#### Edgar Filing: - Form

#### Form

Unknown document format

="font-size: 10pt; color: #000000; background: transparent"> 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> 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*<sup>®</sup> 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*<sup>®</sup> can be a cost-effective technology applicable across multiple market segments, with minimal capital requirements to implement.

The *Clearant Process*® does not require the use of toxic chemicals. The advantage of gamma irradiation over currently available sterilization technologies is that it is inherently reliable, predictable, non-toxic, penetrating, and scalable for a wide variety of products. Traditional uses of gamma irradiation have been proven to be among the best methods for inactivating pathogens that contaminate medical devices. However, prior to the development of the *Clearant Process*®, it was not possible to apply gamma radiation on biological products because the high levels of gamma irradiation necessary to meet or exceed regulatory safety requirements, also damaged the active proteins present in the biological products, compromising its integrity and functionality.

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. 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.

#### Agreements

To date, we have entered into a total of ten agreements with customers to utilize the *Clearant Process*<sup>®</sup> with their products. Through December 2006, we have entered into six licensing agreements with tissue banks, and one with a manufacturer of recombinant protein products, in return for milestone payments and royalties on end-product sales. Through December 2006, four licensees have launched tissue products that were treated using 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. Through 2006, we have signed four such Sterilization Service agreements with tissue banks. Many of the following companies have not implemented the *Clearant Process*<sup>®</sup>, and we cannot estimate when or if they will do so.

Number	Name/Description	Type of Contract Application	Clearant Process® Applied
1	Community Blood Center	Sterilization Service	Tissue
	(d/b/a Community Tissue Services)		
2	DCI Donor Services, Inc.	License	Tissue
3	DCI Donor Services, Inc.	Sterilization Service	Tissue
4	LifeTek LLC	License	Tissue
5	Osprey Biomedical	Sterilization Service	Tissue
6	Recombinant manufacturer	License	Recombinant products
7	The Blood & Tissue Center of Central	License	Tissue
	Texas		
8	Tissue Banks International	License	Tissue
9	Tissue Transplant Technologies	Sterilization Service	Tissue
	(formerly known as Bone Bank Allograft)		
10	Tissuelab SpA	License	Tissue

On January 3, 2007, Clearant received a notice of termination, effective January 31, 2007, from Cryolife, Inc. to terminate its license agreement for the *Clearant Process®*, originally entered into on December 12, 2003. CryoLife cited the reason for the termination to be its discontinuation of certain orthopedic activities. CryoLife has paid Clearant the \$100,000 termination fee and any outstanding license royalties.

On November 28, 2006, Clearant entered into a two-year supply agreement with a tissue bank for the supply of *Clearant Process*® sports medicine implants. Clearant has agreed to pay a transfer fee for the sports medicine implants. The Agreement shall automatically renew for successive one-year terms unless either party terminates upon written notice to the other party.

5

On September 27, 2006, Clearant entered into a renewable two-year supply and distribution agreement (the Osprey Agreement ) with Osprey Biomedical Corp. (Osprey). Under the Osprey Agreement Osprey granted Clearant exclusive rights to place current and future Osprey cervical and lumbar allografts treated with the Clearant Process® in a number of geographic territories and an option for additional geographic territories. In exchange for the exclusive rights under the Osprey Agreement, Clearant is obligated to pay Osprey \$500,000 as a prepayment for certain ordered products to be delivered after October 1, 2007. This prepayment was due upon the earlier of the following: (i) within three business days after Clearant receives debt or equity financing of at least \$1 million, or (ii) October 31, 2006. In addition, Clearant was 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 the end of the fiscal year, all tissue orders had not been delivered by Osprey and the prepayments due at or prior to April 1, 2007 had not been made by the Company. In February 2007, Clearant received notice from Osprey of its termination of the Osprey Agreement, effective within thirty (30) days from receipt of this notification if certain alleged payment defaults were not timely cured by Clearant. Clearant is 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 would result in the disruption of the spinal bone implant supply from Osprey, which would have a material adverse impact on Clearant s ability to distribute spinal bone implants treated with the Clearant Process®.

# Market Opportunity

We believe that we are positioned 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 Food and Drug Administration (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 the possible illegal harvesting of cadavers provided to several tissue banks for processing, the FDA ordered a recall of tissue. Prior to such recall, many of the tissues had been implanted by unsuspecting surgeons raising concerns of bacterial and viral transmissions due to the possible falsification of donor medical records. Affected tissue had been distributed 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 sources of tissue. Due to the adverse patient consequences that can result from communicable disease transmission through the use of tissue, U.S. regulatory authorities have called for the development of validated methods for claims of sterilizing tissue. 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) 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.

The *Clearant Process*® reduces the risk of infectious disease transmission through the use of tissues while at the same time maintaining the tissues functionality and integrity. In addition, 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.

6

Clearant currently distributes *Clearant Process*® tissue to surgeons, hospitals and surgery centers through a direct and indirect sales force. In addition, Clearant provides sterilization service to tissue processors as an alternative to complete implementation of the *Clearant Process*®. Clearant also licenses 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. Clearant earns royalties on these sales, which 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 the Company.

#### The Clearant Solution

The *Clearant Process*<sup>®</sup> uses a combination of patented and trade secret technology, based on a proprietary application of gamma irradiation, to sterilize biologics and inactivate a broad range of known types of pathogens (including enveloped and non-enveloped viruses). The process does not require the use of toxic chemicals and is designed to maintain the integrity and functionality of the biologic. 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, and that, for tissue, the *Clearant Process*<sup>®</sup> is able to validate sterility claims under the GTP regulations. The *Clearant Process*<sup>®</sup> inactivates a broad range of known types of pathogens in a single irradiation step.

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®*, 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.

The *Clearant Process*<sup>®</sup> is designed to provide increased safety to biologics 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). Our research and development expenses for the years ended December 31, 2006 and 2005 were \$926,000 and \$2,050,000, respectively. During the fourth quarter of 2005 and first quarter of 2006, we reduced our research and development personnel and related expenses due to the limitations in our cash position and our shift in focus from research and development to the commercialization of the *Clearant Process*<sup>®</sup>. From December 31, 2005 to December 31, 2006, we reduced our research and development staff from six exployees to one. We anticipate that we will continue to reduce research and development costs. In addition, we are exploring opportunities to complement 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.

# <u>Devitalized Musculoskeletal Tissue Allograft Implants: The Devitalized Musculoskeletal Tissue Allograft Implant</u> Market

We believe that we are positioned to take advantage of the changes facing the devitalized musculoskeletal tissue allograft implant (tissue) market. A number of serious and even deadly diseases have been shown to be transmitted through tissue. Due to the adverse patient consequences that can result from communicable disease transmission through the use of tissues, U.S. regulatory authorities have called for the development of validated methods for claims of sterilizing tissue that also maintain the integrity and functionality of the tissue.

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. The CDC determined that the donor was in the window period (a period shortly after

# Edgar Filing: - Form

infection during which the virus or antibody is not detectible by standard tests), which resulted in the Hepatitis C not being detected during standard donor screening. There have only been two cases of

7

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 74 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 its issuance of the GTP regulations which became effective on May 25, 2005. The Clearant Process® significantly reduces the risk of disease transmission through the use of tissues, while maintaining the tissues integrity and functionality. In addition, we believe the *Clearant Process®* can support a validated sterility claim by tissue processors under the GTP regulations. In addition, we believe that as validated sterile allografts become widely available, tissue, both in number and type, may shift from autografts towards allografts, given the clinical benefits of allografts. Allografts use only one surgical site, and thus reduce recovery time and decrease post-operative problems as compared to autografts. To date doctors have reported to the company no significant difference between patients receiving Clearant Process®-treated tissues as compared to those receiving traditional tissues. Furthermore, Clearant 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 start of the study. The twelve-month outcome results of this study are favorable. 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, Clearant has 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 more unfavorable 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.

Clearant intends to distribute *Clearant Process*<sup>®</sup> tissue to surgeons, hospitals and surgery centers through a direct and indirect sales force. Clearant 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 the Company. Clearant may also consider other types of licensing or processor representative arrangements as it deems appropriate. The U.S. tissue market made up of ligament, tendon and bone allografts is estimated to grow to over \$1.26 billion by 2008. Clearant anticipates that the number of tissue implants may increase as the market perceives these tissues to be safer due to the implementation of the GTP regulations and the availability of an effective sterilization technology like the *Clearant Process*<sup>®</sup>. Beyond the initial allograph tissue market, the Company believes there are opportunities to apply its technology to the broader devitalized human tissue implant market.

## Competition

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; methods that can achieve sterility and 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 harvested from cadavers. Because of this inability to penetrate the tissue effectively to destroy pathogens potentially residing in the interior of tissue, sterility can not 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 used for surgical

8

implantation. Results of studies conducted by Clearant 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 can not 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. There may be other entrants into the market that make claims of sterility which could adversely impact our ability to gain market acceptance.

#### The Clearant Solution for 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 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 Clearant and then Clearant coordinates the irradiation of the tissue at a 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 Clearant 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 through the *Clearant Process®* are not sterilized 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 generated by Clearant 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.

In order to maximize recognition of the increased value of the safety improvements provided by the *Clearant Process®*, Clearant supports its customers—efforts by marketing directly to surgeons, scientists and medical professionals, or through leaders in the industry, and supporting customer 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®*.

We believe that it 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, which became effective in May 2005.

#### Commercialization Strategy

Clearant is currently focusing its development and commercialization efforts relating to *Clearant Process®* 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®* in these markets will generate a two-fold benefit for Clearant: an opportunity to generate near-term cash flow from direct distribution of *Clearant Processed®* tissue, royalties from

# Edgar Filing: - Form

*Clearant Process*®-treated tissue product sales and service fees from the Clearant Sterilization Service agreements, while simultaneously allowing Clearant to validate the *Clearant Process*® more broadly and build an extensive intellectual property portfolio.

9

Clearant has achieved the following milestones in the devitalized human tissue industry:

Two direct sales representatives and two indirect sales groups which have approximately 14-20 sales representatives;

Ten signed agreements with tissue banks, seven of which are active; and

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*® are comparable to the patient s non-operated contralateral knees.

# Other Potential Commercialization Markets: The Plasma Protein Therapeutics Market

The plasma industry develops and manufactures plasma protein therapeutic products which are mainly derived by fractioning 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 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 together in a final package. To date, we have been successful in applying the *Clearant Process®* on a laboratory scale at day zero. Our strategy is to leverage the developed technology and the intellectual property created with these products to develop the *Clearant Process®* as a terminal sterilization technology for recombinant protein products. We are not actively pursuing this market however, we will continue to evaluate opportunities as capital resources and customer demands warrant.

#### 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, Wyteh, 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 its technology to improve and provide solutions for problematic in-process sterilization protocols used in certain recombinant products. We are currently working with a licensee on applying the *Clearant Process*® to products that, due to their method of manufacture, are considered to be at higher risk of pathogen transmission.

Our strategy is 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®* 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.

Although we are not actively pursuing this market at this time, we will continue to evaluate opportunities as capital resources and customer demands warrant.

### 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.

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.

11

#### Other Potential Commercialization Markets: The Clearant Solution for Protein Therapeutic Products

The *Clearant Process®* 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®* 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 and 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 a 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.

Although we are not actively pursuing this market at this time, 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®* 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®* 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 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.

Although we are not actively pursuing this market at this time, we will continue to evaluate opportunities as capital resources and customer demands warrant.

### Regulatory Strategy

Commercial products manufactured incorporating the *Clearant Process®* will be regulated by governmental agencies, including the FDA in the United States 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 Clearant as part of our commercialization strategy to demonstrate the efficacy of the *Clearant Process®*.

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 of its customers, 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. Clearant 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*<sup>®</sup>. 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. Clearant has a total of 94 issued or pending patents. We currently have eleven issued U.S. patents, which will expire between 2013 and 2023, and twenty-six foreign patents protecting our technology. From 2000 through 2007, we expanded our intellectual property portfolio and currently have approximately fourteen pending U.S. patent applications and forty-three other pending foreign patent applications. 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.

13

In 2001, we licensed, with the right to sub-license, certain patents which relate to a narrow aspect of the use of gamma irradiation on biologics to bolster our intellectual property position. In July 2001, we entered into an agreement granting us full ownership of intellectual property, trade secrets and data underlying a portion of the *Clearant Process®* in exchange for future payments and a royalty of 6% on revenue received from licensing the technology, subject to an annual maximum.

## Financial Information about Segments

We currently have three business segments, direct distribution, fee for service and licensing of the *Clearant Process®*, which generated 30%, 12% and 42%, respectively of our revenues for the year ended December 31, 2006. The remaining revenue is derived from milestone payments from outstanding contracts and the finalization of our grant revenue projects.

# **Employees**

As of December 31, 2006, we had approximately 25 full-time employees. Since that time we have reduced our full-time staff to 8 employees.

#### **Executive Officers**

There are no family relationships among any of our directors, executive officers or key employees. Jon Garfield is our only executive officer since Alain Delongchamp, the Company s former Chief Executive Officer, resigned effective January 25, 2007.

### Code of Ethics

We have adopted a Code of Ethics that applies to the Chief Executive Officer, Chief Financial Officer, Controller, and other accounting and financial managers.

#### Reports to Security Holders

We will 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 us at: Investor Relations, Clearant, Inc, 11111 Santa Monica Blvd., Suite 650, Los Angeles, California 90025.

We file reports with the Securities and Exchange Commission (SEC) in accordance with the Securities Exchange Act of 1934, as amended, including annual reports on Form 10-KSB, quarterly reports on Form 10-QSB, 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, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We are an electronic filer, and the SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, which can be found at <a href="http://www.sec.gov">http://www.sec.gov</a>. Additionally, all reports filed with the SEC are 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. The information contained on our website is not part of this report or incorporated by reference herein.

14

#### **Risk Factors**

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

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

Clearant Licensing, Inc., our wholly owned operating subsidiary, was incorporated in April 1999 in order to acquire certain assets of Puresource and Sterways, including patents that comprise a portion of the *Clearant Process®*. We are 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 the Company 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®. Our current cash burn rate is approximately \$0.2-\$0.4 million per month. 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 at approximately the end of 2007 or before if the Company isn t 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 licensing of the *Clearant Process®* and Sterilization Services to generate significant 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 2007 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*® in the tissue market and the successful licensing of such technology or providing sterilization services to third party tissue processors. No assurances can be made that we will be successful in doing this. In addition, if Clearant begins to be a processor representative for certain tissue of its 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 and successfully licensing the *Clearant Process*® 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®* 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

# Edgar Filing: - Form

period between, our expenditures on the development and marketing of our processes and the receipt of revenues.

15

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;

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. Clearant is currently conducting a multi-center clinical study at eight separate facilities across the U.S. The clinical study tracts 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. 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, Clearant has 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. Clearant is 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.

#### **Material Cash Flow Constraints.**

Clearant experienced material cash flow constraints. During this period, and continuing to this date, the Company is past due on many vendors, suppliers, distributors, sales representatives, and other service providers. Clearant is in discussion with many of these accounts and is actively trying to resolve these past due amounts. No assurances can be made that Clearant 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 Clearant on similar terms or at all. If this happens, it could materially impact operations and revenue.

#### **Independent Sales Representatives and distributors.**

The Company utilizes a strategy to contract with independent distributors and sales representatives. These sales teams are not Clearant employees and are independent contractors, and in some cases selling many other product lines. Clearant cannot give any assurances that these sales teams will continue to market Clearant product or how much time and effort they will devote to Clearant versus other product lines. Further, Clearant expects 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. In addition, due to cash constraints experienced by Clearant in the fourth quarter of 2006 and in the first quarter of 2007, Clearant was slow in paying commissions to some of these sales teams. No assurances can be made that Clearant will be successful in reestablishing these relationships to their prior status or that they will market Clearant at there historical levels or trends.

