

CLEARANT INC  
Form 10-K  
March 16, 2006

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 10-K**  
**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)**  
**OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For The Year Ended December 31, 2005**  
**Commission File Number 000-50309**

**Clearant, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation)

**91-2190195**

(I.R.S. Employer Identification Number)

**11111 Santa Monica Boulevard, Suite 650, Los Angeles, California 90025**

(Address of principal executive offices, including zip code)

**(310) 479-4570**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

**Common Stock, par value \$0.0001**

(Title of class)

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

As of June 30, 2005, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$121.9 million based on the \$4.09 closing bid price on OTC Bulletin Board on that date. This amount excludes the value of approximately \$23.6 million shares of common stock directly or indirectly held by the registrant's affiliates.

As of March 1, 2006, there were 39,768,759 shares of registrant's common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's proxy statement for its 2006 annual meeting of stockholders to be held on June 23, 2006 are incorporated by reference into Part III of this Annual Report on Form 10-K.



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**FORM 10-K ANNUAL REPORT**  
**FISCAL YEAR ENDED DECEMBER 31, 2005**

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**PART I**

**Item 1. Business**

**Forward-Looking Statements**

*The forward-looking comments contained in this report 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 following discussion and in the *Risks Factors* set forth below.*

**Overview**

We acquire, develop and market our pathogen inactivation technology, the *Clearant Process*<sup>®</sup>, to producers of biological products such as:

Devitalized musculoskeletal tissue allograft implants (tissue),

Plasma protein therapeutics,

Recombinant protein therapeutics,

Medical devices, and

Blood and blood-related products.

The *Clearant Process*<sup>®</sup> reduces the risk of contamination to biological products by inactivating a broad range of pathogens. The *Clearant Process*<sup>®</sup> is based on exposing a biological product to gamma-irradiation under specialized, proprietary or patented conditions that deliver a predetermined amount of radiation to inactivate a desired level of pathogens, thereby reducing the risk of contamination, while preserving the functionality and integrity of the treated product. The *Clearant Process*<sup>®</sup> is designed to:

Inactivate a broad range of known pathogens irrespective of size, origin or structure,

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

Be used in both intermediate and final stages of production,

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

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

The *Clearant Process*<sup>®</sup> 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*<sup>®</sup> 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*<sup>®</sup>, 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*<sup>®</sup> on tissue used in surgical procedures such as anterior cruciate ligament (ACL) reconstruction, spinal fusion and general orthopedic repair procedures. We are also

focusing on the application of the *Clearant Process*<sup>®</sup> on plasma protein therapeutics, biotechnology recombinant protein products (including biotherapeutics, diagnostics and vaccines), and medical devices. 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 an intermediate to longer-term opportunity.

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To date, we have signed a total of 11 agreements with customers to utilize the *Clearant Process*<sup>®</sup> with their products. Through December 2005, we have signed 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 2005, four licensees have launched tissue products that were treated using the *Clearant Process*<sup>®</sup>. *Clearant Process*<sup>®</sup>-treated tissues produced by our licensees have been implanted by doctors in more than 6,000 patients since January 2004. Additionally, in September 2005, we launched a new sterilization service (the Clearant Sterilization Service) which allows customers to send ready for sterilization tissue to our facility in Chicago to be irradiated under *Clearant Process*<sup>®</sup> conditions by us. To date in 2006, we have signed four such sterilization service agreements with tissue banks. Finally, we continue to work with various other companies at different stages of development with the anticipation that these companies incorporate the *Clearant Process*<sup>®</sup> into their manufacturing process.

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

In addition, Clearant is assessing and implementing opportunities to be a processor representative for certain tissue products of its customers to facilitate market penetration of *Clearant Process*<sup>®</sup>-treated tissues. In February 2006, Clearant ordered approximately \$240,000 of tissues treated with the *Clearant Process*<sup>®</sup>. During the second and third quarters of 2006, Clearant will act as a processor's representative by providing tissue to the marketplace to further demand for tissue treated with the *Clearant Process*<sup>®</sup>. These tissues will be considered inventory of Clearant from the date of receipt until depleted.

**The Merger**

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

**Market Opportunity**

We believe that we are well 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 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 and inappropriate harvesting of cadavers provided to several tissue banks for processing the FDA



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ordered a recall. 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 medical records. Affected tissue had been distributed to New York, Tennessee, Illinois, Iowa and Texas, among other states. As of February 2006, the FDA has determined that at least 761 donors were illegally accessed for tissue. Due to the adverse patient consequences that can result from communicable disease transmission through the use of tissue, U.S. regulatory authorities have called for the development of validated methods for claims of sterilizing tissue. The FDA has an ongoing effort to regulate tissue banks, which resulted in the publication and effectiveness of its current good tissue practices (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 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*<sup>®</sup> 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, Clearant believes the *Clearant Process*<sup>®</sup> can support a validated sterility claim by tissue processors under the GTP regulations.

