Frequently Asked Questions

Introduction

ImmuMed (the “Company”) is a private company that acquired its antibody drug portfolio and associated production platform from the University of Minnesota (UM) after UM Regents terminated commercial drug development within its academic environment. Our technology platform, refined over 25 years, is renowned for its consistent production of highly purified, biologically active therapeutic antibodies which depending on the immunologic activity of the individual active pharmaceutical ingredient (API) are capable of providing passive immunity to a broad spectrum of life-threatening diseases; consequently resulting in a multi-billion dollar revenue opportunity. (See: Series B Convertible Preferred Stock Offering; Sections Global IALG Revenue Opportunity; Additional Markets for Our Lymphocyte-Depleting Antibody Formulations.)

The Company is focused on seeking market approval and successful commercialization of these acquired products; firstly, our lead candidate IALG, a polyclonal antibody prescribed for recipients of solid organ transplants. This study drug was widely accepted by the transplant community, and the API in IALG has been administered to more than 52,000 solid organ transplant recipients when previously administered under the name brand Minnesota Antilymphocyte Globulin (MALG). Historically, MALG’s extensive administration has been the subject of more than 164 studies published in the scientific literature, thus defining certain clinical data and intellectual property. Based on this data, achieving market approval for our rebranded API, IALG, is the Company’s first objective.

Importantly, this lead candidate presents a unique opportunity for early positive cash flow (compared to usual drug development opportunities); and such cash flow will permit the Company to clinically develop the remaining compounds in our acquired drug portfolio without necessarily imposing further obligatory share dilution on early-stage investors. Accordingly, the questions asked and answered in this information piece are solely directed towards the clinical development and market approval for IALG.
IALG

Scientific Background

The role of immunosuppression in solid organ transplantation continues to evolve. In the early 1980s (the “Cyclosporine Era”) the occurrence of acute rejection after renal transplants was very high. Accordingly, the goal was to reduce acute rejection. Prevention of acute rejection (“Induction Therapy”) was effectively managed then by administering the currently proposed study drug ImmuMed ALG (IALG) sequentially followed by Cyclosporine A (CsA) when indicated by organ function. The incidence of acute rejection was reduced then from more than 60% to approximately 40% with this therapy. The combination of MALG and CsA resulted in substantial improvement in 1-year graft survival, which increased from 65% in 1980 to 88% in 1992.

After 1992, other novel molecules emerged, creating multiple new immunosuppressive regimens. Prevalent changes included the declining use of CsA, (94% in 1992 to 39% in 2001), the switch from CsA to Tacrolimus (55% of recipients in 2001). In addition, the licensing of newer agents such as MMF and, and basiliximab and Zenepax for induction therapy. With these immunosuppressive advances, 1-year renal graft survival over the last decade has increased from 83.5% and 92.9% during MALG treatment (circa 1992) to 88.4% and 94.9% in 2000, for deceased and living donors, respectively. Continued emphasis has been on the elimination of morbidity and mortality caused by immunosuppressive agents. Whereas, between 1992 and 2001 nearly all kidney recipients received corticosteroid therapy before hospital discharge, recent trends have been towards steroid sparing (i.e., in 2001 the percentage of recipients receiving corticosteroids dropped from 100% to 94%). With the introduction of MMF, Tacrolimus, interleukin 2 receptor blockers, and rabbit antithymocyte globulin (Thymoglobulin or rATG), interest in avoidance of corticosteroids after transplant has been increasing. When corticosteroid elimination had been attempted previously, such reduction resulted in increased rates of acute rejection and lower long-term graft survival. However, using newer immunosuppressive regimens, corticosteroid-free protocols from both single and multiple center experiences have recently demonstrated at least equal graft survival and lower acute rejection rates.

ImmuMed’s anti-B plus anti-T lymphocyte globulin, equine (IALG) is a sterile solution containing highly purified (greater than 99% monomeric) equine-derived 7s gamma globulin that is immunologically active against all human lymphocytes. The immunogens used to stimulate this equine anti-human antibody activity consist of both thymus-derived human T-cells and
Regulatory

Proposed Indication

ImmuMed is proposing to seek the labeling indication for IALG’s use for the prevention of acute rejection (“Induction Therapy”) in patients receiving a solid organ transplantation under circumstances where the expected incidence of acute rejection is 10% or greater when used as part of an immunosuppressive regimen that may include a calcineurin inhibitor, mycophenolate mofetil (MMF), and corticosteroids.

