

CLEARANT INC  
Form 10-K  
March 24, 2009

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
Form 10-K  
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2008  
Commission file number 000-50309  
Clearant, Inc.  
(Exact name of registrant as specified in its charter)**

**Delaware** **91-2190195**  
(State or other jurisdiction of incorporation) (I.R.S. Employer Identification No.)

**1801 Avenue of the Stars, Suite 435  
Los Angeles, California 90067**  
(Address of principal executive offices, including zip code)

**(310) 479-4570**  
(Registrant's telephone number, including area code)  
Securities registered under Section 12(b) of the Exchange Act: None  
Securities registered pursuant to Section 12(g) of the Exchange Act:

**Common stock, \$0.0001 par value per share**  
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  
Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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

Indicate by check mark if disclosure of delinquent filers in response to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer:  Accelerated filer:  Non-accelerated filer:  Smaller reporting company:

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates (affiliates being, for these purposes only, directors, executive officers and holders of more than 5% of the registrant's common stock) : \$5,908,780 based on 39,391,868 non-affiliate shares outstanding at \$0.15 per share, which is the average bid and asked price of the common shares as of the last business day of the registrant's most recently completed second fiscal quarter.

The number of shares of the registrant's common stock, no par value per share, outstanding as of March 17, 2009 was 48,957,445.

Documents incorporated by reference: none.



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**Forward Looking Statements**

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to the financial condition, results of operations, business strategies, operating efficiencies or synergies, competitive positions, growth opportunities for existing products, plans and objectives of management, markets for stock of Clearant, Inc. and other matters. Statements in this report that are not historical facts are

forward-looking statements for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, (the Exchange Act ) and Section 27A of the Securities Act of 1933, as amended. Such forward-looking statements, including, without limitation, those relating to the future business prospects, revenues and income of Clearant, Inc., wherever they occur, are necessarily estimates reflecting the best judgment of the senior management of Clearant, Inc. on the date on which they were made, or if no date is stated, as of the date of this report. These forward-looking statements are subject to risks, uncertainties and assumptions, including those described in the

Risk Factors described below, that may affect the operations, performance, development and results of our business. Because the factors discussed in this report could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any such forward-looking statements. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should understand that the following important factors, in addition to those discussed in the Risk Factors section could affect our future results and could cause those results to differ materially from those expressed in such forward-looking statements:

general economic conditions;

the effectiveness of our planned advertising, marketing and promotional campaigns;

physician and patient acceptance of our products and services, including newly introduced products;

anticipated trends and conditions in the industry in which we operate, including regulatory changes;

our future capital needs and our ability to obtain financing; and

other risks and uncertainties as may be detailed from time to time in our public announcements and filings with the Securities and Exchange Commission ( SEC ).

Although we believe that our expectations are reasonable, we cannot assure you that our expectations will prove to be correct. Should any one or more of these risks or uncertainties materialize, or should any underlying assumptions prove incorrect, actual results may vary materially from those described in this report as anticipated, believed, estimated, expected or intended.

Except to the extent required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or any other reason. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this report may not occur.

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**PART I**

**Item 1. Business**

**Business Development**

We were incorporated as a corporation in the state of Nevada on March 31, 2003. On March 31, 2005, we sold substantially all of our operating assets and liabilities to three majority stockholders, and changed our name from Bliss Essentials Corp. to Clearant, Inc., and entered into a reverse triangular merger with Clearant, Inc., which was incorporated in the state of California on April 30, 1999. Because Clearant, Inc. was the sole operating company at the time of the merger, the transaction was accounted for as a reverse acquisition, with Clearant, Inc. deemed the acquirer for accounting purposes. On June 30, 2005, we reincorporated from Nevada to Delaware. On December 31, 2005, we merged the subsidiary created by the earlier merger into Clearant, Inc., a Delaware corporation.

**Business of Issuer**

We acquire and develop our pathogen inactivation technology, the Clearant Process<sup>®</sup>, and market it to producers of biological products, most notably devitalized musculoskeletal tissue allograft implants (tissue).

**The Clearant Process<sup>®</sup>**

The Clearant Process<sup>®</sup> is designed to:

Inactivate a broad range of known pathogens irrespective of size, origin or structure including, but not limited to Human Immunodeficiency Virus ( HIV ), West Nile Virus, and Hepatitis C;

Achieve sterility, in some cases with margins of safety greater than that of a medical device;

Be used in both intermediate and final stages of production;

Protect the mechanical and biological properties of the biological product being treated; and

Be applied to a product after it has been sealed into its final package.

The Clearant Process<sup>®</sup> uses a combination of patented and trade secret technology, based on a proprietary application of gamma irradiation. The process does not require the use of toxic chemicals and is designed to maintain the integrity and functionality of the biologic product. By reducing the impact of free radicals on proteins, the destructive effects of gamma radiation on proteins can be controlled by the Clearant Process<sup>®</sup>, allowing sufficiently high doses of radiation to be applied to the product to inactivate a broad range of known types of bacteria. We believe that the Clearant Process<sup>®</sup>, when properly optimized for a particular product, is capable of achieving a significant level of sterility against a broad range of known types of pathogens in a single irradiation step, and that, for tissue, the Clearant Process<sup>®</sup> is able to validate sterility claims under certain governmental regulations.

We believe the advantage of gamma irradiation, over other currently available sterilization technologies, is that it is inherently reliable, predictable, non-toxic, penetrating and scalable. Traditional uses of gamma irradiation have been proven to be among the best methods for inactivating pathogens that contaminate inanimate material medical devices. However, prior to the development of the Clearant Process<sup>®</sup>, it was not possible to apply this technology to the pathogen inactivation of biologics because the necessary high levels of gamma irradiation to achieve sterility also damaged the active proteins present in the biologics, compromising its integrity and functionality.

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The Clearant Process® is designed to provide increased safety to biologic products to which it is applied by virtue of its lack of specificity (it inactivates a broad range of known types of pathogens irrespective of size, origin or structure), and in some cases by being a terminal sterilization process (capable of achieving pathogen inactivation after the product has been sealed into its final package). Beginning in 2005, we started to shift our focus from research and development to the commercialization of the Clearant Process®. Subsequently we closed the laboratory and sold the related lab equipment in 2006 and 2007. The net losses from the disposal are approximately \$0 and \$130,000 for the years ending December 31, 2008 and 2007, respectively. In addition, in the first quarter of 2006 we reduced our research and development staff from six employees to one, and as of January 2007 we eliminated all research and development staff. From time to time, we may explore opportunities to supplement in-house research and development with a third party research and development consulting firm, which we believe will provide a broader expertise in research and development and allow us to maintain a low research and development headcount. Our research and development expenses for the years ended December 31, 2008 and 2007 were \$7,000 and \$80,000, respectively.

The Clearant Process® is designed to be effective against a wider spectrum of pathogens than many competing sterilization technologies, including the inactivation of bacteria, fungi, spores and lipid enveloped and non-enveloped viruses. The Clearant Process® enables our customers to meet the medical need for safer biological products and to satisfy current and future product regulatory safety guidelines. We believe the Clearant Process® can be a cost-effective technology applicable across multiple market segments, with minimal capital requirements to implement.

Our initial area of focus is the application of the Clearant Process® on tissue used in surgical procedures such as anterior cruciate ligament ( ACL ) reconstruction, spinal fusion and general orthopedic repair procedures. Additionally, we will continue to evaluate the opportunity to utilize the Clearant Process® in the following areas as capital resources and customer demand warrant:

Plasma protein therapeutics;

Recombinant protein therapeutics;

Medical devices; and

Blood and blood-related products.

We believe that the tissue market represents a continuing source of near-term revenue and that the medical devices market, the plasma protein therapeutic market and the recombinant protein market present the possibility of an intermediate to longer-term opportunity.

**Area of Focus: The Tissue Market**

We believe the Clearant Process® will address a long-standing problem for patients, surgeons and tissue banks without significantly impacting the current tissue processing cycle. Using the Clearant Process®, the tissue bank prepares and packages its tissues and ships the containers to one of the Food and Drug Administration ( FDA )-licensed gamma irradiation facilities in the United States, where the containers are irradiated using the Clearant Process® without being opened. Turnaround time in the irradiation facility is generally a few days.

Alternatively, using the Clearant sterilization service, the devitalized human tissue bank prepares and packages its tissues and ships the tissue to us and then we coordinate the irradiation of the tissue at an FDA-licensed gamma irradiation facility in the United States. The sterilization service allows devitalized human tissue banks to outsource the irradiation thereby allowing the customer to better utilize internal resources, as well as benefit from economies of scale that we can achieve. In both cases, the tissue never leaves the original packaging and arrives in the operating room for implantation in sterile condition.

Currently, tissues used in surgical allograft procedures that are not treated with the Clearant Process® are not sterilized or cleaned in the final package, and are processed aseptically often incorporating additional steps to reduce bioburden. Our preliminary research indicates that when applied to tissue, the Clearant Process® sterilizes tissue to a standard consistent with, or exceeding, the FDA definition of bacterial sterility for medical devices. The validation protocols,



methodologies and the resulting database that we have generated to establish the sterility of these products signify advancement of the standards of product safety in the tissue industry. We believe that the additional level of safety possible through the use of the Clearant Process® has the potential to shift surgical preference towards the use of allografts and away from autografts, which require more complicated surgical procedures due to the need for two surgical sites (the harvest site and the implant site) and are more painful for patients, but are used today in part due to the safety risks associated with allografts harvested from cadavers.

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In order to maximize recognition of the increased value of the safety improvements provided by the Clearant Process<sup>®</sup>, we support our outside sales representatives' efforts by marketing directly to surgeons, scientists and medical professionals, or through leaders in the industry, and supporting sales representatives with data and other marketing support materials. We believe that educating surgeons and patients about the availability of safer tissue will ultimately increase demand for use of products treated with the Clearant Process<sup>®</sup>.

We believe that the Clearant Process<sup>®</sup> provides tissue processors with sterilization (bacterial) steps and related support that can be validated, which will become increasingly important as the FDA increases regulation in the industry, including through the GTP regulations.

### Commercialization Strategy

We are currently focusing our development and commercialization efforts relating to the Clearant Process<sup>®</sup> on products involving tissue, with a longer-term focus on plasma proteins, recombinant proteins and medical devices. We believe the application of the Clearant Process<sup>®</sup> in these markets will generate a two-fold benefit for us: (1) an opportunity to generate near-term cash flow from direct distribution of Clearant Process<sup>®</sup>-treated tissue, royalties from Clearant Process<sup>®</sup>-treated tissue product sales and service fees from the Clearant sterilization service agreements, (2) while simultaneously gaining market acceptance of the Clearant Process<sup>®</sup>.

We have achieved the following milestones in the devitalized human tissue industry:

Two direct sales representatives and approximately seventeen indirect sales groups, for a total of approximately 173 sales representatives;

The twelve-month initial results of our clinical study are favorable, and the occurrence of complications, stability and strength in the anterior cruciate ligament reconstructions using tissue treated with the Clearant Process<sup>®</sup> are comparable to the patient's non-operated contralateral knees. We are currently gathering information on 24-month results.

### Customer Agreements

To date, we have entered into a total of ten agreements with customers to utilize the Clearant Process<sup>®</sup> with their products. Of these agreements, six are licensing agreements with tissue banks and one is an agreement with a manufacturer of recombinant protein products, in return for milestone payments and royalties on end-product sales. As of December 31, 2008, four of these licensees have launched tissue products that were treated using the Clearant Process<sup>®</sup>, however, they are not treating all of their tissue with the Clearant Process<sup>®</sup>. Additionally, in September 2005, we launched a new sterilization service (the Clearant Sterilization Service or Sterilization Service) which allows customers to send ready for sterilization tissue to our facility near Chicago, Illinois to be irradiated under Clearant Process<sup>®</sup> conditions by us. As of December 31, 2008, we have signed four such Sterilization Service agreements with tissue banks, of which only one is actively using this service. Many of the companies have not yet implemented the Clearant Process<sup>®</sup>, and we cannot estimate when or if they will do so.

Based on these license and Sterilization Service results, we implemented a plan to better market and promote adoption of the Clearant Process<sup>®</sup>, which is to directly distribute Clearant Process<sup>®</sup> sterile implants to our customers in order to facilitate market penetration. We do not intend to actively pursue or promote any of the new or existing license and sterilization agreements. The direct distribution revenue model may have an adverse impact on any current or future license and sterilization agreements.

### Market Opportunity

We hope to take advantage of the changes facing the devitalized musculoskeletal human tissue allograft implant (tissue) market. A number of serious and even deadly infections have been shown to be transmitted through tissues. Based on an investigation precipitated by the November 2001 death of a 23-year-old Minnesota man three days after receiving a tissue implant during reconstructive knee surgery, the Centers for Disease Control (CDC) reported to the FDA in July 2002 that it had received 54 reports of tissue-associated infections. All of these involved traditionally-processed tissue. Additionally in October 2005, due to illegal harvesting of cadavers provided to tissue banks for processing and the falsification of donor medical records, the FDA ordered a recall of certain tissue. Prior to such recall, many of the tissues had been implanted by unsuspecting surgeons raising concerns of bacterial and viral transmissions. Affected tissue had been distributed to organizations in New York, Tennessee, Illinois, Iowa and

Texas, among other states. As of February 2006, the FDA has determined that at least 761 donors were illegally accessed for tissue. Due to the adverse patient consequences that can result from communicable disease transmission through the use of tissue, U.S. regulatory authorities called for the development of validated methods for claims of sterilizing tissue.

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While bacterial contamination of tissue is more prevalent, viral transmission remains a concern as demonstrated by the transmission of Hepatitis C to at least six patients (including one resulting in death) by contaminated tissues from a single cadaver tissue donor in 2002. The CDC determined that the donor was in the window period (a period shortly after infection during which the virus or antibody is not detectable by standard tests), which resulted in the Hepatitis C not being detected during standard donor screening. There have only been two cases of HIV infection through allograft tissue, and both incidents occurred in the 1980s. These reported infections occurred with frozen bone as the vector, but none of the freeze dried grafts from the same donor transmitted the disease (Source: AAOS 2004: All About Allografts Select Highlights of the 71st Annual Meeting of the American Academy of Orthopedic Surgeons, 2004). Tissue processors today generally do not utilize any clinically meaningful viral inactivation technologies. Thus, the demand for new pathogen inactivation technologies applicable to biological products is fueled by the fact that historically there have been no effective methods capable of completely removing or inactivating a broad range of known types of pathogens, including non-enveloped viruses, while maintaining the integrity and functionality of the underlying biologic product.

The FDA is engaged in an ongoing effort to regulate tissue banks, which resulted in the publication and implementation of its current good tissue practices regulations (GTP regulations) on May 25, 2005 (21 CFR 1271.145 through 320). The GTP regulations require, among other things:

Manufacturers to recover, process, store, label, package and distribute human cells, tissues and cellular and tissue-based products in such a way that prevents the introduction, transmission or spread of communicable diseases (including bacteria and viruses); and

Tissue banks that wish to label their products sterile will need to have a validated process to demonstrate sterility.

We believe the Clearant Process® can support a validated sterility claim by tissue processors under the GTP regulations. As validated sterile tissues become widely available, we believe that there will be increasing demand by doctors, buying groups, insurance providers and risk managers for the use of only sterile tissue. In addition we believe there may be a shift from the use of autografts (a patient's own tissue) to the use of allografts (donor tissue). Allografts require only one surgical site (the implant site), reduce recovery time and decrease post-operative problems as compared to autografts, which require two surgical sites. To date doctors have reported to us no significant difference between patients receiving Clearant Process®-treated tissues as compared to those receiving traditional tissues. Furthermore, we conducted a multi-center clinical study at eight separate facilities across the U.S. The clinical study tracked the post-operative results of patients who received human soft allograft tissue that had been treated with the Clearant Process®. Study evaluations include failure rate, range of motion, and joint effusion (swelling) among other metrics which had been previously established by the clinical study committee prior to the beginning of the study. The twelve-month outcome results of this study are favorable and we are currently gathering data on the 24-month results. The occurrence of complications, stability and strength in the anterior cruciate ligament reconstructions using tissue treated with the Clearant Process® are comparable to the patient's non-operated contralateral knee. Notwithstanding such current clinical results, we have received an indication from one participating site that has prior clinical data in addition to that collected in connection with our study that the clinical outcomes are significantly less favorable than the current data collected from the other multi-center sites. We investigated the unfavorable data to understand this discrepancy and the result was favorable to us.

We currently distribute Clearant Process® tissue to surgeons, hospitals and surgery centers through a direct and indirect sales force. In addition, we provide sterilization service to tissue processors as an alternative to complete implementation of the Clearant Process®. We also license the Clearant Process® on a non-exclusive basis to tissue processors and biopharmaceutical companies in return for milestone payments and royalties on end-product sales. These sales make up a portion of the U.S. tissue market comprised of ligament, tendon and bone allografts, estimated to grow to over \$1.26 billion by 2008 (Source: MedMarket Diligence LLC, Emerging Trends, Technologies and Opportunities in the Markets for Orthopedic Biomaterials, Worldwide Report #M625, Pg. 2-5, December 2006). We will continue to maintain and service the existing royalty and sterilization service contracts; however, we are not actively pursuing additional royalty and sterilization service agreements and do not expect this to be the primary

source of revenue growth for us.

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### Competition: Existing Methods

There are a number of existing methods used to attempt to decrease the risk of pathogen transmission in the processing of tissue. These other methods fall into two categories: (1) methods that can achieve sterility; and (2) methods that reduce pathogen transmission but do not achieve medical device sterility levels.

Non-Sterile Methods. The majority of tissue processors today utilize chemical rinse steps for cleaning bone and soft tissue of lipids, fats and bone marrow. While these chemical rinse techniques reduce the level of surface contaminants on the tissue, they have traditionally been limited in their ability to penetrate the tissue effectively to destroy pathogens potentially residing in the interior of tissue. Because of this inability to penetrate the tissue effectively, sterility cannot be assured. Another widely used technique utilizes gamma radiation at significantly lower doses (historical average dose of 18kGy) than those used under the Clearant Process® on tissue products.

We have conducted studies which indicate that doses of 18kGy of radiation to tissues are inadequate to sufficiently inactivate resistant bacteria such as Clostridium spores, and do not significantly inactivate viruses, and thus sterility cannot be assured. The CDC determined that a Clostridium-infected tissue was the source of the infection that resulted in the death of a 23-year old man after an otherwise ordinary knee tissue transplant surgical procedure in 2001.

Sterile Methods. The BioCleanse process marketed by Regeneration Technologies, Inc. ( RTI ) is a specific chemical method of pathogen inactivation that claims sterility. While RTI claims that the BioCleanse process has been validated to eliminate bacteria, fungi, spores and viruses from tissue, BioCleanse uses additives that must be removed from the final container prior to final packaging, requires a substantial capital investment to build the equipment required and is not commonly licensed commercially to other tissue processors. Unlike the Clearant Process®, the BioCleanse procedure is not reported to be a terminal pathogen inactivation process. Finally, traditionally higher doses of radiation without the Clearant Process® could achieve higher levels of sterility but destroy the integrity and functionality of the tissue and therefore have not been commercially used. However, there may be other entrants into the market that make claims of sterility, which could adversely impact our ability to gain market acceptance.

### **Other Potential Commercialization Markets: The Plasma Protein Therapeutics Market**

The plasma industry develops and manufactures plasma protein therapeutic products which are mainly derived by fractionating human plasma. Plasma protein therapeutic products include intravenous immunoglobulin ( IGIV ), Factor VIII, albumin and alpha-one proteinase inhibitor and are produced by companies such as Baxter, Bayer, Octapharma and CSL. Because these products are derived from human plasma, the sterility of these products for therapeutic applications is crucial to their safety and efficacy when used in patients. Today, the manufacturing and processing of these plasma protein therapeutic products involves extensive in-process steps that attempt to ensure the sterility of the final product. However, we believe there is currently no commercially available technology to sterilize plasma protein therapeutic products in their final packaging (i.e. terminal sterilization).

We believe that there is a desire in the marketplace to increase the safety of the plasma protein therapeutics by adopting a manufacturing process that incorporates a terminal sterilization step or an intermediate robust sterilization step that can provide a greater margin of safety with respect to sterility. Terminal sterilization may also better enable new packaging and delivery options, such as medical devices that contain plasma protein therapeutics in a final package. To date, we have been successful in applying the Clearant Process® on a laboratory scale at day zero, using some protein products.

Our strategy would be to leverage the developed technology and the intellectual property created with these products to develop the Clearant Process® as a terminal sterilization technology for plasma protein therapeutics. However, we are not actively pursuing this market at this time, but we will continue to evaluate opportunities as capital resources and customer demands warrant.

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**Other Potential Commercialization Markets: The Recombinant Products Market**

The biotechnology industry develops and manufactures recombinant products, the majority of which are used for therapeutic purposes. Recombinant products are genetically engineered biological products and include, among others, products such as insulin, erythropoietin, monoclonal antibodies, vaccines, interferon, cell growth factors and colony stimulating factors produced by companies such as Amgen, Genentech, Wyte, Bayer and Baxter Healthcare. Understandably, the sterility of these products for therapeutic applications is crucial to their safety and efficacy when used in patients. Today, the manufacturing and processing of these recombinant products involves extensive in-process steps that attempt to ensure the sterility of the final product. However, we believe there is currently no commercially available technology to sterilize recombinant products in their final packaging (i.e. terminal sterilization).

We believe, based on precedents established in the drug industry, that adopting a manufacturing process that incorporates a terminal sterilization step should provide a greater margin of safety at a lower cost relative to those processes that depend on in-process sterilization procedures. Such terminal sterilization may also better enable new packaging and delivery options, such as pre-filled syringes. In addition to the terminal sterilization of recombinant products, we believe that there are opportunities to utilize the technology to improve and provide solutions for problematic in-process sterilization protocols used in certain recombinant products.

Our strategy would be to leverage the technology developed and the intellectual property created with these products and the visibility of working with plasma protein manufacturers to develop the Clearant Process<sup>®</sup> as a terminal sterilization technology for new recombinant protein products that can be economically scaled to accommodate this growth with minimal disruption of an existing manufacturing infrastructure. However, we are not actively pursuing this market at this time, but we will continue to evaluate opportunities as capital resources and customer demands warrant.

**Other Potential Commercialization Markets: The Medical Device Market**

We have generated laboratory scale data that suggests that the Clearant Process<sup>®</sup> can be used in connection with the sterilization of a medical device which incorporates a biologic into such device. We successfully processed, and subsequently performed, mechanical integrity testing of a development-stage medical device in final packaging through the Clearant sterilization service. We believe that traditional sterilization methods for medical devices will not be appropriate when such device incorporates a biologic because traditional uncontrolled irradiation for medical devices would destroy the integrity of the protein. Further, any filtrated biologic would still need to be aseptically applied to the device where contamination could occur. The application of the Clearant Process<sup>®</sup> can be a terminal sterilization step thereby sterilizing both the medical device and biologic in its final packaging. While medical devices are not areas of our near-term focus, we will continue to evaluate their commercial potential through sponsored research agreements or license agreements that are of economic or strategic value to us.

**Competition**

The majority of therapeutic proteins on the market today are manufactured under controlled conditions by fractionating human plasma or from genetically engineered cells. Products manufactured by genetically engineered cells are generally considered to present a very low risk of viral transmission; however, products manufactured by fractionating human plasma contain risks of viral and bacterial transmission from the collection of human plasma. In addition, all therapeutics have a risk of bacterial contamination during manufacturing and filling operations (i.e., the placement of the end-product in the final vial or packaging). The risk of bacterial contamination requires companies to aseptically manufacture and fill their products and perform substantial bacterial testing during the manufacturing process and at its conclusion before releasing batches of product. Maintaining and validating aseptic manufacturing conditions to the level required by the FDA for drugs and related products is extremely expensive and subject to failure. Contamination of therapeutic protein products by bacteria costs biotech companies millions of dollars per year because of the need to rework or destroy product. Such contamination could have clinical consequences and can arise from the contamination of the source cell lines themselves or from unintended introduction of viruses during production.