16

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 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 its willingness of potential users of the *Clearant Process®* to adopt the *Clearant Process®* and on the 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 which became 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.

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. Our Chief Executive Officer, Alain Delongchamp, resigned effective January 25, 2007, however this had no effect on our operations or development.

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.

17

# We need to develop our financial and reporting processes, procedures and controls to support our anticipated growth.

We currently have only a limited number of financial operations personnel and have not historically invested significantly in our financial and reporting systems. To comply with our public reporting requirements, and manage the anticipated growth of our operations and personnel, we will be required to improve existing, or implement new, operational and financial systems, processes and procedures, and to expand, train and manage our employee base. Our current and planned systems, procedures and controls may not be adequate to support our future operations. The laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the Securities and Exchange Commission and the NASD 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. 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, or if compliance can be achieved.

# The *Clearant Process®* has been commercialized only in the tissue market and our future success depends on its 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. 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 Clearant, 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 operation 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 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 our 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 in Chicago 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.

To date, we have only completed development of these transfer procedures and specifications for certain applications of the tissue processors for licenses, and not for customers under a sterilization service agreement. We may not be able to develop appropriate procedures, packaging and specifications for other 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 its 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 its 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. If third parties become aware of parts of our technology that are covered by pending patent applications, we

# Edgar Filing: - Form

will be unable to prevent those parties from using such information until the patents issue. This could delay commercialization of the *Clearant Process*<sup>®</sup>.

19

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 its processes. 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, 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*<sup>®</sup> in a cost-effective manner that does not (i) infringe on such intellectual property and (ii) materially impact the viability of the *Clearant Process*<sup>®</sup>, 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. To determine 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*<sup>®</sup>. We may be liable if it is determined that any of its 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 or 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*<sup>®</sup> 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.

20

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.

We face environmental and other liabilities related to certain hazardous materials used in our operations.

Our research and development involves the controlled use and transport of hazardous materials, including hazardous chemicals and pathogens. Accordingly, we are subject to federal, state and local laws governing the use, handling and disposal of these materials. We may incur significant costs to comply with additional environmental and health and safety regulations in the future. Although we believe that our safety procedures for handling and disposing of hazardous materials comply with regulatory requirements, we cannot eliminate the risk of accidental contamination or injury. If an accident occurs, we could be held liable for any damages that result and could suffer negative publicity.

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®* effectively will depend on the safety, efficacy and cost-effectiveness of the *Clearant Process®*, 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®* and, if applicable, that such benefits outweigh any potential additional cost. As part of its strategy to obtain wide-spread acceptance of the *Clearant Process®*, we have entered into, and intend to continue to seek to enter into, sponsored research agreements with potential users of the *Clearant Process®* to support research on and validation of potential applications of the *Clearant Process®* to such products. While we expect that the *Clearant Process®*, 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®* 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®* may be adversely affected both for that product and for other applications of the *Clearant Process®*.

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®* 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®* to be accepted in the marketplace or to capture market share.

21

We expect the Clearant Process® to encounter significant competition. The Clearant Process® 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® 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*® 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® 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®. 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 its 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 BioCleanseTM 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®, it could materially impact our ability to market and earn revenue from the Clearant Process®. 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, high pressure, supercritical fluids), new chemical agents including photosensitizers (e.g., InactineTM, 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 Clearant. Significant

# Edgar Filing: - Form

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.

22

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 U.S. facilities are owned and operated by two commercial gamma irradiation service providers. If customers, or us in the provision of the sterilization services, are not able to negotiate or maintain favorable terms with such service providers to treat their 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.

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*®, 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®* is used in their manufacture. Future revenues from the use of the *Clearant Process®* 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®* 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®*. 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

# Edgar Filing: - Form

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.

23

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® 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®, and tissue processors and distributors must still meet the other regulatory requirements discussed below. The products enabled by or utilizing the Clearant Process® 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*® 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®. Problems with a product, manufacturer or facility which utilizes the Clearant Process® may harm other manufacturers and the public s perception of the safety of the Clearant Process® generally, which would result in decreased utilization of the Clearant Process® and a decrease or elimination of our revenues, which would adversely affect our business, financial condition and results of operations.

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*<sup>®</sup>.

# 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 it undertakes as part of its 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*® in their manufacturing processes.

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

Our business model is based significantly on receiving royalties or service payments from users of the *Clearant Process*® in our target markets. The success of that model depends on our ability to successfully optimize and commercialize the *Clearant Process*® for use in our target markets and to successfully license the *Clearant Process*® 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*® 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*®-treated products, even if unrelated to the efficacy of the *Clearant Process*®, 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®*. 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®* 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®*, could limit widespread market acceptance of those products, and thus reduce the ability of users of the *Clearant Process®* 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

# Edgar Filing: - Form

the tissue market, or any other targeted market which experiences a similar safety crises, 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.

25

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®* 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.

Potential users of the *Clearant Process®* may depend on third party payers for reimbursement for the use of their products by the end consumer, which 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, CryoLife, Inc. and Northern California Tissue Center have the substantial majority of the tissue market.

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  $Clearant\ Process^{\circledR}$ .

Government agencies promulgate regulations and guidelines directly applicable to us and to products made with the *Clearant Process*<sup>®</sup>. 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*<sup>®</sup> which could adversely affect prevailing market prices for our common stock.

26

# 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;

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 audit opinion could adversely affect our stock price.

Our auditors opinions on our financial statements for the year ended December 31, 2006 contained an explanatory paragraph that expresses doubt about our ability to continue as a going concern due to recurring negative cash flows from operations, significant debt and limited working capital.

# 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. Clearant has and continues to evaluate listing on another market or exchange but there can be no assurance of its ability to move its 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. In April 2007, Clearant issued approximately 93,720,000 shares of our common stock to approximately twenty accredited and institutional investors representing approximately 70% of our 134,642,196 shares of common stock outstanding as of May 9, 2007 at the purchase price of \$.025 per share. Pursuant to the registration rights agreements with the investors the Company is using its best efforts to register the stock. These shares are subject to Rule 144 with no contractual lock-up. The SEC has recently given updated information on Rule 415 and the Company cannot predict when the SEC will permit Clearant to go forward with the registration, nor how many shares it will allow us to register in connection with the registration. Once the shares are registered, we have no control over which of the selling stockholders will actually

sell all or any portion of their shares, or at what price.

27

In addition, future sales of substantial amounts of our common stock, including approximately 25 million shares that we issued in connection with our March 31, 2005 merger transaction, or the expectation of such sales, could adversely affect the market price of our common stock. These shares are subject to Rule 144 restrictions and a contractual lock-up under which in each of the four consecutive three-month periods beginning on March 25, 2006 up to 25% of the common stock held by the holder hereof as of March 25, 2005, on a non-cumulative basis, may be sold, hypothecated or otherwise transferred. As of April 1, 2007 the lock-up expired and all remaining shares can be freely traded.

#### 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 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. Furthermore, if additional equity securities in the Company are issued, investors in this offering could experience dilution of their ownership in the Company.

# Certain investors in our most recent round of financing have alleged misrepresentation in connection with the financing and may seek money damages.

Clearant has received written notice from Rowland W. Day II, on behalf of the following investors: (i) the Day Family Trust; (ii) Rowland W. Day II IRA; and (iii) Ron Nash, alleging that certain misrepresentations were made in connection with the Stock Purchase Agreements entered into on April 3, 2007 wherein Clearant agreed to issue approximately 93,720,000 shares of common stock at a price of \$0.025 per share. Clearant is in discussions with these investors and while no lawsuit has been filed at this time, there is no certainty that the investors will not, in the future, seek, among other things, rescission of the stock purchase agreement and money damages. If successful, this could negatively impact Clearant s cash flow and significantly impair its ability to operate. Rowland W. Day II is a member of the board of directors.

#### 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.

# 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 NASD 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.

28

# 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®*, including withdrawal of products made with the *Clearant Process®* 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 OTC Bulletin Board, 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. Also, any new issuance of common stock may result in a change of control.

29

#### **Item 2: Description of Property**

Our principal executive offices, including all of our sales, marketing and administrative functions, are located in approximately 1,500 square feet of office space at 11111 Santa Monica Boulevard, Suite 650, in Los Angeles, California, under a lease which expires on February 27, 2008. We pay rent of approximately \$5,000 per month plus a portion of operating expenses. We have also entered into a lease of approximately 2,300 square feet of space in Mundelein, Illinois, which runs through March 31, 2009. We pay rent of \$1,800 per month at that location. We believe that the current leased space is adequate even after planned reductions to meet our current needs, 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.

#### **Investment Policies**

Historically, 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 classify investments with maturity dates greater than three months when purchased as marketable securities, which have readily determined fair values as available-for-sale securities. 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.

On December 31, 2006, we had no investments that would create market risk. It is our intention to invest in highly liquid, high grade commercial paper, variable rate securities and certificates of deposit.

# **Item 3: Legal Proceedings**

On December 18, 2006, Epic Brand Group, Inc. filed a complaint against us in the Superior Court of California, County of Orange, Case No. 06CC13046, alleging breach of an Agreement for Professional Services dated as of August 19, 2005, and seeking damages of \$47,574.98 for advertising and marketing services and materials, plus interest, attorney s fees and costs. We have not filed a formal response, and Epic is seeking entry of a default judgment.

On March 27, 2007, we received notice of a claim by John McGinnis in order to preserve his right as outlined in a non-binding term sheet to fund a \$700,000 bridge credit facility. Mr. McGinnis provided \$200,000 under the non-binding term sheet and is seeking return of those funds.

On April 25, 2007, we received notice of a claim on behalf of most of the investors to whom we sold approximately \$2.3 million in common stock on April 3, 2007, including shares beneficially owned by two of our directors, alleging that the financials projections provided to them prior to investing were inaccurate, and seeking rescission of the stock purchase agreements and return of the funds. If such a claim were pursued successfully, it would eliminate our ability to continue to operate as a going concern.

# Item 4: Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2006.

30

#### **PART II**

# Item 5: Market for Common Equity and Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities

#### **Market Information**

Our common stock is quoted on the OTC Bulletin Board under the symbol CLRI. The following table shows the high and low bid prices of our common stock, as quoted on the OTC Bulletin Board, 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 OTC Bulletin Board, for the respective periods.

Fiscal year ended December 31, 2005 <sup>1</sup>	High		Lo	W
First quarter <sup>2</sup>	\$	5.50	\$	2.00
Second quarter		4.35		3.00
Third quarter		4.79		2.16
Fourth quarter		4.49		2.35
Fiscal year ended December 31, 2006 <sup>1</sup>				
First quarter	\$	2.39	\$	1.36
Second quarter		1.31		0.48
Third quarter		0.53		0.34
Fourth quarter		0.42		0.27

- 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.
- Clearant, Inc., merged with the Clearant on March 31, 2005.

#### Edgar Filing: - Form

#### **Holders**

As of May 8, 2007, there were approximately 191 holders of record representing approximately 4,300 beneficial owners of our common stock.

#### 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.

# Recent Sales of Unregistered Securities

CFG Funding, LLC, an investment fund co-managed by John Wehrle, the former Chairman of the board of directors of Clearant, has made an in kind distribution to its equity investors of 1,399,957 shares of common stock of Clearant. The distribution does not represent a sale or disposition of the shares, but rather a distribution to the existing beneficial owners pursuant to the Clearant Investor Rights Agreement. Because Mr. Wehrle was a director of Clearant at the time and a beneficial owner of CFG, the transactions were reported on Form 4 filed with the SEC on April 12, 2006, July 12, 2006, October 26, 2006, and December 26, 2006.

31

On April 3, 2007, we entered into Stock Purchase Agreements and Registration Rights Agreements with approximately twenty accredited and institutional investors for the sale of shares of our common stock in exchange for gross proceeds of approximately \$2.3 million. We agreed to issue approximately 93,720,000 shares of our common stock at a price of \$0.025 per share in the private placements. Purchasers included our Chief Executive Officer. The private placements were exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended, as transactions not involving a public offering.

Each of the purchasers represented their intention to acquire the securities for their own account for investment purposes and not with a view to the distribution thereof other than in accordance with applicable law. Appropriate legends were affixed to the stock certificates issued in the transaction. All purchasers either received or had access to adequate information concerning the investment. Purchasers were also granted customary demand registration rights, obligating us to use our best efforts to file registration statements covering the purchased shares.

We reserve the right to accept oversubscriptions for additional amounts. Unless otherwise required by law, we disclaim any obligation to release publicly any updates or changes in our expectations or any change in events, conditions, or circumstances on which any forward-looking statements are based.

#### 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, 2006:

# **Equity Compensation Plan Information**

				Number of securities remaining available
				for future issuance
	Number of securities			under equity compensation plans
	to be issued upon	Weigh	nted-average	(excluding
	exercise of		ise price of	securities
	outstanding		tstanding	reflected in
	options,		ptions,	column
Plan Category	warrants and rights <sup>1</sup>		rants and rights	$(a))^2$
rian Category	-		-	
Equity compensation plans approved by security	(a)		<b>(b)</b>	(c)
holders	9,511,958	\$	3.35	2,488,652
Equity compensation plans not approved by security				
holders	0	\$	0.00	0
Total	9,511,958	\$	3.35	2,488,652

These options were issued under the 2000 and 2005 Stock Award Plans.

Of this amount no shares were available for

Edgar Filing: - Form

issuance under the 2000 Stock Award Plan and 2,488,652 shares were available for issuance under the 2005 Stock Award Plan.

32

#### Item 6: Management s Discussion and Analysis or Plan of Operation Plan of Operation for the Next Twelve Months

# Liquidity and Capital Resources

The accompanying financial statements have been prepared on the basis that the Company will continue as a going concern. The Company has incurred significant operating losses and negative cash flows from operating activities since its inception. As of December 31, 2006, these conditions raised substantial doubt as to the Company s ability to continue as a going concern. In April 2007, the Company raised additional capital (See Note 18) to supplement its operations. There can be no assurance that the Company will be successful in its efforts to generate, increase, or maintain revenue or raise additional capital on terms acceptable to the Company or that the Company 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.

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.

As of December 31, 2006, we had net cash on hand of approximately \$0.6 million. Excluding non-current accounts payable, accrued liability payments, and inventory related payments, we are expending cash at a rate of approximately \$0.2-\$0.4 million per month, and at present rates, including the April 2007 funding, we will probably need to raise cash prior to the end of 2007. The Company 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. As of March 31, 2007 the Company has \$2,641,000 of accounts payable and accrued liabilities, most of which are non-current.

# Research and Development

For the coming year we plan to focus on generating revenue through our direct distribution revenue model and will expend cash to facilitate that process. In the long term, we plan to re-initiate our research and development spending surrounding blood plasma derivatives and recombinant products.

#### **Expected Purchases or Sales**

None.

#### **Employees**

We will continue to operate at current staffing levels and consider hiring additional personnel as our business expands.

#### Management s Discussion and Analysis of Financial Condition and Results of Operations

#### Results of Operations for the years ended December 31, 2006 and 2005

At December 31, 2006, we had working capital deficit of \$1,074,000 which included accounts payable and accrued liabilities of \$2,260,000. At December 31, 2006, our total assets were \$3,021,000, which consisted primarily of intangible assets and cash from the sale of our common stock.

#### Revenues

Our total revenue increased by \$229,000 or 42%, to \$770,000 for the year ended December 31, 2006, from \$541,000 for the year ended December 31, 2005. Revenues from direct distribution of *Clearant Process*® sterile implants were \$232,000 during the year ended December 31, 2006, which was the first year of implementation. We expect revenue from direct distribution to increase as our sales force becomes fully integrated into the marketplace. This is our primary source of revenue generation and growth by the Company.