Regulatory Information

In 1970, FDA accepted BB-IND 486 for the University of Minnesota (the “University”) to conduct studies of MALG. The University transferred sponsorship over BB-IND 486 to ImmuMed in 1996 when ImmuMed entered into an agreement with the University to acquire certain assets of the University’s MALG Program. At a meeting between ImmuMed (formerly named Transplantation Technologies, Inc.) and the FDA there was a consensus that any information found to be relevant from the BB-IND 486 could be summarized and presented again in a new IND. In reference to the use of previous animal data, the FDA expressed the position that there was sufficient experience with antibody products, and thus minimal, if any, animal data would be required before initiating clinical studies. The Sponsor’s minutes were forwarded to and accepted by the FDA.

Based on the previous discussions with the FDA, ImmuMed intends to submit a new IND and to conduct clinical studies to evaluate the safety and efficacy of IALG for preventing acute rejection in recipients of solid organ transplants.
Proposed Clinical Development Plan

This study drug is widely known and was previously administered under the name Minnesota Antilymphocyte Globulin (MALG). IALG was renamed at FDA’s request from Minnesota Antilymphocyte Globulin (MALG). There are extensive historical clinical safety to support the use of IALG when used on a body-weight basis (10 to 20 mg/kg for duration of 7 to 14 days) to prevent acute rejection following solid organ transplantation, as reflected in the majority of published scientific studies during the era when background immunosuppression consisted of Cyclosporine and Steroids.

The standard of practice for treatment of this patient population has changed since MALG was available for use. Novel molecules have emerged creating new immunosuppressive regimens. Prevalent changes include the declining use of Cyclosporine, the substitution with Tacrolimus® and MMF, and the licensing of Simulect® (basiliximab) and Zenepax® (daclizumab) for induction therapy. Therefore, ImmuMed plans to conduct two additional clinical studies to bridge the prior information and to support the safety and efficacy of IALG. The studies are: (1) a Phase 2, dose-finding, pharmacokinetic/pharmacodynamic study nested into the beginning of (2) an adequate and well-controlled Phase 3 comparative study documenting IALG is “Not-Inferior-To” the current standard of care. ImmuMed plans to submit a marketing application (“BLA”) after this single Phase 3 trial. If the Phase 3 study results indicate that IALG is not inferior to current standard of care for Induction Therapy, ImmuMed will consider opening a treatment IND to allow patient access while marketing approval is being pursued.

Specific Questions and Answers

Q1. Why was the IALG removed from the market in the first place?

A1. ImmuMed’s primary product candidate, IALG, the successor to MALG was administered over a twenty-four year period pursuant to IND 486. During this interval, a scientifically controlled, randomized, blinded pivotal trial comparing MALG to Placebo was conducted, documenting efficacy of the study drug to be > 2.5X the control. The study drug’s Sponsor, the Department of Surgery at the University of Minnesota, considered this a successful study around which they eventually submitted a Product License Application (PLA) and facility license application. These applications were accepted for review by the FDA. However, between the conclusion of the pivotal trial and submission of the filings, approximately as many as another 20,000 patients were treated with the
study drug. The Sponsor was not reporting outcomes to the FDA nor were they monitoring the administration of study drug, nor was the study drug being administered according any protocol that would lead to licensing. The FDA concluded that the Sponsor was not pursuing adequately a clinical development track that would lead to licensing, thus placed the distribution of study drug on clinical hold. In anticipation that the Sponsor was not reliably reporting adverse events the Agency conducted its own audits, finding only five serious adverse events related to drug administration error in approximately 14,000 patients.