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Plasma protein therapeutic products have always been under increasing stringent standards and despite their generally favorable safety record, biotechnology recombinant products are coming under increasingly stringent standards intended to decrease the risk of transmitting infectious agents through their use, including standards meant to address emerging pathogenic agents. Our expectation is that manufacturers will incorporate into their production processes multiple, independent viral inactivation and removal steps. This standard is described in detail in a guidance document governing biotechnology recombinant products developed through the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and which has now been adopted by the United States, the European Union and Japan.

The most commonly used method for pathogen removal for protein therapeutic products is filtration. Filtration methods, currently being marketed by companies such as Asahi Kaisai Corporation, Millipore Corporation and Pall Corporation, can be used only with intermediate liquid materials and cannot be used for terminal sterilization in the final packaging. The efficacy of filters in removing pathogens is further limited by the size of the agent to be removed and the size of the biological product molecule. The molecular size of the active biological product dictates the pore size of the filter used in the process. Thus, any pathogen smaller than this pore size cannot be removed from the biological product using the filter. Many non-enveloped viruses are small (e.g., B19 Parvovirus and transfusion transmitted viruses) and therefore, are unlikely to be removed from the majority of biological products using these filtration methods. As a result, the filtration step may not fully meet the evolving requirements of the regulatory authorities for the safety of biological products (i.e., removal or inactivation of known and unknown lipid-enveloped and non-enveloped viruses including small size viruses). In addition, in plasma protein therapeutic products, many companies use chemicals like solvent-detergent as an additional step for pathogen inactivation. However, to date, methods such as solvent-detergent treatment have failed to significantly inactivate non-enveloped viruses and thereby are an inefficient means of obtaining inactivation of all known types of pathogens.

The Clearant Process<sup>®</sup> offers manufacturers of therapeutic protein products the ability to provide inactivation of a wide spectrum of pathogens at various stages in the manufacturing process, including treatment of source materials, growth media, in-process intermediates or terminal sterilization of the final product. We believe that once the Clearant Process<sup>®</sup> is successfully customized for a customer's product, this level of inactivation, including inactivation of non-lipid enveloped viruses, should enable therapeutic protein products manufacturers to meet the increasingly more rigorous regulatory standards being imposed on a worldwide basis and supplement the performance of existing filtration and solvent-detergent processes.

Based on existing regulatory guidelines for small molecule drugs, which require terminal sterilization whenever possible, we believe that, once established commercially, terminal sterilization may be required by regulators for new protein medicines and new presentations of existing drugs (e.g. novel packaging in pre-filled syringes versus bulk packaging). Developers of new products may prefer terminal sterilization due to the greater assurance of product quality, the safety it provides and anticipated lower costs. In addition, eventually terminal sterilization is anticipated to reduce the cost and shipping delays caused by the bacterial testing that must be done to support the processes by which these products are manufactured today. The convergence of all of these factors over several years may position our technology to become a manufacturing standard for new recombinant products, much as in-process filtration is the standard today.

Based on experience with sterile pharmaceutical products, the FDA requires sterility testing and expensive in-process testing for every batch of products that is manufactured using aseptic sterilization techniques. Sterility testing is destructive (consumes product for testing). Sterility testing and other aspects of quality control/assurance (including facilities monitoring) for aseptically processed products are also expensive to carry out. Terminally sterilized pharmaceutical products can be released for distribution to the public by parametric methods (statistical sampling of product batches) this approach is supported by the FDA and is routine for the pharmaceutical industry. In addition, if a product is sterilized in its final packaging, the quality assurance requirements for facilities monitoring is also considerably less stringent than is the case for aseptically-processed products.

### **Regulatory Strategy**

Commercial products manufactured incorporating the Clearant Process<sup>®</sup> will be regulated by governmental agencies, including the FDA and equivalent regulatory authorities in other countries. Although it will be the responsibility of

our customers whose products incorporate the Clearant Process® to obtain any appropriate regulatory approvals for their products, these third parties may rely in part on studies and tests conducted by us as part of our commercialization strategy to demonstrate the efficacy of the Clearant Process®.

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We do not anticipate that the Clearant Process® itself will be directly regulated, either as a drug, biologic or device, since gamma irradiation should be considered a manufacturing method for regulated products. The commercial gamma irradiation facilities in which the Clearant Process® is carried out, and the equipment therein, are regulated as manufacturing facilities (i.e., subject to registration, product listing, licensing and good manufacturing practice requirements by the FDA). There are a significant number of such facilities which are currently licensed by the FDA throughout the world which currently sterilize such products as medical devices, syringes and surgical gloves. Manufacturers of individual products may also be required to obtain approval from the applicable regulatory bodies to incorporate the Clearant Process® into their products manufacturing processes. Incorporation of the Clearant Process® into a manufacturing process may be accomplished as a manufacturing change for an existing product, or as part of the product development process in the case of a new product. In the case of tissue processors, the incorporation of the Clearant Process® does not require regulatory approval prior to marketing as these products are currently not subject to pre-marketing approval by regulators.

With the introduction of the Clearant sterilization service, the Clearant sterilization service facility became registered with the FDA in February 2006 as a tissue processor for the processing of the devitalized human tissue allografts, and is subject to the applicable rules and regulations of the Current Good Tissue Practice for Human, Cell, Tissue and Cellular and Tissue Based Products (HCT/P s), 21 CFR Parts 16, 1270, and 1271.

To the extent that our customers products are subject to pre-market approval, manufacturers and processors of individual products that wish to incorporate the Clearant Process® into their own products are required to submit product-specific data to regulators. We may conduct some of the in vitro studies, including pathogen inactivation studies, to support these submissions, although some manufacturers will likely choose to conduct these studies themselves or through other contract research organizations. In some cases, clinical data may be required to establish the safety and efficacy of products sterilized by the Clearant Process®. For a new product, these studies will be incorporated into the basic clinical development plan for that product. For existing products for which the introduction of the Clearant Process® represents a manufacturing change, these studies may take the form of comparability studies, an abbreviated type of clinical trial. Such trials will be the responsibility of the individual manufacturers and processors. If required, an investigational device exemption for medical devices, or an investigational new drug application for drugs or biologics, may be submitted to the FDA by the manufacturer or processor. Tissue processors are not required under current regulations to perform any type of clinical trial prior to offering Clearant Process® minimally manipulated treated allografts for sale. At the successful conclusion of such studies as may be required by the FDA, the manufacturers or processors will apply for registration of their biologics incorporating the Clearant Process®. Upon approval by the FDA, the new license for the product will reside with the manufacturer or processor. In the developed markets (e.g., the European Union, Japan and Canada), the regulatory framework and requirements are similar to those in the United States.

### **Intellectual Property**

Our success depends in part on our ability to obtain patents and protect trade secrets. We must also operate without infringing upon the proprietary rights of others, while preventing others from infringing upon our rights. We have been building, and intend to continue to build, a patent portfolio to protect our position in the market.

As of December 31, 2008, we have a total of 87 issued or pending patent applications. We currently have eleven issued U.S. patents, which will expire between 2013 and 2023, and thirty-one patents protecting our technology. We intend to continue to file patent applications, detailing the optimal process conditions for the application of the Clearant Process® to particular products.

We review intellectual property held by others to determine if it may be complementary to our intellectual property portfolio or would impact our ability to operate in the market segments on which we are currently focused. To date we are not aware of any competing intellectual property that would materially limit our ability to operate as currently planned.

### **Employees**

As of December 31, 2008, we have approximately eight total employees of which seven are full-time employees: two executive officers, two operations employees, three sales and marketing employees and one clerical and administrative personnel.



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### **Reports to Security Holders**

We send an annual report including audited financial statements to all of our stockholders of record. Anyone may obtain a copy of our annual report without charge by writing to us at: Investor Relations, Clearant, Inc., 1801 Avenue of the Stars, Suite 435, Los Angeles, California 90067.

We file reports with the SEC in accordance with the Exchange Act, including annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information.

The public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NE, Washington, DC 20549, on official business days during the hours of 10:00 am to 3:00 pm. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, we are an electronic filer, and the SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The website can be found at <http://www.sec.gov>. All reports filed with the SEC are also available, free of charge on our corporate website as soon as reasonably practicable after such reports are filed with, or furnished to, the SEC. Our corporate website is located at [www.clearant.com](http://www.clearant.com). The information contained on our website is not part of this prospectus or incorporated by reference herein.

### **Item 1A. Risk Factors**

*You should carefully consider and evaluate all of the information in this report, including the risk factors listed below. If any of these risks occur, our business, results of operations and financial condition could be harmed, the price of our common stock could decline, and future events and circumstances could differ significantly from those anticipated in the forward-looking statements contained in this report.*

**RISKS AND UNCERTAINTIES IN ADDITION TO THOSE WE DESCRIBE BELOW, THAT MAY NOT BE PRESENTLY KNOWN TO US, OR THAT WE CURRENTLY BELIEVE ARE IMMATERIAL, MAY ALSO HARM OUR BUSINESS AND OPERATIONS. IF ANY OF THESE RISKS OCCUR, OUR BUSINESS, RESULTS OF OPERATIONS AND FINANCIAL CONDITION COULD BE HARMED, THE PRICE OF OUR COMMON STOCK COULD DECLINE, AND FUTURE EVENTS AND CIRCUMSTANCES COULD DIFFER SIGNIFICANTLY FROM THOSE ANTICIPATED IN THE FORWARD-LOOKING STATEMENTS CONTAINED IN THIS REPORT.**

#### ***Risks Related to Our Business***

##### **We will need additional financing to fund our business.**

We will require additional financing in order to carry out our business plan. Such financing may take the form of the issuance of common or preferred stock or debt securities, or may involve bank financing. There can be no assurance that we will obtain such additional capital on a timely basis, on favorable terms, or at all. If we raise additional capital through the incurrence of debt, our business may be affected by the amount of leverage we incur, and our borrowings may subject us to restrictive covenants. If we are unable to generate the required amount of additional capital, our ability to meet our financial obligations and to implement our business plan may be adversely affected and we may be required to delay, reduce or stop operations, any of which would have a material adverse effect on our business. Furthermore, if we issue additional equity securities, current stockholders could experience dilution of their ownership in our company.

##### **Unstable market and economic conditions may have serious adverse consequences on our business.**

Our general business strategy may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. A prolonged or profound economic downturn may result in adverse changes to product reimbursement, pricing or sales levels, which would harm our operating results. There is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which would directly affect our ability to attain our operating goals on schedule and on budget. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon development plans. There is also a possibility that our stock price may decline, due in part to the volatility of the stock market and the general

economic downturn.

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**Our limited operating history may make it difficult to evaluate and forecast our business to date, revenue potential and project our future viability.**

We were incorporated in April 1999 in order to acquire certain assets of PureSource, Inc. and Sterways Pioneer, Inc., including patents that comprise a portion of the Clearant Process<sup>®</sup>. Prior to the second quarter of 2004, we were strictly a research and development company. We are now in the early stage of operations and development, and have only a limited operating history on which to base an evaluation and forecast of our business, revenue potential, and prospects. In addition, our operations and developments are subject to all of the risks inherent in the growth of an early stage company. We may not succeed given the technological, marketing, strategic and competitive challenges we will face. The likelihood of our success must be considered in light of the expenses, ability to increase revenues, maintain existing revenues, difficulties, complications, problems and delays frequently encountered in connection with the growth of a new business, the continuing development of new technology, and the competitive and regulatory environment in which we operate or may choose to operate in the future. We have generated limited revenues to date, and there can be no assurance that we will continue to achieve the historical revenue levels, grow revenues or be able to successfully develop our products and penetrate our target markets. In addition, as we attempt to grow revenue, it is likely that we will experience monthly and quarterly revenue fluctuations. Further, it is likely that significant losses will be incurred through at least the end of the year and probably beyond, as we incur significant expenses associated with the further development, marketing and commercialization of the Clearant Process<sup>®</sup>. If we do not raise any additional funds, our revenues do not increase and we do not reduce our expenses, our cash reserves will be exhausted during approximately the second quarter 2009 or before if we are not able to successfully negotiate with vendors.

**We have a history of and expect to continue to generate substantial losses, may not become profitable and will need to expand our Clearant Process<sup>®</sup> to increase revenues.**

To date, we have generated only limited revenues, and have had limited marketing activities. We expect that we will have significant operating losses and accumulated losses and will record significant net operating cash outflows at least through the end of 2009 and possibly beyond.

Our ability to achieve meaningful near-term revenues is heavily dependent on our current effort to prove the efficacy of the Clearant Process<sup>®</sup> in the tissue market and the successful commercialization of such technology. No assurances can be made that we will be successful in doing this. In addition, if we begin to be a processor representative for certain tissue of our customers, our ability to assist in the distribution of such tissues and recover the purchasing and operating costs will be meaningful in our ability to achieve revenues and control expenses. Our longer term financial performance, on the other hand, is heavily dependent on timely and cost effectively proving the efficacy of the Clearant Process<sup>®</sup> in other markets. We may not successfully prove the efficacy of our pathogen inactivation processes for specific products according to our current development schedule, if at all.

Even if we successfully prove the efficacy of the Clearant Process<sup>®</sup> for specific products, there can be no assurance that we will be able to successfully market that process to third party manufacturers or that our marketing efforts will result in significant revenues. Various other factors could have material, negative impacts on our results of operations, including difficulties encountered by third parties in obtaining governmental approvals for products which are treated with our pathogen inactivation processes; adverse changes in government regulations; the timing of the introduction of new processes; competitive forces within the current and anticipated future markets served by us; and general economic conditions. Fluctuations in results may also occur depending on differences in the timing of, and the time period between, our expenditures on the development and marketing of our processes and the receipt of revenues.

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**The Clearant Process® is at an early stage of commercial development and, if we are not able to clinically validate claims of our effectiveness in our target markets and obtain widespread commercial acceptance of the Clearant Process® in our target markets, we may not be able to grow or attain profitability.**

Our growth and profitability will depend in large part on our unproven ability to:

Continue to successfully demonstrate the efficacy of the Clearant Process® in tissue;

Successfully demonstrate the efficacy of the Clearant Process® in sterilizing other biological products, including plasma protein, recombinant proteins and medical devices;

Successfully market and commercialize the Clearant Process®;

Enter into additional license, sterilization service and processor representative agreements with manufacturers and providers of biological products;

Develop and protect our intellectual property rights;

Complete product-specific development of the Clearant Process® for our target markets; and

Obtain (or have the users of the Clearant Process® obtain) required product regulatory approvals.

Research and development and commercialization efforts may not be successful or, if they are, the Clearant Process® may not obtain market acceptance among major manufacturers and providers of tissues and other biological products. We are currently conducting a multi-center clinical study at eight separate facilities across the U.S. The clinical study tracks the post-operative results of patients who received tissue that had been treated with the Clearant Process®. Study evaluations include failure rate, range of motions and joint effusion (swelling) among other metrics which had been previously established by the clinical study committee prior to the start of the study. The twelve-month outcome results of this study are favorable and we are currently gathering data on the 24-month results. The occurrence of complications, stability and strength in the anterior cruciate ligament reconstructions using tissue treated with the Clearant Process® are comparable to the patient's non-operated contralateral knee. Notwithstanding such current clinical results, we have received an indication from a single site, both participating in such multi-center study and with prior clinical data, that the clinical outcomes are significantly more adverse than the current data collected from the other multi-center sites. We are currently collecting, assessing and investigating such adverse data to understand this discrepancy. If the data and results from the multi-center are negative, it would materially impact the adoption of the Clearant Process® and our revenues.

**We are experiencing material cash flow constraints.**

We are past due on many of our accounts with vendors, suppliers, distributors, sales representatives and other service providers. We are in discussions with many of these accounts and are actively trying to resolve these past due amounts. No assurances can be made that we will be successful in reaching a settlement. Furthermore, many of these outstanding balances are with critical vendors and no assurances can be made that these accounts will continue to conduct business with us on similar terms or at all. If this happens, it could materially impact operations and revenue.

**We utilize Independent Sales Representatives and Distributors.**

We utilize a strategy to contract with independent sales representatives and distributors. These sales teams are not our employees but are independent contractors, and in some cases sell many other product lines. We cannot give any assurances that these sales teams will continue to market our products or how much time and effort they will devote to us versus other product lines. Further, we expect other products and companies to compete for their attention and time. Changes in product offerings or focus by these teams could lead to material fluctuations in revenue and unpredictability in revenue.





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**Achieving market acceptance for the Clearant Process® will depend on our ability to demonstrate the efficacy of the Clearant Process® in our target markets, as well as how the Food and Drug Administration applies the Good Tissue Practice guidelines issued on November 18, 2004 which became effective on May 25, 2005, and the Task Force on Human Tissue Safety created on August 30, 2006.**

We currently have a limited sales force and may need to hire additional sales and business development personnel. Our marketing success will depend, to a significant degree, on our unproven ability to successfully demonstrate the efficacy of the Clearant Process® in our target markets, on the willingness of potential users of the Clearant Process® to adopt the Clearant Process® and on the market's willingness of doctors and patients to utilize Clearant Process®-treated products. We may not be successful in our marketing endeavors or, if we are, we may not be able to adequately, timely and profitably market our pathogen inactivation process.

In addition, adoption of the Clearant Process® by potential users may depend, in part, on how the Good Tissue Practice or GTP regulations issued by the Food and Drug Administration or FDA on November 18, 2004, effective on May 25, 2005, are applied to tissue processors utilizing the Task Force created on August 30, 2006. The requirements may not provide sufficient incentive for tissue processors to adopt technologies that can provide validation for sterility label claims, the Clearant Process® may not prove compatible with the GTP regulations, or the FDA may, as a result of normal inspections of tissue processors, require additional data to allow customers to claim sterility. If the FDA requires additional data from our customers to support label claims of sterility, they may not be able to develop it in a timely and cost-effective manner, or at all. The inability of our customers to obtain or maintain validation of a sterility claim, or the failure to develop additional data if it is required, could materially impact our business, financial condition and results of operations.

**Our success will depend on our ability to retain our managerial personnel and to attract additional personnel.**

Our success will depend largely on our ability to attract and retain managerial personnel. Competition for desirable personnel is intense, and we cannot guarantee that we will be able to attract and retain the necessary staff.

Furthermore, we do not currently have employment contracts with our key employees, except for an employment agreement with our Chief Executive Officer and Chief Financial Officer, Jon Garfield.

The loss of members of managerial, sales or scientific staff could have a material adverse effect on our future operations and on successful development of the Clearant Process® for our target markets.

We also collaborate with scientists and physicians at academic and other institutions, but these scientists and physicians may have other commitments or conflicts of interest that limit their availability. The failure to maintain our management, sales and scientific staff and to attract additional key personnel could materially adversely affect our business, financial condition and results of operations. Although we intend to provide incentive compensation to attract and retain our key personnel, we cannot guarantee that these efforts will be successful. We do not carry key man life insurance for any of our personnel.

We may need to expand our finance, administrative, scientific, sales and marketing and operations staff, and it is currently anticipated that we will need to hire an employee for the product development of tissues, other than musculoskeletal. There are no assurances that we will be able to make such hires. In addition, we may be required to enter into relationships with various strategic partners and other third parties necessary to our business. Planned personnel may not be adequate to support our future operations, management may not be able to hire, train, retain, motivate and manage required personnel or management may not be able to identify, manage and exploit existing and potential strategic relationships and market opportunities. If we fail to manage our growth effectively, it could have a material adverse effect on our business, results of operations and financial condition.

**We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to comply with public company regulations.**

As a public company, we incur significant legal, accounting and other expenses that we would not otherwise incur if we were private. The Securities Exchange Act and rules of the Securities and Exchange Commission (SEC) impose various requirements on public companies, resulting in increased legal and accounting expenses. The Sarbanes-Oxley Act requires us to maintain effective disclosure controls and procedures and internal controls for financial reporting, which requires significant resources and management oversight, increases our legal and financial compliance costs, and makes activities more time-consuming and costly. If we identify deficiencies in our internal controls over

financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Accordingly, from time to time we evaluate whether remaining a public company is in the best interests of our stockholders, or whether we should go private or cease publicly reporting our financial information and results of operations.

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**The Clearant Process® has been commercialized only in the tissue market and our future success depends on our ability to successfully commercialize the Clearant Process® for use in our other, larger target markets.**

The Clearant Process® must be optimized on an individual basis for each product or class of products on which it will be used for pathogen inactivation. While the Clearant Process® has been commercialized for the tissue market, it has not been optimized for all of our target products and we face the risks of failure inherent in developing new technologies. It may not be possible to optimize or commercialize the Clearant Process® for any of our target products. The inability to optimize or commercialize the process in any given case may adversely affect the marketplace's confidence in the effectiveness of the Clearant Process® in such case or in any other case.

We, and our potential customers, may have to conduct significant additional research and animal or human testing before the Clearant Process® can be used by other third parties for a significant number of products. Clinical trials are expensive and have a high risk of failure. If our customers are unable or unwilling to fund these trials, or if these trials fail, our ability to generate revenues will be materially and adversely impacted.

To date, there has been only limited use and testing of Clearant Process®-treated products in humans and, while early indications have been favorable, these limited initial results may not be statistically significant or predictive of future results, either for the tissue market or new products which are treated by the Clearant Process® in the future. Our multi-center clinical study across the U.S. tracks the post-operative results of patients who received tissue that had been treated with the Clearant Process®. Study evaluations include failure rate, range of motions, and joint effusion (swelling) among other metrics which had been previously established by the clinical study committee prior to the start of the study. The twelve-month outcome results of this study are favorable and we are currently gathering data on the 24-month results. Notwithstanding such current clinical results, we have received an indication from a single site, both participating in such multi-center study and with prior clinical data, that the clinical outcomes are significantly more unfavorable than the current data collected from the other multi-center sites. Although we investigated the adverse data to understand this discrepancy and the results were favorable to us, if additional data and results from the multi-center prove to be negative, it would materially impact the adoption of the Clearant Process® and our success. To compete effectively with other pathogen inactivation or removal technologies, our processes must be easy to use, compliant with regulations and cost-effective on a commercial scale. We may not be able to achieve any of these objectives. The Clearant Process® or third-party products using it may fail in one or more testing phases or may not attain market acceptance. Third parties may develop superior products or have proprietary rights that preclude us from marketing the Clearant Process®. If research and testing are not successful, the Clearant Process® will not be commercially viable, and our business, financial condition and results of operations will be materially adversely affected.

**The success of our business will depend on our ability to develop new uses of the Clearant Process® that can be applied cost-effectively on a commercial scale, which may in some cases require potentially costly and time-consuming modification of the Clearant Process®.**

The Clearant Process® has been used in a limited manner on a commercial scale only in the tissue market. It may be difficult or impossible to use the Clearant Process® economically on a commercial scale for products other than those in which the Clearant Process® currently is being used. As part of the commercialization of the Clearant Process®, we transfer the Clearant Process® technology to our licensees in order to allow the licensees to practice the technology and integrate the technology into their facility or manufacturing processes. Additionally, in September 2005, we launched a new sterilization service which allows tissue banks to send ready-for-sterilization tissue to our facility near Chicago, Illinois to be irradiated under Clearant Process® conditions by us. Under either a license agreement or sterilization service agreement, the Clearant Process® is transferred, at least in part, to the customer and such transfer process consists of providing our developed standard procedures and supporting data, packaging specifications, supply lists, irradiator suggestions and irradiation specifications.

