise, the terms “we”, “us”, “our”, “company”, “management”, or similar terms collectively refer to GammaCan International, Inc., a Delaware corporation, and its subsidiary, as well as their respective predecessors. Some of the statements in this “Prospectus Summary” are forward-looking statements. See “Special Note Regarding Forward-Looking Statements”. All dollar amounts refer to US dollars unless otherwise indicated.

Our Business

General

We are a life sciences company focused upon the development of immunotherapy and related approaches to treat cancer. To date, we have focused upon the use of intravenous immunoglobulin, or *IgG*, derived from human plasma provided by healthy donors to treat melanoma, prostate, and colon cancers. We believe that *IgG* may be the basis of more effective and efficient cancer treatment both, as mono- or combination therapy and adjuvant cancer treatments. Our business objective is to become a recognized leader in the development of immunotherapy and related approaches to treat cancer.

Based upon our research, it appears that non-specific *IgG* has anti-cancer properties. These properties appear to be due to both the immunomodulatory effects of *IgG*, as well as direct effects of certain antibody populations present in the *IgG* mixture. We have demonstrated a reduction in metastatic lesions and an improved survival in mice injected with human sarcoma or human melanoma cells when the animals were treated with *IgG*. There is also anecdotal clinical evidence suggesting that *IgG*-based therapy is efficacious in some human cancers, including melanoma, soft tissue sarcoma, and Kaposi’s sarcoma. *IgG* has also been found to dramatically reduce the white blood count in chronic lymphocytic leukemia. Based upon the foregoing, we recognize that *IgG*-based therapies possess the following distinctive features as a result of an excess of thirty years of clinical experience from treating immune deficiency and autoimmune diseases as well as manufacturing know-how:

- *Superior product safety* - *IgG* is safe and non-toxic; and
- *Minimal manufacturing risk* – The manufacturing process for *IgG* is well established and optimized as a result of the numerous products that have been developed from human plasma to date.

We have developed and are developing additional product candidates on the basis of our research and development to date. 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 2% of the general population. We are initially utilizing VitiGam™ to target melanoma. We have demonstrated that plasma from individuals with vitiligo contains anti-melanoma activities and we are using this discovery to develop VitiGam™ for the treatment of Stage III and Stage IV melanoma. The incidence of melanoma, despite new developments in other cancers, continues to increase and has experienced little if any therapeutic progress in the last ten years. In addition to VitiGam™, we are developing the following:

- *Adjuvant therapies* - *IgG*-based adjuvant therapies to modulate both the proliferation of cancer cells and the metastasis of tumor cells.
- *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 that 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* will also allow 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 mechanism associated with VitiGam™, we may be in a position to develop such a vaccine in the future.

We embarked on a non-FDA Phase II clinical trial to test the safety and efficacy of “standard” (e.g., collected and manufactured from healthy donors) *IgG* in patients with three types of late stage malignancies that have failed to respond to all other standard therapies as well as certain experimental therapies. The cancers evaluated in the non-FDA, open-label Phase II trial were:

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melanoma, prostate, and colon cancer. Patients in the study received standard IgG at a consistent dose every 28 days (a cycle). Patients were evaluated by standard criteria for tumor progression and other markers after three cycles, and if stable or improved, such treatment continues for three additional cycles. The study closed in June 2007. Results from melanoma patients are promising and can be summarized as follows:

- No serious untoward effects of IgG were noted; and
- One patient with melanoma (out of 8) and one with prostate cancer (out of 9) have been stable or improved at six cycles of therapy or beyond. Indeed, the melanoma patient has completed twelve cycles, after which tumor progression was noted.

In addition to the body of pre-clinical evidence accumulated using vitiligo derived plasma or IgG, observations with melanoma patients in this study provide a clinical foundation for the current plan to develop VitiGam™.

We plan to file an Investigational New Drug Application, or *IND*, for VitiGam™ in late 2007. We believe that the FDA is well acquainted with IgG-based therapies and their non-toxic characteristics from a long history of approvals of products based on plasma.

We own a significant portfolio of patents and patent applications covering our technology and are aggressively protecting our technology developments on a worldwide basis. In addition to protecting our intellectual property, we are currently applying for a U.S. Orphan Drug Status designation for VitiGam™. Orphan Drug Status is granted by the U.S. FDA to promote the development of drugs for diseases affecting less than 200,000 people in the United States. This status will provide, if granted, a seven year period of market exclusivity as well as regulatory and income tax advantages. We are continuously evaluating in-licensing and/or acquisition opportunities to broaden our product portfolio and technology base.

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

Our Background

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 businesses and acquisition plans. On August 17, 2004, 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*”), GammaCan Ltd. completed the acquisition of ARP’s intellectual property (the “*Intellectual Property*”) in consideration for the issuance to ARP of 12.5% of the common shares of GammaCan, Ltd. As a result, we own beneficially and of record 87.5% of the outstanding capital stock of our subsidiary, GammaCan, Ltd. On August 19, 2004, we changed the name of our company to GammaCan International, Inc. in the State of Delaware.

The Offering

Common stock offered	16,583,753 shares
Common stock outstanding after this offering	61,458,917 shares (1)
Use of proceeds after expenses	For general corporate purposes and working capital. See "Use of Proceeds."
OTC Bulletin Board Trading Symbol.	GCAN.OB

(1) Assumes the exercise in full of the Warrants.