**Q2. What has changed since the product was pulled to make re-introduction a good idea?**

**A2. Specifically Bstandard of medical care.** The scientific literature documents a trend towards therapeutic sparing B meaning the reduction of the dosage of immunosuppressive medication to the extent possible, as quickly as possible, to hopefully decrease the long-term deleterious effects of these medications on the patient’s well-being. With specificity, the transplant population is being categorized by their transplant risk; the treatment regimen determined according to this risk assessment; steroid avoidance or rapid steroid reduction is now instituted; steroids are replaced by the therapeutic protocol -- Induction Therapy -- the administration of antibody to prevent early acute rejection during that period of time for the therapeutic effects of the calcineurin inhibitors and DNA inhibitors take effect. In other words, sequential combination therapy. Historically, there have been two schools of thought about antibody use in transplant immunosuppression, the John Najarian followers (companionate use of antibody therapy to prevent the occurrence of rejection) and the Tom Starzl followers (wait for rejection and treat when it occurs). In the late 80s and early 90s about 54% followed Najarian and 46% followed Starzl. (Evans, et. Al; Transplantation 1993;55:1297-1305). Today, the distribution is closer to 75%-Najarian and 25%-Starzl, as the market indicates.

**Q3. What is the unmet clinical need that this product addresses that cannot be addressed by, for example, Cellcept, Zenapax, Tacrolimus, etc.?**

**A3. Presently only the monoclonal antibodies are licensed for Induction Therapy (IALG’s proposed label indication) whereas, the polyclonal antibodies are licensed only for treatment of acute rejection, consequently are now used off-label for induction therapy. As indicated above, Tacrolimus7 (calcineurin inhibitor) and Cellcept7 (DNA inhibitor) are administered daily (maintenance drugs) whereas monoclonal or polyclonal antibodies (adjuvant drugs) are administered for short periods to
either prevent rejection (Induction) or to treat acute rejection. The scientific literature supports the belief that antibody administration improves transplant outcomes and that in the transplant model polyclonal antibodies are significantly more effective (about 2.5X). Accordingly, monoclonal antibodies (Simulect® and Zenapax®) are not indicated for induction therapy in high-risk patients. Today, as many as 70% of transplant procedures may be high risk. The global antibody sales appear to reflect this statistic.

Q4. IALG appears to be off patent; what is the IP strategy to address this issue?

A4. Immune globulins have been administered to transfer passive immunity for more than 100 years, thus the gamma globulin molecule, per se, is clearly off-patent. The same is true for IALG’s competitor, Thymoglobin. However, the Company believes it has a strong IP position based on the following:

**Asset Purchase Agreement with the University of Minnesota**

ImmuMed acquired ALG from the University of Minnesota (the “University”) in 1996 under an agreement to purchase assets of the Minnesota Antilymphocyte Globulin (MALG) Program. The purchase of the Program provided ImmuMed with a proprietary interest in ALG, as well as supplied various other antibody compounds and medical devices in a portfolio that had either been under development or in clinical testing since 1970. The agreement included books and records related to the R&D of IALG and multiple other products, clinical data, manufacturing technology, related patents, posterity samples, associated goodwill, and transfer of the regulatory authority and FDA filings. Under the agreement, the University is designated to receive a 4% royalty on future net commercial sales of ALG for 11 years after the Company’s first commercial sale. The University had already invested roughly $66 million on R&D and product development prior to selling the products to ImmuMed.

**Regulatory Protection**

IALG, ImmuMed’s primary product candidate, is classified as a biologic product under section 351 of the Public Health Service Act. Biologics consist of vaccines, blood products or derivatives, allergenic products, serums, toxins, antitoxins, and other similar products used to prevent, treat, or cure disease or injury. In contrast to drugs that are chemically synthesized, biologics are derived from living sources, such as humans, animals, and microorganisms. Most biologics are complex mixtures that are not easily identified or characterized, and are
manufactured using biotechnology (Source: Center for Biologics Evaluation and Research [CBER]). Because ALG is considered a true biologic under section 351, it is supervised and controlled by the FDA’s CBER division.