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To date, we have completed development of these transfer procedures and specifications for musculo-skeletal applications of allograft tissue processor licensees, some of which use the Chicago facility. We may not be able to develop appropriate procedures, packaging and specifications for other (tissue and non-tissue) markets and licensees without substantial additional development time and expense, if at all.

The cost and amount of time required to transfer the technology to a customer is dependent upon several factors, including the customer's current manufacturing processes, facilities, personnel, product and packaging. In addition, as a result of limitations associated with product-specific requirements for particular applications of the Clearant Process® or otherwise, we may face future situations which could require greater cost and time than anticipated to transfer the technology or where it is unable to effectively transfer the technology at all for use on a commercial scale. In such case, we would be required to modify the parameters pursuant to which the Clearant Process® is applied to the applicable product, which could lead to the need for additional testing and clinical trials by the third party user. If we were required to modify the Clearant Process®, our development costs would increase and our programs could be delayed significantly, with a similar delay in receipt of potential licensing and sterilization service revenues. In any such circumstance, we may not be able to successfully modify the Clearant Process® at all for use on a particular product on a commercial scale. If we are unable to timely and cost-effectively develop successful technology transfer procedures for our target markets, including appropriate procedures, packaging and specifications, our ability to market and license the Clearant Process® and to generate licensing and sterilization service revenues, and our business, financial condition and results of operations, will be adversely affected.

**The success of our business will depend on our ability to develop and protect our intellectual property rights, which could be expensive, as well as our ability to conduct our business without infringing the intellectual property rights of others.**

The Clearant Process® and our other technologies will be protected from unauthorized use by others only to the extent that they are covered by valid and enforceable patents or effectively maintained as trade secrets. As a result, our success depends in part on our ability to obtain patents, protect trade secrets, operate without infringing upon the proprietary rights of others and prevent others from infringing on our proprietary rights. The steps we take to prevent misappropriation of the Clearant Process® and our other technologies may not be effective, particularly in foreign countries where laws or law enforcement practices may not protect our proprietary rights as fully as in the United States.

We cannot be certain that our patents or patents that we license from others will be enforceable and afford protection against competitors. Our patents or patent applications, if issued, may be challenged, invalidated or circumvented. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Even if our patents are valid, we cannot guarantee that competitors will not independently develop alternative technologies that duplicate the functionality of our technology. Due to the extensive time required for development, testing and regulatory review of customers' use of our processes, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents. In addition, if third parties become aware of parts of our technology that are covered by pending patent applications, we will be unable to prevent those parties from using such information until the patents issue. This could delay commercialization of the Clearant Process®.

We also cannot be certain that we were the first to make the inventions covered by each of our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. In that case, the affected patent or patent application would not be valid, and we may need to license the right to use third-party patents and intellectual property to continue development and marketing of our processes. We may not be able to acquire such required licenses on acceptable terms, if at all. If we do not obtain such licenses, we may need to design around other parties' patents or we may not be able to proceed with the development, manufacture or licensing of our processes.

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Although we are not aware of any interfering patents or other intellectual property held by others, such intellectual property may impact our ability to operate in the market segments on which we are currently focused or may target in the future. Further, we have not conducted a freedom to operate search with respect to our intellectual property, which is a comprehensive search of existing patents and pending applications that would (or in the case of pending patent applications, if granted) prohibit us from protecting our intellectual property. If there are interfering patents or other intellectual property and we are unable to license such interfering patents or other intellectual property on commercially reasonable terms or to modify the Clearant Process® in a cost-effective manner that does not (i) infringe on such intellectual property and (ii) materially impact the viability of the Clearant Process®, our business, results of operations and financial condition could be adversely affected.

We may face litigation to defend against claims of infringement, assert claims of infringement, enforce our patents, protect our trade secrets or know-how, or determine the scope and validity of others' proprietary rights. Patent and other intellectual property litigation is costly. In addition, we may be required to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine the priority of inventions relating to our patent applications. Determining the scope of our competitors' rights could be costly in terms of our scientists' and management's time and resources.

Furthermore, we may rely on trade secret law to protect technologies and proprietary information that we cannot or have chosen not to patent. Trade secrets, however, are difficult to protect. Although we attempt to maintain protection through confidentiality agreements with necessary personnel, contractors and consultants, we cannot guarantee that such contracts will not be breached. Further, confidentiality agreements may conflict with other agreements which personnel, contractors and consultants signed with prior employers or clients. In the event of a breach of a confidentiality agreement or divulgence of proprietary information, we may not have adequate legal remedies to maintain our trade secret protection. Litigation to determine the scope of intellectual property rights, even if ultimately successful, could be costly and could divert management's attention away from business.

**We may be subject to products liability with respect to products which are treated with the Clearant Process® under license, processor representative or sterilization service agreements and which cause harm to others or damage to products, including related and costly litigation or other proceedings, and our products liability insurance may not provide adequate coverage and may not be available in the future.**

We are exposed to potential liability risks inherent in the testing, marketing, licensing, distributing and treating of biotherapeutics and tissue products treated with the Clearant Process®. We may be liable if it is determined that any of our pathogen inactivation processes, or the products of any third party which utilize those processes, causes injury, illness or death. Furthermore, to the extent that a pathogen inactivation process adversely alters a product and such causes injury, illness, death or damage to the product, we may be liable. The regulatory compliance of pathogen inactivation levels is measured by the number of pathogens that are inactivated. Thus, it is possible that biological products heavily contaminated with pathogens could be treated by customers with the Clearant Process® and achieve levels of pathogen inactivation sufficient to meet regulatory standards for sterilization or viral inactivation, yet still contain sufficient pathogens to be harmful to humans.

We have obtained product liability insurance covering the commercial introduction of any product that utilizes our pathogen inactivation processes, but we do not know whether we will be able to maintain such insurance on acceptable terms, if at all. Any insurance we have or may obtain in the future may not provide adequate coverage against potential liabilities. A liability claim, regardless of merit or eventual outcome, and regardless of whether the user of the Clearant Process® complied with our standards and procedures for its proper use, could affect manufacturers and the public's perception of the safety and efficacy of the Clearant Process®, delay, impede or otherwise reduce the licensing and use of the Clearant Process® by third parties and materially adversely affect our business, results of operation and financial condition.

In addition, successful product liability claims made against competitors could cause a perception that we are also vulnerable to similar claims and could negatively affect public perception of the technology and thus third parties' willingness to use the Clearant Process®, and thus adversely affect our business, results of operation and financial condition.



**Table of Contents****If our sterilization technology is not accepted by manufacturers of biological products in our target markets and the health care community at large, our business will suffer and we will not be able to successfully implement our business plan.**

We believe that our ability to commercialize the Clearant Process<sup>®</sup> effectively will depend on the safety, efficacy and cost-effectiveness of the Clearant Process<sup>®</sup>, as well as the willingness of manufacturers of biological products to adopt new pathogen inactivation technologies. We believe that market acceptance will depend on the extent to which manufacturers and distributors of tissues and other biological products, as well as physicians, patients and health care payers, perceive the benefits of using the Clearant Process<sup>®</sup> and, if applicable, that such benefits outweigh any potential additional cost. As part of our strategy to obtain wide-spread acceptance of the Clearant Process<sup>®</sup>, we have entered into, and intend to continue to seek to enter into, sponsored research agreements with potential users of the Clearant Process<sup>®</sup> to support research on and validation of potential applications of the Clearant Process<sup>®</sup> to such products. While we expect that the Clearant Process<sup>®</sup>, when optimized for application to a particular product, will be capable of inactivating a broad range of known types of pathogenic microorganisms, a product processor or manufacturer may direct us, or may choose, not to optimize the Clearant Process<sup>®</sup> to inactivate the broad range of known types of pathogenic microorganisms in a particular application. If a product produced with such a process results in infections from pathogens that were not adequately inactivated, the marketplace's overall confidence in the Clearant Process<sup>®</sup> may be adversely affected both for that product and for other applications of the Clearant Process<sup>®</sup>. Even if our processes and the third party products on which they will be used receive the necessary regulatory approvals, our processes may not achieve any significant degree of market acceptance among biological product manufacturers, physicians, patients and health care payers. For various reasons, such as implementation costs, ineffectiveness against all types of pathogens, differing regulatory requirements and logistical concerns, the biological products industry has not always integrated new inactivation technologies into their processes. Although we believe the Clearant Process<sup>®</sup> can significantly improve the safety of tissues and other biological products, we cannot provide assurances that our technologies will be accepted rapidly or, other than in the tissue market, at all. If our processes fail to achieve market acceptance, we will be unable to implement successfully our licensing strategy and our business, results of operations and financial condition would be materially adversely affected.

**We face competition from a number of companies, which may have greater resources or better technologies than we do, and rapid changes in technology in the sterilization industry could result in the failure of the Clearant Process<sup>®</sup> to be accepted in the marketplace or to capture market share.**

We expect the Clearant Process<sup>®</sup> to encounter significant competition. The Clearant Process<sup>®</sup> may compete with other approaches to pathogen inactivation currently in use, as well as with future processes that may be developed. Similarly, products that are treated with the Clearant Process<sup>®</sup> may compete with products that are currently treated with alternative pathogen inactivation or removal techniques, as well as with future products that may be developed. Our success will depend in part on our ability to respond quickly to medical and technological changes through the development and introduction of the Clearant Process<sup>®</sup> to new and existing products. Product development is risky and uncertain, and we may not be able to develop our processes successfully. Competitors' processes, products or technologies may make the Clearant Process<sup>®</sup> obsolete or non-competitive before we are able to generate any significant revenue. Many of our competitors or potential competitors have substantially greater financial, human, technical, marketing and other resources than we have. They may also have greater experience in preclinical testing, human clinical trials, process implementation and other regulatory approval procedures and have developed substantial relationships with the small market of potential customers for the Clearant Process<sup>®</sup>. Our ability to compete successfully will depend, in part, on our ability to attract and retain skilled scientific personnel, develop technologically superior processes that can be implemented on a commercial scale, develop lower cost processes, obtain patent or other proprietary protection for our technologies and enforce those patents, obtain (or have third parties obtain) required regulatory approvals for our processes, be early entrants to the market and market and sell our processes, independently or through collaborations.

Several companies are developing technologies that are, or in the future may be, the basis for products that will directly compete with or reduce the market for our pathogen inactivation processes. Most tissue processors currently utilize chemical rinse steps or low levels of gamma irradiation to reduce pathogens in devitalized human tissue



products. Several companies are developing or have developed other technologies or combinations of existing technologies (including BioCleanse used by Regeneration Technologies, Inc.). Some of these technologies may have more animal and clinical data than we do to support the efficacy of their processes. There are currently no regulatory requirements that establish specific pathogen inactivation or sterility requirements for these products. If tissue processors choose to maintain their current processing methods or elect to adopt technologies other than the Clearant Process<sup>®</sup>, it could materially impact our ability to market and earn revenue from the Clearant Process<sup>®</sup>.

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For biotherapeutic products comprising protein concentrates (e.g., plasma derivatives, monoclonal antibodies, recombinant and transgenic proteins), other technologies exist to inactivate or remove viruses, including the application of heat, certain chemicals like solvent-detergent, nanofiltration and partitioning during purification. Other technologies are in various stages of research and development, including novel uses of heat and other physical processes (e.g., microwave and supercritical fluids), new chemical agents including photosensitizers (e.g., Inactine , riboflavin, psoralens), and applications of radiation other than the Clearant Process® (e.g., broad spectrum visible light, ultraviolet light and high energy electrons). If any of these technologies is successfully developed, it could have an adverse effect on our business, financial condition and results of operations.

One or more of these technologies could prove to be superior to the Clearant Process® in one or more of our target markets by virtue of being more effective, safer, more cost-effective or easier to implement. Our prospective clients may choose alternative technologies over ours for any of these reasons or for other reasons. If this were the case, we may not be able to successfully market the Clearant Process® to manufacturers of biological products, which could have a material adverse effect on our business, results of operations and financial condition.

### **Under our new processor representative arrangement, uncertainties regarding future health care reimbursement exist and may affect the amount and timing of revenues.**

Even though we do not receive payments directly from third-party health care payors, their reimbursement methods and policies impact the demand for Clearant Process®-treated tissue and other services and products. Third-party healthcare payors provide reimbursement for medical procedures at a specified rate without additional reimbursement for tissue, services and products used in such procedures. Our ability to act as a processor's representative by providing tissue to the marketplace and to collect payment of tissues may be particularly susceptible to third-party cost containment measures.

Changes in the reimbursement methods and policies utilized by third-party health care payors, including Medicare, with respect to Clearant Process®-treated tissue could have a material adverse effect on us. Significant uncertainty exists as to the reimbursement status of newly introduced health care products and services and there can be no assurance that adequate third-party coverage will be available for us to maintain price levels sufficient for realization of an appropriate return on our investment in developing new products.

Government, hospitals, and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new products. If adequate coverage and reimbursement levels are not provided by government and other third-party payors for uses of our products, market acceptance of these products would be adversely affected, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

### ***Risks Related To Our Industry***

#### **Our ability to commercialize our technology in our target markets will depend on the rates charged by operators of commercial gamma irradiation facilities at which the Clearant Process® will be applied.**

The use of the Clearant Process® on a commercial scale requires the use of commercial gamma irradiation facilities. While there are a number of commercial gamma irradiation service providers in the United States and internationally, the vast majority of facilities in the United States are owned and operated by two commercial gamma irradiation service providers. If we, or our customers, in the provision of the sterilization services, are not able to negotiate or maintain favorable terms with such service providers to treat products, our efforts to commercialize the process with additional customers may be hindered.

#### **Products which could utilize the Clearant Process® are in general subject to extensive regulation by domestic and foreign government agencies, which could result in significant delays in approval, or rejection, of the Clearant Process® for use in connection with a particular product or significant additional costs to the manufacturers of such products, which would hinder the widespread adoption of the Clearant Process®.**

New, planned and future third-party products which could utilize the Clearant Process® and anticipated future uses that result from the Clearant Process® are subject to extensive and rigorous regulation by local, state, federal and foreign regulatory authorities. These regulations are wide-ranging and govern, among other things, product development, product testing, product manufacturing, product labeling, product storage, product pre-market clearance or approval, product sales and distribution, product advertising and promotion. The irradiation facilities in which the

Clearant Process® will be carried out commercially are also subject to state and federal safety, environmental and licensing requirements. Failure by manufacturers and processors to meet any of these regulatory requirements could prevent the manufacturing or marketing of a product made with the Clearant Process® and could adversely affect our future revenues.

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The FDA and other agencies in the United States and in foreign countries impose substantial requirements upon the manufacturing and marketing of third party products (whether currently available or under development) which will or could utilize our processes for pathogen inactivation. The process of obtaining FDA and other required regulatory approvals is long, expensive and uncertain. The time required for regulatory approvals is uncertain and the process typically takes a number of years, depending on the type, complexity and novelty of the process or product. Third parties to whom we intend to market our pathogen inactivation processes may encounter significant delays or excessive costs in their efforts to secure necessary approvals or licenses. These delays would result in similar delays in our receipt of licensing revenues from these third parties. Similarly, if third parties suffer excessive costs in connection with obtaining required regulatory approvals, the third parties could decide not to introduce products treated with the Clearant Process<sup>®</sup>, which would adversely affect our ability to generate licensing revenues and thus adversely affect our business, financial condition and results of operations.

Sponsors of innovative biotherapeutic products or medical devices incorporating biological materials must obtain biological products licenses or pre-market approvals before legally marketing these products, regardless of whether the Clearant Process<sup>®</sup> is used in their manufacture. Future revenues from the use of the Clearant Process<sup>®</sup> for innovative biotherapeutic products will depend on the sponsors' success and timeliness in obtaining initial FDA or other required regulatory approval for these products.

Manufacturers of existing, approved products would have to submit supplements to their licenses or pre-market approvals in order to incorporate the Clearant Process<sup>®</sup> into the manufacturing processes for these products. In most cases, the FDA would have to review and approve these supplements prior to marketing an already approved product made with the Clearant Process<sup>®</sup>. These requirements or FDA or other regulatory delays in approving these initial applications or supplements may deter some biological product manufacturers from using our processes. Sponsors and manufacturers that submit initial applications or supplements may face disapproval or delays in approval that could provide further delay or deter them from using our processes. The regulatory impact on potential customers could slow or limit the potential market for our processes. In addition, it is unclear what affect the FDA's adoption of the GTP regulations will have on potential customers. The GTP requirements may cause tissue processors to delay the implementation of new processes or procedures and the delay may impact the timing of revenue to us.

Some tissue products for surgical implantation have been exempted by the FDA from the requirements for licensing new products or having manufacturing changes approved prior to implementation. While this may expedite adoption of the Clearant Process<sup>®</sup> for these products by eliminating the regulatory review period, distributors must nevertheless satisfy themselves of the safety and effectiveness of tissue manufactured using the Clearant Process<sup>®</sup>, and tissue processors and distributors must still meet the other regulatory requirements discussed below.

The products enabled by or utilizing the Clearant Process<sup>®</sup> may not receive FDA or other required regulatory approval in a timely manner, if at all. Even if approvals are obtained, the marketing and manufacturing of such products are subject to continuing FDA and other regulatory requirements, such as requirements to comply with good manufacturing practices. The failure to comply with such requirements could result in enforcement action against third party manufacturers which utilize our processes, which could adversely affect our business because our revenues from users of the Clearant Process<sup>®</sup> would be reduced or eliminated. Later discovery of problems with a product, manufacturer or facility may result in additional restrictions on the product or manufacturer, including withdrawal of the product from the market or a prohibition against the use of the Clearant Process<sup>®</sup>. Problems with a product, manufacturer or facility which utilizes the Clearant Process<sup>®</sup> may harm other manufacturers and the public's perception of the safety of the Clearant Process<sup>®</sup> generally, which would result in decreased utilization of the Clearant Process<sup>®</sup> and a decrease or elimination of our revenues, which would adversely affect our business, financial condition and results of operations.

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The government may impose new regulations as a result of a problem or otherwise that could further delay or preclude regulatory approval of third parties' potential processes and products that might incorporate the Clearant Process®. Products enabled by or utilizing the Clearant Process® may not meet new regulations and use of the Clearant Process® may be precluded by new regulations. We cannot predict the impact of adverse governmental regulation that might arise from future legislative or administrative action. However, any such regulations which delayed implementation of the Clearant Process® in our target markets would delay our receipt of revenues, potentially increase our development costs or the costs for third parties to treat products with the Clearant Process®, and adversely affect our business, financial condition and results of operations.

We also intend to generate revenue from marketing and licensing our pathogen inactivation processes outside the United States. Distribution of products made with our processes outside the United States will be subject to extensive government regulation. These regulations, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations, vary by jurisdiction. In the developed markets (e.g., the European Union, Japan and Canada), the regulatory framework and requirements are similar to those in the United States. It is uncertain whether the users of our processes will obtain regulatory approvals in such countries, and they may incur significant costs in obtaining or maintaining foreign regulatory approvals. Failure of third parties to obtain necessary regulatory approvals or any other failure to comply with regulatory requirements could result in reduced revenue from users of the Clearant Process®.

**The success of our business depends on the results of clinical trials performed by third parties incorporating the Clearant Process® into their products and no such clinical trials have been completed to date.**

Most third parties incorporating our processes into their products, other than tissue, will have to provide the FDA and foreign regulatory authorities with data that demonstrate the safety and efficacy of such products before they are approved for commercial use in the case of new products, or demonstrate clinical comparability in the case of existing products. Clinical development, including preclinical testing, is a long, expensive and uncertain process. Because the Clearant Process® itself is not expected to be subject to regulatory approval on its own, most prospective customers will undertake any applicable testing required to gain approval of products incorporating the Clearant Process®. Some products may require several years to complete applicable testing, and failure can occur at any stage of testing. In addition, this testing may need to be repeated for each application of the Clearant Process® to a new third-party product. Third parties incorporating our processes cannot rely on interim results of trials to predict their final results, and acceptable results in early trials might not be repeated in later trials.

Any preclinical or clinical trial may fail to produce results satisfactory to the FDA or other regulatory authorities with jurisdiction. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results or adverse medical events during a trial could cause a trial to be repeated or a program to be terminated. Third parties incorporating our processes into their products may rely on third-party clinical investigators to conduct their clinical trials and other third-party organizations to perform data collection and analysis, and as a result, certain additional factors outside our control may delay regulatory approvals needed by third parties using our processes. These factors include difficulty in enrolling qualified subjects, inadequately trained or insufficient personnel at the study site, and delays in approvals from a study site's review board. The occurrence of any of these factors could delay the commercialization of our processes.

We cannot provide assurances that planned trials will begin on time or be completed on schedule or at all, that any trials will result in marketable products or that the Clearant Process® will be commercially successful in one or more applications even if they have been approved by the FDA for marketing. Our process development costs will increase if any third party incorporating our processes has delays in testing or approvals. Similarly, our process development costs will increase if we experience any delays in any testing or studies we undertake as part of our marketing strategy. If any of these delays is significant, our business, financial condition and results of operations will be adversely affected.

To date, we have commercialized the Clearant Process® only for the tissue market, for which neither we nor the tissue processors were required to obtain any regulatory approval. However, based upon public disclosures, we believe that a certain tissue processor has not been prohibited by the FDA from labeling certain tissues as sterile based upon a comprehensive validation of its manufacturing process including but not limited to the Clearant Process® as the

terminal pathogen inactivation step. We do not have any direct or other experience to date with respect to the ability of third-party manufacturers to obtain regulatory approval for use of the Clearant Process<sup>®</sup> in their manufacturing processes.

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**Because our business model is partially based on the receipt of royalties or service payments from users of the Clearant Process<sup>®</sup>, our success may be dependent on the ability of our customers to successfully market their products which have been treated by the Clearant Process<sup>®</sup>, which is dependent on events and developments in their businesses which are beyond our control.**

Our business model is partially based on receiving royalties or service payments from users of the Clearant Process<sup>®</sup> in our target markets. The success of that model depends on our ability to successfully optimize and commercialize the Clearant Process<sup>®</sup> for use in our target markets and to successfully license the Clearant Process<sup>®</sup> to customers in those markets and ultimately on the ability of those customers to sell sufficient dollar volumes of their products that have been treated with the Clearant Process<sup>®</sup> to provide us with a substantial revenue stream. Accordingly, any events or developments in the business of our customers which adversely affect their ability to sell their Clearant Process<sup>®</sup>-treated products, even if unrelated to the efficacy of the Clearant Process<sup>®</sup>, will adversely affect our ability to generate revenues and thus our business, financial condition and results of operations. We will not have control over any such events or developments.

Our success will depend in part on the availability of a sufficient volume of biological products, including tissues, for sale by the third party manufacturers, and thus potentially being available for treatment by the Clearant Process<sup>®</sup>. For example, allograft providers depend heavily upon a limited number of sources of human tissue, and any failure to obtain tissue from these sources in a timely manner would interfere with their ability to process and distribute allografts. If a provider so affected was utilizing the Clearant Process<sup>®</sup> for sterilization of its products, that would result in a reduction in our revenues.

Our success will also be subject to the widespread acceptance of the customers' end products. Negative publicity, both in the United States and internationally, concerning improperly sterilized biological products leading to transmission of disease or death, whether or not those products were treated by the Clearant Process<sup>®</sup>, could limit widespread market acceptance of those products, and thus reduce the ability of users of the Clearant Process<sup>®</sup> to sell such products and thus generate revenue for us. For example, recent instances of bacterial transmission through traditionally-processed tissues, one of which resulted in death, resulted in the withdrawal of tissue from the market by one major processor, and may affect the willingness of patients and surgeons to use allografts. Thus, our customers in the tissue market, or any other targeted market which experiences a similar safety crisis, may have to overcome a public perception that their products may be unsafe, whether or not they have been treated with the Clearant Process<sup>®</sup>. If our customers are unable to overcome such a perception, our ability to generate revenues and thus our business, financial condition and results of operations may be adversely affected.