33

Revenues from licensing activities increased \$112,000 or 52%, to \$327,000 for the year ended December 31, 2006, from \$215,000 for the year ended December 31, 2005, as a result of greater implementation of the *Clearant Process®* into our customers manufacturing processes and greater market acceptance of human tissue treated with the *Clearant Process®*. Revenues from fees for service activities were \$90,000 for the year ended December 31, 2006, as we introduced an opportunity for potential customers to try the *Clearant Process®*. These increases were a result of greater implementation of the *Clearant Process®* into our customers manufacturing processes and greater market acceptance of human tissue treated with the *Clearant Process®*. While the Company is continuing to grow the existing license and fee for service agreements, it is 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 \$137,000 or 59% to \$94,000 for the year ended December 31, 2006, from \$231,000 for the year ended December 31, 2005. The decrease is primarily related to non-recurring contract milestone payments and contract research completed during 2005. Grant revenue decreased by \$68,000 or 72%, to \$27,000 for the year ended December 31, 2006 from \$95,000 for the year ended December 31, 2005, as a result of the completion of a majority of our grant research projects in 2005.

During 2005 and 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 and grant revenue to decrease. We expect direct distribution, license and sterilization revenue to be more characteristic of recurring revenue.

#### Cost of Sales

Our total cost of sales increased by \$1,192,000 to \$1,209,000 for the year ended December 31, 2006, from \$17,000 for the year ended December 31, 2005. This increase is due to the implementation of the direct distribution and sterilization service revenue models and the write down of \$811,000 in inventory and inventory related prepayments during 2006. In addition, 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 Expenses

Sales, general and administrative expenses decreased by \$856,000 or 9%, to \$8,707,000 for the year ended December 31, 2006, from \$9,563,000 for the year ended December 31, 2005.

Included in the \$8,707,000 for the year ended December 31, 2006, are approximately \$490,000 of non-cash stock-based compensation and \$278,000 of non-cash stock option grants to consultants, \$280,000 of non-cash patent-related write-offs in accordance with SFAS 144, \$250,000 for a one-time consulting expense for services rendered, \$118,000 of sales-related expenses associated with the initial setup of the direct distribution sales force, and approximately \$500,000 of legal costs associated with a civil action involving certain statements regarding a competitor s product claim which was settled during the year, regulatory matters and due diligence efforts. We incurred \$490,000 in non-cash stock-based compensation for the year ended December 31, 2006, which is related to the implementation of SFAS 123(R) in 2006. In addition, we issued common stock and stock options to outside consultants for services rendered during the year ended December 31, 2006 and 2005, resulting in non-cash expense of \$278,000 and \$626,000, respectively. This decrease was due to a non-recurring grant of stock options to non-employees made during the year ended December 31, 2005. In addition, there was an increase in non-cash patent-related write-offs of \$280,000 for the year ended December 31, 2006, compared to \$148,000 for the same period in 2005. From time to time, we may issue common stock to consultants for services rendered and incur patent-related costs.

The \$856,000 decrease for the year ended December 31, 2006, from the year ended December 31, 2005 was principally due to a concerted effort to decrease our overall expenses during the fourth quarter of 2006. 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.

Table of Contents 49

34

During the first quarter of 2007, the Company reduced the number of employees from 25 to 8, eliminated several marketing, PR & IR initiatives, and prepared to move into less expensive office space, which had the result of decreasing ongoing expenses. After the reduction in these expenses, the Company s monthly SG&A is reduced to approximately \$200,000 to \$400,000. The Company 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. As of December 31, 2006, we had a working capital deficit of \$1,074,000 and approximately \$2,260,000 of accounts payable and accrued liabilities of which a significant amount was past due.

# Research and Development Expenses

Research and development expenses decreased by \$1,124,000 or 55%, to \$926,000 for the year ended December 31, 2006, from \$2,050,000 for the year ended December 31, 2005. This decrease was largely a result of reduced research and development costs associated with the closing of the Maryland facility during the year ended December 31, 2006, compared to the same period in 2005. Throughout the latter part of 2005 and during the first quarter of 2006, we closed our Maryland facility and reduced our R&D personnel and related expenses due to our shift in focus from research and development to the commercialization of the *Clearant Process*®. Further reductions in research and development costs were achieved in the 1st quarter of 2007, to approximately \$30,000.

In addition to the elimination of certain costs and the completion of certain projects, we have complemented 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, 2006, we recognized \$192,000 in net interest income compared to \$1,802,000 in net interest expense for the same year last year. The expense was primarily the result of the issuance of additional bridge loans in the beginning of 2005 and subsequent payoff of all outstanding loan interest prior to the reverse merger transaction during 2005. In addition, we have \$563,000 cash on hand as of December 31, 2006, which we are currently investing in short-term conservative money market funds. We expect to earn interest income in 2007, although this amount will decrease as the cash is depleted. Additionally there was an \$117,000 gain on extinguishment of debt and a \$35,000 loss on disposal of fixed assets in connection with the closing of the Maryland facility for the year ended December 31, 2006. From time to time, we may participate in these infrequent events.

#### Preferred Stock Dividend and Financing Costs

Preferred stock dividend and financing costs decreased to \$0 for the year ended December 31, 2006, from \$2,161,000 for the year ended December 31, 2005. The decrease was principally due to the conversion of preferred stock in conjunction with the reverse merger transaction during 2005. As of December 31, 2006, there were no shares of preferred stock outstanding.

# Liquidity and Capital Resources

Net cash used in operating activities was \$9,253,000 for the year ended December 31, 2006, compared to \$11,829,000 for the year ended December 31, 2005. During the year ended December 31, 2006, cash used by operations resulted in a \$9,798,000 net loss along with a \$422,000 decrease in accounts payable and accrued liabilities, which was related to unpaid wages as of December 31, 2005 and decreased accrued professional fees such as public relations, accounting and outside legal fees. Significant non-cash adjustments to operating activities for the year ended December 31, 2006, included depreciation and amortization expense of \$532,000 and non-cash charges of \$490,000 for stock-based compensation.

35

During 2005, cash used in operations resulted in an \$11,590,000 net loss and a \$1,915,000 decrease in accounts payable and accrued liabilities. The decrease in accounts payable and accrued liabilities are primarily related to wages, public relations and marketing fees that were accrued as of December 31, 2004, and paid in 2005. Significant non-cash adjustments to operating activities for 2005, included depreciation and amortization expense of \$470,000, non-cash charges of \$1,795,000 in interest expense, \$1,173,000 in merger-related gains and \$626,000 for stock-based compensation.

Our net cash used in investing activities was \$337,000 for the year ended December 31, 2006 compared to net cash used in investing activities of \$236,000 for the year ended December 31, 2005. During 2006 and 2005, 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 \$12,000 for the year ended December 31, 2006, compared to \$22,042,000 for the year ended December 31, 2005. Cash provided by financing activities for the year ended December 31, 2006 consisted primarily of the exercise of stock options, leaving a balance of approximately \$563,000 in cash and cash equivalents at December 31, 2006. Cash provided by financing activities in 2005 consisted primarily of \$19,554,000 in net proceeds from issuance of common stock in conjunction with our reverse merger transaction completed in March 2005 and our secondary placement completed in November 2005. Additionally, cash was provided by the issuance of bridge loans for \$2,811,000 in January 2005, leaving a balance of approximately \$10,141,000 in cash and cash equivalents at December 31, 2005.

We have been unprofitable since our inception and we expect to incur additional operating losses through at least the end of 2007 and into 2008 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.

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 2007. In addition, during the first and second quarters of 2007, the Company was unable to make regular payments to trade vendors which resulted in the increase of accounts payable and accrued liabilities to \$2,641,000 as of March 31, 2007. The Company s ability to settle these payments with vendors will have a material impact to the Company s cash flow and the timing for the Company to raise additional capital.

The Company s ability to have sufficient capital through the end of 2007 is dependant on successful settlement of these

vendor claims, and the Company will need to raise additional capital prior to the end of 2007. As of December 31, 2006, we had a working capital deficit of \$1,074,000 and approximately \$2,260,000 of accounts payable and accrued liabilities of which a significant amount was past due. As of March 31, 2007, the Company had accounts payable and accrued liabilities of \$2,641,000 and has been unable to meet cash obligations as they become due. To date, most of these amounts continue to be past due. We are in settlement discussions with many of these vendors. 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.

Table of Contents

51

#### Contractual Obligations and Commercial Commitments

We lease facilities and equipment under non-cancelable operating leases with various expirations through 2011. The future minimum lease payments under these leases and other contractual obligations as of December 31, 2006 are as follows (\$ in 000 s):

Contractual Obligations	,	<b>Fotal</b>	t	Less han 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Lease obligations	\$	67	\$	44	\$ 23		
Bridge loan	\$	106	\$	106			
Purchase obligations	\$	9,500	\$	4,950	\$ 4,550		
Total	\$	9,673	\$	5,100	\$ 4,573		

In September 2006, Clearant entered into a renewable two-year spinal supply and distribution agreement which supersedes its prior supply agreement, pursuant to which the Company has the exclusive rights to place current and future spinal bone implants treated with the Clearant Process® in a number of geographic territories and an option for additional geographic territories, which in aggregate represent approximately 60% or more of the United States market. In exchange for these exclusive rights, the Company agreed to pay \$1,150,000 as a prepayment on October 31, 2006, for ordered spinal bone implants to be delivered in 2007. In addition, the Company will be required to make prepayments to be applied towards future spinal bone implants ordered in the amounts of \$3,800,000 and \$4,550,000 for 2007 and 2008, respectively. As of December 31, 2006, the \$1,150,000 payment has not been made by the Company, and all tissue orders have not been delivered by the supplier. In February 2007, the Company received notification of termination of the Agreement. The Company is in ongoing discussions with the supplier to resolve the issues, which could include but is not limited to, reduction in exclusive territories or termination. The termination of the Agreement may result in the disruption of the spinal bone implant supply, which would have a material adverse impact to the Company s ability to distribute spinal bone implants treated with the Clearant Proces. The forward-looking comments contained in the above discussion involve risks and uncertainties. Our actual results may differ materially from those discussed here due to factors such as, among others, limited operating history, difficulty in developing, exploiting and protecting proprietary technologies, intense competition and substantial regulation in the healthcare industry. Additional factors that could cause or contribute to such differences can be found in the discussion in Item 7, as well as under the Risk Factors section above.

# Off-Balance Sheet Arrangements

Except for operating lease commitments disclosed above, as of December 31, 2006, we had no off-balance sheet arrangements.

#### 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.

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. In addition, we recognize revenues from government grants. 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. 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 sales. We evaluate the collectability of accounts receivables and provide a reserve for credit losses, as appropriate. As of December 31, 2006 and 2005, we reserved for credit losses of \$20,000 and \$20,000 respectively.

#### Cost of Revenues

Cost of revenues consists of costs associated with direct distribution of *Clearant Process*<sup>®</sup> sterile implants to a customer and with providing sterilization services to customers. For the years ended December 31, 2006 and 2005, we had inventory write-downs of \$811,000 and \$0, respectively, which were recorded as a cost of revenue. Prior to 2006, cost of revenues consists of minimum royalties paid on certain contracting activities and are recognized when the related revenue is recognized.

#### **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 written down from time to time based on market conditions or other factors.

In accordance with the terms of the spinal Supply and Distribution Agreement (See Note 14), we are required to make prepayments. Upon receipt of the inventory the prepayments will be reclassified as inventory until distributed. <u>Identifiable Intangibles</u>

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 its patent costs and trademarks quarterly based on estimated undiscounted future cash flows.

# Research and Development Costs

Research and development costs are expensed as incurred.

38

#### **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.

#### **Stock-Based Compensation**

On January 1, 2006, we adopted Statements of Financial Accounting Standards (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 its adoption of SFAS 123(R).

We adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006. The financial statements as of and for the year ended December 31, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, the financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R).

#### Fair Value of Financial Instruments

The carrying amounts reported in the balance sheet for cash, cash equivalents, marketable securities, accounts receivable, accounts payable and accrued liabilities 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**

In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of Accounting Research Bulletin No. 43 (SFAS 151). SFAS 151 requires idle facility expenses, freight, handling costs, and wasted material (spoilage) costs to be excluded from the cost of inventory and expensed when incurred. It also requires that allocation of fixed overheads to the costs of conversion be based on the normal capacity of the production facilities. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS 151 in 2006 did not have a material impact on our financial reporting and disclosures.

In March 2006, the FASB issued SFAS No. 156, Accounting for Servicing of Financial Assets an amendment of FASB Statement No. 140 (SFAS 156). The provisions of SFAS 156 are effective for fiscal years beginning after September 15, 2006. This statement was issued to simplify the accounting for servicing rights and to reduce the volatility that results from using different measurement attributes. The adoption of SFAS 156 in 2006 did not have a material impact on our financial reporting and disclosures.

39

In July 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109 (FIN 48). FIN 48 requires a new evaluation process for all tax positions taken. If the probability for sustaining said tax position is greater than 50%, then the tax position is warranted and recognition should be at the highest amount which would be expected to be realized upon ultimate settlement. FIN 48 requires expanded disclosure at each annual reporting period unless a significant change occurs in an interim period. For interim periods in the year of initial adoption, all disclosures required by FIN 48 will be presented. Differences between the amounts recognized in the statements of financial position prior to the adoption of FIN 48 and the amounts reported after adoption are to be accounted for as an adjustment to the beginning balance of retained earnings. FIN 48 will be adopted by the Company on January 1, 2007. We do not anticipate that the adoption of FIN 48 will have a material affect on its results of operations or financial position, although we are continuing to evaluate the full impact of the adoption of FIN 48.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS 157). SFAS 157 establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are required to adopt the provision of SFAS 157, as applicable, beginning in fiscal year 2008. We do not believe the adoption of SFAS 157 will have a material impact on our financial position or results of operations.

In September 2006, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. (SAB) 108 (Topic 1N), Considering the Effects of Prior Year Misstatement when Quantifying Misstatements in Current Year Financial Statements (SAB 108). SAB 108 requires SEC registrants (i) to quantify misstatements using a combined approach that considers both the balance-sheet and income-statement approaches, (ii) to evaluate whether either approach results in quantifying an error that is material in light of relevant quantitative and qualitative factors, and (iii) to adjust their financial statements if the new combined approach results in a conclusion that an error is material. SAB 108 is effective for fiscal years ending after November 15, 2006. The adoption of SAB 108 did not have an impact on our results of operations and financial position.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS 159). SFAS 159 expands opportunities to use fair value measurement in financial reporting and permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We have not decided if we will early adopt SFAS 159 or if it will choose to measure any eligible financial assets and liabilities at fair value.

In May 2007, the FASB issued FSP No. FIN 48-1 Definition of Settlement in FASB Interpretation No. 48, (FSP FIN 48-1), was issued. FSP FIN 48-1 amends FIN 48 to provide guidance on how an entity should determine whether a tax provision is effectively settled for the purpose of recognizing previously unrecognized tax benefits. The term effectively settled replaces the term ultimately settled when used to describe recognition, and the terms settlement or settled replace the terms ultimate settlement or ultimately settled when used to describe measurement of a tax position under FIN 48. FSP FIN 48-1 clarifies that a tax position can be effectively settled upon the completion of an examination by a taxing authority without being legally extinguished. For tax positions considered effectively settled,

an entity would recognize the full amount of tax benefit, even if the tax position is not considered more likely than not to be sustained based solely on the basis of its technical merits and the statute of limitations remains open. We do not anticipate that the adoption of FSP FIN 48-1 will have a material affect on its results of operations or financial position, although we are continuing to evaluate the full impact of the adoption of FSP FIN 48-1.

40

# Edgar Filing: - Form

# **Table of Contents**

# **Item 7: Financial Statements**

# **CONTENTS**

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM	PAGE F-2
FINANCIAL STATEMENTS	
BALANCE SHEET	F-3
STATEMENTS OF OPERATIONS	F-4
STATEMENTS OF STOCKHOLDERS EQUITY	F-5
STATEMENTS OF CASH FLOWS	F-6
NOTES TO FINANCIAL STATEMENTS	F-7
F-1	

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors

Clearant, Inc.