As a large biologic molecule, ALG has inherent regulatory protection, because the Public Health Service Act does not provide an approval pathway for the commercialization of generic biologics (also known as “follow-on” proteins), which are recognized for providing the same level of medication as the original product, but at a reduced cost. Whereas, in the pharmaceutical industry, generic products are widely available, currently, the only potential pathway for follow-on biological proteins is under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. (However, most biologics, including ALG, are licensed under section 351 of the Public Health Service Act, which does not address abbreviated [generic] applications.) Even under the Federal Food, Drug, and Cosmetic Act, a biological protein could only receive generic approval if it has demonstrated bioequivalence to the original product. Bioequivalence is not as easy to achieve for biological products as it is for small-molecule chemical compounds. As a result, there are concerns that differences in manufacturing processes for follow-on proteins could create varying immunogenicity profiles and unpredictable side effect risks.

Accordingly, ImmuMed’s most valuable intellectual property is its confidential, proprietary data associated with ALG’s IND filed with the FDA, and the statutory protection the Company receives from potential generic versions that are based solely on bioequivalence to its product. In addition, when considered in the context of today’s drug development costs, the ability to reference and use current data in future FDA applications is highly valuable to the Company.

Additional Protections

The Company has engaged the Faegre & Benson LLP legal firm to assist with its intellectual property portfolio. Based on the firm’s analysis, the Company’s intellectual property could be considered appropriate for patent applications in several venues. Additionally, the processes used to concentrate antibodies from hyperimmune plasma were developed through more than 20 years of research and preclinical studies, resulting in several well-tested manufacturing techniques. Because these processes are known to preserve high binding capacity and biological activity, the Company believes that it is positioned to become a leading developer of effective therapeutic antibody candidates. With the current submission of an additional IND, ImmuMed could have an opportunity to submit new patents with respect to both process and composition. To ImmuMed’s knowledge, ALG is the only polyclonal antibody intentionally formulated
as a blend of hyperimmune plasma against both human T- and B-cell lymphocytes.

The Company has determined that it could propose provisional patent applications for the following: (1) manufacturing methods; (2) ALG’s formulation (unique B- and T-cell blend), administration route, and administration with other current treatment regimens; and (3) uses of the Company’s products or technologies for non-solid organ transplants, autoimmune diseases, and hematological disorders, among others.

**Proprietary Trade Secrets**

In addition to the inherent regulatory protection that ALG receives, several of the compound’s production methods remain the Company’s proprietary trade secrets. The Company believes its production methods actively stimulate a high-titer antibody with anti-B-cell activity in exogenous sources, resulting in hyperimmune plasma with unique and distinctive immunologic properties. The specifics of ImmuMed’s trade secrets are not public knowledge, nor have they been published. Instead, the Company relies on maintaining confidentiality to protect the critical details of its technology, as briefly highlighted below.

**Antigen Composition: B-cell Line**

ImmuMed utilizes T-cells, which are widely used in many antibody products, but also blends B-cell antibodies with its T-cells. The B-cell line is unique and has grown in continuous culture in the Company’s possession since 1967. ImmuMed does not anticipate offering its B-cell line for sale since the cell line creates a proprietary and unique antigen composition for the Company.

**Host Immunization**

ImmuMed’s method for immunizing its horses required step in the antibody production process (e.g. immunizing a donor horse for the production of ALG) is unique to the Company and is believed to result in a more effective antibody.

**T- and B-cell Blend**

ImmuMed utilizes a software package to blend the various elements of the Company’s inventory – T- and B-cell generated plasma into a beginning raw material product which is of both constant and effective composition. This serves to maintain a specific product
formulation, keeping the compound consistent from lot-to-lot and unique in its biologic activity.

Q5. Why are B-cells important?

A5. In the natural immune cascade, B-cells along with helper proteins carry the imprint of any foreign protein to the T-cells to activate the T-cell response. Thus, the B-cell is positioned as a major component early in the immunology of rejection, and the added emphasis on decreasing the circulating B-cells before a transplant reduces the innate response to recognize foreign proteins. There is both experimental and clinical evidence to support this postulate.

Experimentally, a mouse tumor model was developed to study the T+B question. In this instance, horses were immunized against mouse Thymus (T) and Bursa (B) cells, and the resulting antibodies were processed into a murine anti-T cell ALG, and a murine anti-B cell ALG. In the experimental model, mice were injected with tumor cells and the death rate (LD50) was measured. When the mouse has active lymphocytes to combat the tumor cells they survive longer, and with lymphocytes depletion (antibody effect), they succumb sooner. Experimentally, the LD50 was greatest when a blend of anti-T and anti-B antibodies was administered compared to when anti-T and anti-B antibodies were administered independently. Accordingly, in the mouse model, the T+B blended product was better than either one alone.