In addition, development of alternatives to biological products which may be sterilized more easily and cost-effectively would likely result in decreased consumer demand for biological products in medical procedures. This would result in a decrease in sales by manufacturers which utilize, or could potentially utilize, the Clearant Process<sup>®</sup> and thus reduce our current and potential future revenue streams. For example, if synthetic technologies are successfully developed which stimulate the growth of tissue surrounding an implant, it could result in a decline in demand for tissue allografts, which is one of our target markets.

**We depend heavily upon limited sources of human tissue, and any failure to obtain tissue from these sources in a timely manner will interfere with our ability to process and distribute allografts.**

In 2008 we relied on three suppliers for the sourcing of our human tissue. The limited supply of human tissue has at times limited our growth, and may not be sufficient to meet our future needs. If we were to lose any of these major suppliers, there can be no assurances that we would be able to locate new suppliers or that we would be able to fulfill our current needs with the existing suppliers.

In addition, due to seasonal changes in mortality rates, some scarce tissues that we use for our allografts are at times in particularly short supply. We cannot be sure that our supply of tissue will continue to be available at current levels or will be sufficient to meet our needs. If we are no longer able to obtain tissue from these sources sufficient to meet our needs, we may not be able to locate replacement sources of tissue on commercially reasonable terms, if at all. Any interruption of our business caused by the need to locate additional sources of tissue would significantly impair our revenues, which could cause the market price of our common stock to decline. We expect our revenues would continue to suffer for at least as long as needed tissue is in short supply.





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**Potential users of the Clearant Process® may depend on third party payers for reimbursement for the use of their products by the end consumer, who may not be willing to reimburse the users at levels sufficient to permit us to generate significant payments.**

Potential users of the Clearant Process® may depend on third party payers for reimbursement for the use of their products by the end consumer. To the extent that users of the Clearant Process® depend on reimbursement of patients medical expenses by government health care programs and private health insurers, the willingness of governments and private insurers to cover the applicable procedure and if so, the level of payment which may apply will affect the revenues they receive for their products and thus the revenues that we ultimately receive. Third-party payers may not reimburse users of the Clearant Process® at levels which will, in turn, be profitable to us.

**Outside influences on healthcare regulation may negatively impact our revenues or increase our expenses.**

Political, economic and regulatory influences subject the healthcare industry in the United States to fundamental change. Any new federal or state legislation could result in significant changes in the availability, delivery, pricing or payment for healthcare services and products. While we cannot predict what form any new legislation will take, it is possible that any significant healthcare legislation, if adopted, could lower the amounts paid to biologic product providers for their products, which would decrease their revenues and thus our revenue.

**Because the markets for our technology are dominated by a small number of participants, if we fail to properly market, price or license the Clearant Process® to even a small number of the large potential customers in our markets, our business could be substantially harmed.**

Our target markets are generally characterized by a small number of market participants. For example, the tissue market segment is controlled by a small number of entities in the United States: Musculoskeletal Tissue Foundation; AlloSource; Community Tissue Services; University of Florida Tissue Bank; Lifenet; Northwest Tissue Center; Tissue Bank International; Regeneration Technologies; and Northern California Tissue Center.

If we fail to properly market, price or license our processes to even a small number of the large customers in these markets, our business, financial condition and results of operations could be adversely affected.

**Guidelines and recommendations published by various organizations could reduce the use of products made with the Clearant Process®.**

Government agencies promulgate regulations and guidelines directly applicable to us and to products made with the Clearant Process®. Also, professional societies, practice management groups, private health/science foundations, and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Changes in the regulations, or recommendations or guidelines that are followed by patients and health care providers could result in decreased use of products made with the Clearant Process® which could adversely affect prevailing market prices for our common stock.

**If we acquire any companies or technologies in the future, they could prove difficult to integrate, disrupt our business, dilute stockholder value and adversely affect our operating results.**

We may acquire or make investments in complementary companies, services and technologies in the future. We have not made any acquisitions or investments to date, and therefore our ability as an organization to make acquisitions or investments is unproven. Acquisitions and investments involve numerous risks, including:

difficulties in integrating operations, technologies, services and personnel;

diversion of financial and managerial resources from existing operations;

risk of entering new markets;

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potential write-offs of acquired assets or investments;

potential loss of key employees;

inability to generate sufficient revenue to offset acquisition or investment costs; and

delays in customer purchases due to uncertainty.

In addition, if we finance acquisitions by issuing convertible debt or equity securities, our existing stockholders may be diluted which could affect the market price of our stock. Furthermore, any such acquisition may increase our expenses and therefore change our requirements and timing for additional capital. As a result, if we fail to properly evaluate and execute acquisitions or investments, our business and prospects may be seriously harmed.

***Risks Related to Our Common Stock***

**Our independent registered public accounting firm has doubt as to our ability to continue as a going concern and this may adversely affect our stock price.**

As a result of our lack of liquidity, recurring negative cash flows from operations, limited capital resources and accumulated debt, our independent registered public accounting firm has concluded that there is substantial doubt as to our ability to continue as a going concern, and accordingly, our independent registered public accounting firm has included this in our financial statement for the year ended December 31, 2008. Our independent registered public accounting firm's conclusion may cause uncertainty among investors and may adversely affect our stock price.

**Our stock price may be subject to substantial volatility, and you may lose all or a substantial part of your investment.**

Our common stock is traded on the OTC Bulletin Board (the "OTCBB"). There is a limited public float, and trading volume historically has been limited and sporadic. As a result, the current price for our common stock on the OTCBB is not necessarily a reliable indicator of our fair market value. The price at which our common stock will trade may be highly volatile and may fluctuate as a result of a number of factors, including, without limitation, the number of shares available for sale in the market, quarterly variations in our operating results and actual or anticipated announcements of new products or services by us or competitors, regulatory investigations or determinations, acquisitions or strategic alliances by us or our competitors, recruitment or departures of key personnel, the gain or loss of significant customers, changes in the estimates of our operating performance, market conditions in our industry and the economy as a whole. We have and continue to evaluate listing on another market or exchange but there can be no assurance of our ability to move our listing. Issues such as market price, trading volume and volatility all contribute to lack of ability to move to another market or exchange.

**The sale of shares by our stockholders may significantly impact the market price of our common stock.**

The sale of shares by our stockholders may significantly affect the market price of our stock. Once shares of our common stock are registered, we have no control over which of the stockholders will actually sell all or any portion of their shares, or at what price. Sales of substantial amounts of our common stock, including approximately 46,000,000 shares that we issued in connection with the April and August 2007 private placements may impact the market price of our common stock.

**We have never paid cash dividends and do not intend to do so.**

We have never declared or paid cash dividends on our common stock. We currently plan to retain any earnings to finance the growth of our business rather than to pay cash dividends. Payments of any cash dividends in the future will depend on our financial condition, results of operations and capital requirements, as well as other factors deemed relevant by our board of directors.

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**We may incur increased costs as a result of recently enacted and proposed changes in laws and regulations relating to corporate governance matters.**

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the SEC and the Financial Industry Regulatory Authority ( FINRA ) will result in increased costs to us as we evaluate the implications of any new rules and respond to their requirements. New rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs to comply with any new rules and regulations.

**Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable federal and state regulations.**

The development, distribution, pricing, sales and marketing of our products, together with our general operations, is subject to extensive federal and state regulation. While we have developed and instituted a corporate compliance program based on current best practices, we cannot assure you that we or our employees are, or will be, in compliance with all potentially applicable federal and state laws and regulations. If we fail to comply with any of these laws or regulations, a range of actions could result, including, but not limited to, the termination of clinical trials, restrictions on products made with the Clearant Process<sup>®</sup>, including withdrawal of products made with the Clearant Process<sup>®</sup> from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation.

**Our common stock may be considered a penny stock and may be difficult to sell when desired.**

The SEC has adopted regulations which generally define 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 specific exemptions. The market price of our common stock is currently less than \$5.00 per share. This designation requires any broker or dealer selling these securities to disclose specified information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell our common stock and may affect the ability of stockholders to sell their shares. In addition, since our common stock is currently quoted on the OTCBB, stockholders may find it difficult to obtain accurate quotations of our common stock and may experience a lack of buyers to purchase our shares or a lack of market makers to support the stock price.

**The possible issuance of additional shares may impact the price of our stock.**

Our board of directors has the power to issue additional common stock without stockholder approval. Potential investors should be aware that any stock issuances might result in a reduction of the book value or market price, if any, of the then outstanding common stock. If we were to issue additional common stock, such issuance will reduce proportionate ownership and voting power of the other stockholders. Exercise of stock options or warrants may also have a dilutive effect on our common stock. Also, any new issuance of common stock may result in a change of control.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Description of Property**

Our principal executive offices, including all of our sales, marketing and administrative functions, are located in approximately 2,500 square feet of office space at 1801 Avenue of the Stars, Suite 435, Los Angeles, California 90067, under a lease which expires on January 31, 2010. We pay rent of approximately \$7,500 per month including operating expenses. We have also entered into a lease of approximately 2,300 square feet of space in Mundelein, Illinois, under a lease which expires March 31, 2010. This facility operates our sterilization service. We pay rent of approximately \$1,800 per month at that location.



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We believe that the current leased space is adequate, and that additional facilities will be available for lease to meet any future needs. If we expand, we may lease additional regional office facilities, as necessary, to service our customer base.

**Item 3. *Legal Proceedings***

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. We are currently involved in the following material legal proceedings:

On September 27, 2006, we entered into a renewable two-year supply and distribution agreement (the Osprey Agreement ) with Osprey Biomedical Corp. ( Osprey ). Under the Osprey Agreement, Osprey granted us exclusive rights to place current and future Osprey cervical and lumbar allografts treated with the Clearant Process® in certain geographic territories with an option for additional geographic territories. In exchange for the exclusive rights under the Osprey Agreement, we were obligated to pay Osprey \$500,000 as a prepayment for certain ordered products to be delivered after October 1, 2006. This prepayment was due upon the earlier of the following: (i) within three business days after we receive debt or equity financing of at least \$1 million, or (ii) October 31, 2006. In addition, we were required to make the following quarterly payments to be applied to payments for ordered products: \$650,000 by October 31, 2006; \$750,000 by January 1, 2007; \$850,000 by April 1, 2007; \$1 million by July 1, 2007; \$1.2 million by October 1, 2007; \$1.3 million by January 1, 2008; \$1.5 million by April 1, 2008; and \$1.75 million by July 1, 2008.

As of December 31, 2008, all tissue orders had not been delivered by Osprey and we have not made the prepayments. In February 2007, we received notice from Osprey of its termination of the Osprey Agreement, effective within thirty days from receipt of the notification if we did not timely cure certain alleged payment defaults. We are in ongoing discussions with Osprey to resolve these issues, which could include, but is not limited to, reduction in exclusive territories or termination of the Osprey Agreement. The termination of the agreement has resulted in the discontinuation or disruption of the spinal bone implant supply, which has had a material adverse impact on our ability to distribute spinal bone implants treated with the Clearant Process®. In addition, the lack of supply of the ordered products has had a material impact on our revenues and cash flows.

**Item 4. *Submission of Matters to a Vote of Security Holders***

Not applicable.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities****Market Information**

Our common stock is quoted on the OTCBB under the symbol CLRA. The following table shows the high and low bid prices of our common stock, as quoted on the OTCBB, by quarter during each of our last two fiscal years. These quotes reflect inter-dealer prices, without retail markup, markdown or commissions and may not represent actual transactions. The information below was obtained from the OTCBB, for the respective periods.

	<b>High</b>	<b>Low</b>
<b>Year Ending December 31, 2009</b>		
1st Quarter (through March 17, 2009)	\$ 0.10	\$ 0.03
<b>Year Ended December 31, 2008<sup>1</sup></b>		
1st Quarter	\$ 0.32	\$ 0.14
2nd Quarter	0.25	0.10
3rd Quarter	0.20	0.09
4th Quarter	0.19	0.03
<b>Year Ended December 31, 2007<sup>2</sup></b>		
1st Quarter	\$ 0.28	\$ 0.11
2nd Quarter	0.17	0.02
3rd Quarter	1.99	0.40
4th Quarter	1.03	0.24

<sup>1</sup> Over-the-counter market quotations may reflect inter-dealer prices, without retail mark-up, mark-down or commissions and may not necessarily represent actual transactions.

<sup>2</sup> On August 3, 2007, after recommendation by our board of directors, the holders of a majority of our common stock approved an amendment to our Certificate of Incorporation to

permit us to effect a 1:14 reverse stock split of our common stock. The reverse stock split is effective as of August 23, 2007. The prices quoted reflect the reverse stock split.

**Holders**

As of March 17, 2009, there were approximately 185 holders of record of our common stock. This number does not include beneficial owners of common stock whose shares are held in the names of various dealers, clearing agencies, banks, brokers and other fiduciaries.

**Dividends**

We have never declared or paid any dividends. We anticipate, as our board of directors deems appropriate, that we will continue to retain all earnings for use in our business.

**Table of Contents****Securities Authorized For Issuance Under Equity Compensation Plans**

The following table provides information about our common stock that may be issued upon the exercise of equity instruments under all of our existing equity compensation plans as of December 31, 2008:

<b>Plan Category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights <sup>1</sup></b> <b>(a)</b>	<b>Weighted-average exercise price of outstanding options, warrants and rights</b> <b>(b)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) <sup>2</sup></b> <b>(c)</b>
<b>Equity compensation plans approved by security holders</b>	4,870,907	\$ 1.28	7,673,723
<b>Equity compensation plans not approved by security holders</b>	0	\$ 0.00	0
<b>Total</b>	4,870,907	\$ 1.28	7,673,723

<sup>1</sup> On August 3, 2007, at our annual meeting, the stockholders approved a 6,000,000 share increase in our 2005 Stock Award Plan. As of December 31, 2008, there were 2,113,052 shares of our common stock reserved for issuance upon the exercise of warrants and 2,757,855



shares of  
common stock  
reserved for  
issuance upon  
the exercise of  
options.

<sup>2</sup> These options  
were issued  
under the 2000  
and 2005 Stock  
Award Plans.

<sup>3</sup> Of this amount,  
no shares were  
available for  
issuance under  
the 2000 Stock  
Award Plan and  
7,673,723  
shares were  
available for  
issuance under  
the 2005 Stock  
Award Plan.

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**Item 6. Selected Financial Data**

We are a smaller reporting company as defined in 17 CFR 229.10(f)(1) and are not required to provide information required by this item, per Item 301 of Regulation S-K (17 CFR 229.201).

**Item 7. Management's Discussion and Analysis or Plan of Operation**

**Results of Operations for the years ended December 31, 2008 and 2007**

At December 31, 2008, we had a working capital deficit of \$1,301,000 which included accounts payable and accrued liabilities of \$1,806,000, compared to a working capital deficit of \$585,000 which included accounts payable and accrued liabilities of \$1,943,000 for the year ended December 31, 2007. At December 31, 2008, our total assets were \$1,717,000, compared to \$2,609,000 for the year ended December 31, 2007, which consisted primarily of intangible assets and cash from the sale of our common stock.

**Liquidity and Capital Resources**

Net cash used in operating activities was \$1,477,000 for the year ended December 31, 2008, compared to \$2,530,000 for the year ended December 31, 2007. Significant non-cash adjustments to operating activities for the year ended December 31, 2008, included depreciation and amortization expense of \$131,000, and non-cash charges of \$571,000 for stock-based compensation.

Significant non-cash adjustments to operating activities for 2007 included depreciation and amortization expense of \$407,000, provision for inventory reserve of \$444,000, and non-cash charges of \$368,000 for stock-based compensation. These were offset by a gain on settlement of obligations of \$382,000 for the settlement of outstanding payables.

Our net cash used in investing activities was \$67,000 for the year ended December 31, 2008 compared to net cash used in investing activities of \$46,000 for the year ended December 31, 2007. During 2008 and 2007, our investing activities consisted primarily of intellectual property expenditures and capital expenditures.

We have financed our operations since inception primarily through the sale of shares of our stock and convertible notes. Our net cash provided by financing activities was \$747,000 for the year ended December 31, 2008, compared to \$3,075,000 for the year ended December 31, 2007. Cash provided by financing activities for the year ended December 31, 2008 consisted of the net proceeds from the issuance of a related party convertible secured promissory note in conjunction with the capital raise in 2008, leaving a balance of approximately \$265,000 in cash and cash equivalents at December 31, 2008. Cash provided by financing activities for the year ended December 31, 2007 consisted primarily of the net proceeds from the issuance of common stock in conjunction with the capital raise in 2007, leaving a balance of approximately \$1,062,000 in cash and cash equivalents at December 31, 2007.

We have been unprofitable since our inception and we expect to incur additional operating losses through at least the end of 2009 and into 2010 as we incur expenditures on sales and marketing, commercial operations and research and development. Our activities to date are not as broad in depth or scope as the activities we may undertake in the future, and our historical operations and financial information are not necessarily indicative of our future operating results, financial condition or ability to operate profitably as a commercial enterprise.

The financial statements in Item 8 have been prepared on the basis that we will continue as a going concern. We have incurred significant operating losses and negative cash flows from operating activities since our inception. As of December 31, 2008, these conditions raised substantial doubt as to our ability to continue as a going concern. There can be no assurance that we will be successful in our efforts to generate, increase, or maintain revenue or raise additional capital on terms acceptable to us or that we will be able to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability of the carrying amount of the recorded assets or the amount of liabilities that might result from the outcome of this uncertainty.

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Our future capital requirements will depend upon many factors, including progress with marketing our technologies, payment of outstanding accounts payable and accrued liabilities, the ramp-up of revenue from our existing and new contracts, future decisions to purchase tissue, costs required to represent the tissue banks in the distribution of the tissue, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, the necessity of, and time and costs involved in obtaining, regulatory approvals, competing technological and market developments and our ability to establish collaborative arrangements, effective commercialization, marketing activities and other arrangements. We expect to continue to incur negative cash flows and net losses through at least the end of 2009 and into 2010.

**Off-Balance Sheet Arrangements**

Except for operating lease commitments, as of December 31, 2008, we had no off-balance sheet arrangements.

**Revenues**

Our total revenue increased by \$799,000 or 74%, to \$1,883,000 for the year ended December 31, 2008, from \$1,084,000 for the year ended December 31, 2007. Revenues from direct distribution of Clearant Process® sterile implants were \$1,599,000 during the year ended December 31, 2008. We hope that revenue from direct distribution may increase as our sales force becomes more fully integrated into the marketplace. This is our primary source of revenue generation and growth.

Revenues from licensing activities decreased \$7,000 or 8%, to \$83,000 for the year ended December 31, 2008, from \$90,000 for the year ended December 31, 2007, as a result of the loss of one licensing customer in the first quarter of 2007 as well as our strategy of focusing on direct distribution rather than depending on licensing fees. Revenues from fees for service activities decreased \$26,000 or 23%, to \$89,000 for the year ended December 31, 2008 from \$115,000 for the year ended December 31, 2007 as we continued to offer customers the opportunity to use our sterilization service. These figures are consistent with our strategy of moving away from a royalty model and aggressively targeting a direct distribution strategy. While we are continuing to service the existing license and fee for service agreements, we are not actively pursuing new license or fee for service agreements, and it is unlikely that there will be near-term material growth in licensing or fee for service revenue.

Revenues from contract research and milestones decreased \$71,000 or 39% to \$112,000 for the year ended December 31, 2008, from \$183,000 for the year ended December 31, 2007. This decrease is primarily the result of a one-time termination fee from one of our licensing customers in the first quarter of 2007.

Beginning in 2006, we changed our emphasis away from one-time, generally non-recurring research and grant revenue to direct distribution of Clearant Process® sterile implants and obtaining license and sterilization service customers. We expect to continue this strategy and expect contract research, license and sterilization revenue to decrease. We expect direct distribution revenue to be more characteristic of recurring revenue.

**Cost of Revenues**

Our total cost of revenues increased by \$35,000, or 4% to \$1,016,000 for the year ended December 31, 2008, from \$981,000 for the year ended December 31, 2007. This increase is primarily related to the increase in direct distribution revenue offset by a reserve of inventory and inventory related prepayment during 2007 of \$444,000. We do not expect any further reserves based upon current inventory levels. We expect that the costs associated with the direct distribution and sterilization services to increase in conjunction with the revenue increase.

**Sales, General and Administrative and Stock Based Compensation Expenses**

Sales, general and administrative and stock based compensation expenses decreased by \$760,000 or 20%, to \$2,982,000 for the year ended December 31, 2008, from \$3,742,000 for the year ended December 31, 2007. Included in the \$2,982,000 for the year ended December 31, 2008, are approximately \$571,000 of non-cash stock-based compensation, \$28,000 of non-cash patent-related write-offs in accordance with SFAS 144, and approximately \$208,000 of legal costs associated with on-going legal matters, including the legal dispute with one of our suppliers of hard tissue.

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We incurred \$571,000 in non-cash stock-based compensation for the year ended December 31, 2008 compared to \$368,000 for the year ended December 31, 2007. The increase is primarily related to the grant of options to employees and directors during the third quarter of 2007.

The \$760,000 decrease in sales, general and administrative expense for the year ended December 31, 2008, from the year ended December 31, 2007 was principally due to the downsizing of personnel in the first quarter of 2007 as well as an overall concerted effort to decrease expenses in 2008. Reimbursement expense related to the Chief Executive Officer's travel related expenses to our Los Angeles office was approximately \$36,000 and \$36,000 for the years ending December 31, 2008 and 2007, respectively. Sales and marketing expense increases or decreases will be affected by the revenue, effort and timing required to provide Clearant Process® sterile implants to the marketplace. During the first quarter of 2007, we reduced the number of employees from 25 to 8, eliminated several marketing, public and investor relations initiatives, and prepared to move into less expensive office space, which had the result of decreasing ongoing expenses. We cannot make any assurances that operations can be maintained at this reduced expense level and may be required to increase expenses or employee count to properly continue normal operations.

**Research and Development Expenses**

Research and development expenses decreased 91% to \$7,000 for the year ended December 31, 2008, from \$80,000 for the year ended December 31, 2007. This decrease was largely a result of reduced research and development costs associated with the reduction of our research and development personnel and related expenses. This was accomplished by our shift in focus from research and development to the commercialization of the Clearant Process®. We expect to maintain minimal research and development costs in 2009, however we cannot make any assurances that we will stay ahead of competition at these low levels of expenditures. From time-to-time we may complement our in-house research and development with universities and third party research and development consulting firms, which we believe, provides a broader expertise in research and development and allows us to maintain a low research and development headcount.

**Other Income/Expense**

For the year ended December 31, 2008, we recognized \$45,000 in net interest expense compared to \$20,000 in net interest income for the same time last year. The increase in net interest expense is due to interest recorded on the July 2008 related party convertible secured promissory note. For the year ended December 31, 2008 we recognized \$5,000 as a gain of settlement of obligations compared to \$382,000 for the year ended December 31, 2007. This decrease relates to the larger settlement of outstanding payables in 2007. In addition, we incurred a \$0 and \$130,000 loss on disposal of fixed assets during the year ended December 31, 2008 and 2007, respectively. The decrease in the loss on disposal of fixed asset was due to the downsizing of employees in 2007 as well as the sale of the remaining assets related to the closing of our research & development facility. We have \$265,000 cash on hand as of December 31, 2008, which we are currently investing in short-term conservative money market funds. We expect to earn interest income in 2009, although this amount will decrease as the cash is depleted.