As validated "sterile" tissues become widely available, Clearant believes that there will be increasing demand by doctors, buying groups, insurance providers and risk managers for the use of only sterile tissue. In addition Clearant believes there may be a shift from the use of autografts (a patient's own tissue) to the use of allografts. 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. *Clearant Process*<sup>®</sup>-treated tissues produced by Clearant licensees have been implanted by doctors in more than 6,000 patients since January 2004.

Clearant currently licenses the *Clearant Process*<sup>®</sup> on a non-exclusive basis to tissue processors and biopharmaceutical companies in return for milestone payments and royalties on end-product sales. Based on early successes with use of the *Clearant Process*<sup>®</sup>, Clearant has begun to earn royalties on a portion of the estimated 2005 \$800 million to \$1 billion U.S. tissue market made up of ligament, tendon and bone allografts. (Sources: Piper Jaffray & Co.) Clearant believes that it will capture a portion of this expanding market. To date we have signed a total of 11 agreements with customers to utilize the *Clearant Process*<sup>®</sup> with their products. Through December 2005, we have signed 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 2005, 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 which allows customers to send ready for sterilization tissue to our facility in Chicago to be irradiated under *Clearant Process*<sup>®</sup> conditions by us. To date in 2006, we have signed four such sterilization service agreements with tissue banks. In addition, Clearant is assessing and implementing opportunities to be a processor representative for certain tissue products of its customers to facilitate market penetration of *Clearant Process*<sup>®</sup>-treated tissues. In February 2006, Clearant ordered approximately \$240,000 of tissues treated with the *Clearant Process*<sup>®</sup>. During the second and third quarters of 2006, Clearant will act as a processor's representative by providing tissue to the marketplace to further demand for tissue treated with the *Clearant Process*<sup>®</sup>. These tissues will be considered inventory of Clearant from the date of receipt until depleted.

Over the past two decades, a number of deadly infections have been transmitted through improperly sterilized tissues, plasma, biological and blood products due to the limitations of traditional pathogen reduction technology. In August 2002, the FDA ordered the tissue bank that supplied the contaminated tissue to recall all of its devitalized human tissue allograft implants from the market because the FDA deemed this tissue bank's product not to be safe for human implant surgery due to contamination concerns. Similarly, in July 2002, another tissue processing company received a warning letter from the FDA because the FDA concluded that the company had distributed bone tissue from a cadaver that tested positive for the *Clostridium* bacteria. The CDC reported to the FDA in July 2002 that it had received reports of 54 cases of tissue-associated infections involving *Clostridium* and other bacteria transmission

through contaminated

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tissue. Additional bacterial infections have been reported by the CDC, including one as recently as December 2003, demonstrating the continued risk of infection from the use of non-sterile tissues.

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

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). Clearant's research and development expenses for the year ended December 31, 2005, 2004 and 2003 were \$2,050,000, \$5,190,000 and \$6,142,000, respectively. During the fourth quarter of 2004 and first quarter of 2005, we reduced our R&D personnel and related expenses due to the limitations in our current cash position and our shift in focus from research and development to the commercialization of the *Clearant Process*<sup>®</sup>. Research and development headcount for the year ended December 31, 2005 and 2004 was 6 and 31 employees, respectively. 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.

**Devitalized Musculoskeletal Tissue Allograft Implants*****The Devitalized Musculoskeletal Tissue Allograft Implant Market***

Clearant believes that it is well 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 infection during which the virus or antibody is not detectable by standard tests), which resulted in the Hepatitis C not being detected during standard donor screening. 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

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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 has 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*<sup>®</sup> significantly reduces the risk of disease transmission through the use of tissues, while maintaining the tissues' integrity and functionality. In addition, Clearant believes the *Clearant Process*<sup>®</sup> can support a validated sterility claim by tissue processors under the GTP regulations.