Clinically, single center results (University) illustrate that in 1992 the sequential use of MALG plus Cyclosporine achieved results very similar to outcomes observed today following the addition of MMF and changing to Tacrolimus (2005 UNOS data). Additionally, long term follow-up in 4,411 patients indicates a lower incidence of post-transplant B-cell mediated lymphoma (PTLD). It is postulated in the literature (J. Clin Investigation (58); July 1976: 212-220) that when an anti-T cell only antibody is administered even though both T- and B-cell lymphopenia occurs, proportionately the T-cells are more severely affected, thus providing a period where B-cells may dominate, and that this wild-cell reversal of cell population ratios after anti-T cell therapy may account for an increased incidence of PTLD compared to our T+B product.

Q6. Polyclonal products are typically very difficult to QA batch-to-batch; does the company have any proprietary advantage in addressing this issue?

A6. Specifically - yes. One of the assets purchased from the University was the “recipe book” (SOP’s) developed and perfected over a twenty-two year period. Basically, gamma globulin
puriﬁcation is a process based on protein concentration, therefore, if one has a standardized method for measuring accurately protein concentrations, very little variability should enter the process as the result of puriﬁcation. Lot-to-lot comparability (biologic activity) is a quality that is determined by the accuracy of the composition of the starting raw material lot. Within the “recipe book” there is a sophisticated method for maintaining lot-to-lot consistency of starting raw material lots. While these methods remain proprietary trade secrets (unpublished) the outcomes on our lot-to-lot characterizations have been published. Bourdage, et al; Transplantation (59) 1194-1200 (6) April 27,1966.

Q7. Is there scientiﬁc consensus on the speciﬁc type (monoclonal vs. polyclonal) and use of antibodies (therapeutic indication)?

A7. Transplant immunosuppression literature is ﬁlled with numerous single center comparative studies, each expressing the advantage their particular approach, consequently, a clear consensus may not be apparent. However, with increasing frequency statements such as the following (1 and 2 below) appear to support an evolving aﬃrmative consensus:

1. The administration of antibody, regardless of type, in conjunction with a treatment regimen is clearly better than no antibody at all (placebo). Both IALG (polyclonal) and Simulect7 and Zenapax7 (monoclonal) in multicenter studies have demonstrated better outcomes than the comparative study arm (with placebo). It is not uncommon to ﬁnd conclusions in the literature such as, “We conclude that the combination of ATG/ALG and CSA is superior to CSA alone.”

2. Antilymphocyte antibody appears effective and is experiencing increasing use in bone marrow transplantation, aplastic anemia and autoimmune diseases.

Q8. Is there scientiﬁc consensus on the speciﬁcity of antibody to use in Induction Therapy, i.e. monoclonal vs. polyclonal?

A8. Except for high-risk transplant patients, the choice between monoclonal or polyclonal is center speciﬁc. Examples of such variation are illustrated in paragraphs 1 to 4 below:

1. Brennan has published the multicenter comparison of monoclonal antibody (Simulect®) with polyclonal (Thymoglobulin) for use in induction therapy with high-risk renal transplants. The incidence of composite adverse events (Acute Rejection, Graft Loss and Patient Death)
was significantly greater at one year in the monoclonal group (40.17%) vs the polyclonal group (29.1%). *N. Engl J Med.* 2006;355:1967-1977, 2033-2035.