**Doubt About Our Ability to Continue As Going Concern**

The accompanying financial statements have been prepared on the basis that we will continue as a going concern. We have incurred significant operating losses and negative cash flows from operating activities since our inception. As of December 31, 2008, these conditions raised substantial doubt as to our ability to continue as a going concern. In July 2008, we raised additional capital to supplement our operations by entering into a \$2,000,000 related party convertible secured promissory note. The \$2,000,000 related party convertible secured promissory note was scheduled to be funded, net of fees of approximately \$250,000, in tranches of: \$400,000 on July 8, 2008; \$400,000 on August 22, 2008 of which \$252,000 was received on September 5, 2008, and \$108,000 was received on October 1, 2008; \$600,000 scheduled on October 6, 2008 of which \$68,000 was received on December 12, 2008, \$50,000 was received on January 8, 2009, and \$155,000 was received on February 26, 2009; and \$600,000 scheduled on February 16, 2009 which has not yet been received. On February 20, 2009, we entered into an amendment to the related party convertible secured promissory note. The amendment extends the closing dates for the amounts due on October 6, 2008 and February 16, 2009, to March 31, 2009 and April 30, 2009, respectively. The amendment extending the closing date for the amounts due on October 6, 2008 accounts for payments previously made, as discussed above, and requires a payment of \$160,000 on February 20, 2009, of which we received \$155,000 on

February 26, 2009 and \$5,000 on March 12, 2009, a payment of \$100,000 due before March 10, 2009, of which we received \$72,000 on March 12, 2009 and a payment of \$222,000 due before March 31, 2009. The amendment also gives us the option to extend the initial maturity date of each promissory note to January 8, 2012. There can be no assurance that we will receive any of the remaining amounts due on the secured promissory note. Regardless of whether we receive the full amount of the remaining amounts, we will still require and continue to seek additional capital to fund our ongoing operations. There can be no assurance that we will be successful in our efforts to generate, increase, or maintain revenue or raise additional capital on terms acceptable to us or that we will be able to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability of the carrying amount of the recorded assets or the amount of liabilities that might result from the outcome of this uncertainty.

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We have incurred significant operating losses and negative cash flows from operating activities, and have limited available cash, which raises substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, reduce expenditures, attain further operating efficiencies, and ultimately, to generate greater revenue.

We expect to incur operating losses and negative cash flows for the foreseeable future. Our ability to execute on our current business plan is dependent upon our ability to develop and market our products, and ultimately, to generate revenue.

Options for raising capital include issuing common stock, preferred stock, convertible notes, warrants, or a combination of these equity securities. Equity financing may be supplemented with additional debt financing for inventory, accounts receivable and working capital.

We may not be successful in obtaining financing, and if funding is obtained it may be on terms considered unfavorable to us or our existing shareholders. The inability or failure to raise capital before our available cash is depleted will have a material adverse effect on our business and may result in bankruptcy or discontinuation of operations.

As of February 28, 2009, we had cash on-hand of approximately \$300,000. Our ability to have sufficient capital through the end of 2009 is dependent on successful settlement of vendor claims, and we will need to raise additional capital prior to the end of 2009. Failure to raise additional capital and to reach settlements with these vendors could result in the discontinuation of operations. Also, changes in our business strategy, technology development or marketing plans or other events affecting our operating plans and expenses may result in the expenditure of existing cash before that time. If this occurs, our ability to meet our cash obligations as they become due and payable will depend on our ability to sell securities, borrow funds or some combination thereof. We may not be successful in raising necessary funds on acceptable terms, or at all.

**Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. Generally accepted accounting principles require management to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities. We base our estimates on experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that may not be readily apparent from other sources. Our actual results may differ from those estimates.

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We consider our critical accounting policies to be those that involve significant uncertainties, require judgments or estimates that are more difficult for management to determine or that may produce materially different results when using different assumptions. We consider the following accounting policies to be critical:

**Revenue Recognition and Deferred Revenue**

We recognize revenue in accordance with the provisions of Staff Accounting Bulletin No. 104, Revenue Recognition ( SAB 104 ). Our revenue sources are direct distribution of Clearant Process® sterile implants, and licensing fees and sterilization services to customers who incorporate the Clearant Process® technology into their product and manufacturing processes, which may include performance milestones and contract research activities. We recognize direct distribution revenue upon the sourcing of tissue by a customer. Licensing revenue is recognized when a customer distributes products incorporating the Clearant Process® and revenue related to the sterilization service is recognized when the service is substantially complete. We recognize revenue related to milestones and contract research in accordance with Statement of Position 81-1, Accounting for Performance of Construction-Type and Certain Production-Type Contracts ( SOP 81-1 ). Revenue related to a performance milestone is recognized upon customer acceptance of the achievement of that milestone, as defined in the respective agreements. Revenue related to contract research activities is recognized on a percentage-of-completion basis. In the event cash is received in advance of service performed, we will defer the related revenue recognition until the underlying performance milestone is achieved or the contract research activities commence. In the event advanced cash payments are not attributable to any performance milestone and or contract research activity, we will recognize the underlying amounts into revenue on a straight-line basis over the term of the underlying agreement. We include shipping charges in the gross invoice price to customers and classify the total amount as revenue in accordance with Emerging Issues Task Force ( EITF ) No. 00-10, Accounting for Shipping and Handling Fees and Costs. Shipping costs are recorded as cost of revenues. We evaluate the collectability of accounts receivables and provide a reserve for credit losses, as appropriate. As of December 31, 2008 and 2007, we reserved for credit losses of \$91,000 and 26,000, respectively.

**Cost of Revenues**

Cost of revenues consists of costs associated with direct distribution of Clearant Process® sterile implants to a customer and with providing sterilization services to customers. For the years ended December 31, 2008 and 2007, we had inventory reserves of \$0 and \$444,000, respectively, which were recorded as a cost of revenue.

**Inventories and Inventory Related Prepayments**

Inventories are primarily comprised of implantable donor tissue treated with the Clearant Process® and are valued at the lower of cost or market with cost determined using the first-in, first-out method. Inventories are located at contracted tissue banks and on consignment in hospitals. Inventories may be reserved from time to time based on market conditions or other factors. For the years ended December 31, 2008 and 2007, we had inventory and inventory related prepayment reserves of \$1,315,000 and \$1,255,000, respectively.

In accordance with the terms of the spinal Supply and Distribution Agreement (See Note 13 to our financial statements), we are required to make prepayments. Upon receipt of the inventory, the prepayments will be reclassified as inventory until distributed.

**Identifiable Intangibles**

Certain costs associated with obtaining and licensing patents and trademarks are capitalized as incurred and are amortized on a straight-line basis over the shorter of their estimated useful lives or their legal lives of 17 to 20 years. Amortization of such costs begins once the patent or trademark has been issued. We evaluate the recoverability of our patent costs and trademarks quarterly based on estimated undiscounted future cash flows.

**Research and Development Costs**

Research and development costs are expensed as incurred.

**Income Taxes**

Income taxes are accounted for under Statement of Financial Accounting Standards ( SFAS ) No. 109, *Accounting for Income Taxes* ( SFAS 109 ), using the liability method. Under SFAS 109, deferred tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities, and are measured using the enacted tax rates and laws that are expected to be in effect when the differences reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.





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We adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ( FIN 48 ), on January 1, 2007. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. Due to the fact that we have substantial net operating loss carryforwards, adoption of FIN 48 had no impact on our beginning retained earnings, balance sheets, or statements of operations.

**Stock-Based Compensation**

On January 1, 2006, we adopted SFAS No. 123 (revised 2004), *Share-Based Payment*, ( SFAS 123(R) ) which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors based on estimated fair values. SFAS 123(R) supersedes our previous accounting under Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ) for periods beginning in fiscal 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin ( SAB ) No. 107 ( SAB 107 ) relating to SFAS 123(R). We have applied the provisions of SAB 107 in our adoption of SFAS 123(R).

The financial statements as of and for the years ended December 31, 2008 and 2007, reflect the impact of SFAS 123(R).

**Fair Value of Financial Instruments**

Fair value of financial instruments are accounted for under SFAS No. 157, *Fair Value Measurements*, ( SFAS 157 ) which requires the carrying amounts reported in the balance sheet for cash, cash equivalents, accounts receivable, accounts payable and accrued liabilities to approximate fair value because of the immediate or short-term maturity of these financial instruments. Bridge loans are estimated to approximate fair value based upon current market borrowing rates for loans with similar terms and maturities.

**Legal Proceedings**

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. Except as described in Item 3. Legal Proceedings, as of the date of this report we are not currently involved in any legal proceeding that we believe would have a material adverse effect on our business, financial condition or operating results.

**Recent Accounting Pronouncements**

On November 5, 2007, the SEC issued SAB No. 109, *Written Loan Commitments Recorded at Fair Value Through Earnings* ( SAB 109 ). SAB 109 provides guidance on the accounting for written loan commitments recorded at fair value under generally accepted accounting principles. Specifically, the SAB revises the Staff's views on incorporating expected net future cash flows related to loan servicing activities in the fair value measurement of a written loan commitment. SAB 109, which supersedes SAB 105, *Application of Accounting Principles to Loan Commitments*, requires the expected net future cash flows related to the associated servicing of the loan be included in the measurement of all written loan commitments that are accounted for at fair value through earnings. SAB 109 is effective in fiscal quarters beginning after December 15, 2007. The adoption of SAB 109 did not have a material impact on our financial statements.

In December 2007, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 141(R), *Business Combinations*, which replaces SFAS No. 141. SFAS No. 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. The statement also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combination. SFAS 141(R) is effective for calendar year companies on January 1, 2009. We do not anticipate that the adoption of SFAS 141(R) will have a material effect on accounting for business combinations once adopted, but the effect is dependent upon acquisitions at that time.

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In December 2007, the SEC issued SAB 110. SAB 110 expresses the views of the staff regarding the use of a simplified method, as discussed in SAB No. 107 ( SAB 107 ), in developing an estimate of expected term of plain vanilla share options in accordance with SFAS No. 123 (revised 2004) which is effective on January 1, 2008. The adoption of SAB 110 did not have a material impact on our financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities*, and amendment of SFAS No. 133 ( SFAS No. 161 ). This statement will require additional disclosures about how and why we use derivative financial instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* , as amended and interpreted ( SFAS No. 133 ), and how derivative instruments and related hedged items affect our financial position, results of operations, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008; however early adoption is encouraged, as are comparative disclosures for earlier periods. We do not believe that the adoption of SFAS No. 161 will have a material impact on our financial statements.

In April 2008, the FASB issued FASB Staff Position ( FSP ) No. SFAS 142-3, *Determination of the Useful Life of Intangible Assets*, ( SFAS 142-3 ). FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142,

*Goodwill and Other Intangible Assets* and also requires expanded disclosure related to the determination of intangible asset useful lives. SFAS 142-3 is effective for fiscal years beginning after December 15, 2008. Early adoption is prohibited. We do not believe the adoption of SFAS 142-3 will have a material impact on our financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ( SFAS No. 162 ). SFAS No. 162 identifies the sources of accounting principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. This Statement is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. We currently adhere to the hierarchy of GAAP as presented in SFAS No. 162, and do not expect its adoption will have a material impact on our results of operations and financial condition.

In May 2008, the FASB issued FSP APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ( FSP APB 14-1 ). FSP APB 14-1 requires issuers of convertible debt instruments that may be settled in cash upon conversion to account separately for the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. FSP APB 14-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We do not anticipate that the adoption of FSP APB 14-1 will have a material effect on our results of operations or financial position.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

At December 31, 2008, we have invested our cash in short term commercial paper, certificates of deposit, money market accounts and marketable securities. We consider any liquid investment with an original maturity of three months or less when purchased to be cash equivalents. We adhere to an investment policy which requires that all investments be investment grade quality and no more than ten percent of our portfolio may be invested in any one security or with one institution.

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**Item 8. *Financial Statements and Supplementary Data***

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors  
Clearant, Inc.  
Los Angeles, California

We have audited the accompanying balance sheets of Clearant, Inc. (the Company) as of December 31, 2008 and 2007, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Clearant, Inc. as of December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles. We were not engaged to examine management's assessment of the effectiveness of Clearant, Inc.'s internal control over financial reporting as of December 31, 2008, included in the accompanying Report of Management on Internal Control Over Financial Reporting and, accordingly, we do not express an opinion thereon.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and negative cashflow from operations. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ SINGERLEWAK LLP  
Los Angeles, California  
March 20, 2009

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**CLEARANT, INC.**  
**BALANCE SHEETS**  
(in thousands, except par value amounts)

	December 31, 2008	December 31, 2007
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 265	\$ 1,062
Accounts receivable, net of allowance of \$91 and \$26 at December 31, 2008 and 2007, respectively	276	341
Inventory, net of \$909 and \$849 inventory allowance at December 31, 2008 and 2007, respectively	15	
Inventory related prepayments, net of \$406 and \$406 inventory allowance at December 31, 2008 and 2007, respectively		
Prepays and other assets	62	68
 Total current assets	 618	 1,471
 Property and equipment, net of \$146 and \$83 accumulated depreciation at December 31, 2008 and 2007, respectively	 44	 87
Identifiable intangibles, net of \$1,285 and \$1,217 accumulated amortization at December 31, 2008 and 2007, respectively	970	991
Deposits and other assets	85	60
 Total assets	 \$ 1,717	 \$ 2,609
 <b>Liabilities, Preferred Stock and Stockholders Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,070	\$ 1,210
Accrued liabilities	736	733
Bridge loans	106	106
Deferred revenue	7	7
 Total current liabilities	 1,919	 2,056
 Convertible promissory note related party, net of debt discount of \$135 and \$0 at December 31, 2008 and 2007, respectively	 758	
Deferred Revenue noncurrent		4
 Total liabilities	 2,677	 2,060

Stockholders' equity (deficit):

Series A preferred stock (\$0.0001 par value; 50,000 shares authorized; 0 and 0 share issued and outstanding at December 31, 2008 and 2007, respectively)

Common stock (\$0.0001 par value; 200,000 shares authorized; 48,957 and 48,957 shares issued and outstanding at December 31, 2008 and 2007, respectively)

	5	5
Additional paid-in capital	87,013	86,360
Accumulated deficit	(87,978)	(85,816)

Total stockholders' equity (deficit)	(960)	549
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Total liabilities and stockholders' equity (deficit)	\$ 1,717	\$ 2,609
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*See accompanying notes to financial statements.*

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**CLEARANT, INC.**  
**STATEMENTS OF OPERATIONS**  
**(in thousands, except per share amounts)**

	Fiscal Year Ended December 31,	
	2008	2007
Revenues:		
Licensing	\$ 83	\$ 90
Direct distribution	1,599	696
Fee for service	89	115
Contract research and milestones	112	183
Total revenues	1,883	1,084
Cost of revenues	1,016	981
Gross profit	867	103
Operating expenses:		
Sales, general and administrative	2,411	3,374
Stock based compensation	571	368
Research and development	7	80
Total operating expenses	2,989	3,822
Loss from operations	(2,122)	(3,719)
Other income (expense):		
Interest income (expense), net	(45)	20
Gain on settlement of obligation	5	382
Loss on disposal of property and equipment		(130)
Loss before provision (benefit) for income taxes	(2,162)	(3,447)
Provision (benefit) for income taxes		
Net loss attributable to common stock	\$ (2,162)	\$ (3,447)
Net loss per share:		
Basic and diluted	\$ (0.04)	\$ (0.16)

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Number of weighted average shares used in per share calculation:

Basic and diluted

48,957

21,517

*See accompanying notes to financial statements.*

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**CLEARANT, INC.**  
**STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)**  
(in thousands, except par value amounts)

	Series A Preferred Stock	Common Stock, \$0.0001 par value		Additional Paid-in Capital	Accumulated Deficit	Other Comprehensive Loss	Stock- holders Equity (Deficit)
	Shares Amount	Shares	Amount				
<b>Balance at December 31, 2006</b>	\$	2,870	\$	\$ 82,953	\$ (82,369)	\$	\$ 584
Issuance of common stock to consultants for services		22		60			60
Issuance of common stock as settlement of debt		31		109			109
Issuance of common stock		46,034	5	3,214			3,219
Issuance costs				(344)			(344)
Stock-based compensation				368			368
Net Loss					(3,447)		(3,447)
<b>Balance at December 31, 2007</b>	\$	48,957	\$ 5	\$ 86,360	\$ (85,816)	\$	\$ 549
Issuance of preferred stock in connection with related party convertible promissory note							
Issuance of warrants in connection with related party convertible promissory note				63			63
Issuance of warrants to consultants for services				10			10
Settlement of issuance costs				9			9
Stock-based compensation				571			571
Net Loss					(2,162)		(2,162)

**Balance at December 31,  
2008**

**\$ 48,957 \$ 5 \$ 87,013 \$ (87,978) \$ (960)**

*See accompanying notes to financial statements.*

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**CLEARANT, INC.**  
**STATEMENTS OF CASH FLOWS**  
(in thousands, except for share and per share data)

	Year Ended December 31,	
	2008	2007
<b>Operating activities</b>		
Net loss	\$ (2,162)	\$ (3,447)
Adjustments to reconcile net loss to net cash used in operating activities:		
Provision for inventory and inventory related prepayments write down		444
Loss on disposal of fixed assets		130
Depreciation and amortization	131	407
Stock-based compensation	571	368
Issuance of common stock to consultants for accounts payable		109
Issuance of common stock to consultants for services rendered		103
Issuance of warrants to consultants for services rendered	10	
Accretion of debt discount	47	
Gain on settlement of obligation	(5)	(382)
Changes in operating assets and liabilities:		
Accounts receivable	65	(67)
Inventory and inventory related prepayment	(15)	(59)
Prepays	5	(82)
Accounts payable	(135)	12
Accrued liabilities	12	(37)
Deferred revenue	(3)	(61)
Other assets and liabilities	2	32
Net cash used in operating activities	(1,477)	(2,530)
<b>Investing activities</b>		
Cost of identified intangibles	(47)	(58)
Capital expenditures	(20)	(10)
Proceeds from sales of property and equipment, net		22
Net cash used in investing activities	(67)	(46)
<b>Financing activities</b>		
Proceeds from convertible promissory note related party, net of fees of \$122	747	
Proceeds from the issuance of common stock, net of costs of \$344		2,875
Proceeds from the issuance of bridge loan		200
Net cash provided by financing activities	747	3,075

<b>Change in cash and cash equivalents</b>	(797)	499
<b>Cash and cash equivalents, beginning of period</b>	1,062	563
<b>Cash and cash equivalents, end of period</b>	\$ 265	\$ 1,062
<b>Supplemental Disclosure of Cash Flow Information:</b>		
Cash paid for interest	\$ 13	\$
<b>Supplemental Disclosure of Non Cash Investing and Financing Activities</b>		
Issuance of common stock as settlement of debt	\$	\$ 109
Issuance of common stock to consultants for services	\$	\$ 103
Issuance of warrants to consultants for services	\$ 10	\$
Conversion of debt to equity	\$	\$ 200
Settlement of issuance costs	\$ 9	\$
Issuance of warrants in connection with related party convertible promissory note	\$ 63	\$

*See accompanying notes to financial statements.*

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**CLEARANT, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**(in thousands, except for share and per share data)**

**NOTE 1 NATURE OF OPERATIONS**

We were incorporated as a California corporation and commenced operations on April 30, 1999. We have developed a proprietary technology, the Clearant Process<sup>®</sup> that inactivates pathogens that may contaminate biological products such as tissue allograft implants, recombinant protein therapeutics, plasma protein therapeutics, blood and blood-related products. The Clearant Process<sup>®</sup> enables customers to meet the medical need for safer biological products and to satisfy current and future product safety guidelines. Our primary business model is to distribute Clearant Process<sup>®</sup> tissue to surgeons, hospitals and surgery centers through a direct and indirect sales force. Clearant continues to provide customers the ability to apply the Clearant Process<sup>®</sup> internally or through our sterilization service. Customers pay us for assistance in applying the process to their manufacturing processes or to apply the process for them at our sterilization service center. During 2003 and 2004, our primary sources of revenue were contract research and government grants. During 2005, we changed our emphasis from one-time, generally non-recurring research and grant revenue to obtaining license and sterilization service customers. During 2006, we implemented a plan to better market and promote adoption of the Clearant Process<sup>®</sup>, which is to directly distribute Clearant Process<sup>®</sup> sterile implants to customers in order to facilitate market penetration. We do not intend to continue to pursue any new license and sterilization agreements. The direct distribution revenue model will be our primary focus. Our ability to achieve a profitable level of operations will depend on our ability to continue to increase customer acceptance of the Clearant Process<sup>®</sup> and increased recognition by end users of the value of the Clearant Process<sup>®</sup> in assuring sterile products.

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and reflect all adjustments, consisting solely of normal recurring adjustments, needed to fairly present the financial results. These financial statements include some amounts that are based on management's best estimates and judgments. These estimates may be adjusted as more information becomes available, and any adjustment could be significant. The impact of any change in estimates is included in the determination of earnings in the period in which the change in estimate is identified.

All share data has been restated to reflect any reverse stock splits that took place following the periods presented. Certain reclassifications, where needed, were made in prior periods to be consistent with current period presentation.

**NOTE 2 GOING CONCERN**

The accompanying financial statements have been prepared on the basis that we will continue as a going concern. We have incurred significant operating losses and negative cash flows from operating activities since our inception. As of December 31, 2008, these conditions raised substantial doubt as to our ability to continue as a going concern. In July 2008, we raised additional capital to supplement our operations by entering into a \$2,000 related party convertible secured promissory note. The \$2,000 related party convertible secured promissory note was scheduled to be funded, net of fees of approximately \$250, in tranches of: \$400 on July 8, 2008; \$400 on August 22, 2008 of which \$252 was received on September 5, 2008, and \$108 was received on October 1, 2008; \$600 scheduled on October 6, 2008 of which \$68 was received on December 12, 2008, \$50 was received on January 8, 2009, and \$155 was received on February 26, 2009; and \$600 scheduled on February 16, 2009 which has not yet been received. On February 20, 2009, we entered into an amendment to the related party convertible secured promissory note. The amendment extends the closing dates for the amounts due on October 6, 2008 and February 16, 2009, to March 31, 2009 and April 30, 2009, respectively. The amendment extending the closing date for the amounts due on October 6, 2008 accounts for payments previously made, as discussed above, and requires a payment of \$160 on February 20, 2009, of which we received \$155 on February 26, 2009 and \$5 on March 12, 2009, a payment of \$100 due before March 10, 2009, of which we received \$72 on March 12, 2009 and a payment of \$222 due before March 31, 2009. The amendment also gives us the option to extend the initial maturity date of each promissory note to January 8, 2012. There can be no assurance that we will receive any of the remaining amounts due on the secured promissory note. Regardless of whether we receive the full amount of the remaining amounts, we will still require and continue to seek additional capital to fund our ongoing operations. There can be no assurance that we will be successful in our efforts

to generate, increase, or maintain revenue or raise additional capital on terms acceptable to us or that we will be able to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability of the carrying amount of the recorded assets or the amount of liabilities that might result from the outcome of this uncertainty.