In addition, Clearant believes 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. *Clearant Process*<sup>®</sup>-treated tissues have been implanted in more than 6,000 patients since January 2004. To date doctors have reported to the company no significant difference between patients receiving *Clearant Process*<sup>®</sup>-treated tissues as compared to those receiving traditional tissues. Furthermore, Clearant is conducting a multi-center clinical study at eight separate facilities across the U.S. The clinical study tracks the post-operative results of patients who received human soft allograft tissue that had been treated with the *Clearant Process*<sup>®</sup>. 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 six-month outcome results of this study, collected as of January 2006, are favorable. The occurrence of complications, stability and strength in the anterior cruciate ligament reconstructions using tissue treated with the *Clearant Process*<sup>®</sup> are comparable to the patients' 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. Clearant has begun to earn royalties on a portion of the estimated 2005 \$800 million to \$1 billion U.S. tissue market, which includes ligament, tendon and bone allografts.

Clearant intends to continue to non-exclusively license its technology to the suppliers of tissue in return for royalties on end-product sales of tissue. In addition, Clearant intends to continue to enter into service agreements for its Sterilization Service with tissue banks. Clearant may also consider other types of licensing or processor representative arrangements as it deems appropriate. The estimated 2005 \$800 million to \$1 billion U.S. tissue market made up of ligament, tendon and bone allografts is expected to grow to an estimated of 15 - 20% per year (Source: Emerging Growth Equities). Clearant anticipates that the number of tissue implants may increase as the market perceives these tissues to be safer due to the GTP regulations and the availability of an effective sterilization technology like the *Clearant Process*<sup>®</sup>.

Beyond the initial allograft 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 sterility.

*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*<sup>®</sup> on tissue products used for surgical implantation. Based on studies conducted by Clearant, 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



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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 licensed commercially to other tissue processors. Unlike the *Clearant Process*<sup>®</sup>, the BioCleanse procedure is not reported to be a terminal pathogen inactivation process. Finally, traditionally higher doses of radiation without the *Clearant Process*<sup>®</sup> could achieve higher levels of sterility but destroy the integrity and functionality of the tissue and therefore have not been commercially used.

***The Clearant Solution for the Tissue Market***

Clearant believes the *Clearant Process*<sup>®</sup> will address a long-standing problem for patients, surgeons and tissue banks without significantly impacting the current processing cycle. With the use of the *Clearant Process*<sup>®</sup>, 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*<sup>®</sup> without being opened. Turnaround time in the irradiation facility is generally a few days.

Alternatively, under 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 facilities 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.

The non *Clearant Process*<sup>®</sup> treated tissues currently used in surgical allograft procedures are not sterilized in the final package, and are processed aseptically often incorporating steps to reduce bioburden. Clearant's preliminary research indicates that when applied to tissue, the *Clearant Process*<sup>®</sup> 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. Clearant believes that the additional level of safety possible through the use of the *Clearant Process*<sup>®</sup> 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*<sup>®</sup>, Clearant supports its customers' efforts by marketing directly to surgeons, scientists and medical professionals, or thought leaders in the industry, and supporting customer sales representatives with data and other marketing support materials. Clearant believes that educating surgeons and patients about the availability of safer tissue will ultimately increase demand for use of products treated with the *Clearant Process*<sup>®</sup>.

Clearant believes 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, are enforced. In fact, one of Clearant's customers has indicated its products treated with the *Clearant Process*<sup>®</sup> are labeled sterile based on a validated claim.

***Commercialization Strategy***

Clearant is currently focusing development and commercialization efforts of the *Clearant Process*<sup>®</sup> on products involving tissue, with a longer-term focus on plasma proteins, recombinant proteins and medical devices. The application of the *Clearant Process*<sup>®</sup> in these markets will generate a two-fold benefit for Clearant: an opportunity to

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generate near-term cash flow from royalties from *Clearant Process*<sup>®</sup>-treated tissue product sales and service fees from the Clearant Sterilization Service agreements, while simultaneously allowing Clearant to validate the *Clearant Process*<sup>®</sup> more broadly and build an extensive intellectual property estate.

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

Ten signed agreements with tissue banks

Six signed license agreements with tissue banks

Four signed sterilization service agreements with tissue banks

Commercial release of *Clearant Process*<sup>®</sup>-treated tissue by four of Clearant s customers to date, with additional tissue bank licensees anticipated to launch products during 2006

The six-month outcome results of Clearant s clinical study, collected as of January 2006, are favorable and the occurrence of complications, stability and strength in the anterior cruciate ligament reconstructions using tissue treated with the *Clearant Process*<sup>®</sup> are comparable to the patient s non-operated contralateral knee

Implantation by surgeons of *Clearant Process*<sup>®</sup>-treated tissue in over 6,000 patients with comparable performance to that of traditionally-processed tissues as reported to the Company by physicians

**Protein Therapeutic Products**

***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 therefore 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, Clearant believes there is currently no commercially available technology to sterilize plasma protein therapeutic products in their final packaging (i.e. terminal sterilization).