Los Angeles, California

We have audited the balance sheet of Clearant, Inc. (the Company) as of December 31, 2006, and the related statements of operations, stockholders equity, and cash flows for each of the two years in the period ended December 31, 2006. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit 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 audit provides 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 the Company as of December 31, 2006, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles. As discussed in Note 3 to the financial statements, in 2006 the Company adopted Statement of Financial Accounting Standards No 123 (Revised 2004). Share-Based Payment.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and negative cash flow 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/ SINGER LEWAK GREENBAUM & GOLDSTEIN LLP

Los Angeles, California

May 17, 2007

F-2

outstanding)

# CLEARANT, INC. BALANCE SHEET (in thousands, except par value amounts)

Assets	Dec	cember 31, 2006
Current assets: Cash and cash equivalents Accounts receivable, net of allowances of \$20 Inventory, net of \$405 of inventory allowance Inventory related prepayments, net of \$406 of inventory allowance Prepaids and other assets	\$	563 274 278 107 137
Total current assets		1,359
Property and equipment, net of \$1,076 of accumulated depreciation Identifiable intangibles, net of \$871 of accumulated amortization Deposits and other assets		290 1,279 93
Total assets	\$	3,021
Liabilities, Redeemable Preferred Stock and Stockholders Equity		
Current liabilities: Accounts payable Accrued liabilities Bridge loans, net Deferred revenue	\$	1,653 607 106 67
Total current liabilities		2,433
Deferred revenue noncurrent		4
Total liabilities		2,437
Series A Redeemable Preferred Stock: Series A Redeemable Convertible preferred stock (50,000 shares authorized; 0 issued and		

# Edgar Filing: - Form

Stockholders equity (deficit): Common stock (\$0.0001 par value; 200,000 shares authorized; 40,178 issued and outstanding) Additional paid-in capital Accumulated deficit	4 82,949 (82,369)
Total stockholders equity	584
Total liabilities, redeemable preferred stock and stockholders equity	\$ 3,021
See accompanying notes to financial statements.	

F-3

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

	al Year Endec 2006	ember 31, 2005
Revenues: Licensing Direct distribution Fee for service	\$ 327 232 90	\$ 215
Contract research and milestones Grants	94 27	231 95
Total revenues	770	541
Cost of sales	1,209	17
Gross profit (Loss)	(439)	524
Operating expenses: Sales, general and administrative Research and development	8,707 926	9,563 2,050
Total operating expenses	9,633	11,643
Loss from operations	(10,072)	(11,119)
Other income (expense): Interest income (expense), net Gain on extinguishment of debt and other	192 82	(1,802) 1,331
Loss before provision (benefit) for income taxes	(9,798)	(11,590)
Provision (benefit) for income taxes		
Net loss Add: Preferred stock dividend and financing costs	(9,798)	(11,590) (2,161)
Net loss attributable to common stock	\$ (9,798)	\$ (13,751)

# Edgar Filing: - Form

Net loss per share:

Basic and diluted \$ (0.25) \$ (0.47)

Number of shares used in weighted average per share calculation:

Basic and diluted 39,883 29,498

See accompanying notes to financial statements.

F-4

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

										Stock-
	Sei	ries B		ies C erred	Comn   Stock   \$0.0001	k,	Additional	I	Other	holders'
	Prefer Shares	red Stock Amount	St	ock	valu	e	Paid-in Ant Capital	Accumulat <b>ech</b> Deficit	nprehens Loss	iv <b>E</b> quity (Deficit)
Balance, December 31, 2004	6,630	\$ 16,386	37	\$ 86	7,372	\$ 1	\$ 17,398	\$ (58,820)	<b>\$</b> (46)	\$ (24,995)
Issuance of warrants to January 2005 Bridge Holders Settlement of							93			93
debt for common stock Exchange of					31		64			64
warrants for common stock Beneficial return to preferred shareholders from allocation of shares from					77		158			158
common to preferred stockholders Conversion of preferred stock							2,100			2,100
into common stock Exchange of	(6,630)	(16,386	(37)	(86)	11,542	1	30,566			14,095
bridge loan warrants Conversion of Series A							(1,349)			(1,349)
Preferred dividend Conversion of Series C					2,141		3,794			3,794
Preferred dividend Conversion of 2004 bridge loans into common					3 3,834	1	5 6,724			5 6,725

# Edgar Filing: - Form

stock					
Bliss Essential,					
Corp. shares					
issued in					
connection with					
the merger					
transaction	7,136	1 16			17
Issuance of					
common stock in					
conjunction with					
Private	• • • •				
Placement	2,910	8,413			8,413
Conversion of					
Publico Bridge					
Loans into					
common stock	783	2,373			2,373
Exercise of					
common stock					
options	83	52			52
Issuance of					
common stock to					
consultants for	<b>7</b> 2	250			250
services	73	278			278
Compensation					
expenses incurred					
in connection					
with issuance of					
options and					
warrants to		450			450
non-employees		458			458
Secondary	2 774	11,036			11.026
placement Comprehensive	3,774	11,030			11,036
_					
loss: Net Loss			(11,590)		(11,590)
Other			(11,390)		(11,390)
comprehensive					
loss				(13)	(13)
Cumulative				(13)	(13)
translation loss					
attributable to the					
dissolution of					
foreign					
subsidiaries				59	59
Total					
Comprehensive					
loss			(11,590)	46	(11,544)
Preferred stock					/
dividend and					
financing costs			(2,161)		(2,161)
-			•		•

Balance at December 31, 2005	\$ \$	39,759	\$ 4 \$ 82,179	\$ (72,571) \$	\$ 9,612
Exercise of common stock options Issuance of common stock to consultants for		44	26		26
services		375	254		254
Stock-based compensation			490		490
Net Loss				(9,798)	(9,798)
Balance at December 31, 2006	\$ \$	40,178	\$ 4 \$ 82,949	\$ (82,369) \$	\$ 584

See accompanying notes to financial statements.

F-5

# CLEARANT, INC. STATEMENTS OF CASH FLOWS (in thousands)

		ear Ended I 2006	December 31, 2005	
Operating activities				
Net loss	\$	(9,798)	\$	(11,590)
Adjustments to reconcile net loss to net cash used in operating activities:				
Provision for inventory and inventory related prepayments write down		811		
Provision for accounts receivable allowance				20
Depreciation and amortization		532		470
Stock-based compensation		490		
Issuance of common stock to consultants for services rendered		154		626
Non-cash interest expense associated with convertible debt financings				1,795
Gain on extinguishment of debt and other		(82)		(1,331)
Warrants exchanged for common stock				158
Cumulative translation loss attributable to the dissolution of foreign				
subsidiaries				59
Changes in operating assets and liabilities:				
Accounts receivable		(66)		(101)
Inventory		(683)		, ,
Inventory related prepayments		(513)		
Prepaids		127		223
Accounts payable		616		(555)
Accrued liabilities		(1,038)		(1,360)
Deferred revenue		(37)		(161)
Other assets and liabilities		234		(82)
Net cash used in operating activities		(9,253)		(11,829)
Investing activities				
Cost of identified intangibles		(203)		(129)
Capital expenditures		(134)		(132)
Proceeds from sales of fixed assets, net		` ,		25
Net cash used in investing activities		(337)		(236)
Financing activities				
Issuance of common stock, net of costs				19,554
Issuance of convertible notes payable, net of costs				2,811
Exercise of common stock options		26		50
Payments on bridge loans				(366)
Principal payments on capital lease obligations		(14)		(7)
Net cash provided by financing activities		12		22,042
Effect of translation adjustments on cash and cash equivalents				(13)
Change in cash and cash equivalents		(9,578)		9,964

# Edgar Filing: - Form

Cash and cash equivalents, beginning of period		10,141		177
Cash and cash equivalents, end of period	\$	563	\$	10,141
Supplemental Disclosure of Cash Flow Information: During the year ended December 31, 2006, the Company paid accounts payable of \$124 with 275,987 shares of common stock Cash paid for interest Cash paid for taxes Accumulated preferred stock dividend and amortization of financing costs	\$ \$ \$ \$	124 2 1	\$ \$ \$ \$	9 1 2,161

F-6

# CLEARANT, INC. STATEMENTS OF CASH FLOWS (in thousands)

# **Supplemental Disclosure of Cash Flow Information:**

11		
Conversion of Series A Preferred Stock into common stock	\$	\$ 17,883
Conversion of Series B Preferred Stock into common stock	\$	\$ 16,386
Conversion of Series C Preferred Stock into common stock	\$	\$ 188
Conversion of Publico bridge loan into common stock	\$	\$ 2,373
Issuance of warrants to 2005 bridge loan holders	\$	\$ 103
Exchange of all warrants issued and outstanding in conjunction with the 20	05	
and 2004 bridge loan financings into common stock	\$	\$ 1,350
Issuance of common stock to consultants for services	\$	\$ 278
Property and equipment financed through capital lease obligations	\$	\$ 42
See accompanying notes to financial ste	t am ants	

See accompanying notes to financial statements.

F-7

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

(in thousands, except for share and per share data)

#### NOTE 1 DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

Clearant, Inc. ( Clearant or the Company ) was incorporated as a California corporation and commenced operations on April 30, 1999. The Company has developed a proprietary technology, the *Clearant Process*® 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®* enables customers to meet the medical need for safer biological products and to satisfy current and future product safety guidelines. The Company s primary business model is to provide customers the ability to apply the *Clearant Process* internally or through the Company's sterilization service. Customers pay the Company for assistance in applying the process to their manufacturing processes or to apply the process for them at the Company s sterilization service center. During 2003 and 2004, the Company s primary sources of revenue were contract research and government grants. During 2005, the Company changed its emphasis from one-time, generally non-recurring research and grant revenue to obtaining license and sterilization service customers. During 2006, the Company implemented a plan to better market and promote adoption of the Clearant Process®, which is to directly distribute Clearant Process® sterile implants of customers in order to facilitate market penetration. The Company intends to continue to pursue the license and sterilization agreements, although the direct distribution revenue model may have an adverse impact on the pursuit of such agreements. The Company s ability to achieve a profitable level of operations will depend its ability to continue to increase customer acceptance of the Clearant Process and increased recognition by end users of the value of the Clearant Process ® 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. As described more fully in Note 10, the Company consummated a reverse merger with a public company in the first quarter of 2005, whereby the Company raised capital through a private placement of common stock. Just prior to the closing, the Company effected a 1-for-1.15 reverse stock split of common stock. All references to common stock and per share amounts for all prior periods presented have been retroactively restated to reflect this split. In connection with the closing, the Company raised gross proceeds of \$11,080, net of costs of approximately \$242, and converted all bridge loans and preferred stock issued and outstanding at December 31, 2004, and a majority of the bridge loans issued in the first quarter of 2005, into common shares.

In June 2005, the registrant, Clearant, Inc., formerly known as Bliss Essentials Corp., changed its state of incorporation from Nevada to Delaware. In conjunction with the reincorporation, Clearant had authorized common stock consisting of 200 million shares, \$0.0001 par value, of which 40,103,387 shares are issued and outstanding, and 50 million shares of preferred stock, \$0.0001 par value, none of which are issued and outstanding. Additional information pertaining to the Company s reincorporation in Delaware can be found on Form 14A filed with the Securities and Exchange Commission on June 16, 2005. The carrying value of the common stock has been revalued in accordance with the reincorporation. On December 31, 2005, the Company merged Clearant Licensing, Inc. into Clearant, Inc., a Delaware corporation.

In November 2005, the Company closed a secondary placement of 3,774,465 shares of its common stock and warrants to purchase 1,698,509 additional shares of common stock for an aggregate purchase price of approximately \$12,000, or a unit price of \$3.18. Each warrant is exercisable for one share of common stock at an exercise price of \$4.96 per share. The Company received approximately \$11,036, which is net of costs of approximately \$967. In addition, the Company granted a warrant to purchase 164,189 shares of common stock at an exercise price of \$4.96 per share to the

F-8

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

(in thousands, except for share and per share data)

#### NOTE 2 GOING CONCERN

The accompanying financial statements have been prepared on the basis that the Company will continue as a going concern. The Company has incurred significant operating losses and negative cash flows from operating activities since its inception. As of December 31, 2006, these conditions raised substantial doubt as to the Company s ability to continue as a going concern. In April 2007, the Company raised additional capital (See Note 18) to supplement its operations. There can be no assurance that the Company will be successful in its efforts to generate, increase, or maintain revenue or raise additional capital on terms acceptable to the Company or that the Company 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.

#### NOTE 3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

## Revenue Recognition and Deferred Revenue

The Company recognizes revenue in accordance with the provisions of Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104). The Company s 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. In addition, the Company recognizes revenues from government grants. The Company recognizes 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. 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, the Company 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, the Company will recognize the underlying amounts into revenue on a straight-line basis over the term of the underlying agreement. The Company includes shipping charges in the gross invoice price to customers and classifies 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 sales. The Company evaluates the collectability of accounts receivables and provides a reserve for credit losses, as appropriate. As of December 31, 2006 and 2005, the Company reserved for credit losses of \$20 and \$20, respectively.

#### Grants

The Company receives certain grants that support the Company s research efforts in defined research projects, usually specific product applications of the *Clearant Process* <sup>®</sup>. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenue associated with these grants is generally recognized ratably over each grant period and as costs under each grant are incurred.

F-9

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

(in thousands, except for share and per share data)

#### 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, 2006 and 2005, the Company had inventory write-downs of \$811, and \$0, respectively, which were recorded as a cost of revenue. Prior to 2006, cost of revenues consists of minimum royalties paid on certain contracting activities and are recognized when the related revenue is recognized.

#### **Extinguishment of Debt**

Extinguishment of debt consists of a gain recognized for the settlement of outstanding payables for the fiscal year ended December 31, 2006, which, while unusual in nature, is not an infrequent transaction for the Company. For the twelve months ended December 31, 2005, a gain was recognized for the exchange of warrants for outstanding debt in conjunction with the merger transaction.

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, short-term investments, and accounts receivable. Cash is deposited with what the Company believes are highly credited, quality financial institutions and may exceed FDIC insured limits. For and at the years ended December 31, 2006 and 2005, three customers accounted for approximately 49% and 59% of revenues, respectively, and three customers accounted for approximately 35% and 38% of accounts receivable, 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 written down from time to time based on market conditions or other factors. For the year ended December 31, 2006 the Company had inventory and inventory related prepayment write-downs of \$811.

In accordance with the terms of the Company s spinal Supply and Distribution Agreement (See Note 14), the Company is 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.

#### 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.

F-10

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

# (in thousands, except for share and per share data)

Amortization of such costs begins once the patent or trademark has been issued. The Company evaluates the recoverability of its patent costs and trademarks quarterly based on estimated undiscounted future cash flows. In accordance with Statement of Financial Accounting Standards (FAS) No. 144. Accounting for the Impairment or Disposal of Long-Lived Assets—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 the Company s valuation assessments of its patents no impairment exists for the year ended December 31, 2006.

## Research and Development Costs

Research and development costs are expensed as incurred.

## Other Comprehensive Loss

Other comprehensive loss consists of foreign currency translation adjustments recorded upon consolidation of our foreign subsidiaries. In 2005, the Company s wholly-owned foreign subsidiaries were consolidated into Clearant, Inc. 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. The significant components of the provision for income taxes for the fiscal year ended December 31, 2006 and 2005 were \$1 and \$1, respectively, for the current state provision. There was no state deferred and federal tax provision. Due to its current net loss position, the Company has provided a valuation allowance in full on its net deferred tax assets in accordance with SFAS 109 and in light of the uncertainty regarding ultimate realization of the net deferred tax assets.