2. The incidence in the use of induction therapy in kidney transplants is increasing from 33% of patients in 1998 to 81% of patients in 2005. Approximately 55% of these received polyclonal antibody. (OPTN Annual Report 2005). In a 2007 “Best Practices” survey antibody use is compiled for renal transplants from 4,416 deceased donor and 1,904 living donors.
3. A randomized controlled trial comparing monoclonal antibody to rATG for induction therapy in renal allografts reported the following:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Monoclonal N = 50</th>
<th>P value</th>
<th>Thymoglobulin N = 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Rejection @ 3 months</td>
<td>31%</td>
<td>NS</td>
<td>26%</td>
</tr>
<tr>
<td>Graft Loss @ 12 months</td>
<td>14%</td>
<td>NS</td>
<td>16%</td>
</tr>
<tr>
<td>Total Infections</td>
<td>47</td>
<td>NS</td>
<td>72</td>
</tr>
<tr>
<td>Serum Sickness</td>
<td>0</td>
<td>.001</td>
<td>28</td>
</tr>
</tbody>
</table>


4. A six-month follow-up evaluating the efficacy and adverse events profiles comparing monoclonal antibody (Simulect®) to Thymoglobulin for the prevention of rejection in kidney transplant receiving current background immunosuppressive cocktail reports the following results:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Simulect N = 50</th>
<th>Thymoglobulin N=50</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least one biopsy-proven acute rejection</td>
<td>4 (8%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Acute rejection requiring antibody treatment</td>
<td>0</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Acute rejection requiring FK 506 treatment</td>
<td>1 (2%)</td>
<td>0</td>
</tr>
<tr>
<td>Graft Loss</td>
<td>2 (4%)</td>
<td>0</td>
</tr>
<tr>
<td>Death</td>
<td>1 (2%)</td>
<td>0</td>
</tr>
<tr>
<td>Treatment Failures</td>
<td>0</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>No. Patients with Adverse Events related to drug</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>No. Adverse Events related to drug</td>
<td>12</td>
<td>43</td>
</tr>
<tr>
<td>Number of Infections</td>
<td>68</td>
<td>103</td>
</tr>
<tr>
<td>No. Patients with CMV infection</td>
<td>6</td>
<td>19</td>
</tr>
</tbody>
</table>


In summary, a diffuse spectrum of opinions about the choice of antibody to employ for induction therapy is embodied in single-center studies in the scientific literature, as well as about the treatment duration and the timing of drug administration. The bottom line is that physician choice of the preferential drug to use is a complex matter that depends upon multiple factors that at least includes efficacy, safety, ease of administration, toxicity during administration, reliable availability and significantly -- the drug’s cost. For example, the following conclusions best describes the multiple factors involved in drug selection “. . . . .Treating 100 recipients with tacrolimus instead of ciclosporin for the first year after transplantation avoids 12 patients having acute rejection and two losing their graft but causes an extra five patients to develop insulin dependent diabetes. Optimal drug choice may vary between patients.” (British Medical Journal: 331;810; 12 September 2005)
Q9. Will physicians switch back to using IALG with rATG in the market?

A9. ImmuMed’s goal is to re-enter the induction therapy market with an effective polyclonal antibody, anticipating to reasonably share that market with rATG, and not with the goal of replacing rATG (an Avis vs. Hertz comparison). There are multiple reasons to believe IALG can compete effectively, as follows:

1. Absence of scientific consensus on antibody use in transplantation means there is significant opportunity for a product to enter this market and compete for market share based on the factors noted above (efficacy, safety and cost) that drive physician preferences. The Company believes that IALG is competitive on each of the choice factors that determine drug preference; in particular, based on manufacturing techniques IALG possesses a considerable "gross profit" advantage versus rATG, thus providing ImmuMed the ability to compress the pricing if necessary, although this is not the initial market strategy.

2. The current absence of comparative data between IALG and rATG. There is only one clinical study published comparing rATG to IALG. This study demonstrated equivalence, which is to be expected because both agents were administered under circumstances where multiple other immunosuppressive agents were also administered. In the transplant model with multiple agents in the background, it is possible to distinguish between outcomes when antibody is administered and when antibody is absent, nevertheless it is difficult to differentiate efficacy between individual agents. Most often, the drug of choice is physician preference based upon all the factors noted above.

3. One can be quite confident that when IALG is available multiple centers will immediately begin their own comparative trials. There are multiple factors that enable IALG to compete favorable, such factors resulting from our method of manufacturing IALG. The Company plans to associate with proven market-growth methods, specifically offering a equally effective product at a competitive price. We believe that IALG has marketing advantages based on its safety, T+B formulation and its “On-label” administration.