Unless otherwise indicated, the information contained in this prospectus does not give effect to the issuance of shares of our common stock upon exercise of the Warrants.

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with different information. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate as of the date on the front cover of this prospectus only. Our business, prospects, financial condition, and results of operations may have changed since that date.

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Summary Consolidated Financial Data of Gammacan International, Inc.

The following statement of operations data for the years ended September 30, 2006 and 2005, and the balance sheet data at September 30, 2006 and 2005, are derived from our audited consolidated financial statements and the related notes. Our consolidated financial statements and the related notes as of September 30, 2006 and 2005 and for the two years then ended are included elsewhere herein. The statement of operations data for the six months ended March 31, 2007 and 2006, and the balance sheet data at March 31, 2007 and 2006, are derived from our unaudited consolidated financial statements, which have been prepared on a basis consistent with our audited financial statements except for the change in accounting for stock based compensation upon the adoption of FAS 123R on October 1, 2006, and, in the opinion of management, include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of our financial position and results of operations. The results of operations for any interim period are not necessarily indicative of results to be expected for the entire year. The following data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

Statement of Operations Data:

	Years Ended September 30,		Period from October 6, 1998 through September 30,	Six Months Ended March 31,		Period from October 6, 1998 through March 31,
	2006	2005	2006	2007	2006	2007
Research and development costs	\$ 802,254	\$ 545,928	\$ 1,515,174	\$ 482,870	\$ 599,543	\$ 1,998,044
General and administrative expenses	1,263,070	666,477	2,288,711	1,631,800	455,188	3,920,511
Operating losses	2,065,324	1,212,405	3,803,885	2,114,670	1,054,731	5,918,555
Financial income	(44,130)	(20,703)	(64,833)	(32,138)	(23,787)	(96,971)
Financial expenses	14,979	6,830	22,144	21,467	6,699	43,581
Loss before taxes on income	2,063,173	1,198,532	3,761,166	2,103,999	1,037,643	5,865,165
Taxes on income	28,622	—	28,622	16,856	—	45,478
Loss from operations of the company and its consolidated subsidiary	2,064,795	1,198,532	3,789,788	2,120,855	1,037,643	5,910,643
Minority interests in losses of a subsidiary	—	—	(12,375)	—	—	(12,375)
Net loss	\$ (2,064,795)	\$ (1,198,532)	\$ (3,777,413)	\$ (2,120,855)	\$ (1,037,643)	\$ (5,898,268)

Earnings per Share

Information:

Basic and diluted net loss per share	\$ (0.074)	\$ (0.046)	\$ (0.068)	\$ (0.038)
Shares used in computing basic and diluted loss per common share	28,052,065	26,099,260	31,204,923	27,650,399

Balance Sheet Data:

At September 30,

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	At March 31,		
	2006	2005	2007
Cash and cash equivalents	\$ 538,738	\$ 713,342	\$ 1,463,098
Short-term deposit	—	—	4,300,000
Working capital(1)	222,133	567,753	4,964,896
Total assets	619,820	764,787	5,914,903
Long-term debt	31,531	13,725	45,924
Stockholders' equity	259,190	577,028	4,996,637

(1) Working capital is calculated by subtracting the current liabilities from the current assets.

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. If sufficient capital is not available, we would likely be required to scale back or terminate our research and development efforts. We estimate that, as a result of the 2007 Private Placement, our cash reserves will be sufficient to permit us to continue our anticipated level of operations for at least five months from the date of this prospectus. However, we plan to increase research and development, product development, and administrative expenses relating to our business during 2007 and 2008, including expenses related to research and development related to our IgG technology. We intend to use these resources, as well as others in the event that they shall be available on commercially reasonable terms, to fund 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. 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.

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 of 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. We have experienced net losses and negative cash flows from operating activities since inception and expect such losses and negative cash flows to continue in the foreseeable future. As of September 30, 2006 and 2005 and as of March 31,

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2007, we had working capital of \$222,133, \$567,753, and \$4,964,896, respectively, and stockholders' equity of \$259,190, \$577,028, and \$4,996,637, respectively. See the consolidated financial statements and the related notes. We have generated no revenues to date. We have incurred net losses since inception and expect to continue to operate at a loss for the foreseeable future. For the period from our inception in October 6, 1998 through March 31, 2007, the years ended September 30, 2006 and 2005, and for the six months ended March 31, 2007, we incurred net losses of \$(5,898,268), \$(2,064,795), \$(1,198,532), and \$(2,120,855), respectively. We may never achieve profitability. See "Management's Discussion and Analysis of Financial Condition and Results of Operations".

We are a development stage company with a history of high general and administrative expenses.

We are a development stage company and have historically incurred high general and administrative expenses. For the period from our inception in October 6, 1998 through March 31, 2007, the years ended September 30, 2006 and 2005, and for the six months ended March 31, 2007, we incurred general and administrative expenses of \$3,920,511, \$1,263,070, \$666,477, and \$1,631,800, respectively. Of these costs, \$1,065,453, \$163,517, \$0, and \$839,336, respectively, are non-cash expenses related to employees and consultants stock based compensation expenses. We estimate that our non-cash expenses related to employees and consultants stock based compensation will increase in future years as a result of additional stock based compensation issued as well as the implementation of FAS 123R. The general and administrative expenses is estimated to continue increasing and future funds raised will be used to cover these expenses as well as the continuing of our research and development programs.

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 at 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 IgG 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 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 o