# **Stock-Based Compensation**

On January 1, 2006, the Company adopted Statements of Financial Accounting Standards (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 the Company s 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). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

The Company adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company s fiscal year 2006. The financial statements as of and for the year ended December 31, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, the financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). There was no stock-based compensation expense related to employees or directors stock options recognized during the year ended December 31, 2005. Stock-based compensation expense recognized under SFAS 123(R) for employees and directors for the year ended December 31, 2006 was \$490. Basic and diluted loss per share for the year ended December 31, 2006 would have been \$0.23, if the Company had not adopted SFAS 123(R), compared to reported basic and diluted loss per share of \$0.25.

F-11

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

### (in thousands, except for share and per share data)

The estimated fair value of options granted to employees and directors during the year ended December 31, 2006 was \$1,245. Assumptions used to value the options granted were as follows:

Expected volatility	79.6%-93.0%
Risk-free interest rate	4.46%-5.18%
Expected life in years	5.17-10
Expected dividend yield	0%

The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions of SFAS 123(R) to stock-based awards granted under the Company s stock option plans for the year ended December 31, 2005. For purposes of this pro-forma disclosure, the fair value of the options is estimated using the Black-Scholes-Merton option-pricing formula (Black-Scholes model) and amortized to expense over the options contractual term.

	Year ended December 31, 2005		
Net loss as reported Less: Stock-based expense determined under fair value based method	\$	(13,751) (682)	
Pro forma net loss	\$	(14,433)	
Net loss per share As reported basic and diluted Pro forma basic and diluted	\$ \$	(0.47) (0.49)	

On June 30, 2005, the Company granted options to non-employees to purchase 120,000 shares of common stock. The options were fully vested and exercisable upon grant. The Company valued the options using the Black-Scholes option-pricing model and the following assumptions: risk-free interest rate 3.94%, expected life 10 years, dividend yield 0% and volatility 71%. The full value of the options, \$386, were charged to stock-based compensation expense for the year ended December 31, 2005, as all services related to the options had been completed.

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards to employees and directors on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in our Statements of Operations. Prior to the adoption of SFAS 123(R), the Company accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123). Under the intrinsic value method, no stock-based compensation expense had been recognized in the Statements of Operations for awards to employees and directors because the exercise price of our stock options equaled the fair market value of the underlying stock at the date of grant.

Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized in the Statements of Operations for the year ended December 31, 2006 included compensation expense for share-based payment awards granted prior to, but not yet vested as of January 1, 2006 based on the grant date fair value estimated in accordance with the pro-forma provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to January 1, 2006 based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). For stock-based awards issued to employees and directors, stock-based compensation is attributed to expense using the straight-line single option method, which is consistent with how the prior-period pro formas were provided. As stock-based compensation expense recognized in the Statements of Operations for the year ended December 31, 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures which the Company estimates to be approximately 49%. The forfeiture rate

# Edgar Filing: - Form

takes into consideration the significant downsizing of the business in the first quarter of 2007 (See Note 18). In 2007, the forfeiture rate will be approximately 11%. To date, stock-based compensation expense has been reduced by forfeitures of approximately \$280. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In our pro-forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred.

F-12

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

# (in thousands, except for share and per share data)

The Company determines the fair value of share-based payment awards to employees and directors on the date of grant using the Black-Scholes model, which is affected by the Company s stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to the Company s expected stock price volatility over the term of the awards. Prior to 2006, when valuing awards the Company used the award s contractual terms as a proxy for its expected terms. For new grants after December 31, 2005, the Company estimates expected term using the safe harbor provisions provided in SAB 107. The Company uses historical data to estimate forfeitures.

The Company has elected to adopt the detailed method provided in SFAS 123(R) for calculating the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee stock-based compensation, and to determine the subsequent impact on the APIC pool and Statements of Cash Flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of SFAS 123(R). Fair Value of Financial Instruments

The carrying amounts reported in the balance sheet for cash, cash equivalents, marketable securities, accounts receivable, accounts payable and accrued liabilities 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.

# New Accounting Pronouncements

In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of Accounting Research Bulletin No. 43 (SFAS 151). SFAS 151 requires idle facility expenses, freight, handling costs, and wasted material (spoilage) costs to be excluded from the cost of inventory and expensed when incurred. It also requires that allocation of fixed overheads to the costs of conversion be based on the normal capacity of the production facilities. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS 151 in 2006 did not have a material impact on the Company s financial reporting and disclosures. In March 2006, the FASB issued SFAS No. 156, Accounting for Servicing of Financial Assets an amendment of FASB Statement No. 140 (SFAS 156). The provisions of SFAS 156 are effective for fiscal years beginning after September 15, 2006. This statement was issued to simplify the accounting for servicing rights and to reduce the volatility that results from using different measurement attributes. The adoption of SFAS 156 in 2006 did not have a material impact on the Company s financial reporting and disclosures.

In July 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109 (FIN 48). FIN 48 requires a new evaluation process for all tax positions taken. If the probability for sustaining said tax position is greater than 50%, then the tax position is warranted and recognition should be at the highest amount which would be expected to be realized upon ultimate settlement. FIN 48 requires expanded disclosure at each annual reporting period unless a significant change occurs in an interim period. For interim periods in the year of initial adoption, all disclosures required by FIN 48 will be presented. Differences between the amounts recognized in the statements of financial position prior to the adoption of FIN 48 and the amounts reported after adoption are to be accounted for as an adjustment to the beginning balance of retained earnings. FIN 48 will be adopted by the Company on January 1, 2007. The Company does not anticipate that the adoption of FIN 48 will have a material affect on its results of operations or financial position, although the Company is continuing to evaluate the full impact of the adoption of FIN 48.

F-13

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

## (in thousands, except for share and per share data)

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS 157). SFAS 157 establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is required to adopt the provision of SFAS 157, as applicable, beginning in fiscal year 2008. Management does not believe the adoption of SFAS 157 will have a material impact on the Company s financial position or results of operations.

In September 2006, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. (SAB) 108 (Topic 1N), Considering the Effects of Prior Year Misstatement when Quantifying Misstatements in Current Year Financial Statements (SAB 108). SAB 108 requires SEC registrants (i) to quantify misstatements using a combined approach that considers both the balance-sheet and income-statement approaches, (ii) to evaluate whether either approach results in quantifying an error that is material in light of relevant quantitative and qualitative factors, and (iii) to adjust their financial statements if the new combined approach results in a conclusion that an error is material. SAB 108 is effective for fiscal years ending after November 15, 2006. The adoption of SAB 108 did not have an impact on the Company s results of operations and financial position.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS 159). SFAS 159 expands opportunities to use fair value measurement in financial reporting and permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company has not decided if it will early adopt SFAS 159 or if it will choose to measure any eligible financial assets and liabilities at fair value.

In May 2007, the FASB issued FSP No. FIN 48-1 Definition of Settlement in FASB Interpretation No. 48, (FSP FIN 48-1), was issued. FSP FIN 48-1 amends FIN 48 to provide guidance on how an entity should determine whether a tax provision is effectively settled for the purpose of recognizing previously unrecognized tax benefits. The term effectively settled replaces the term ultimately settled when used to describe recognition, and the terms settlement or settled replace the terms ultimate settlement or ultimately settled when used to describe measurement of a tax position under FIN 48. FSP FIN 48-1 clarifies that a tax position can be effectively settled upon the completion of an examination by a taxing authority without being legally extinguished. For tax positions considered effectively settled, an entity would recognize the full amount of tax benefit, even if the tax position is not considered more likely than not

to be sustained based solely on the basis of its technical merits and the statute of limitations remains open. We do not

anticipate that the adoption of FSP FIN 48-1 will have a material affect on its results of operations or financial

position, although we are continuing to evaluate the full impact of the adoption of FSP FIN 48-1.

#### NOTE 4 NET LOSS PER SHARE

The Company computes 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.

F-14

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

# (in thousands, except for share and per share data)

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	For the Year Ended December 31,		
	2006	2005		
Stock Options	4,000,000	2,776,000		
Warrants	5,512,000	5,179,000		

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

	For the year ended December 31, 2006 2005			
Basic and diluted net loss per share:				
Numerator:				
Net loss attributable to common stock	\$ (9,798)	\$	(13,751)	
Denominator:				
Weighted average common stock shares outstanding	39,883		29,498	
Net loss per share, basic and diluted	\$ (0.25)	\$	(0.47)	

## NOTE 5 INVENTORY AND INVENTORY RELATED PREPAYMENTS

Inventories as of December 31 are comprised of the following:

	Decemb	er 31,
	200	)6
Tissue in process, net	\$	107
Implantable donor tissue, net		254
Radio protectant solution		24
	\$	385

For the years ended December 31, 2006 and 2005, the Company had inventory write-downs of \$811, and \$0, respectively.

## NOTE 6 PROPERTY AND EQUIPMENT

Property and equipment consists of the following at December 31:

	,	2006
Equipment	\$	764
Computer equipment and software		524
Furniture and fixtures		68
Leasehold improvements		10
		1,366
Less accumulated depreciation		(1,076)

\$ 290

F-15

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

# (in thousands, except for share and per share data)

Included in property and equipment is equipment leased under capital leases of \$30 at December 31, 2006. Accumulated depreciation relating to these capital leases for the years ended December 31, 2006 was \$10. Depreciation expense was \$205 and \$282 for the years ended December 31, 2006 and 2005, respectively.

#### NOTE 7 IDENTIFIABLE INTANGIBLES

Identifiable intangibles consist of the following at December 31:

	2006
Trademarks	\$ 37
Patents	2,113
	2,150
Less accumulated amortization	(871)
	\$ 1,279

Over the period January 1, 2007 to December 31, 2011, the Company projects cumulative amortization expense related to its patents and trademarks issued at December 31, 2006 to be approximately \$210. Because the Company evaluates the recoverability of its intangibles on a quarterly basis, and anticipates that new patents will be granted and issued in 2007 throughout 2011, actual amortization expense recorded over January 1, 2007 to December 31, 2011 could fluctuate significantly from the projected amount over the same period.

During the year ended December 31, 2006 and 2005, the Company recorded approximately \$280 and \$148, respectively, of expense associated with patent impairment.

#### NOTE 8 RESTRICTED CASH

As of December 31, 2006, the Company had cash deposits of approximately \$42, which is included in deposits and other assets on the balance sheet.

#### NOTE 9 INCOME TAXES

The significant components of the provision for income taxes for the years ended December 31, 2006 and 2005 were \$1 and \$1, respectively, for the current state provision. 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, 2006 and 2005 are as follows:

	2006	2005
Deferred tax assets:		
Net operating loss carryforwards	\$ 26,716	\$ 23,178
Purchase in-process research and development	496	549
Research and development credits	1,379	1,338
Depreciation, accrued expenses and other	471	462
Net deferred tax assets	29,062	25,527
Less valuation allowance	(29,062)	(25,527)
	\$	\$

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

## (in thousands, except for share and per share data)

During 2006, the Company s valuation allowance on deferred tax assets increased from \$25,527 as of December 31, 2005 to \$29,062 as of December 31, 2006, 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 years ended December 31, 2006 and 2005 was approximately \$9,798 and \$0, respectively, \$11,160 and \$430, respectively.

The Company has provided a valuation allowance in full on its 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:

	2006	2005
Federal statutory rate	(34%)	(34%)
State taxes	(5%)	(5%)
Tax credits & other	3%	(1%)
Foreign loss with no benefit	0%	7%
Valuation allowance	36%	33%

At December 31, 2006 and 2005, the Company had net operating losses (NOL) for federal and state income tax purposes of approximately \$141,642 and \$123,237, which begin expiring in 2020 and 2007, 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 March 2005 transaction (Note 10), the Company will evaluate whether there are limitations on the use of its NOL carryforwards beyond December 31, 2005 under Section 382, including, as needed, the impact of cumulative changes in the ownership of the Company s common stock. The NOLs and credit carryforwards noted above may be limited under Internal Revenue Code Sections 382 and 383, respectively. As of December 31, 2006, the Company has not performed an analysis in order to determine whether such limitations exist.

The Company also has federal and state research and development tax credit carryforwards as of December 31, 2006 and 2005, of approximately \$1,440 and \$1,401, respectively, which begin to expire in 2023 and 2019, respectively.

#### NOTE 10 REVERSE MERGER TRANSACTION

In March 2005, a wholly-owned subsidiary of the Company merged with and into Clearant. The Company had approximately \$17 in cash and no operations as of the date of the merger. Concurrent with the merger, the Company raised gross proceeds of approximately \$11,080 through a private placement of shares of its Common Stock at \$3.00 per share, including the conversion of approximately \$2,350 of bridge loans in the form of promissory notes. The Company completed the merger and placement effective March 31, 2005. Because the registrant had substantially no other operating assets or liabilities and Clearant was the sole operating business as of the merger date, the merger was accounted for as a reverse acquisition. Accordingly, Clearant s financial statements now reflect the Company s financial results and operations on a carry over basis.

Details and analysis of the capital transactions and adjustments recorded to the Company s balance sheet in conjunction with the merger are more fully described in the Company s December 31, 2005 Form 10-K filed with the Securities and Exchange Commission on March 16, 2006.

F-17

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

(in thousands, except for share and per share data)

#### NOTE 11 CAPITALIZATION

### Common Stock Transactions and Non-cash Financing Activities

During 2006, the Company issued 100,000 shares of common stock with a fair value of \$130 to consultants for services to be rendered to the Company over a twelve month contract. Accordingly, \$87 is reflected in sales, general and administrative expenses for 2006.

During 2006, the Company paid accounts payable of \$124 with 275,987 shares of common stock.

During 2005, the Company issued 57,979 shares of common stock with a fair value of \$235 to consultants for services rendered to the Company. A portion of the fair value, \$203, is for services to be rendered over a twelve month contract. Accordingly, \$67 and \$136 is reflected in sales, general and administrative expenses for 2006 and 2005, respectively.

# Lock-up Period

For a period beginning on March 25, 2005 and ending on March 25, 2006, the existing holders of Clearant s common stock immediately prior to the merger (Note 10) cannot (i) sell, offer to sell, contract or agree to sell, hypothecate, pledge, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of or agree to dispose of, directly or indirectly, any common stock of the Corporation or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any of the common stock in cash or otherwise, whether or not for consideration, and in each of the four consecutive three-month periods beginning on March 25, 2006 will not transfer, on a non-cumulative basis, more than 25% of the common stock held by any such person as of March 25, 2005. As of April 1, 2007, there shall be no further transfer restrictions except as provided by law.

## Series A Redeemable Preferred Stock

The Company has 50,000,000 shares authorized and 0 shares outstanding as of December 31, 2006. For the years ended December 31, 2006 and 2005 the Company recognized \$0 and \$61, respectively, of amortization expense associated with the Series A Preferred issuance costs.

#### NOTE 12 STOCK OPTIONS

Effective March 31, 2005 and in conjunction with the merger (Note 10), the Company cancelled all stock options previously issued to employees and non-employees with exercise prices greater than \$3.50 per share (the 2005 Option Cancellations). As a result of the 2005 Options Cancellations, the Company retained stock options to employees and non-employees at March 31, 2005 of approximately 1,918,588 shares (the Existing Options), which are grandfathered under the Company s 2000 Stock Award Plan, as amended (the 2000 Plan). As of December 31, 2005, there are no future grants available under the 2000 Plan.

On June 30, 2005, the stockholders approved the Company 2005 Stock Award Plan (the 2005 Plan). There are 5,081,412 shares of common stock authorized for issuance under the Plan. In addition, the Company assumed options to purchase 1,918,588 shares of common stock in connection with the reverse merger consummated on March 31, 2005. Accordingly, an aggregate of 7,000,000 shares of common stock are reserved for issuance upon exercise of options. The terms of the 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 of such option, owns stock representing more than 10% of the voting power of all classes of stock of the Company, 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.