4. The comparative safety profile is important. rATG’s label discloses 90% purity, whereas, IALG’s chemical formulation discloses 99% purity. That is nearly a 10% difference in the presence of microaggregates. Adverse events associated with the IV administration of complement activating microaggregates are well described in the medical literature.
5. Peripheral Administration. New methods of manufacturing are anticipated to result in a 5X increase in yield of gamma globulin per liter (12.5% to 62%). At the cost of yield, it is the Company’s intent to explore the possibility of completely eliminating or greatly reducing reactions with formed blood elements with the goal of being able to achieve peripheral vein administration.

6. Our current strategy is one of -- quick to market -- on the most cost-effective pathway, realizing that physician drug preference will be determined by multiple factors, and one important factor not to be diminished is the importance of “On-label” administration in order to relieve the physician of the legal responsibility for off-label drug administration.

Q10. What is the Company's marketing strategy?

A10. Our marketing strategy may be disclosed in full under confidentiality; however, it primarily involves leveraging the relationship between trial design, site selection, pre-approval product distribution, direct marketing based on pre-approval distribution and marketing through distribution representatives. Marketing in transplantation is different from traditional drug sales. A large internal sales force (i.e. large vs. small company) is not a guarantee for success. The consumers in transplantation are a tightly knit group of targeted physicians who annually attend several scientific meetings. Widespread industry acceptance for a product more commonly results after a “thought-leader” in the transplant field reports the product’s success at these meetings. Consequently, word-of-mouth is the greatest marketing force. Historically, IALG achieved its market dominance on the basis of “word of mouth influences” and not by an established sales force. The Company’s pending clinical trial will target these experts – capitalizing on the industry’s prior widespread familiarity with IALG, leveraging this to restore former relationships with U.S., Canadian and European transplant centers.

Q11. Long-long-term follow-up graft survival (15 - 25 years) is now becoming an important scientific investigation. What such data does the Company have?

A11. The Company is not aware of any published scientific data in this regard, but the Company does that the historic patient population that received IALG to answer this question and will publish such results in conjunction with its marketing efforts.
Q12. Is there any additional information that would permit a comparison between IALG and rATG?

A12. Yes – certain assumptions can be made on a historical basis absent current scientific data.

For example:

1. We have excellent comparative safety data and intend to exploit this difference. Considerable primate toxicity data with the use of rATG is available. Thus our first comparison of IALG with rATG will be a small study demonstrating the superiority in the absence of toxicity in the primate model.

2. Based on manufacturing methods, IALG has a significantly better gross margin. There is a growing body of pharmaco-economic literature on the importance of cost.

3. There are one or two published studies retrospectively comparing the use of Thymoglobulin with IALG’s prior use when the standard of care was different than today’s. The conclusion was that the outcomes are similar, but that a smaller dose of rATG was administered, which means, the lot-release cytotoxicity standard used by the individual products is different.

4. Intuitive deductions can be formulated based on comparing rATG with other products. For example, Atgam was about 90% as effective as rATG in reversing acute rejection. In a Not-Inferior-To (NIT) trial a 90% margin would be considered as equivalence.

Q13. Given that small molecule drugs like Cellcept are blockbusters in this category, is the total market size for IALG large enough to produce an attractive return for investors?

A13. ROI is observer dependant. ImmuMed believes it possesses one of the best ROI opportunities available, based on size of investment and risk. ImmuMed’s pathway to market is clearly defined, beginning with an established product and defined regulatory circumstance. The antibody market in transplantation is anticipated to be $500 million in 2014, growing between 18% and 20% annually, and polyclonal revenues are 70% to 80% of this amount. Based on quotations resulting from ImmuMed’s RFP=s submitted to vendors, the Company believes it can achieve market approval for IALG within $20 million. ImmuMed’s pro forma are conservative, achieving $100 million in sales in five years from funding, assuming only 19.3% market share priced at 65% of the
competitive price. These assumptions provide significant opportunity on the upside, and, our gross margins provide significant pricing flexibility, if need be. IALG is competitive based on its safety profile, (greater purity mean significantly less microaggregates administered), equivalent efficacy, and potentially better pricing. In the Company’s view IALG has a significantly better cost-benefit profile, a critical factor directing physician choice in today’s marketplace.