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**CLEARANT, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**(in thousands, except for share and per share data)**

**NOTE 3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Revenue Recognition and Deferred Revenue**

We recognize revenue in accordance with the provisions of Staff Accounting Bulletin ( SAB ) No. 104, Revenue Recognition. Our revenue sources are direct distribution of Clearant Process® sterile implants, and licensing fees and sterilization services to customers who incorporate the Clearant Process® technology into their product and manufacturing processes, which may include performance milestones and contract research activities. We recognize direct distribution revenue upon the sourcing of tissue by a customer. Licensing revenue is recognized when a customer distributes products incorporating the Clearant Process® and revenue related to the sterilization service is recognized when the service is substantially complete. We recognize revenue related to performance milestones and contract research in accordance with Statement of Position 81-1, Accounting for Performance of Construction-Type and Certain Production-Type Contracts ( SOP 81-1 ). Revenue related to a performance milestone is recognized upon customer acceptance of the achievement of that milestone, as defined in the respective agreements. Revenue related to contract research activities is recognized on a percentage-of-completion basis. In the event cash is received in advance of service performed, we will defer the related revenue recognition until the underlying performance milestone is achieved and or the contract research activities commence. In the event advance cash payments are not attributable to any performance milestone and or contract research activity, we will recognize the underlying amounts into revenue on a straight-line basis over the term of the underlying agreement. We include shipping charges in the gross invoice price to customers and classify the total amount as revenue in accordance with Emerging Issues Task Force Issue ( EITF ) 00-10, Accounting for Shipping and Handling Fees and Costs. Shipping costs are recorded as cost of revenues. We evaluate the collectability of accounts receivables and provide a reserve for credit losses, as appropriate. As of December 31, 2008 and 2007, we reserved for credit losses of \$91 and \$26, respectively.

**Cost of Revenues**

Cost of revenues consists of costs associated with direct distribution of Clearant Process® sterile implants to a customer and with providing sterilization services to customers. For the years ended December 31, 2008 and 2007, we had inventory reserves of \$0 and \$444, respectively, which were recorded as a cost of revenue.

**Settlement of Obligation**

Settlement of obligation consists of a gain recognized for the settlement of outstanding payables for the fiscal years ended December 31, 2008 and 2007.

**Use of Estimates**

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

**Cash Equivalents and Concentration of Credit Risk**

We consider all highly liquid investments with an original maturity of three months or less to be cash equivalents. Financial instruments that potentially subject us to a concentration of credit risk consist of cash and cash equivalents, and accounts receivable. Cash is deposited with what we believe are highly credited, quality financial institutions and may exceed Federal Deposit Insurance Corporation insured limits. For and at the years ended December 31, 2008 and 2007, three customers accounted for approximately 20% and 33% of revenues, respectively, and three customers accounted for approximately 25% and 24% of accounts receivable, respectively.

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**CLEARANT, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**(in thousands, except for share and per share data)**

**Accounts Receivable and Allowance for Doubtful Accounts**

Accounts receivable are recorded at the invoiced amount and do not bear interest. Provisions for doubtful accounts are recorded in general and administrative expenses. The allowance for doubtful accounts is based on the best estimate of the amount of probable credit losses in existing accounts receivable. The allowance for doubtful accounts is determined based on historical write-off experience, current customer information and other relevant data. Clearant reviews the allowance for doubtful accounts monthly. Account balances are charged off against the allowance when management believes it is probable the receivable will not be recovered. As of December 31, 2008 and 2007, the allowance for doubtful accounts was \$91 and \$26, respectively.

**Inventories and Inventory Related Prepayments**

Inventories are primarily comprised of implantable donor tissue treated with the Clearant Process® and are valued at the lower of cost or market with cost determined using the first-in, first-out method. Inventories are located at contracted tissue banks and on consignment in hospitals. Inventories may be reserved from time to time based on market conditions or other factors. As of December 31, 2008 and 2007, we had inventory and inventory related prepayment reserves of \$1,315 and \$1,255, respectively.

In accordance with the terms of our spinal Supply and Distribution Agreement (See Note 13), we are required to make prepayments. Upon receipt of the inventory the prepayments will be reclassified as inventory until distributed.

**Property and Equipment**

Property and equipment are stated at cost. Depreciation is provided using the straight-line method based upon estimated useful lives of the assets, which are generally three to seven years. Leasehold improvements are amortized over the estimated useful lives of the assets or related lease terms, whichever is shorter. Repair and maintenance expenditures are charged to appropriate expense accounts in the period incurred. For the years ended December 31, 2008 and 2007, we sold no property or equipment.

**Fair Value Measurements**

Effective January 1, 2008, we adopted Statement of Financial Accounting Standards ( SFAS ) No. 157, *Fair Value Measurements* ( SFAS 157 ), except as it applies to the nonfinancial assets and nonfinancial liabilities subject to Financial Staff Position SFAS 157-2. SFAS 157 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering such assumptions, SFAS 157 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

- Level 1 Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.
- Level 2 Include other inputs that are directly or indirectly observable in the marketplace.
- Level 3 Unobservable inputs which are supported by little or no market activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

In accordance with SFAS 157, we measure our cash equivalents at fair value. Our cash equivalents are classified within Level 1. Cash equivalents are valued primarily using quoted market prices utilizing market observable inputs. At December 31, 2008, cash equivalents consisted of money market funds measured at fair value on a recurring basis. Fair value of our money market funds was \$219 at December 31, 2008.



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**CLEARANT, INC.**  
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**Long-Lived Assets**

We review and evaluate our long-lived assets for impairment when events or changes in circumstances indicate that the related carrying amounts may not be recoverable. An impairment loss is measured as the amount by which the asset carrying value exceeds its fair value. Fair value is generally determined using valuation techniques such as estimated future cash flows. An impairment is considered to exist if total estimated future cash flows on an undiscounted basis are less than the carrying amount of the asset. An impairment loss is measured and recorded based on discounted estimated future cash flows. Assumptions underlying future cash flow estimates are subject to risks and uncertainties. No impairment losses were recorded during the years ended December 31, 2008 and 2007.

**Identifiable Intangibles**

Certain costs associated with obtaining and licensing patents and trademarks are capitalized as incurred and are amortized on a straight-line basis over the shorter of their estimated useful lives or their legal lives of 17 to 20 years. Amortization of such costs begins once the patent or trademark has been issued. We evaluate the recoverability of our patent costs and trademarks quarterly based on estimated undiscounted future cash flows. In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ( SFAS 144 ), the carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. Based on our valuation assessments of our patents, no impairment exists for the years ended December 31, 2008 and 2007.

**Research and Development Costs**

Research and development costs are expensed as incurred.

**Income Taxes**

Income taxes are accounted for under SFAS No. 109, *Accounting for Income Taxes* ( SFAS 109 ), using the liability method. Under SFAS 109, deferred tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities, and are measured using the enacted tax rates and laws that are expected to be in effect when the differences reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The significant components of the provision for income taxes for the fiscal year ended December 31, 2008 and 2007 were \$0 and \$0, respectively, for the current state provision. There was no state deferred and federal tax provision. Due to our current net loss position, we have provided a valuation allowance in full on our net deferred tax assets in accordance with SFAS 109 and in light of the uncertainty regarding ultimate realization of the net deferred tax assets. We adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ( FIN 48 ), on January 1, 2007. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. Due to the fact that we have substantial net operating loss carryforwards, adoption of FIN 48 had no impact on our beginning retained earnings, balance sheets, or statements of operations.

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**CLEARANT, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**(in thousands, except for share and per share data)**

**Stock-Based Compensation**

Stock-based compensation expense is recognized under SFAS No. 123(R), *Share Based Payment* ( SFAS 123R ), which requires the measurement and recognition of compensation expense for all share-based payment awards to employees and directors based on estimated fair value. Stock-based compensation expense for employees, directors, and consultants for the years ended December 31, 2008 and 2007 was \$571 and \$368, respectively.

There were 0 and 3,267,180 options granted to employees, directors, and consultants during the years ended December 31, 2008 and 2007, respectively.

Options issued to consultants are being accounted for in accordance with the provisions of Emerging Issues Task Force ( EITF ) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* (EITF 96-18).

As stock-based compensation expense recognized for the year ended December 31, 2008 and 2007 is based on awards ultimately expected to vest, it has been reduced for forfeitures, which we estimate to be approximately 7%, respectively. As of December 31, 2008 and 2007, stock-based compensation expense has been reduced by estimated forfeitures not yet incurred of approximately \$15 and \$56, respectively.

**Fair Value of Financial Instruments**

Fair value of financial instruments are accounted for under SFAS No. 157, *Fair Value Measurements*, ( SFAS 157 ) which requires the carrying amounts reported in the balance sheet for cash, cash equivalents, accounts receivable, accounts payable and accrued liabilities to approximate fair value because of the immediate or short-term maturity of these financial instruments. Bridge loans are estimated to approximate fair value based upon current market borrowing rates for loans with similar terms and maturities.

**Recent Accounting Pronouncements**

On November 5, 2007, the SEC issued Staff Accounting Bulletin ( SAB ) No. 109, *Written Loan Commitments Recorded at Fair Value Through Earnings* ( SAB 109 ). SAB 109 provides guidance on the accounting for written loan commitments recorded at fair value under generally accepted accounting principles (GAAP). Specifically, the SAB revises the Staff's views on incorporating expected net future cash flows related to loan servicing activities in the fair value measurement of a written loan commitment. SAB 109, which supersedes SAB 105, *Application of Accounting Principles to Loan Commitments*, requires the expected net future cash flows related to the associated servicing of the loan be included in the measurement of all written loan commitments that are accounted for at fair value through earnings. SAB 109 is effective in fiscal quarters beginning after December 15, 2007. SAB 109 did not have a material impact on our financial statements.

In December 2007, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 141(R), *Business Combinations* ( SFAS 141(R) ), which replaces SFAS No. 141. SFAS 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. The Statement also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combination. SFAS 141(R) is effective for calendar year companies on January 1, 2009. We do not anticipate that the adoption of SFAS 141(R) will have a material affect on accounting for business combinations once adopted, but the effect is dependent upon acquisitions at that time.

In December 2007, the SEC issued SAB 110. SAB 110 expresses the views of the staff regarding the use of a simplified method, as discussed in SAB No. 107 ( SAB 107 ), in developing an estimate of expected term of plain vanilla share options in accordance with SFAS No. 123 (revised 2004) which is effective on January 1, 2008. The adoption of SAB 110 did not have a material impact on our financial statements.

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**CLEARANT, INC.**  
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**(in thousands, except for share and per share data)**

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities*, and amendment of SFAS No. 133 ( SFAS No. 161 ). This statement will require additional disclosures about how and why we use derivative financial instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* , as amended and interpreted ( SFAS No. 133 ), and how derivative instruments and related hedged items affect our financial position, results of operations, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008; however early adoption is encouraged, as are comparative disclosures for earlier periods. We do not believe that the adoption of SFAS No. 161 will have a material impact on our financial statements.

In April 2008, the FASB issued FASB Staff Position ( FSP ) No. SFAS 142-3, *Determination of the Useful Life of Intangible Assets*, ( SFAS 142-3 ). FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142,

*Goodwill and Other Intangible Assets* and also requires expanded disclosure related to the determination of intangible asset useful lives. SFAS 142-3 is effective for fiscal years beginning after December 15, 2008. Early adoption is prohibited. We do not believe the adoption of SFAS 142-3 will have a material impact on our financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ( SFAS 162 ). SFAS 162 identifies the sources of accounting principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP in the United States. This Statement is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. We currently adhere to the hierarchy of GAAP as presented in SFAS No. 162, and do not expect its adoption will have a material impact on our results of operations and financial condition.

In May 2008, the FASB issued FSP APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ( FSP APB 14-1 ). FSP APB 14-1 requires issuers of convertible debt instruments that may be settled in cash upon conversion to account separately for the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. FSP APB 14-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We do not anticipate that the adoption of FSP APB 14-1 will have a material effect on our results of operations or financial position.

**NOTE 4 NET LOSS PER SHARE**

We compute net loss per share in accordance with SFAS No. 128, *Earnings Per Share* ( SFAS 128 ). Under the provisions of SFAS 128, basic loss per share is computed by dividing net loss by the weighted average number of common stock shares outstanding during the periods presented. Diluted earnings would customarily include, if dilutive, potential common stock shares issuable upon the exercise of stock options and warrants. The dilutive effect of outstanding stock options and warrants is reflected in earnings per share in accordance with SFAS 128 by application of the treasury stock method. For the periods presented, the computation of diluted loss per share equaled basic loss per share as the inclusion of any dilutive instruments would have had an antidilutive effect on the earnings per share calculation in the periods presented.

The following potential common shares have been excluded from the computation of diluted net loss per share since their effect would have been antidilutive:

	For the Year Ended December 31,	
	2008	2007
Stock Options	2,757,855	3,416,844
Warrants	2,113,052	156,780



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**CLEARANT, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
**(in thousands, except for share and per share data)**

The following table sets forth the computation of basic and diluted net loss per share:

	For the Year Ended December 31,	
	2008	2007
Basic and diluted net loss per share:		
Numerator:		
Net loss attributable to common stock	\$ (2,162)	\$ (3,447)
Denominator:		
Weighted average common stock shares outstanding	48,957	21,517
Net loss per share, basic and diluted	\$ (0.04)	\$ (0.16)

**NOTE 5 PROPERTY AND EQUIPMENT**

Property and equipment consists of the following at December 31, 2008 and 2007:

	2008	2007
Equipment	\$ 89	\$ 69
Computer equipment and software	66	66
Furniture and fixtures	27	27
Leasehold improvements	8	8
	190	170
Less accumulated depreciation	(146)	(83)
	\$ 44	\$ 87

We had no property or equipment that was leased as part of a capital lease agreement for the years ended December 31, 2008 and 2007, respectively. Depreciation expense was \$64 and \$61 for the years ended December 31, 2008 and 2007, respectively.

**NOTE 6 IDENTIFIABLE INTANGIBLES**

Identifiable intangibles consist of the following at December 31, 2008 and 2007:

	2008	2007
Trademarks	37	37
Patents	2,218	2,171
	2,255	2,208
Less accumulated amortization	(1,285)	(1,217)
	\$ 970	\$ 991

Over the period January 1, 2009 to December 31, 2013, we project cumulative amortization expense related to our patents and trademarks issued at December 31, 2008 to be approximately \$196, expensed equally over the five years. Because we evaluate the recoverability of our intangibles on a quarterly basis, and anticipate that new patents will be granted and issued in 2009 through 2013, actual amortization expense recorded over January 1, 2009 to December 31,

2013 could fluctuate significantly from the projected amount over the same period.

During the years ended December 31, 2008 and 2007, we recorded \$68 and \$345, respectively, of amortization and write-off of patent costs.

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**CLEARANT, INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
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**NOTE 7 INCOME TAXES**

The current provision for income taxes for the years ended December 31, 2008 and 2007 were \$0 and \$0, respectively. There was no state deferred and federal tax provision.

The significant components of the deferred tax assets and liabilities, along with the related valuation allowance at December 31, 2008 and 2007 are as follows:

	2008	2007
Deferred tax assets:		
Net operating loss carryforwards	\$ 28,245	\$ 27,790
Purchase in-process research and development	545	521
Research and development credits	1,362	1,369
Depreciation, accrued expenses and other	978	718
Net deferred tax assets	31,130	30,398
Less valuation allowance	(31,130)	(30,398)
	\$	\$

Our valuation allowance on deferred tax assets increased from \$30,398 as of December 31, 2007 to \$31,130 as of December 31, 2008, due to continued operating losses as management has concluded that it is not more likely than not such assets will be realized.

The U.S. and foreign pretax losses for the year ended December 31, 2008 was approximately \$2,162 and \$0, respectively, and for the year ended December 31, 2007 was approximately \$3,447 and \$0, respectively.

We have provided a valuation allowance in full on our net deferred tax assets in accordance with SFAS 109 and in light of the uncertainty regarding ultimate realization of the net deferred tax assets. The difference between the effective tax rate and that computed under the federal statutory rate is as follows:

	2008	2007
Federal statutory rate	(34%)	(34%)
State taxes	(6%)	(6%)
Tax credits & other	6%	(9%)
Foreign loss with no benefit	0%	0%
Valuation allowance	34%	49%
	0%	0%

At December 31, 2008 and 2007, we had net operating losses ( NOL ) for federal and state income tax purposes of approximately \$149,125 and \$146,502, respectively. Section 382 of the Internal Revenue Code (Section 382) imposes, amongst other things, annual limitations restricting the timing and amounts of the future use of available NOL carryforwards at the time a change in ownership occurs. The utilization of these NOL carryforwards could be restricted in future periods as a result of any future change in ownership, as defined in Section 382. Such future change in ownership, if any, may result in significant amounts of these NOL carryforwards expiring unused. In conjunction with the August 2007 transaction (See Note 10), we will evaluate whether there are limitations on the use of our NOL carryforwards beyond December 31, 2008 under Section 382, including, as needed, the impact of cumulative changes in the ownership of our common stock. The credit carryforwards noted above may be limited

under Internal Revenue Code Section 383. As of December 31, 2008, we have not performed an analysis in order to determine whether such limitations exist.

We also have federal and state research and development tax credit carryforwards as of December 31, 2008 and 2007, of approximately \$1,362 and \$1,369, respectively, which begin to expire in 2023.



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**NOTE 8 CONVERTIBLE SECURED PROMISSORY NOTE RELATED PARTY**

On July 9, 2008, we entered into an Agreement dated as of July 8, 2008 with CPI Investments, Inc. ( CPI ) whereby CPI agreed to loan us the aggregate amount of \$2,000 (the CPI Agreement ).

The loan is payable, net of fees of approximately \$250, in tranches of: \$400 which was funded on July 8, 2008; \$400 of which \$252 was funded on September 5, 2008, and \$108 was funded on October 1, 2008; \$600 scheduled to be funded on October 6, 2008 of which \$68 was received on December 12, 2008, \$50 was received on January 8, 2009, \$155 was received on February 26, 2009; and \$600 scheduled to be funded which has not been received. On February 20, 2009, we entered into an amendment to the CPI Agreement. The amendment extends the closing dates for the amounts due on October 6, 2008 and February 16, 2009, to March 31, 2009 and April 30, 2009, respectively. The amendment extending the closing date for the amounts due on October 6, 2008 accounts for payments previously made, as discussed above, and requires a payment of \$160 on February 20, 2009, of which we received \$155 on February 26, 2009 and \$5 on March 12, 2009, a payment of \$100 due before March 10, 2009, of which we received \$72 on March 12, 2009, and a payment of \$222 due before March 31, 2009. The amendment also gives us the option to extend the initial maturity date of each promissory note to January 8, 2012. The principal amounts loaned have a 3-year term and will bear interest at 12% per year payable monthly with no prepayment option. The loan is convertible into 18,181,818 shares of our restricted common stock at a conversion price of \$0.11. There was no beneficial conversion feature as calculated under EITF 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*, ( EITF 00-27 ).

According to APB Opinion No. 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants* ( APB 14 ), we allocated the proceeds received to the convertible debt and warrants based upon relative fair value. We allocated \$63 to the warrants and \$146 to the debt discount which are being amortized over the life of the debt. Interest expense recognized for the year ended December 31, 2008 was \$60.

Pursuant to the CPI Agreement, we granted CPI 2-year warrants to purchase (a) 4,500,000 shares of common stock at a \$0.30 exercise price, and (b) 200,000 shares of common stock at a \$0.15 exercise price, both vesting pro-rata upon funding of each tranche. We accounted for these warrants in accordance with EITF Issue No. 00-19, *Accounting for Derivative Financial Statements Indexed to, and Potentially Settled in a Company's own stock*, ( EITF 00-19 ).

In addition, we also granted CPI one share of our Series A Preferred Stock, which votes together with our common stock and has votes equal to 45,454,545 shares of common stock. Those votes will be reduced by 2.5 votes for every 1 share of common stock into which the loan is converted. Provided that CPI meets its funding obligations under the CPI Agreement, CPI will maintain its voting rights throughout the term of the loan.

Under the terms of the Agreement, CPI appointed 3 board members to our board of directors, Michael Bartlett, Kenneth W. Davidson and Alan S. Blazei. Michael Bartlett also serves as the president of CPI. CPI is a related party to the Company.

**NOTE 9 DEBT**

In February, 2007, we entered into a non-binding term sheet with a bridge lender for \$700. Under the terms of the non-binding term sheet, the bridge lender was required to lend us \$200 upon the signing of the non-binding term sheet and \$500 upon signing of the definitive agreement. In addition to requiring funding of \$700, the non-binding term sheet provided that the lender would receive 2,500,000 shares of our common stock, a first lien on all of our assets including our intellectual property, repayment of the \$700 by May 1, 2007 and interest of 10% per annum. On February 20, 2007, we received \$200. The \$500 was never funded and neither party entered into a definitive agreement. On March 27, 2007, we received notice of a claim by the bridge lender to preserve his right as outlined in the non-binding term sheet to fund the \$700 bridge credit facility. On July 16, 2007, as disclosed on our Current Report on Form 8-K/A filed with the SEC on August 9, 2007, we entered into a settlement and conversion agreement with the bridge lender whereby we issued 2,857,143 shares for the \$200 loan payable at \$0.005 per share. The costs associated with the transaction are \$16. The settlement and conversion agreement released us from all outstanding claims from the bridge lender including the claim on our intellectual property by the bridge lender. The shares were

issued on August 23, 2007.

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**NOTE 10 CAPITALIZATION**

**Common Stock Transactions and Non-Cash Financing Activities**

In August, 2007, we entered into stock purchase agreements and registration rights agreements with approximately 11 accredited and institutional investors for the sale of 7,511,875 shares of our common stock ( shares ) at \$0.005 per share, in a private offering, in exchange for gross proceeds of approximately \$525. This private placement was made in connection with the private placement we previously entered into on April 3, 2007 (the April private placement ), pursuant to which approximately 20 accredited and institutional investors purchased 6,694,299 shares at \$0.025 in exchange for gross proceeds of approximately \$2,300. The costs associated with the transaction are \$344. On August 23, 2007, pursuant to the antidilution provisions in the stock purchase agreements, 7,511,875 shares were issued to the new investors and 26,777,141 additional shares were issued to the April private placement investors to adjust their selling price to \$0.005 per share. These shares have been recorded as an adjustment between additional paid in capital and par value as it represents an adjustment to the original sale price of common stock.

In August, 2007, we entered into a Settlement and Conversion Agreement with the bridge lender pursuant to which the bridge lender would be issued 2,857,143 shares for the \$200 loan payable at \$0.005 per share. As part of the Settlement and Conversion Agreement, the lender purchased an additional 2,142,859 shares at a price of \$0.005 per share in exchange for aggregate proceeds of \$142 and interest accrued on the bridge loan of \$8. The bridge lender was also issued 51,021 shares as part of the original non-binding term sheet entered into by us in February 2007. The Settlement and Conversion Agreement directly caused the antidilution provision of the April private placement investors. The shares were issued on August 23, 2007.

On August 8, 2007, we announced a 1-for-14 reverse stock split which was previously authorized at our annual meeting of stockholders held on August 3, 2007. The record date for the reverse split was August 23, 2007 and we began trading on the NASD Electronic Bulletin Board (OTCBB) on a split adjusted basis on September 6, 2007 under the new symbol CLRA.OB.

For the year ended December 31, 2008 and 2007, we paid accounts payable of \$0 and \$109 with 0 and 31,092 shares of common stock, respectively.

For the year ended December 31, 2008 and 2007, we paid consultants \$0 and \$60 with 0 and 22,038 shares of common stock, respectively.

**Series A Preferred Stock**

We have 50,000,000 shares authorized and 1 share outstanding as of December 31, 2008.

**NOTE 11 STOCK OPTIONS**

On June 30, 2005, the stockholders approved our 2005 Stock Award Plan (the 2005 Plan ). There are 5,081,412 shares of common stock authorized for issuance under the 2005 Plan. In addition, we assumed options to purchase 137,042 shares of common stock in connection with the reverse merger consummated on March 31, 2005 from the 2000 Stock Award Plan of which 71,528 remain outstanding as of December 31, 2008. There are no future grants available under the 2000 stock Award Plan as of March 31, 2005. On August 3, 2007, at our annual meeting, the stockholders approved a 6,000,000 share increase in our 2005 Plan. Accordingly, an aggregate of 11,152,940 shares of common stock are reserved for issuance upon exercise of options.