F-18

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

(in thousands, except for share and per share data)

The following table sets forth the activity of the 2000 and 2005 Plan and Non-Plan Options issued for the years ended December 31, 2006 and 2005:

	Empl	oyees	ees Non-Employees		Total		
		Exercise		Exercise		Exercise	
	Shares	Price	Shares	Price	Shares	Price	
Outstanding at							
<b>December 31, 2004</b>	5,253,000	\$ 0.60-\$7.94	319,000	\$ 0.60-\$7.22	5,572,000	\$ 0.60-\$7.94	
Granted	1,254,000	\$ 3.86-\$4.51	120,000	\$ 4.12	1,374,000	\$ 3.86-\$4.51	
Exercised	(86,000)	\$ 0.60		\$	(86,000)	\$ 0.60	
Change in status	(226,000)	\$ 0.60-\$2.30	226,000	\$ 0.60-\$2.30			
Canceled	(3,799,000)	\$ 0.60-\$7.94	(285,000)	\$ 0.60-\$7.22	(4,084,000)	\$ 0.60-\$7.94	
Outstanding at							
<b>December 31, 2005</b>	2,396,000	\$ 0.60-\$7.94	380,000	\$ 0.60-\$7.22	2,776,000	\$ 0.60-\$7.94	
Granted	1,671,000	\$ 0.44-\$1.64	45,000	\$ 0.35-\$0.48	1,716,000	\$ 0.35-\$1.64	
Exercised	(3,000)	\$ 0.60	(41,000)	\$ 0.60	(44,000)	\$ 0.60	
Change in status	(263,000)	\$ 0.60-\$3.17	263,000	\$ 0.60-\$3.17		\$ 0.60-\$3.17	
Canceled	(396,000)	\$ 0.60-\$4.51	(52,000)	\$ 2.30-\$4.12	(448,000)	\$ 0.60-\$4.51	
Outstanding at							
<b>December 31, 2006</b>	3,405,000	\$ 0.44-\$7.94	595,000	\$ 0.35-\$7.22	4,000,000	\$ 0.35-\$7.94	

The weighted average exercise prices for options granted and exercisable and the weighted average remaining contractual life for options outstanding as of December 31, 2005 and December 31, 2006 was as follows:

		Wa	iahtad	Weighted		
	Number Of	Weighted Average Exercise		Average Remaining Contractual	J	Intrinsic
	Shares	P	rice	Life (Years)	Value	
As of December 31, 2005:						
Employees Outstanding	2,396,000	\$	2.83	7.17	\$	692,000
Employees Expected to Vest	2,376,000	\$	2.82	7.16	\$	692,000
Employees Exercisable	1,563,000	\$	2.25	6.03	\$	692,000
Non-Employees Outstanding	380,000	\$	2.04	5.78	\$	287,000
Non-Employees Expected to Vest	380,000	\$	2.04	5.78	\$	287,000
Non-Employees Exercisable	380,000	\$	2.04	5.78	\$	287,000
As of December 31, 2006:						
Employees Outstanding	3,405,000	\$	1.89	8.01	\$	
Employees Expected to Vest	2,126,000	\$	2.00	7.47	\$	
Employees Exercisable	1,449,000	\$	2.40	6.45	\$	
Non-Employees Options Outstanding	595,000	\$	2.19	4.49	\$	

 Non-Employees
 Expected to Vest
 595,000
 \$
 2.19
 4.49
 \$

 Non-Employees
 Options Exercisable
 570,000
 \$
 2.27
 4.28
 \$

F-19

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

### (in thousands, except for share and per share data)

The total intrinsic value of options exercised for the year ended December 31, 2005 was \$297. Cash received from stock options exercised during the year ended December 31, 2006 and 2005 were \$26, and \$50, respectively. The total intrinsic value of options exercised during the year ended 2006 was \$18. The total fair value of shares vested during the years ended December 31, 2005, were approximately \$1,480. The weighted average grant-date fair value of options granted during the year ended December 31, 2006 was \$0.73.

Included in the table above, at December 31, 2006 and 2005, were options outstanding for 595,000 and 380,000 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, 2006, there was \$1,676 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 2.8 years.

When options are exercised, our policy is to issue previously unissued shares of common stock to satisfy share option exercises. As of December 31, 2006 the Company had 2,488,652 shares of unissued shares reserved for issuance under our 2005 Plan.

#### NOTE 13 WARRANTS

During 2006, the Company issued two-year warrants to holders to purchase an aggregate 332,220 shares of our common stock at an exercise price of \$4.96 per share with a fair value of \$99 as of March 31, 2006, in connection with a settlement of disputed claims, at the discretion of the Company.

In November 2005 and in conjunction with the Company s secondary placement of common stock, the Company issued five-year warrants to such holders to purchase an aggregate 1,698,509 shares of the Company s common stock at an exercise price of \$4.96 per share. In addition, the Company issued five-year warrants to the placement agent to purchase an aggregate 164,189 shares of common stock at an exercise price of \$4.96 per share.

In March 2005 and pursuant to the Merger Agreement and in conjunction with the Transaction (Note 10) all of the Company is outstanding warrants immediately prior to the Reverse Merger were cancelled and the Company issued two-year warrants to purchase approximately 3,316,645 shares of the Company is common stock with an exercise price of \$4.00 per share to the previous holders of certain bridge loans, including holders of the Publico Bridge Loans. In conjunction with the Company is bridge loan financings in 2005, the Company issued five-year warrants to such holders to purchase an aggregate 167,547 shares of the Company is common stock at \$2.75 per share (collectively, the 2005 Bridge Warrants). The aggregate fair value of the 2005 Bridge Warrants was approximately \$92 (calculated in accordance with APB Opinion No. 14. Accounting for Convertible Debt and Debt Issued with Stock Purchase

accordance with APB Opinion No. 14, Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants) and was recorded as a discount to the bridge loan payable in 2005. Both the number of shares purchasable under the 2005 Bridge Warrants and the exercise price are subject to adjustment based upon the price per share of the Company s next equity round of financing.

Including those described above, all warrants have an exercise price of between \$4.00 and \$4.96 per share and terms of two to five years. The weighted average exercise prices and the weighted average remaining contractual life for warrants issued as of December 31, 2006 were as follows:

	Warrants Outstanding	
Number	Exercise	Weighted Average of Remaining
of Shares	Price	Contractual Life (Years)
3,316,645	\$4.00	0.25
2,194,918	\$4.96	3.46

Edgar Filing: - Form

F-20

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

# (in thousands, except for share and per share data)

All of the warrants granted to non-employees are valued based on the Company s 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	3.0%-5.5%
Expected life in years	2-5
Dividend yield	0%
Expected volatility	70% to 80%

The weighted average deemed fair value of warrants granted to non-employees for the years ended December 31, 2006 and 2005 was \$0.30 and \$1.66 per share, respectively.

#### NOTE 14 COMMITMENTS AND CONTINGENCIES

#### <u>Leases</u>

The Company leases 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, 2006, are as follows:

2007	\$ 44
2008	21
2009	1
2010 and thereafter	1

#### Net minimum lease payments

\$ 67

Rental expense on non-cancelable operating leases for the years ended December 31, 2006 and 2005 was \$341 and \$744, respectively.

The Company has obligations under capital leases for the years ended December 31, 2006 and 2005 of \$27 and \$42, respectively. As of December 31, 2006, the Company has one capital lease for equipment with a monthly payment including interest, of approximately \$1, that expires in two years. The liabilities related to the capital lease are recorded in accrued liabilities on the Balance Sheet.

#### Litigation

From time-to-time, the Company is involved in litigation relating to claims arising in the normal course of business. The Company does not believe that any currently pending or threatening litigation will have a material adverse effect on the Company s results of operations or financial condition as of December 31, 2006.

#### Supply and Distribution Agreements

In September 2006, the Company entered into a renewable two-year spinal supply and distribution agreement which supersedes its prior supply agreement, pursuant to which the Company has the exclusive rights to place current and future spinal bone implants treated with the *Clearant Process®* in a number of geographic territories and an option for additional geographic territories, which in aggregate represent approximately 60% or more of the United States market. In exchange for these exclusive rights, the Company agreed to pay \$1,150 as a prepayment on October 31, 2006, for ordered spinal bone implants to be delivered in 2007. In addition, the Company will be required to make prepayments to be applied towards future spinal bone implants ordered in the amounts of \$3,800 and \$4,550 for 2007 and 2008, respectively.

F-21

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

(in thousands, except for share and per share data)

Pursuant to the Company s spinal Supply and Distribution Agreement (Agreement), dated September 27, 2006, in consideration for the exclusive distribution and/or representation in various United States markets, the Company was required to remit a prepayment in the amount of \$1,150 on October 31, 2006. As of December 31, 2006, all tissue orders have not been delivered and this payment has not been made by the Company. In February 2007, the Company received notification of termination of the Agreement. The Company is in ongoing discussions with the supplier to resolve the issues, which could include but is not limited to, reduction in exclusive territories or termination. The termination of the Agreement may result in the discontinuation or disruption of the spinal bone implant supply, which would have a material adverse impact to the Company s ability to distribute spinal bone implants treated with the Clearant Process®.

#### NOTE 15 401K PLAN

The Company has 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, 2006 and 2005.

#### NOTE 16 FACILITY CLOSING CHARGES

At December 31, 2004, the Company no longer considered itself a development stage enterprise as defined by Statement of Financial Accounting Standards (SFAS) No. 7, Accounting and Reporting by Development Stage Companies, and accordingly, the accompanying financial statements do not represent those of a development stage enterprise. Additionally, in 2005, the Company developed an initiative designed to reduce the workforce and consolidate and move the lab to Los Angeles. The resulting facility closing charges for 2005 of \$305 related to severance costs communicated in 2005 but to be remunerated in 2006. There were additional period costs incurred in 2006 of \$53 in connection with the closing of the lab and moving of the equipment. The plan was approved by the Company s executive management team and the board of directors.

### NOTE 17 SELECTED QUARTERLY FINANCIAL DATA (Unaudited)

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

	Quarter ended							
	M	lar. 31,	J	un. 30,	S	ept. 30,	D	ec. 31,
2006								
Total revenues	\$	190	\$	106	\$	191	\$	283
Gross profit (loss)		136		48		78		(701)
Total operating expenses		2,802		2,455		2,733		1,643
Loss from operations		(2,666)		(2,407)		(2,655)		(2,344)
Other expense, net		153		64		41		16
Net loss		(2,513)		(2,343)		(2,614)		(2,328)
Preferred stock dividend and financing costs								
Net loss attributable to common stock	\$	(2,513)	\$	(2,343)	\$	(2,614)	\$	(2,328)
Net loss per share Basic and diluted	\$	(0.06)	\$	(0.06)	\$	(0.07)	\$	(0.06)
Number of shares Basic and diluted		39,764		39,849		39,912		40,004
2005								
Total revenues	\$	107	\$	191	\$	154	\$	89
Gross margin		103		186		150		85
Total operating expenses		2,746		2,513		2,810		3,574
Loss from operations		(2,643)		(2,327)		(2,660)		(3,489)

# Edgar Filing: - Form

Other expense, net	(457)			(14)
Net loss	(3,100)	(2,327)	(2,660)	(3,503)
Preferred stock dividend and financing costs	(2,161)			
Net loss attributable to common stock	\$ (5,261)	\$ (2,327)	\$ (2,660)	\$ (3,503)
Net loss per share Basic and diluted	\$ (0.71)	\$ (0.06)	\$ (0.07)	\$ (0.09)
Number of shares Basic and diluted	7,370	35,860	35,923	38,102

F-22

# CLEARANT, INC. NOTES TO FINANCIAL STATEMENTS

(in thousands, except for share and per share data)

#### NOTE 18 SUBSEQUENT EVENTS

On April 3, 2007, the Company agreed to issue approximately 93,720,000 shares of its common stock at a price of \$0.025 per share in private placements to approximately twenty accredited and institutional investors for gross proceeds of approximately \$2,300 subject to adjustment for over allotted orders. Purchasers included our Chief Executive Officer. The private placements were exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended, as transactions not involving a public offering. However, pursuant to the registration rights agreements with the investors the Company is using its best efforts to register the stock. Concurrent with the public offering directors John Wehrle, Nolan Sigal, and Herve de Kergrohan as well as the CEO of the Company were granted 400,000 stock options at a price of \$0.025 per share which vested immediately upon grant. On April 26, 2007 all three board members resigned.

Clearant has received written notice from Rowland W. Day, on behalf of the following investors: (i) the Day Family Trust; (ii) Rowland W. Day II IRA; and (iii) Ron Nash, alleging that certain misrepresentations were made in connection with the Stock Purchase Agreements entered into on April 3, 2007 where Clearant agreed to issue approximately 93,720,000 shares of common stock at a price of \$0.025 per share. Clearant is in discussions with these investors and while no lawsuit has been filed at this time, there is no certainty that the investors will not, in the future, seek, among other things, money damages. If successful, this may negatively impact Clearant s cash flow and significantly impair its ability to operate. Rowland W. Day is a member of the board of directors.

In February, 2007 the Company 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 the Company \$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 the Company s common stock, a first lien on all of the assets of the Company including it s IP, repayment of the \$700 by May 1, 2007, and interest of 10% per annum. On February 20, 2007 the Company received \$200. The \$500 was never funded and neither party entered into a definitive agreement. The Company is currently in discussion with the Bridge Lender as it relates the non-funding of the remaining \$500.

Pursuant to the Company s spinal Supply and Distribution Agreement (Agreement), dated September 27, 2006, in consideration for the exclusive distribution and/or representation in various United States markets, the Company was required to remit a prepayment in the amount of \$1,150 on October 31, 2006. As of December 31, 2006, all tissue orders have not been delivered by the supplier and the payment has not been made by the Company. In February 2007, the Company received notification of termination of the Agreement. The Company is in ongoing discussions with the supplier to resolve the issues, which could include but is not limited to, reduction in exclusive territories or termination. The termination of the Agreement may result in the disruption of the spinal bone implant supply, which would have a material adverse impact to the Company s ability to distribute spinal bone implants treated with the Clearant Process<sup>®</sup>.

F-23

# Item 8. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure None

#### **Item 8A. Controls and Procedures**

#### Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive and financial officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rule 13a-15(e) or Rule 15d-15(e) under the U.S. Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report and, based on his evaluation, our principal executive and financial officer has concluded that these controls and procedures were effective as of December 31, 2006. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and financial officer, as appropriate to allow timely decisions regarding required disclosure.

#### Evaluation of Disclosure Controls and Procedures

We have evaluated, with the participation of our Chief Executive Officer, the effectiveness of our system of disclosure controls and procedures as of the end of the period covered by this report. Based on this evaluation our Chief Executive Officer has determined that our disclosure controls and procedures are effective in timely alerting the disclosure of material information required to be included in this report.

# Management s Report on Internal Control over Financial Reporting

N/A

#### Changes in Internal Control

There has been no change in our internal control over financial reporting during our most recent fiscal year that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **Item 8B. Other Information**

None.

41

#### **PART III**

# Item 9. Directors, Executive Officers, Promoters, Control Persons and Corporate Governance; Compliance with Section 16(a) of the Exchange Act

## 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.

			Director
Name	Age	Position	Since
Alain Delongchamp <sup>1</sup>	48	Chief Executive Officer (Principal	N/A
		Executive Officer) and Director	
Jon Garfield <sup>6</sup>	43	Secretary and Chief Financial Officer	N/A
		(Principal Financial and Accounting	
		Officer)	
John S. Wehrle <sup>2</sup>	54	Chairman of the Board of Directors	N/A
Rowland Day <sup>3</sup>	51	Director	2007
Michael Elek <sup>3</sup>	45	Director	2007
Gaddo Cardini <sup>3</sup>	62	Director	2007
Hervé de Kergrohen <sup>2</sup>	49	Director	N/A
Alexander Man-Kit Ngan <sup>4</sup>	56	Director	N/A
Nolan H. Sigal <sup>2</sup>	57	Director	N/A
Richard A. Anderson <sup>5</sup>	37	Director	N/A

1 Resigned as

Chief Executive

Officer of

Clearant

effective

January 25,

2007. Jon

Garfield has

been appointed

as the Chief

Executive

Officer of

Clearant

effective

January 25,

2007.

