GAMMACAN INTERNATIONAL INC
Form POS AM
August 26, 2008

As filed with the Securities and Exchange Commission on August 26, 2008

File No. 333-145026

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 2
ON FORM S-1
TO
FORM SB-2
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

GAMMACAN INTERNATIONAL, INC.

(Exact Name of Registrant as Specified In Its Charter)

Delaware	**2836**	**33-0956433**
(State Or Other Jurisdiction Of Incorporation Or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

Kiryat Ono Mall
Azorim Center A
39 Jerusalem St.
55423 Kiryat Ono, Israel
(Telephone Number 011-972-3-738-2616)
(Address, Including Zip Code, and Telephone Number, including Area Code, of Registrant s Principal Place of Business)

Mr. Patrick NJ Schnegelsberg
Chief Executive Officer
Gammacan International, Inc.
Kiryat Ono Mall
Azorim Center A
39 Jerusalem St.
55423 Kiryat Ono, Israel
(Telephone Number 011-972-3-738-2616)
(Name, Address, Including Zip Code, and Telephone Number, including Area Code, Of Registrant s Agent for Service)

Copies to:

Robert Steven Brown
Gary M. Emmanuel
Reitler Brown & Rosenblatt LLC
800 Third Avenue, 21st Floor
New York, New York 10022

(212) 209-3050 / (212) 371-5500 (Telecopy)
rbrown@reitlerbrown.com

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box: x

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering: o

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering: o

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering: o

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

The information in this prospectus is not complete and may be changed without notice. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and the selling stockholders are not soliciting offers to buy these securities, in any state where the offer or sale of these securities is not permitted.

Prospectus, Subject to Completion

August 26, 2008

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 "*2007 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 August 18, 2008, the closing sales price of our common stock on the OTCBB was $0.27 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 [_____], 2008.

TABLE OF CONTENTS

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 to treat melanoma and other cancers. We believe that IgG may be the basis for safer, more effective and efficient cancer treatment, as a mono-therapy and adjuvant cancer treatment. 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.

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.

3

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 2007 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 five 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.

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 knowhow.

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 business models and acquisition plans, until in June 2004, approximately 27% of our then outstanding shares of common stock were 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 August 13, 2008, ARP sold to us 12.5% of the issued and outstanding shares of our subsidiary such that we now own 100% of the outstanding shares of our subsidiary. In consideration for such sale, we issued to ARP 3,389,902 shares of our common stock. In connection with the sale, our subsidiary entered 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.

The Offering

Common stock offered	16,583,753 shares
Common stock outstanding after this offering	64,848,819 shares (1)
Use of proceeds after expenses	We will not receive any proceeds from the sale of Shares by the Selling Stockholders.
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.

Summary Consolidated Financial Data of Gammacan International, Inc.

The following statement of operations data for the years ended September 30, 2007 and 2006, and the balance sheet data at September 30, 2007 and 2006, are derived from our audited consolidated financial statements and the related notes. Our consolidated financial statements and the related notes as of September 30, 2007 and 2006 and for the two years then ended are included elsewhere herein. The unaudited selected statement of operations data for the nine months ended June 30, 2008 and 2007, and the unaudited consolidated selected balance sheet data at June 30, 2008, are derived from our unaudited financial statements, which have been prepared on a basis consistent with our audited financial statements 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,	Nine Months Ended June 30,		Perio Octo 19 thr
	2007	2006	2007	2008	2007	Jun 2
Research and development costs	$ 1,198,004	$ 802,254	$ 2,713,178	$ 1,350,956	$ 762,778	$ 4,0
General and administrative expenses	4,090,163	1,263,070	6,378,874	1,979,379	2,902,678	8,3
Operating losses	5,288,167	2,065,324	9,092,052	3,330,335	3,665,456	12,4
Financial income	(152,088)	(44,130)	(216,921)	(62,446)	(97,462)	(2
Financial expenses	41,317	14,979	63,431	41,771	33,135	1
Loss before taxes on income	5,177,396	2,063,173	8,938,562	3,309,660	3,601,129	12,2
Taxes on income	1,378	28,622	30,000	--	37,013	
Loss from operations of the company and its consolidated subsidiary	5,178,774	2,064,795	8,968,562	3,309,660	3,638,142	12,2
Minority interests in losses of a subsidiary	--	--	(12,375)	--	--	
Net loss	$ (5,178,774)	$ (2,064,795)	$ (8,956,187)	$ (3,309,660)	$ (3,638,142)	$ (12,2
Earnings per Share Information:						
Basic and diluted net income per share	$ (0.14)	$ (0.07)		$ (0.07)	$ (0.10)	
Shares used in computing basic and diluted loss per common share	38,043,043	28,052,065		44,958,917	35,744,894	