The terms of the 2005 Plan provide for grants of stock options ( NSO ), stock appreciation rights, restricted stock, deferred stock, bonus stock, dividend equivalents, other stock-related awards and performance awards that may be settled in cash, stock or other property. Employees, officers, directors and consultants are eligible for awards under the plan. However, incentive stock options ( ISO ) may only be granted to employees. An ISO will have the terms stated in the option agreement, provided, however, that the term shall be no more than ten years from the date of grant and the exercise price shall be no less than 100% of the estimated fair market value per share on the date of grant. NSOs shall have a term of no more than 10 years from the date of grant and an exercise price of no less than 85% of the estimated fair market value per share on the date of grant. Options granted to an individual who, at the time of grant of such option, owns stock representing more than 10% of the voting power of all classes of our stock , shall have an exercise

price equal to no less than 110% of fair market value and a term of no more than five years from the date of grant. The vesting period for ISOs and NSOs is generally four years from the date of grant.

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The following table sets forth the activity of the 2000 and 2005 Plan and Non-Plan Options issued for the years ended December 31, 2008 and 2007:

	Employees		Non-Employees		Total	
	Shares	Exercise Price	Shares	Exercise Price	Shares	Exercise Price
<b>Outstanding at December 31, 2006</b>	243,000	\$ 6.16-\$63.14	43,000	\$ 4.90-\$57.68	286,000	\$ 4.90-\$63.14
Granted	3,137,000	\$ 0.35-\$0.45	130,000	\$ 0.70	3,267,000	\$ 0.35-\$0.70
Exercised		\$		\$		\$
Change in status		\$		\$		\$
Forfeited or expired	(136,000)	\$ 0.35-\$63.14		\$	(136,000)	\$ 0.35-\$63.14
<b>Outstanding at December 31, 2007</b>	3,244,000	\$ 0.35-\$63.14	173,000	\$ 0.70-\$57.68	3,417,000	\$ 0.35-\$63.14
Granted		\$		\$		\$
Exercised		\$		\$		\$
Change in status		\$		\$		\$
Forfeited or expired	(659,000)	\$ 0.35-\$57.68		\$	(659,000)	\$ 0.35-\$57.68
<b>Outstanding at December 31, 2008</b>	2,585,000	\$ 0.35-\$63.14	173,000	\$ 0.70-\$57.68	2,758,000	\$ 0.35-\$63.14

The weighted average exercise prices for options granted and exercisable and the weighted average remaining contractual life for options outstanding as of December 31, 2008 and December 31, 2007 was as follows:

	Number Of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Intrinsic Value
<i>As of December 31, 2007:</i>				
Employees Outstanding	3,244,000	\$ 1.31	9.57	\$
Employees Expected to Vest	3,079,000	\$ 1.31	9.57	\$
Employees Exercisable	188,000	\$ 10.69	7.85	\$
Non-Employees Outstanding	173,000	\$ 8.09	8.30	\$
Non-Employees Expected to Vest	173,000	\$ 8.09	8.30	\$
Non-Employees Exercisable	41,000	\$ 31.47	3.34	\$
<i>As of December 31, 2008:</i>				
Employees Outstanding	2,585,000	\$ 1.43	8.56	\$
Employees Expected to Vest	2,423,000	\$ 1.44	8.55	\$
Employees Exercisable	919,000	\$ 2.67	8.35	\$
Non-Employees Outstanding	173,000	\$ 8.09	7.70	\$
Non-Employees Expected to Vest	173,000	\$ 8.09	7.70	\$
Non-Employees Exercisable	107,000	\$ 12.61	6.99	\$



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Of the shares issued to employees, the number of shares outstanding, expected to vest, and exercisable to officers and directors is 2,210,000, 2,076,000, and 793,000, respectively.

Cash received from stock options exercised during the year ended December 31, 2008 and 2007 was \$0 and \$0, respectively. The total intrinsic value of options exercised during the year ended 2008 and 2007 was \$0 and \$0, respectively. The weighted average grant-date fair value of options granted during the year ended December 31, 2008 and 2007, was \$0.00 and \$0.43.

Included in the table above, at December 31, 2008 and 2007, were options outstanding for 173,000 shares, respectively, granted to consultants. These options generally vest over zero to four years and are expensed when the services are performed and benefit is received as provided by the Emerging Issues Task Force ( EITF ) 96-18,

Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services ( EITF 96-18 ).

As of December 31, 2008 and 2007, there were \$861 and \$1,724, respectively of total unrecognized compensation costs related to non-vested share-based compensation arrangements granted under the 2005 Plan. That cost is expected to be recognized over the weighted-average period of 2.3 and 3.2 years, respectively.

When options are exercised, our policy is to issue previously unissued shares of common stock to satisfy share option exercises. As of December 31, 2008, we had 7,673,723 shares of unissued shares reserved for issuance under our 2005 Plan.

**NOTE 12 WARRANTS**

On August 13, 2008, we issued a 10-year warrant to a distributor to purchase an aggregate 100,000 shares of our common stock at an exercise price of \$0.10 per share with a fair value of \$10 which is reflected in our sales, general, and administrative expenses.

Pursuant to the CPI Agreement the Company issued 2-year warrants to purchase common stock (see Note 6 in the accompanying footnotes to the financial statements). On July 8, 2008, we issued 2-year warrants to CPI Investments to purchase 900,000 and 40,000 shares of our common stock at \$0.30 and \$0.15, respectively with a fair value of \$75 which is reflected as part of our debt discount. On September 5, 2008 we issued 2-year warrants to CPI Investments to purchase 900,000 and 40,000 shares of our common stock at \$0.30 and \$0.15, respectively with a fair value of \$71 which is reflected as part of our debt discount. We accounted for these warrants in equity in accordance with EITF 00-19.

In November 2005 and in conjunction with our secondary placement of common stock, we issued five-year warrants to such holders to purchase an aggregate 121,324 shares of our common stock at an exercise price of \$69.44 per share. In addition, we issued five-year warrants to the placement agent to purchase an aggregate 11,728 shares of common stock at an exercise price of \$69.44 per share. Due to the antidilution clause set forth in such holders warrant agreements, the exercise price of the above-mentioned shares was reduced to \$4.21 per share due to the private placement entered into in 2007.

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Including those described above, all warrants have an exercise price of between \$0.10 and \$4.21 per share and terms of two to ten years. The weighted average exercise prices and the weighted average remaining contractual life for warrants issued as of December 31, 2008 were as follows:

Number of Shares	Warrants Outstanding Exercise Price	Weighted Average of Remaining Contractual Life (Years)
133,052	\$ 4.21	1.85
1,800,000	\$ 0.30	1.52
80,000	\$ 0.15	1.52
100,000	\$ 0.10	9.62

All of the warrants granted to non-employees during 2008 are valued based on our deemed fair value at the date the warrants are issued, using the Black-Scholes option pricing model prescribed by FAS No. 123R and the following assumptions:

Risk-free interest rate	2.1%-3.2%
Expected life in years	2-5
Dividend yield	0%
Expected volatility	217%

The weighted average deemed fair value of warrants granted to non-employees for the years ended December 31, 2008 and 2007 was \$0.28 and \$0.00 per share, respectively.

**NOTE 13 COMMITMENTS AND CONTINGENCIES**Leases

We lease certain facilities and equipment under non-cancelable operating leases with various expirations through 2011. The future minimum lease payments under these leases as of December 31, 2008, are as follows:

2009	\$ 121
2010	20
2011 and thereafter	
Net minimum lease payments	\$ 141

Rental expense on non-cancelable operating leases for the years ended December 31, 2008 and 2007 was \$170 and \$165, respectively.

As of December 31, 2008 and 2007, we have no capital leases for equipment.

Litigation

From time-to-time, we are involved in litigation relating to claims arising in the normal course of business. Other than the Osprey legal dispute discussed under Supply and Distribution Agreements below we do not believe that any currently pending or threatening litigation will have a material adverse effect on our results of operations or financial condition as of December 31, 2008.



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**Supply and Distribution Agreements**

On September 27, 2006, we entered into a renewable two-year supply and distribution agreement (the Osprey Agreement ) with Osprey Biomedical Corp. ( Osprey ). Under the Osprey Agreement, Osprey granted us exclusive rights to place current and future Osprey cervical and lumbar allografts treated with the Clearant Process® in certain geographic territories with an option for additional geographic territories. In exchange for the exclusive rights under the Osprey Agreement, we were obligated to pay Osprey \$500 as a prepayment for certain ordered products to be delivered after October 1, 2006. This prepayment was due upon the earlier of the following: (i) within three business days after we receive debt or equity financing of at least \$1 million, or (ii) October 31, 2006. In addition, we were required to make the following quarterly payments to be applied to payments for ordered products: \$650 by October 31, 2006; \$750 by January 1, 2007; \$850 by April 1, 2007; \$1 million by July 1, 2007; \$1.2 million by October 1, 2007; \$1.3 million by January 1, 2008; \$1.5 million by April 1, 2008; and \$1.75 million by July 1, 2008. As of December 31, 2008, all tissue orders had not been delivered by Osprey and we have not made the prepayments. In February 2007, we received notice from Osprey of its termination of the Osprey Agreement, effective within thirty days from receipt of the notification if we did not timely cure certain alleged payment defaults. We are in ongoing discussions with Osprey to resolve these issues, which could include, but is not limited to, reduction in exclusive territories or termination of the Osprey Agreement. The termination of the Osprey Agreement has resulted in the discontinuation or disruption of the spinal bone implant supply, which has had a material adverse impact on our ability to distribute spinal bone implants treated with the Clearant Process®. In addition, the lack of supply of the ordered products has had a material impact on our revenues and cash flows.

**NOTE 14 401K PLAN**

We have a defined contribution profit sharing plan covering all full-time employees. Employees may make pre-tax contributions up to the maximum allowable by the Internal Revenue Code. Participants are immediately vested in their employee contributions. No employer contributions were made for the years ended December 31, 2008 and 2007.

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**NOTE 15 SELECTED QUARTERLY FINANCIAL DATA**

The following table presents summarized quarterly financial data (in thousands, except per share data):

	<b>Quarter ended</b>			
	<b>Mar. 31,</b>	<b>Jun. 30,</b>	<b>Sept. 30,</b>	<b>Dec. 31,</b>
<b>2008</b>				
Total revenues	\$ 465	\$ 504	\$ 462	\$ 452
Gross profit	252	215	201	199
Total operating expenses	815	692	747	735
Loss from operations	(563)	(477)	(546)	(536)
Other income (expense), net	9	3	(20)	(32)
Net loss	(554)	(474)	(566)	(568)
Net loss attributable to common stock	\$ (554)	\$ (474)	\$ (566)	\$ (568)
Net loss per share Basic and diluted	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.01)
Number of weighted average shares	48,957	48,957	48,957	48,957
<b>2007</b>				
Total revenues	\$ 435	\$ 168	\$ 160	\$ 321
Gross profit (loss)	287	76	57	(317)
Total operating expenses	1,174	920	989	739
Loss from operations	(887)	(844)	(932)	(1,056)
Other income (expense), net	(80)	(4)	356	0
Net loss	(967)	(848)	(576)	(1,056)
Net loss attributable to common stock	\$ (967)	\$ (848)	\$ (576)	\$ (1,056)
Net loss per share Basic and diluted	\$ (0.33)	\$ (0.11)	\$ (0.02)	\$ (0.02)
Number of weighted average shares	2,911	7,778	25,866	48,957

**NOTE 16 SUBSEQUENT EVENTS**

As previously discussed in Note 8, we entered into an amendment to the Agreement dated as of July, 8, 2008 with CPI, whereby CPI agreed to loan us the aggregate amount of \$2,000, effective February 20, 2009.

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**Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

There have not been any disagreements between us and our independent registered public accounting firm on any matter of accounting principles, practices or financial statement disclosure.

**Item 9A(T). *Controls and Procedures***

Under the supervision and with the participation of management, including our principal executive officer, principal financial officer, and principal accounting officer, we have evaluated the effectiveness of its disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act for the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our principal executive officer and principal financial officer have concluded that these controls and procedures are effective in all material respects, including those to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the SEC, and is accumulated and communicated to management, including the principal executive officer and the principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system will be met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events.

**Report of Management on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, (iii) provide reasonable assurance that receipts and expenditures of the company are being made only in accordance with authorization of management and directors of the company, and (iv) provide reasonable assurance regarding prevention or timely detection of the unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Management has assessed our internal control over financial reporting as of December 31, 2008. The assessment was based on criteria for effective internal control over financial reporting described in the Internal Control Integrated Framework issued by the Sponsoring Organizations of the Treadway Commission. Based on the assessment, Management believes that we maintained effective internal control over financial reporting as of December 31, 2008. This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only management's report in this annual report.

**Changes in Internal Controls**

We have evaluated, with the participation of our principal executive officer, principal financial officer, and principal accounting officer, that there have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting. Inherent limitations exist in any system of control including the possibility of human error and the potential of overriding controls. The effectiveness of an internal control system may also be affected by changes in conditions.

**Table of Contents****Item 9B. Other Information**

None.

**PART III****Item 10. Directors, Executive Officers and Corporate Governance****Directors and Executive Officers**

Our current officers, directors and significant employees are listed below. Each of our directors will serve for one year or until their respective successors are elected and qualified. Our officers serve at the pleasure of the board of directors.

<b>Name</b>	<b>Age</b>	<b>Position</b>	<b>Start of Term</b>
Jon Garfield	45	Chief Executive Officer	January 25, 2007
		Chief Financial Officer	August 2, 2005
		Director	August 3, 2007
		Secretary	August 2, 2005
Michael Elek	48	Director	August 3, 2007
Michael Bartlett	66	Chairman of the Board	December 9, 2008
		Director	July 11, 2008
Kenneth W. Davidson	61	Director	September 11, 2008
Alan S. Blazei	53	Director	September 11, 2008
Susan E. Etzel	35	Chief Accounting Officer	December 9, 2008
		Controller	July 5, 2005

**Jon Garfield**, age 45, was appointed as our Chief Executive Officer, effective January 25, 2007. Mr. Garfield is also our Chief Financial Officer and Secretary. Mr. Garfield has served as a member of our board of directors since May 24, 2007 and was re-elected on August 3, 2007 to a one year term or until his respective successor is elected and qualified. From 2001 until August 2005, Mr. Garfield served as an independent financial consultant, providing financial services including SEC reporting obligations and Sarbanes-Oxley compliance. From 1998 until January 2001, he served as Chief Financial Officer of a telecom service provider and a software developer. From 1996 to 1998, he served as Vice President of Acquisitions for formally New York Stock Exchange listed ground transportation consolidator Coach USA, Inc. From 1991 to 1996, Mr. Garfield served as Corporate Assistant Controller of Maxxim Medical, Inc. Maxxim was a formally New York Stock Exchange listed manufacturer and distributor of medical products. During 1986 to 1991 Mr. Garfield practiced public accounting with Arthur Andersen and PricewaterhouseCoopers. Mr. Garfield received a Bachelor of Business Administration in Accounting from the University of Texas, Austin.

**Michael Elek**, age 48, has served as a member of our board of directors since April 5, 2007 and was re-elected on August 3, 2007 to a one year term or until his respective successor is elected and qualified. Mr. Elek is a private investor in varied interests such as European real estate and private equity. Mr. Elek received an undergraduate degree from McGill University of Montreal, and an MBA with honors from St. John's University.

**Michael Bartlett**, age 66, was appointed as a member of our board of directors on July 11, 2008 pursuant to a Subscription and Purchase Agreement we entered into with CPI Investments on July 9, 2009. Mr. Bartlett has served as our Chairman of the Board since December 9, 2008. He also has served as President and CEO of Leisure Capital & Management, Inc., a financial advisor for private and public start-up and growth companies since 1986. Mr. Bartlett owns 4,261 shares of our common stock.

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**Kenneth W. Davidson**, age 61 was appointed as a member of our board of directors on September 11, 2008 pursuant to our agreement entered into with CPI Investments on July 9, 2009. He also is the Chairman of the Board of Directors of DJO LLC, a global provider of high-quality, orthopedic devices, with a broad range of products used for rehabilitation, pain management and physical therapy with approximately \$1 billion in revenues. From October 2000 to November 2007, Mr. Davidson served as Chief Executive Officer and in various other executive and board capacities with ReAble Therapeutics, Inc., a portfolio company of the Blackstone Group, and its predecessor Encore Medical, a publicly held orthopedic company. From 1986 to 2000, Mr. Davidson served as Chairman, President and CEO of Maxxim Medical, Inc., a publicly held medical supply company. Previously, Mr. Davidson held various positions with Intermedics, Inc., a pacemaker equipment manufacturer, Baxter Laboratories, a publicly held healthcare product and service company, and Merck & Co, a human and animal health care product company. Mr. Davidson is also a Board Member of Medical Action Industries, a leading supplier of medical and surgical products.

**Alan S. Blazei**, age 53, was appointed as a member of our board of directors on September 11, 2008 pursuant to a Subscription and Purchase Agreement we entered into with CPI Investments on July 9, 2009. He also is the Chief Financial Officer and a member of the Board of Directors of Entelos, a life sciences company improving human health through predictive biosimulation since 2001. From 1989 to 2000, Mr. Blazei served as the Executive Vice President and Chief Financial Officer of Maxxim Medical. From 1986 to 1989 he served as the Vice President of Finance for NTRON, a division of Sunrise Medical, Inc., a manufacturer and distributor of electro-medical equipment. From 1984 to 1986, he served as Partner for Madera Associates, a computer distributor and consulting group. Mr. Blazei received an M.B.A. from University of Minnesota and his B.B.A. from St. Cloud State University. He is also a certified public accountant.

**Susan E. Etzel**, age 35, became our Chief Accounting Officer effective December 9, 2008. She has been our Controller since July 2005. From September 2004 until July 2005, Ms. Etzel served as Manager of Financial Reporting for Digital Insight, Inc. a provider of online banking solutions for midsized banks and credit unions. From May 2000 to September 2004, she served as Assistant Controller of Knowledge Universe, Inc. a leading global education company. From 1999 to 2000, Ms. Etzel served as a Financial Analyst of Paramount Pictures in the TV Finance group. From 1996 to 1999 she practiced public accounting with Arthur Andersen. Ms. Etzel received a Bachelor of Business Economics with an emphasis in Accounting from the University of California, Santa Barbara. She is also a Certified Public Accountant.

***Family Relationships***

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

***Legal Proceedings***

There have been no events under any bankruptcy act, no criminal proceedings and no judgments, injunctions, orders or decrees, including judgments finding violations of any federal or state securities or commodities law, material to the evaluation of the ability and integrity of any of our directors, executive officers, promoters or control persons during the past five years.

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

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our officers and directors and persons who beneficially own more than 10% of our common stock to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. These insiders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file, including Forms 3, 4 and 5. Based solely upon our review of copies of such forms we have received, and other information available to us, to the best of our knowledge all required forms under Section 16(a) were filed timely during the most recent fiscal year.

***Code of Ethics***

We have adopted a Code of Ethics that applies to the Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer, Controller and other accounting and financial managers and have attached it to this annual report as Exhibit 14.1. Our Code of Ethics is also available on our website at <http://www.clearant.com>.



**Table of Contents****Audit Committee**

Our Audit Committee consists of Maurice Dewald, Alan S. Blazei, and Kenneth W. Davidson, with Mr. Dewald serving as Chairman. The Audit Committee of our board oversees our corporate accounting and financial reporting process and audits of our financial statements. For this purpose, the Audit Committee performs several functions. The Audit Committee evaluates the performance of and assesses the qualifications of the independent auditors; determines and approves the engagement of the independent auditors; determines whether to retain or terminate the existing independent auditors or to appoint and engage new independent auditors; reviews and approves the retention of the independent auditors to perform any proposed permissible non-audit services; monitors the rotation of partners of the independent auditors on our audit engagement team as required by law; confers with management and the independent auditors regarding the effectiveness of internal controls over financial reporting; establishes procedures, as required under applicable law, for the receipt, retention and treatment of complaints received by our company regarding accounting, internal accounting controls or auditing matters and the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters; reviews and approves all related party transactions; reviews the financial statements to be included in our Annual Report on Form 10-K and quarterly reports on Form 10-Q; and discusses with management and the independent auditors the results of the annual audit and the results of the reviews of our quarterly financial statements. The Audit Committee met five times during the 2008 fiscal year. A current copy of the Audit Committee Charter, which has been adopted and approved by our board of directors, is available on our website at <http://www.clearant.com> (the contents of such website are not incorporated into this annual statement).

Our board of directors has reviewed NASDAQ Stock Market's definition of independence for Audit Committee members and has determined that all members of our Audit Committee are independent under the listing standards of NASDAQ. Our board of directors has determined that Maurice DeWald qualifies as an audit committee financial expert, as defined in applicable Securities Exchange Commission (SEC) rules. Our board of directors made a qualitative assessment of DeWald's level of knowledge and experience based on a number of factors, including his formal education, his experience as a Chairman and Chief Executive Officer of Verity Financial Group, Inc., a private financial advisory firm that he founded in 1992, his previous positions as director and Managing Partner KPMG LLC, a Big Four accounting and tax consulting firm, and his current positions as a director of Integrated Healthcare Holdings, Inc., Advanced Materials Group, Inc., NNN Healthcare/Office REIT, Inc. and Aperture Health. Our board of directors has determined that such simultaneous service does not impair Mr. DeWald's ability to effectively serve on the Audit Committee. Mr. DeWald resigned as a member of our board of directors effective December 31, 2008. Mr. Blazei was appointed as chair of our Audit Committee on January 20, 2009. Our board of directors has determined that Mr. Blazei qualifies as an audit committee financial expert. Our board of directors made a qualitative assessment of Mr. Blazei's level of knowledge and experience based on a number of factors, including his formal education, his previous experience as Executive Vice President and Chief Financial Officer of Maxxim Medical, his previous position as the Vice President of Finance for NTRON, a division of Sunrise Medical, Inc., a manufacturer and distributor of electro-medical equipment, his previous relationship with Madera Associates, a computer distributor and consulting group, and his current position as Chief Financial Officer and a member of the Board of Directors of Entelos, a life science company improving human health through predictive biosimulation. Our board of directors has determined that such simultaneous service does not impair Mr. Blazei's ability to effectively serve on the Audit Committee.

**Compensation Committee**

Our Compensation Committee consists of Michael Elek, Alan S. Blazei, and Kenneth W. Davidson, with Mr. Elek serving as its chair. The compensation committee's principal responsibilities are to administer our stock plans and to set the salary and incentive compensation, including bonuses and stock option grants, for our executive chairman, our president and chief executive officer and our other executive officers. We believe that our compensation committee members meet the requirements for independence under the current requirements of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated by NASDAQ and the SEC. We have made this determination based on information received by our board of directors, including questionnaires provided by the members of our compensation committee. We intend to comply with future requirements established by NASDAQ or the SEC to the

extent they become applicable to us. The Compensation Committee did not meet during the 2008 fiscal year. A current copy of the Compensation Committee Charter, which has been adopted and approved by our board of directors, is available on our website at <http://www.clearant.com> (the contents of such website are not incorporated into this annual statement). The compensation committee's report is included in this proxy statement.



**Table of Contents****Independent Registered Public Accounting Firm**

The firm of SingerLewak LLP has been appointed to serve as our independent registered public accounting firm for the 2009 fiscal year unless the Audit Committee deems it advisable to make a substitution.