2 Resigned as a

member of the

board of

directors of

Clearant

effective

April 26, 2007.

- 3 Appointed as a member of the board of directors of Clearant effective April 5, 2007.
- 4 Resigned as a member of the board of directors of Clearant effective January 16, 2007.
- 5 Resigned as a member of the board of directors of Clearant effective March 6, 2006.
- Appointed Chief
  Executive
  officer of
  Clearant
  effective
  January 25,
  2007 and
  currently serves
  as both Chief
  Executive
  Officer as well
  as the Chief
  Financial
  Officer

Jon Garfield, age 43, was appointed as the Company s Chief Executive Officer, effective January 25, 2007. Mr. Garfield is also the Chief Financial Officer and Secretary of the Company. From 2001 until August 2005, Mr. Garfield served as an independent financial consultant, including Securities and Exchange Commission 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. From 1986 to 1991 Mr. Garfield practiced public accounting with PricewaterhouseCoopers and Arthur Andersen. Mr. Garfield received a Bachelor of Business Administration in Accounting from the University of Texas, Austin.

42

**Rowland W. Day II**, age 51, was appointed to the Company s board of directors on April 5, 2007. Mr. Day has been a corporate lawyer, representing public and private companies for over twenty years. From 2006 to present, Mr. Day has been a sole practitioner. From 2003 to 2006, Mr. Day was a partner of Day and Campbell, LLP. Prior to that time, he was of counsel to Tressler, Soderstrom, Maloney and Priess. Mr. Day serves as a member of the boards of directors of Restaurants on the Run and RE3W Worldwide. He is a member of the State Bar of California. He received a bachelor s degree from California State University, Fullerton, and a J.D. from Whittier Law School.

**Michael Elek**, age 45, was appointed to our board of directors on April 5, 2007. 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.

**Gaddo L.O. Cardini**, age 62, was appointed to the Company s board of directors on April 5, 2007. Mr. Cardini is CEO of Loninton Enterprises, a financial promoter and adviser to banks and industries, and CEO of Heaven Energy, LTD., which sells and buys aircrafts and offers shared ownership to individuals and corporations.

John S. Wehrle, age 54, resigned as Chairman of the board of directors and member of the board of directors of Clearant, Inc. on April 26, 2007 after serving since October 2004. He is also a member of the Company s Audit Committee and Nominating Committee. He is a Managing Partner in Gryphon Investments and a Partner in Acartha Group, LLC. Gryphon Investments is the general partner of Gryphon Holdings, L.P. (1999) and Gryphon Holdings II, LLP (2000), St. Louis-based private equity funds focused on investments in development and market stage applied technology opportunities. Mr. Wehrle is a Director and Chairman of the Audit Committee of CD&L, Inc. (Amex: CDV), a New Jersey-based same day delivery and logistics concern and is a director of several Gryphon Investments investee companies. He was President and Chief Executive Officer of Heartland Capital Partners, L.P., a Dallas-based private equity fund, from 1997 to 1998. Mr. Wehrle served as Managing Director and Head of Mergers and Acquisitions for A.G. Edwards & Sons, Inc., from 1994 to 1997. From 1989 to 1994, he was a Vice President of The Dyson-Kissner-Moran Corporation, a New York-based holding company engaged in the leveraged acquisition and development of portfolio companies. Mr. Wehrle served as a Managing Director of the Chase Manhattan Bank, N.A., from 1986 to 1989 where he led a structured finance group, participating in the majority of LBO transactions financed by Chase Manhattan Bank during this period. He was associated with Touche Ross & Co. (St. Louis) and Price Waterhouse (New York and London) from 1977 to 1986. Mr. Wehrle is a graduate of Washington University in St. Louis and St. Louis University School of Law.

Alain Delongchamp, age 48, has served as Chief Executive Officer of Clearant, Inc., since February 2005 until his resignation in January 2007. Mr Delongchamp served as Chief Operating Officer of Clearant, Inc. from January 2001 to February 2005. From 1996 to January 2001, Mr. Delongchamp held several titles at Aventis Behring most recently Senior Vice President of Commercial Operations, and Vice President, General Manager and Vice President, Global Strategic Marketing. While at Aventis Behring, he was responsible for their \$400 million American Marketing & Sales Division, including developing and implementing long- and short-term product strategies for all therapeutic products. From 1994 to 1996, he served as Senior Director of Marketing at Sanofi Winthrop Pharmaceuticals. Mr. Delongchamp received his B.S. in Pharmacy from University of Montreal. Mr. Delongchamp resigned as Chief Executive Officer of Clearant effective January 25, 2007.

Nolan H. Sigal, M.D., Ph.D., age 57, resigned as a member of the board of directors of Clearant, Inc. on April 26, 2007. Dr. Sigal is President of Trellis Bioscience, Inc., in South San Francisco, CA, a biotechnology company focused on cellular informatics and novel antibody detection technology. From 2000 through 2002, Dr. Sigal served as Executive Vice President, Research and Development, and Chief Scientific Officer at Cytokinetics, Inc. (Nasdaq: CYTK), a biotechnology company. From 1994 to 1999, he served as Senior Vice President, Drug Discovery for Pharmacopeia, Inc. (Nasdaq: PCOP), where he was a founder and Vice President of Biology. From 1984 through 1994, Dr. Sigal held several scientific and management positions with Merck & Co. Inc. (NYSE: MRK), including Executive Director of Immunology Research where he was responsible for the development of novel therapies for autoimmune diseases and allograft rejection. He is the author of over 100 publications and several patents. Dr. Sigal graduated magna cum laude from Princeton University with an A.B., in Chemistry, and received M.D., and Ph.D., degrees from University of Pennsylvania.

43

Hervé de Kergrohen, M.D., age 49, resigned as a member of the board of directors of Clearant, Inc. on April 26, 2007. Dr. de Kergrohen has been a partner with the European venture capital firm CDC Ixis Innovation in Paris since August 2002, and an advisor to several financial institutions, including Lombard Odier Darier Hentsch & Cie, in Geneva, and Global Biomedical Partners, in Zurich. Since 2001, Dr. de Kergrohen has been Chairman of BioData, an international healthcare conference in Geneva. He has served as a Director and member of the audit committee of Hythiam, Inc. (Nasdaq: HYTM) since September 2003. In addition, he sits on several boards of U.S. and European private health care companies, including the Swiss company Kuros BioSurgery and Bioring SA (since 2003), and the French company Exonhit and Entomed (since 2002). From 1999 to 2001, Dr. de Kergrohen was Head Analyst for Darier Hentsch, Geneva and Manager of its CHF 700 million health care fund. From 1997 to 1998, he was the Head Strategist for the international health care sector with UBS Brinson of Chicago, and a Manager of CHF 700 billion for UBS AG, Zurich. Dr. de Kergrohen received his medical degree from Université Louis Pasteur in Strasbourg, France and holds an MBA from Insead, Fontainebleau, France.

Alexander Man-Kit Ngan, age 56, resigned as a member of the board of directors of Clearant, Inc. on January 16, 2007. Mr. Ngan has served as a Director of Singamas Container Holdings, Ltd., (0716.HK), the world second largest manufacturer of containers, since July 2003. From 1993 through May 2002 he was a partner at ChinaVest Limited, a private equity investment firm. From May 1998 to October 2001, Mr. Ngan served as President and CEO of OEM manufacturer Zindart Ltd. (Nasdaq: ZNDT). From 1991 to 1993, he was a financial consultant specializing in taking companies public. From 1990 to 1991, Mr. Ngan served as Head of Private Banking in Asia for Royal Bank of Canada. From 1984 to 1990, he served as a Vice President and Director with Chase Manhattan Bank. From 1973 to 1984, he served with The Chase Manhattan Bank, N.A., HK, Bank of British Columbia (now known as the Hong Kong Bank of Canada), Pemberton Securities Ltd., and Canarim Investments, Ltd. Mr. Ngan received a Bachelor of Mathematics from University of Waterloo in Canada. Mr. Ngan resigned as a member of the board of directors of Clearant effective January 16, 2007.

**Richard A. Anderson**, age 37, resigned as a member of the board of directors of Clearant effective March 6, 2006. *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 material to the evaluation of the ability and integrity of any director, executive officer, promoter or control person of our Company 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 have been filed on a timely basis.

## **Code of Ethics**

We have adopted a Code of Ethics that applies to the Chief Executive Officer, Chief Financial Officer, Controller, and other accounting and financial managers

44

#### **Corporate Governance and Nominating Committee**

The Corporate Governance and Nominating Committee Charter provides for a Corporate Governance and Nominating Committee consisting of at least two independent directors. During the fiscal year 2006, the committee consisted of Dr. Sigal (Chairman) and Mr. Wehrle. Dr. Sigal and Mr. Wehrle were both independent directors as defined in the listing standards for The Nasdaq Stock Market. We do not currently have an operating Corporate Governance and Nominating Committee. We are in the process of identifying and recruiting additional board and committee members. Audit Committee

Our Audit Committee Charter provides for an Audit Committee consisting of at least three financially literate directors all of whom are independent and at least one of whom meets the requirements of an audit committee financial expert. During the fiscal year 2006, the committee consisted of Mr. Wehrle (Chairman), Mr. Ngan and Dr. de Kergrohen. All were independent as defined by the applicable rules, and met the applicable requirements for audit committee members, including Rule 10A-3(b) under the Securities Exchange Act of 1934, as amended, and qualified as an audit committee financial expert as defined by Item 407(d) of Regulation S-B. We do not currently have an operating Audit Committee. We are in the process of identifying and recruiting additional board and committee members. Pursuant to SEC Release No. 33-8220, the entire board of directors will operate as the Audit Committee until such additional committee members are identified and recruited.

The Audit Committee has the sole authority to select, evaluate and if appropriate replace our independent registered public accounting firm, and to pre-approve all auditing and permitted non-auditing services performed by them for us including their fees and other terms.

Management is responsible for the preparation, presentation and integrity of our financial statements, establishing, maintaining and evaluating the effectiveness of internal and disclosure controls and procedures; and evaluating any change in internal control over financial reporting that materially affect, or is reasonably likely to materially affect, internal control over financial reporting. Our independent registered public accounting firm is responsible for performing an independent audit of our consolidated financial statements and expressing an opinion as to their conformity with U.S. generally accepted accounting principles. The Audit Committee s responsibility is to monitor and oversee these processes. Members of the audit committee rely on the information provided to them and on the representations made by management and the independent registered public accounting firm.

In fulfilling its responsibilities, the Audit Committee will meet with management and the independent registered public accounting firm, including sessions at which management is not present, and review and discuss the unaudited financial statements contained in our Quarterly Reports on Form 10-QSB, and the audited financial statements contained in our Annual Reports on Form 10-KSB, prior to their filing with the Securities and Exchange Commission. The Audit Committee will discuss the matters required to be discussed by Statement on Auditing Standards No. 61, Communications with Audit Committees, as currently in effect, including the independent registered public accounting firm s overall evaluations of the quality, not just the acceptability, of our accounting principles, the critical accounting policies and practices used in the preparation of the financial statements, the reasonableness of significant judgments, and such other matters as are required to be discussed with the Committee under generally accepted auditing standards. The Audit Committee will also receive the written disclosures and the letter required by Independence Standards Board Standard No. 1, Independence Discussion with Audit Committees, and review with the independent registered public accounting firm its independence.

The Audit Committee oversees the quality of our financial statements and our financial reporting. Management has the primary responsibility for the financial statements, maintaining appropriate accounting and financial reporting principles and policies and the reporting process, including internal controls and procedures designed to assure compliance with accounting standards and applicable laws and regulations. Singer Lewak Greenbaum & Goldstein LLP, our independent registered public accounting firm, is responsible for expressing opinions on our annual financial statements as of the end of the fiscal year. It is not the duty nor responsibility of the Audit Committee or its members to conduct any type of auditing or accounting review or procedure, and each member of the Audit Committee relies on the integrity of those persons and organizations within and outside Clearant from whom it receives information and the accuracy of the financial and other information provided to the Audit Committee.

45

The members of the Audit Committee during fiscal year 2006 were Messrs. John Wehrle, Herve de Kergrohen and Alexander Man-Kit Ngan. At all times during the fiscal year 2006 the Audit Committee has consisted of three directors each of whom, in the judgment of the Board, is an independent director as defined in the listing standards for The NASDAQ Stock Market. The Board had determined that Mr. Wehrle is the audit committee financial expert as such term is defined in the rules of the SEC. Currently, the board of directors constitutes the Audit Committee. The Audit Committee has discussed and reviewed with the independent auditors all matters required to be discussed under Statement on Auditing Standards No. 61, Communication with Audit Committees, SEC rules and other professional standards. The Audit Committee has received from the independent auditors a formal written statement describing all relationships between the auditors and Clearant that might bear on the auditors independence consistent with Independence Standards Board Standard No. 1, Independence Discussions with Audit Committees, discussed with the independent auditors any relationships that may impact their objectivity and independence, and satisfied itself as to the independent auditors independence.

The Audit Committee has discussed with our independent auditors the overall scope and plans for their respective audits. The Audit Committee has met with the independent auditors, with and without management present, to discuss the results of their audit of our financial statements as of the end of the fiscal year, our internal audits and the overall quality of our financial reporting. Additionally, the Audit Committee has discussed and reviewed with management the audited financial statements as of the end of the fiscal year.

Based on the reviews and discussions referred to above, the Audit Committee recommended that the audited financial statements be included in the Annual Report on Form 10-KSB for the year ended December 31, 2006 for filing with the SEC. The Audit Committee and the board of directors have also recommended ratification of Singer Lewak Greenbaum & Goldstein LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2007.

The aggregate fees billed for professional services rendered for the audit of our annual financial statements as of the end of the fiscal year by Singer Lewak Greenbaum & Goldstein LLP for fiscal year 2006 and for their review of the interim financial statements included in our Forms 10-Q for fiscal year 2006, including accounting consultations on matters addressed during the annual audit and interim reviews, were \$148,468.

### Independent Registered Public Accounting Firm

The firm of Singer Lewak Greenbaum & Goldstein LLP has been appointed to serve as our independent registered public accounting firm for the 2007 fiscal year unless the Audit Committee deems it advisable to make a substitution. We anticipate that representatives of the firm will attend the annual meeting, will have the opportunity to make a statement if they desire, and will be available to respond to appropriate questions.

46

## **Item 10. Executive Compensation**

The following table sets forth the total compensation received by the named executive officer during the fiscal years ended December 31, 2006 and 2005:

#### SUMMARY COMPENSATION TABLE

			Non-EquityNonqualified							
							Incentive	2	All	
Name and				Stock	Opt	tion	Plan	Deferred	Other	
principal		Salary	Bonus	Awards	Aw	ard€	Compensat	i <b>©ø</b> mpensati <b>©</b>	ompensati	on
								Earnings		
position	Year	(\$)	$(\$)^1$	(\$)	(\$	$(5)^2$	(\$)	(\$)	(\$)	Total (\$)
Alain										
Delongchamp,	2006	\$ 350,000	\$	\$	\$	0	\$	\$	\$	\$350,000
Chief Executive										
Officer <sup>3</sup>	2005	\$ 331,244	\$60,000	\$	\$	0	\$	\$	\$	\$391,244
Jon Garfield,	2006	\$ 240,000	\$	\$	\$	0	\$	\$	\$	\$ 240,000
Chief Financial										
Officer <sup>4</sup>	2005	\$ 90,000	\$25,000	\$	\$	0	\$	\$	\$	\$ 115,000

- Bonuses are based on performance. For more information, see Report of the Compensation Committee on Executive Compensation.
- All options were granted under the 2005 Stock Award Plan. The intrinsic value of the options granted to Mr. Delongchamp and Mr. Garfield in 2006 and 2005 is \$0.
- Mr. Delongchamp
  was appointed as
  the Chief
  Executive Officer
  and Director in
  February 2005 and
  resigned in
  January 2007.
  Mr. Delongchamp

was granted 900,000 and 150,000 stock options for the years ended December 31, 2006 and 2005, respectively, for his role as Chief Executive Officer. In connection with his services as a Director, Mr. Delongchamp received \$0.