Balance Sheet Data:

	At September 30,		At June 30,
	2007	2006	2008
Cash and cash equivalents	$ 4,048,583	$ 538,738	$ 861,531
Working capital (1)	3,177,967	222,133	412,240
Total assets	4,199,914	619,820	964,695
Long-term debt	71,338	31,531	21,296
Stockholders' equity	3,200,838	259,190	428,264

(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. We estimate that our cash reserves and proceeds from anticipated financings will be sufficient to permit us to continue at our anticipated level of operations for a minimum of twelve months from the date of this prospectus. 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 from anticipated financings 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 or that the anticipated financings will close in the amounts or at the times we may require or at all. 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.

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, and as of June 30, 2008, we had working capital of $3,177,967 and $222,133, and $412,240, respectively, and stockholders equity

of $3,200,838 and $259,190, and $428,264, respectively. We generated no revenues to date. For the period from our inception on October 6, 1998 through June 30, 2008 we incurred net losses of $(12,265,847). For the years ended September 30, 2007 and 2006, and the nine months ended June 30, 2008 we incurred net losses of $(5,178,774), and $(2,064,795) and $(3,309,660), 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 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 of our projects, the nature 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 cash flow and proceeds from anticipated financings will be sufficient to meet our anticipated working capital needs for at least the next twelve months from the date of this prospectus. Notwithstanding the foregoing, 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 clinical trials and 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 or that the anticipated financings will close on a timely basis, 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 its 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 and its proposed use in cancer therapeutics. 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.

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 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 or 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 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 or 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; we may be unable to effectively manage growth with our limited resources.

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.

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-K. Under current rules, we will be subject to this requirement beginning with our annual report on Form 10-K 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-K 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.

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* .

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. Our 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 the 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 this Offering

In recent years, the stock market in general has experienced periodic price and volume fluctuations. This volatility has had a significant effect on the market price of securities issued by many companies for reasons often unrelated to their operating performance. These broad market fluctuations may adversely affect our stock price, regardless of our operating results. As the market price of our common stock may fluctuate significantly, it may be difficult for you to resell your shares of common stock when you want or at prices you find attractive.

The price of the common stock is quoted on the OTCBB and constantly changes. We expect that the market price of the 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 financial 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 of 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;

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 the common stock or convertible into, or exchangeable or exercisable for, common stock could materially adversely affect the trading price of the 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 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.

If penny stock regulations impose restrictions on the marketability of our common stock, the ability of our stockholders to sell shares of our stock could be impaired.

The Commission has adopted regulations that generally define a penny stock to be an equity security that has a market price of less than $5.00 per share or an exercise price of less than $5.00 per share subject to certain exceptions. Exceptions include equity securities issued by an issuer that has (i) net tangible assets of at least $2,000,000, if such issuer has been in continuous operation for more than three years, or (ii) net tangible assets of at least $5,000,000, if such issuer has been in continuous operation for less than three years, or (iii) average revenue of at least $6,000,000 for the preceding three years. Unless an exception is available, the regulations require that prior to any transaction involving a penny stock, and a risk disclosure schedule must be delivered to the buyer explaining the penny stock market and its risks. Our common stock currently trades on a limited basis. Based on our most recent financial statements as of the date of this prospectus, our common stock will be considered a penny stock. As suc