**Item 11. Executive Compensation**

The following table sets forth the total compensation received by the named executive officer during the fiscal years ended December 31, 2008 and 2007:

**SUMMARY COMPENSATION TABLE**

Name and principal position	Year	Salary (\$)	Bonus (\$) <sup>1</sup>	Nonqualified Non-Equity Deferred Incentive			All Other Compensation (\$)	Total (\$)
				Stock Option Awards (\$)	Plan Compensation (\$)	Earnings (\$)		
Jon Garfield, Chief Executive Officer and Chief Financial Officer <sup>2</sup>	2008	\$ 240,000	\$ 0	\$ 0	\$ 0	\$ 0	\$ 2,869	\$ 242,869
	2007	\$ 240,000	\$ 0	\$ 0	\$ 0	\$ 0	\$ 2,869	\$ 242,869
Susan Etzel, Chief Accounting Officer <sup>5</sup>	2008	\$ 145,625	\$ 5,000	\$ 0	\$ 0	\$ 0	\$ 102	\$ 150,727
	2007	\$ 129,896	\$ 10,000	\$ 0	\$ 0	\$ 0	\$ 115	\$ 140,011

<sup>1</sup> Bonuses are based on performance.

<sup>2</sup> Mr. Garfield joined us as the Chief Financial Officer in August 2005 and was appointed as Chief Executive Officer in January 2007. Upon appointment as Chief Executive Officer, Mr. Garfield's employment agreement was extended for 3 years. Under the terms of the agreement his salary was to be

increased to \$280,000. This increase has been accrued, but no adjustment to his salary has been made to date.

- 3 Mr. Garfield was granted 0 and 1,228,572 stock options for the years ended December 31, 2008 and 2007, respectively, under the terms of his employment agreement for his role as an officer and director. All options were granted under the 2005 Stock Award Plan. The intrinsic value of the options granted in 2008 and 2007 is \$0.
- 4 Mr. Garfield receives \$360,000 worth of life insurance for which premiums of \$829 is paid annually and a sports club membership for which we pay \$2,040.
- 5 Ms. Etzel joined us as Controller in May 2005 and was appointed as Chief

Accounting  
Officer in  
December 2008.

- 6 Ms. Etzel was granted 0 and 260,258 stock options for the years ended December 31, 2008 and 2007, respectively. All options were granted under the 2005 Stock Award Plan. The intrinsic value of the options granted in 2008 and 2007 is \$0.
- 7 Ms. Etzel receives \$50,000 worth of life insurance for which premiums of \$102 and \$115 were paid for the years ended December 31, 2008 and 2007.

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**Employment Agreements**

We have an employment agreement with Jon Garfield, which has been extended through June 2010. The agreement, as amended upon Mr. Garfield's appointment as Chief Executive Officer, provides that Mr. Garfield will serve as our Chief Executive Officer and Chief Financial Officer. Mr. Garfield's salary for 2008 was \$240,000 and may be increased annually in accordance with our compensation policies. He is also eligible for an annual bonus at our board's sole discretion, which is targeted at a minimum of one-hundred percent (100%) of his base salary. In addition, Mr. Garfield is eligible for stock options in the sole discretion of our board of directors.

Mr. Garfield also receives executive benefits including group medical and dental insurance, \$360,000 of term life insurance, accidental death and long-term disability insurance and a sports club membership.

We may terminate Mr. Garfield's employment for cause and he shall be entitled to his pro-rated salary through the date of termination and all benefits accrued through such date. We shall have no further obligations to pay any compensation or benefits to Mr. Garfield and all of his unvested stock options will terminate. If we terminate Mr. Garfield without cause, he is entitled to a lump sum payment of an amount equal to his base salary through the end of his term and all of his unvested stock options will vest immediately provided that he signs a full general release.

Mr. Garfield's agreement also provides that if he is terminated or his position is materially reduced within 12 months of a change of control, he shall be entitled to a lump sum payment in an amount equal to: (i) one and one-half years of salary (at the rate in effect at the time of his termination); and (ii) one and one-half times his full targeted bonus for that year. In addition, all of his unvested stock options will immediately vest. To be eligible for these payments, Mr. Garfield must sign a full general release.

Rowland W. Day II resigned as Chairman of the Board on December 9, 2008. Mr. Day no longer takes the \$7,500 monthly payment for his services to the Company.

**Material Modification to Stock Options**

On August 3, 2007, after recommendation by our board of directors, the holders of a majority of our common stock approved an amendment to our Certificate of Incorporation to permit us to effect a 1:14 reverse stock split of our common stock. The reverse stock split is effective as of August 23, 2007. This reverse stock split reduced all outstanding stock options by 14.

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

The following table sets forth information concerning unexercised options; stock that has not vested; and equity incentive plan awards for each named executive officer outstanding as of December 31, 2008:

**OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END**

Name	OPTION AWARDS				STOCK AWARDS			
	Number of Securities Underlying Unexercised Options (#) 1	Number of Securities Underlying Unexercised Options (#) 2	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Market Value of Shares or Units That Have Not Vested (#)	Market Value of Shares or Units That Have Not Vested (\$)	Number of Shares or Units That Have Not Vested (#)	Payout Value of Shares or Units That Have Not Vested (\$)
Jon Garfield Chief Executive Officer and Chief Financial Officer	359,527	922,618	14,286 @ \$54.04 1,786 @ \$22.96 1,786 @ \$15.68 35,715 @ \$12.74 28,572 @ \$0.35 1,200,000 @ \$0.45	\$54.04 \$22.96 \$15.68 \$12.74 \$0.35 \$0.45	14,286 @ 8/30/15 1,786 @ 1/27/16 1,786 @ 4/14/16 35,715 @ 5/1/16 28,572 @ 4/4/17 1,200,000 @ 9/12/17			
Susan E. Etzel Chief Accounting Officer	69,009	193,929	1,072 @ \$63.14 1,072 @ \$15.68 536 @ \$12.74 3,115 @ \$0.35	\$63.14 \$15.68 \$12.74 \$0.35	1,072 @ 7/29/15 1,072 @ 4/14/16 536 @ 5/1/16 3,115 @ 4/4/17			

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57,143 @ \$0.56	57,143 @ 8/14/17
200,000 @ \$0.45	200,000 @ 9/12/17

- <sup>1</sup> Represents shares that are vested and/or immediately exercisable. All option shares were granted under the 2005 Stock Award Plan and are post-reverse stock split.
- <sup>2</sup> Represents shares that are unvested and not immediately exercisable.

**Table of Contents****Compensation Of Directors**

Our directors are compensated with stock options from time to time under our 2005 Stock Award Plan. The following table reflects the compensation of directors for our fiscal year ended December 31, 2008:

**DIRECTOR COMPENSATION**

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)	Non-Equity	Non-Qualified	All Other Compensation (\$)	Total (\$)
				Incentive Plan Compensation (\$)	Deferred Compensation Earnings (\$)		
Rowland W. Day II <sup>1</sup>	\$	\$	\$ 07	\$	\$	\$ 75,000	\$ 75,000
Michael Elek <sup>2</sup>	\$	\$	\$ 07	\$	\$	\$	\$ 0
Maurice DeWald <sup>3</sup>	\$	\$	\$ 07	\$	\$	\$	\$ 0
Michael Bartlett <sup>4</sup>	\$	\$	\$	\$	\$	\$	\$ 0
Kenneth W. Davidson <sup>5</sup>	\$	\$	\$	\$	\$	\$	\$ 0
Alan S. Blazei <sup>6</sup>	\$	\$	\$	\$	\$	\$	\$ 0

<sup>1</sup> Mr. Day was appointed as a member of our board of directors effective April 5, 2007. On April 1, 2007, Mr. Day began taking \$7,500 a month for his services to the Company. Payments were made through October 31, 2008. Mr. Day resigned as Chairman of the Board effective December 9, 2008 and resigned as a member of our

board of directors effective December 31, 2008. As of December 31, 2008, Mr. Day has not exercised any of his options and 300,000 have expired. Mr. Day has taken the position that we owe him compensation for his services through December 9, 2008.

2 Mr. Elek has received no compensation for his services.

3 Mr. DeWald resigned as a member of our board of directors effective December 31, 2008. As of December 31, 2008, Mr. DeWald has not exercised any of his options and 300,000 have expired. Mr. DeWald has received no compensation for his services.

4 Appointed as a member of our board of



directors  
effective July 9,  
2008.

5 Appointed as a  
member of our  
board of  
directors  
effective  
September 11,  
2008.

6 Appointed as a  
member of our  
board of  
directors  
effective  
September 11,  
2008.

7 On  
September 13,  
2007, Mr. Day,  
Mr. Elek and  
Mr. DeWald  
were each  
granted 400,000  
stock options.  
These options  
vest 25%  
annually over  
four years. As  
of December 31,  
2008 100,000 of  
these stock  
options are  
vested. The  
intrinsic value  
of the options  
granted is \$0.

**Table of Contents****Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters. Equity Compensation Plans**

The following table provides information about our common stock that may be issued upon the exercise of equity instruments under all of our existing equity compensation plans as of December 31, 2008:

**EQUITY COMPENSATION PLAN INFORMATION**

<b>Plan Category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights <sup>1</sup></b>	<b>Weighted-average exercise price of outstanding options, warrants and rights</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) <sup>2</sup></b>
	<b>(a)</b>	<b>(b)</b>	<b>(c)</b>
<b>Equity compensation plans approved by security holders</b>	4,870,907	\$ 1.28	7,673,723
<b>Equity compensation plans not approved by security holders</b>		\$ 0.00	
<b>Total</b>	4,870,907	\$ 1.28	7,673,723

<sup>1</sup> On August 3, 2007, at our annual meeting, the stockholders approved a 6,000,000 share increase in our 2005 Stock Award Plan. As of December 31, 2008, there were 2,113,052 shares of our common stock reserved for issuance upon

the exercise of warrants and 2,757,855 shares of common stock reserved for issuance upon the exercise of options.

<sup>2</sup> These options were issued under the 2000 and 2005 Stock Award Plans.

<sup>3</sup> Of this amount, no shares were available for issuance under the 2000 Stock Award Plan and 7,673,723 shares were available for issuance under the 2005 Stock Award Plan.

***Security Ownership of Certain Beneficial Owners and Management***

The following table sets forth the securities ownership of our directors, named executive officers, and any person or group who is known to us to be the beneficial owner of more than five percent of our voting stock as of March 17, 2009:

<b>Title of Class</b>	<b>Name and Address of Beneficial Owner <sup>1</sup></b>	<b>Amount and Nature of Beneficial Owner <sup>1</sup></b>	<b>Percent of class</b>
Common stock	Michael Elek <sup>2</sup>	5,714,288	11.7%
Common stock	Terren S. Peizer <sup>3</sup>	4,695,391	9.6%
Common stock	John McGinnis <sup>4</sup>	3,622,451	7.4%
Common stock	Rowland W. Day II <sup>5</sup>	3,137,003	6.4%
Common stock	Jay and Mel Seid, JTWROS <sup>6</sup>	2,869,591	5.9%
Common stock	Jon M. Garfield <sup>7</sup>	1,083,932	2.2%
Common stock	Maurice J. DeWald	0	0%

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Preferred stock	Michael Bartlett <sup>8</sup>	45,454,545	100%
Common stock	Kenneth W. Davidson	0	0%
Common stock	Alan S. Blazei	0	0%
Common stock	Susan Etzel <sup>9</sup>	69,411	0%
Common stock	All directors and executive officers as a group (4 persons)	55,459,179	58.7%

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<sup>1</sup> Applicable percentage ownership is based on 94,411,990 shares of total voting stock outstanding at March 17, 2009. The number of shares of voting stock owned are those beneficially owned as determined under the rules of the SEC, including any shares of voting stock as to which a person has sole or shared voting or investment power and any shares of voting stock which the person has the right to acquire within sixty days through the exercise of any option, warrant or right. All addresses are c/o 1801 Avenue of the Stars, Suite 435, Los Angeles, California 90067, unless otherwise noted.

<sup>2</sup> Includes 1,428,572 shares of common stock

held in the name  
Summerlight  
Trading Corp.,  
1,428,572  
shares of  
common stock  
held in the name  
Norpot Corp.,  
1,428,572  
shares of  
common stock  
held in the name  
Snowball  
Overseas SA  
and 1,428,572  
shares of  
common stock  
held in the name  
Cherwell Assets  
Corp. Excludes  
2,571,430  
shares  
beneficially  
owned by  
family members  
of Michael Elek.  
Mr. Elek  
disclaims any  
controlling or  
beneficial  
interest in such  
shares.

- <sup>3</sup> Excludes 17,858  
shares of  
common stock  
held of record  
by Reserva  
Capital, LLC,  
which has been  
previously  
pledged as  
security for a  
loan as to which  
interest  
payments have  
not been made.  
Includes  
277,634 shares  
held by  
Bowmore, LLC,

14,613 shares held by Porfidio, LLC and 4,285,715 shares held by Advanced Technology Holdings, LLC, all of which Terren S. Peizer is the sole managing member and options held by Mr. Peizer to purchase 21,286 shares of common stock at \$9.24 per share and 16,143 shares at \$31.50 per share which expire July 22, 2012 and December 1, 2011, respectively. Assumes the exercise of all options held by Mr. Peizer. Mr. Peizer's business address is 11150 Santa Monica Blvd., Suite 1500, Los Angeles, California 90025.

- 4 Includes 1,785,715 shares issued to West Valley Financial Management. Excludes 1,428,572 shares beneficially

owned by RMR  
Assets  
Management  
Co.  
Mr. McGinnis  
disclaims any  
controlling or  
beneficial  
interest in such  
shares.

5 Includes  
3,137,003  
shares of  
common stock  
issued to  
Rowland W.  
Day II, as  
trustee of the  
Day Family  
Trust (2,865,458  
shares) and the  
Rowland W.  
Day II Rollover  
IRA (271,545  
shares), with  
Rowland W.  
Day in his  
individual  
capacity as the  
beneficial owner  
of all 3,137,003  
shares.  
Mr. Day's  
business address  
is 1 Hampshire  
Court, Newport  
Beach, CA  
92660.

6 Includes 12,448  
shares of  
common stock  
held of record  
by Melvin Seid.

7 Includes  
714,286 shares  
of common  
stock, and  
outstanding



options issued,  
vested and  
exercisable  
within sixty  
days of  
March 17, 2009  
to purchase an  
aggregate  
369,646 shares  
of common  
stock.

- 8 Includes 1 share  
of Series A  
Preferred Stock  
held of record  
by CPI  
Investments,  
Inc. of which  
Mr. Bartlett is  
the president. 1  
share of  
Series A  
Preferred Stock  
votes together  
with our  
common stock  
and has votes  
equal to  
45,454,545  
shares of  
common stock.

- 9 Includes 69,411  
options issued,  
vested and  
exercisable  
within sixty  
days of  
March 17, 2009  
to purchase to  
purchase shares  
of common  
stock.

Unless otherwise indicated, we believe that all persons named in the table have sole voting and investment power with respect to all Shares beneficially owned by them. A person is deemed to be the beneficial owner of securities which may be acquired by such person within sixty days from the date on which beneficial ownership is to be determined, upon the exercise of options, warrants or convertible securities. Each beneficial owner's percentage ownership is determined by assuming that options, warrants and convertible securities that are held by such person (but not those held by any other person) and which are exercisable, convertible or exchangeable within such sixty day period, have been so exercised, converted or exchanged.



**Table of Contents****Item 13. *Certain Relationships and Related Transactions and Director Independence***  
**Transactions with Related Persons**

A Current member of our board of directors, Michael Bartlett, also serves as a member of the board of directors and president of CPI. As discussed above, we entered into a Subscription and Purchase Agreement with CPI dated July 8, 2008, as amended February 20, 2009, whereby CPI agreed to loan us an aggregate of \$2 million. CPI is currently in default of its obligation to fund \$28,000 in the third tranche. CPI is the owner of one share of our Series A Preferred Stock, which votes together with our common stock and has votes equal to 45,454,545 shares of our common stock. In addition, we have a consulting agreement with Cameron and Associates Corporate Finance, Inc. ( CA ), whereby CA is paid \$10,000 per month. Michael Bartlett's wholly owned company Leisure Capital and Management, Inc. receives 50% of the consulting fees paid by Clearant to CA. Both principals of Leisure Capital Management, Inc. and CA are also principals in CPI. CA has been paid \$51,301 through December 31, 2008.

**Director Independence**

After review of all of the relevant transactions or relationships between each director (and his family members) and us, our senior management, our board of directors has determined that Maurice Dewald, Kenneth W. Davidson, Alan S. Blazei, and Michael Elek are defined as independent by The NASDAQ Stock Market rules and the SEC rules. There are no family relationships among any of our directors, executive officers or key employees. On March 4, 2008, Mr. Elek purchased the beneficial interest of four companies who collectively own 11.7% of our common stock. Consequently, Mr. Elek was no longer an independent director pursuant to the SEC rules as of March 4, 2008 and did not continue as a member of our Audit Committee as of November 2008. Mr. DeWald resigned as a member of our board of directors effective December 31, 2008.

**Item 14. *Principal Accounting Fees and Services******Audit Fees***

The following table sets forth the aggregate fees billed to us for the fiscal years ended December 31, 2008 and 2007 by SingerLewak LLP:

	<b>Fiscal Year 2008</b>	<b>Fiscal Year 2007</b>
Audit Fees	\$ 115,175	\$ 146,118
Audit-Related Fees	\$	\$
Tax Fees	\$	\$
All Other Fees	\$	\$

Audit-related fees billed during fiscal years 2008 and 2007 were primarily for services provided in connection with the filing of the registrations statements and consulting related to stock-based compensation. All of the foregoing fees were approved by the Audit Committee in accordance with Rule 2-01(c)(7)(i)(C) of Regulation S-X. During fiscal 2008, no portion of the Audit-Related Fees or All Other Fees was approved by the Audit Committee after services had been rendered pursuant to the de minimis exception established by the SEC.

Representatives of SingerLewak LLP usually attend most meetings of the Audit Committee. The Audit Committee's policy is to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services. The independent registered public accounting firm and management are required to periodically report to the Audit Committee regarding the extent of services provided by the independent registered public accounting firm in accordance with this pre-approval policy.

***Tax Fees***

We paid \$17,043 and \$16,187 for professional services with respect to tax compliance, tax advice or tax planning to Good Swartz Brown & Berns, a division of J.H. Cohn LLP, for the fiscal year ended December 31, 2008 and 2007, respectively.



**Table of Contents*****All Other Fees***

Total fees billed for professional services rendered by our auditors for consultation related to research of various accounting issues addressed in SEC comments and assistance in preparation of responses to the SEC during the years ended December 31, 2008 and 2007 were \$0 and \$0, respectively.

***Pre-Approval Policy for Audit Services***

Our Audit Committee has responsibility for the approval of all audit and non-audit services before we engage an independent registered public accounting firm. All of the services rendered to us by SingerLewak LLP are pre-approved by the Audit Committee before the engagement of the independent registered public accounting firm for such services. Our pre-approval policy expressly provides for the annual pre-approval of all audits, audit-related and all non-audit services proposed to be rendered by the independent registered public accounting firm for the fiscal year, as specifically described in the independent registered public accounting firm engagement letter, such annual pre-approval to be performed by the Audit Committee.

***Item 15. Exhibits, Financial Statement Schedules***

<b>No.</b>	<b>Description</b>
2.1	Merger Agreement and Plan of Reorganization, dated March 31, 2005, by and among Clearant, Inc., Bliss Essentials Corp., and Thomas Gelfand, Howard Gelfand and Kathleen Rufh, Incorporated by reference to Exhibit 10.1 on our Current Report on Form 8-K, filed with the SEC on April 4, 2005.
2.2	Asset Purchase Agreement, dated March 31, 2005, by and among Clearant, Inc., Bliss Essentials Corp., and Thomas Gelfand, Howard Gelfand and Kathleen Rufh, Incorporated by reference to Exhibit 10.2 on our Current Report on Form 8-K, filed with the SEC on April 4, 2005.
2.3	Merger Agreement and Plan of Merger, dated June 30, 2005, by and between Clearant, Inc. and CI Merger Corporation, Incorporated by reference to our Proxy Statement on Form DEF14A for our annual meeting of stockholders held on June 30, 2005, filed with the SEC on April 4, 2005.
3.1	Amended and Restated Certificate of Incorporation Clearant, Inc., a Delaware corporation, Incorporated by reference to Exhibit 3.1 on our Current Report on Form 10-KSB filed with the SEC on April 1, 2008.
3.2	Bylaws of Clearant, Inc., a Delaware corporation, Incorporated by reference to our Proxy Statement on Form DEF14A for our annual meeting of stockholders held on June 30, 2005, filed with the SEC on April 4, 2005.
4.1	Specimen Common Stock Certificate, Incorporated by reference to Exhibit 4.2 on our Registration Statement on Form S-3, filed with the SEC on November 23, 2005.
10.1*	2005 Stock Award Plan, Incorporated by reference to Appendix F to our Proxy Statement on Form DEF14A for our annual meeting of stockholders held on June 30, 2005, filed with the SEC on April 4, 2005.
10.2	Amended and Restated Employment Agreement between Clearant, Inc. and Jon M. Garfield dated as of June 7, 2006, effective as of August 1, 2005, Incorporated by reference to Exhibit 10.2 on our Current Report on Form 10-KSB filed with the SEC on April 1, 2008.
10.3	Purchase Agreement, dated April 3, 2007 and August 3, 2007, Incorporated by reference to our Current Report on Form 8-K, filed with the SEC on April 4, 2008.
10.4	Amendment No.1 to Subscription and Purchase Agreement, dated February 20, 2009, Incorporated by reference to Exhibit 10.1 on our Current Report on Form 8-K filed with the SEC on February 25, 2009.



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<b>No.</b>	<b>Description</b>
10.5	Registration Rights Agreement, dated April 3, 2007 and August 3, 2007, Incorporated by reference to Exhibit 10.2 on our Current Report on Form 8-K, filed with the SEC on April 4, 2007.
10.6	Subscription and Purchase Agreement, dated July 8, 2008 by and between Clearant, Inc. and CPI Investments, Inc, Incorporated by reference to Exhibit 1.1 on our Current Report on Form 8-K, filed with the SEC on July 11, 2008.
10.7	Conversion Agreement, dated August 3, 2007 by and between Clearant, Inc. and John McGiannis, Incorporated by reference to Exhibit 10.1 on our Current Report on Form 8-K, filed with the SEC on August 6, 2007.
10.8	Strategic Services Agreement, dated August 1, 2008 by and between Clearant, Inc. and Cameron & Associates Corporate Finance, Inc., Incorporated by reference to Exhibit 10.1 on our Current Report on Form 10-Q filed on November 14, 2008.
14.1	Codes of Ethics, Incorporated by reference to our Proxy Statement on Form DEF14A for our annual meeting of stockholders held on June 30, 2005, filed with the SEC on April 4, 2005.
23.1	Consent of Independent Registered Accountants.
31.1	Rule 13a-14(a) Certification of Chief Executive Officer and Chief Financial Officer.
32.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* The referenced exhibit is a compensatory contract, plan or arrangement.

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**SIGNATURES**

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this Form 10-K to be signed on its behalf by its duly authorized representatives.

**CLEARANT, INC.**

By: /s/ Jon Garfield  
 Jon Garfield,  
 Chief Executive Officer and Chief Financial  
 Officer

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title(s)	Date
/s/ Jon Garfield Jon Garfield	Chief Executive Officer, Chief Financial Officer and Director	March 24, 2009
/s/ Michael Elek Michael Elek	Director	March 24, 2009
/s/ Michael Bartlett Michael Bartlett	Chairman of the Board and Director	March 24, 2009
/s/ Kenneth W. Davidson Kenneth W. Davidson	Director	March 24, 2009
/s/ Alan S. Blazei Alan S. Blazei	Director	March 24, 2009
/s/ Susan E. Etzel Susan E. Etzel	Chief Accounting Officer and Controller	March 24, 2009



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