Mr. Garfield joined Clearant, Inc. as the Chief Financial Officer in August 2005 and was appointed as Chief Executive Officer in January 2007. Mr. Garfield was granted 550,000 and 200,000 stock options for the years ended December 31, 2006 and 2005, respectively, for his role as Chief Financial Officer. Upon appointment as Chief Executive Officer, Mr. Garfield s employment agreement was extended for 3 years. Under the terms on the agreement his salary was increased to \$280,000 to be effective upon the

Company raising capital, no

# Edgar Filing: - Form

adjustment to his salary has been made to date. In addition, in April 2007 Mr. Garfield was granted 400,000 stock options which vested immediately upon grant.

47

# 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, 2006:

# OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

OPTION AWARDS STOCK AWARDS

			Equity Incentive Plan Awards:					Equity Incentive Plan Awards: Number of Unearned
	Underlying Unexercise		Number of Securities Underlying Unexercised	Option	Option	Number of Shares or Units of Stock	Market Value of Shares or Units of Stock	Shares, Units or Other Rights
	Options (#) Exercisable	Options (#) Unexercisable		Exercise	Expiration	That Have	That Have	That Have
	1	2	Options (#)	Price (\$)	Date	Not Vested (#)	Not Vested (\$)	Not Vested (#)
amp <sup>3</sup>	437,500	1,012,500	_	76,000 @ \$0.60;	76,000 @ 7/22/12;			
	50,000	700,000		324,000 @ \$2.80; 150,000 @ \$4.12; 150,000 @ \$1.64; 25,000 @ \$1.12; 725,000 @ \$0.91 200,000 @ \$3.86; 25,000 @ \$1.64; 25,000 @ \$1.12; 500,000 @ \$0.91	324,000 @ 2/1/14; 150,000 @ 7/1/15; 150,000 @ 1/27/16; 25,000 @ 4/14/16; 725,000 @ 5/1/16 200,000 @ 8/30/15; 25,000 @ 1/27/16; 25,000 @ 4/14/16; 500,000 @ 5/1/16			
	that and/oimm exercoption	resents shares are vested or ediately cisable. All on shares wer						

option shares were granted under either the 2000 or 2005 Stock Award Plan.

Represents shares that are unvested

and not immediately

## exercisable.

Mr. Delongchamp was appointed as the Chief Executive Officer and Director in February 2005 and resigned in January 2007. As of May 11, 2007 Mr. Delongchamp has not exercised any of his options and all of his options have expired.

48

# **Compensation Of Directors**

The following table reflects the compensation of directors for our fiscal year ended December 31, 2006:

# 2006 DIRECTOR COMPENSATION

	Non-Equity								
	Fees			Incentive	Non-Qualified	All			
	Earned								
	or	Stock	Option	Plan	Deferred	Other			
	Paid in	Awards	Awards	Compensatio	orCompensationC	Compensatio	n		
					Earnings				
Name	Cash (\$)	(\$)	(\$)	(\$)	(\$)	(\$)	Total (\$)		
John S. Wehrle <sup>1</sup>	\$ 46,000	\$	\$	\$	\$	\$	\$ 46,000		
Nolan H. Sigal <sup>1</sup>	\$ 18,000	\$	\$	\$	\$	\$	\$ 18,000		
Herve de Kergrohen <sup>1</sup>	\$ 20,000	\$	\$	\$	\$	\$	\$ 20,000		
Alexander Man-Kit Ngan <sup>2</sup>	\$ 12,000	\$	\$	\$	\$	\$	\$ 12,000		
Richard A. Anderson <sup>3</sup>	\$ 2,000	\$	\$	\$	\$	\$	\$ 2,000		
Rowland W. Day II <sup>4</sup>	\$ 66,375	\$	\$	\$	\$	\$	\$ 66,375		
Michael Elek <sup>4</sup>	\$	\$	\$	\$	\$	\$	\$		
Gaddo Cardini <sup>4</sup>	\$	\$	\$	\$	\$	\$	\$		

- Resigned as a member of the board of directors of Clearant effective April 26, 2007.
- Resigned as a member of the board of directors of Clearant effective January 16, 2007. As of May 11, 2007 Mr. Ngan has not exercised any of his options and all of his options have expired.
- Resigned as a member of the board of directors of Clearant

effective March 6, 2006.

Appointed as a member of the board of directors of Clearant effective April 5, 2007.

49

# Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters *Equity Compensation Plans*

The following table sets forth information with respect to compensation plans as of December 31, 2006:

# **Equity Compensation Plan Information**

	Number of securities to be issued upon exercise of outstanding options, warrants and	exer out o	ted-average cise price of standing ptions, rants and	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column
	rights		rights	(a))
Plan category	rights (a)		rights (b)	(a)) (c)
Plan category Equity compensation plans approved by security	rights (a)		rights (b)	(a)) (c)
Plan category Equity compensation plans approved by security holders	_		_	
Equity compensation plans approved by security	(a)	]	(b)	(c)
Equity compensation plans approved by security holders	(a)	]	(b)	(c)

50

## 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 common stock as of May 1, 2007:

Name and address of beneficial owner <sup>1</sup> Terren S. Peizer <sup>2</sup>	Amount and nature of beneficial ownership <sup>1</sup> 16,615,441	Percent of class
Rowland W. Day II <sup>3</sup>	8,871,828	6.6%
Gaddo Lensi Orlandi Cardini <sup>4</sup>	4,000,000	3.0%
Jon M. Garfield <sup>5</sup>	2,591,666	1.7%
Nolan H. Sigal <sup>6</sup>	483,333	0%
Hervé de Kergrohen <sup>7</sup>	470,833	0%
John S. Wehrle <sup>8</sup>	433,333	0%
Alain Delongchamp <sup>9</sup>	0	0%
Alexander Man-Kit Ngan <sup>9</sup>	0	0%
Michael Elek <sup>11</sup>	0	0%
All directors and executive officers as a group (4 persons)	15,463,494	11.5%

Applicable percentage ownership is based on 134,642,196 shares of Common Stock outstanding at May 1, 2007. The number of shares of common stock owned are those beneficially owned as determined under the rules of the SEC,

including any shares of common stock as to which a person has sole or shared voting or investment power and any shares of common stock which the person has the right to acquire within sixty (60) days through the exercise of any option, warrant or right. All addresses are c/o Clearant, Inc., 11111 Santa Monica Boulevard, Suite 650, Los Angeles, California 90025, unless otherwise noted.

<sup>2</sup> Includes

524,000 options,

3,886,869

shares by

Bowmore, LLC,

204,572 shares

by Porfidio,

LLC, and

12,000,000

shares to be

delivered to

Advanced

Technology

Holdings, LLC

pursuant to a

share exchange

agreement.

Excludes

250,000 shares

by Reserva

Capital, LLC

previously pledged as security for a loan as to which interest payments have not been made. Mr. Peizer s business address is 11150 Santa Monica Blvd., Suite 1500, Los Angeles, California 90025.

Includes 8,720,000 shares of Common Stock issued with the private placement on April 3, 2007, as well as 151,828 shares previously owned directly by Mr. Day, 3 Imperial Promenade, Suite 960, Santa Ana, CA 92707.

Includes 4,000,000 shares of Common Stock held of record by Loninton Enterprises, Ltd. issued in connection with the private placement on April 3, 2007, directly or indirectly owned by Mr. Cardini, 11111 Santa

Monica Blvd, Suite 650, Los Angeles, CA 90025.

51

- Includes 2,000,000 shares of Common Stock issued in connection with the private placement on April 3, 2007, and outstanding options issued, vested and exercisable within 60 days of May 1, 2007 to purchase an aggregate 591,666 shares of Common Stock.
- Includes outstanding options issued, vested and exercisable within 60 days of May 1, 2007 to purchase an aggregate 483,333 shares of Common Stock. Mr. Sigal resigned from the board of directors, effective April 26, 2007.
- 7 Includes outstanding options issued, vested and exercisable within 60 days of May 1, 2007 to purchase an aggregate 470,833 shares of Common Stock. Mr. de Kergrohen resigned from the board of directors.

effective April 26, 2007.

- Includes outstanding options issued, vested and exercisable within 60 days of May 1, 2007 to purchase an aggregate 433,333 shares of Common Stock. Mr. Wehrle resigned from the board of directors, effective April 26, 2007.
- Mr. Delongchamp resigned as Chief Executive Officer and from the board of directors, effective January 2007.
- Mr. Ngan resigned from the board of directors, effective January 16, 2007.
- 11 Excludes
  6,000,000 shares
  beneficially
  owned by a
  family member of
  Mr. Elek. Mr.
  Elek disclaims
  any controlling or
  beneficial interest
  in such shares.

Unless otherwise indicated, we believe that all persons named in the table have sole voting and investment power with respect to all shares of our common stock beneficially owned by them. A person is deemed to be the beneficial owner of securities which may be acquired by such person within 60 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

## Edgar Filing: - Form

(but not those held by any other person) and which are exercisable, convertible or exchangeable within such 60 day period, have been so exercised, converted or exchanged.

## **Item 12. Certain Relationships and Related Transactions**

## Transactions with Related Persons

Rowland W. Day II, a member of the board of directors of Clearant, and in his capacity as a corporate attorney, rendered legal services to Clearant and its investors during 2007. As of April 26, 2007, the legal fees for which Clearant is responsible for total \$66,375. It is anticipated that these fees will be paid to Mr. Day, or an arrangement for payment will be entered into, prior to the annual meeting.

# Director Independence

After review of all of the relevant transactions or relationships between each director (and his family members) and us, our senior management and our independent registered public accountants, our board of directors has determined that Mr. Wehrle, and Drs. Sigal and de Kergrohen were independent as defined by applicable rules. Due to the recent resignations from and appointments to our board of directors, Mr. Elek is defined as independent by the applicable rules, as of April 2007. There are no family relationships among any of our directors, executive officers or key employees.

52

#### **Item 13: Exhibits**

## No. Description

- 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<sup>(1)</sup>
- 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<sup>(1)</sup>
- 2.3 Merger Agreement and Plan of Merger, dated June 30, 2005, by and between Clearant, Inc. and CI Merger Corporation<sup>(2)</sup>
- 3.1 Certificate of Incorporation Clearant, Inc., a Delaware corporation<sup>(2)</sup>
- 3.2 Bylaws of Clearant, Inc., a Delaware corporation<sup>(2)</sup>
- 4.1 Specimen Common Stock Certificate<sup>(3)</sup>
- 10.1\* 2005 Stock Award Plan (4)
- 10.2 Form of Subscription Agreement<sup>(1)</sup>
- 10.3 Form of Registration Rights Agreement<sup>(1)</sup>
- 10.4 Form of Warrant<sup>(5)</sup>
- 10.5 Securities Purchase Agreement, dated November 7, 2005<sup>(5)</sup>
- 10.6 Registration Rights Agreement, dated November 7, 2005<sup>(5)</sup>
- 10.7 Purchase Agreement, dated April 3, 2007 (6)
- 10.8 Registration Rights Agreement, dated April 3, 2007 (6)
- 14.1 Codes of Ethics<sup>(2)</sup>
- 16.1 Letter from former accountant BDO Seidman, LLP (3)
- 23.1 Consent of Singer Lewak Greenbaum & Goldstein LLP, Independent Registered Accounting Firm
- 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.
- (1) Incorporated by reference to our Current Report on Form 8-K, filed with the SEC on April 4, 2005.
- (2) 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) Incorporated by reference to our Registration Statement on Form S-3, filed with the SEC on November 23, 2005.
  - (4) 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.
- (5) Incorporated by reference to our Current Report on Form 8-K,

filed with the SEC on November 10, 2005.

(6) Incorporated by reference to our Current Report on Form 8-K, filed with the SEC on April 4, 2007.

53

## **Item 14: Principal Accountant Fees and Services**

#### Audit Fee

The following table sets forth the aggregate fees billed to Clearant for the fiscal years ended December 31, 2006 and 2005 by Singer Lewak Greenbaum & Goldstein, LLP:

	Fis	Fiscal Year		Fiscal Year	
		2006		2005	
Audit Fees	\$	141,746	\$	44,815	
Audit-Related Fees	\$	6,722	\$	243,184	
Tax Fees	\$		\$		
All Other Fees	\$		\$	15,724	

Audit-related fees billed during fiscal years 2006 and 2005 were primarily for services provided in connection with the consultations related to compliance with the Sarbanes-Oxley Act of 2002, the filing of corporate documents and quarterly reviews of financial statements. 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 2006, 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 Singer Lewak Greenbaum & Goldstein, 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 auditors. These services may include audit services, audit-related services, tax services and other services. The independent auditors and management are required to periodically report to the Audit Committee regarding the extent of services provided by the independent auditors in accordance with this pre-approval policy.

#### Tax Fees

We paid \$36,197 and \$20,000 for professional services with respect to tax compliance, tax advice, or tax planning to Ernst & Young LLP for the fiscal year ended December 31, 2006 and 2005, respectively.

#### 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, 2006 and 2005 were \$0 and \$15,724, 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 accountant. All of the services rendered to us by Singer Lewak Greenbaum & Goldstein, LLP are pre-approved by the Audit Committee before the engagement of the auditors 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 auditor for the fiscal year, as specifically described in the auditor s engagement letter, such annual pre-approval to be performed by the Audit Committee.

54

## **SIGNATURES**

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this Form 10-KSB 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	Chief Executive Officer, Secretary and	May 17, 2007
Jon Garfield	Chief Financial Officer (Principal Financial and Accounting Officer)	
/s/ ROWLAND DAY	Director	May 17, 2007
Rowland Day		
/s/ MICHAEL ELEK	Director	May 17, 2007
Michael Elek		
Gaddo Cardini	Director	May 17, 2007
	55	
	55	

# **EXHIBIT INDEX**

Exhibit No.	Description
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 <sup>(1)</sup>
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 <sup>(1)</sup>
2.3	Merger Agreement and Plan of Merger, dated June 30, 2005, by and between Clearant, Inc. and CI Merger Corporation <sup>(2)</sup>
3.1	Certificate of Incorporation Clearant, Inc., a Delaware corporation <sup>(2)</sup>
3.2	Bylaws of Clearant, Inc., a Delaware corporation <sup>(2)</sup>
4.1	Specimen Common Stock Certificate <sup>(3)</sup>
10.1*	2005 Stock Award Plan (4)
10.2	Form of Subscription Agreement <sup>(1)</sup>
10.3	Form of Registration Rights Agreement <sup>(1)</sup>
10.4	Form of Warrant <sup>(5)</sup>
10.5	Securities Purchase Agreement, dated November 7, 2005 <sup>(5)</sup>
10.6	Registration Rights Agreement, dated November 7, 2005 <sup>(5)</sup>
10.7	Purchase Agreement, dated April 3, 2007 (6)
10.8	Registration Rights Agreement, dated April 3, 2007 (6)
14.1	Codes of Ethics <sup>(2)</sup>
16.1	Letter from former accountant BDO Seidman, LLP (3)
23.1	Consent of Singer Lewak Greenbaum & Goldstein LLP, Independent Registered Accounting Firm
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.
- (1) Incorporated by reference to our Current Report on Form 8-K, filed with the SEC on April 4, 2005.
- (2) 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) Incorporated by reference to our Registration Statement on Form S-3, filed with the SEC on November 23, 2005.
- (4) 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.
- (5) Incorporated by reference to our Current Report

on Form 8-K, filed with the SEC on November 10, 2005.

(6) Incorporated by reference to our Current Report on Form 8-K, filed with the SEC on April 4, 2007.

56