Clearant believes that there is a desire 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 could provide a greater margin of safety. 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, Clearant has been successful in applying the *Clearant Process*<sup>®</sup> on a laboratory scale at day zero. Clearant continue to conduct experiments including formulation work to ensure stability of *Clearant Process*<sup>®</sup> treated products after day zero, and anticipate initiation of such work in the second quarter of 2006.

Clearant s strategy is to leverage the technology developed and the intellectual property created with these products to develop the *Clearant Process*<sup>®</sup> as a terminal sterilization technology for recombinant protein products. Worldwide plasma protein derivatives sales were estimated to have been \$6.7 billion in 2003 and are expected to grow to \$7.3 billion in 2006.

***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 therefore 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, Clearant believes there is currently no commercially available technology to sterilize recombinant products in their final packaging (i.e. terminal sterilization).





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Clearant believes, 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 substantially 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, Clearant believes that there are opportunities to utilize its technology to improve and provide solutions for problematic in-process sterilization protocols used in certain recombinant products. Clearant is currently working with a licensee on applying the *Clearant Process*<sup>®</sup> to products that, due to their method of manufacture, are considered to be at higher risk of pathogen transmission.

Clearant's 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*<sup>®</sup> as a terminal sterilization technology for new recombinant protein products. Worldwide end-product sales of biotechnology recombinant products are estimated to have been approximately \$46.6 billion in 2003 and are expected to be approximately \$74.6 billion in 2006, highlighting the need for a terminal sterilization step that can be economically scaled to accommodate this growth with minimal disruption of an existing manufacturing infrastructure. (Source: Ernst & Young 2004 Global Biotechnology Report.)

**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. Clearant's 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 inefficient means of obtaining inactivation of all known types of pathogens.

**Table of Contents*****The Clearant Solution for Protein Therapeutic Products***

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

Based on existing regulatory guidelines for small molecule drugs, which require terminal sterilization whenever possible, Clearant believes 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 Clearant's 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.

**Other Market Opportunities*****The Medical Device Market***

Clearant has generated laboratory scale data supporting the ability to apply the *Clearant Process*<sup>®</sup> to a medical device which incorporates a biologic into such device. Clearant successfully processed and subsequently performed mechanical integrity testing of a development-stage medical device in final packaging through the Clearant Sterilization Service. Clearant expects the device manufacturer to file a marketing authorization for the product with the FDA later this year. Clearant believe that traditional sterilization methods for medical devices will not be appropriate when such device incorporates a biologic because traditional uncontrolled irradiation for medical devices would destroy the integrity of the protein. Further, any filtrated biologic would still need to be aseptically applied to the device where contamination could occur. The application of the *Clearant Process*<sup>®</sup> can be a terminal sterilization step thereby sterilizing both the medical device and biologic in its final packaging. While medical devices are not areas of 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 Clearant.

**Regulatory Strategy**

Commercial products manufactured incorporating the *Clearant Process*<sup>®</sup> 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 Clearant's customers whose products incorporate the *Clearant Process*<sup>®</sup> 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 Clearant's commercialization strategy to demonstrate the efficacy of the *Clearant Process*<sup>®</sup>

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Clearant expects that the *Clearant Process*<sup>®</sup> itself will not 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*<sup>®</sup> 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*<sup>®</sup> into their products manufacturing processes. Incorporation of the *Clearant Process*<sup>®</sup> 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*<sup>®</sup> does not require regulatory approval 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 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*<sup>®</sup> into their own products will be 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*<sup>®</sup>. 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*<sup>®</sup> 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*<sup>®</sup>-treated products 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 estate to protect our position in the market.

Clearant has a total of 112 issued or pending patents. We currently have eleven issued U.S. patents, which will expire between 2013 and 2023, and twenty-five foreign patents protecting our technology. From 2000 through 2005, we expanded our intellectual property portfolio and currently have approximately twenty pending U.S. patent applications, three pending Patent Cooperation Treaty (PCT) patent applications, and fifty-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*<sup>®</sup> to particular products.

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

In 2001, we licensed, with the right to sub-license, 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*<sup>®</sup> 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 only one business segment, licensing of the *Clearant Process*<sup>®</sup>, which generated 100% of our revenues for the year ended December 31, 2005. In the future, we anticipate that we will generate revenue from the fees we collect with our sterilization service. In addition, Clearant is assessing and implementing opportunities to be a processor representative for certain tissue products of its customers to facilitate market penetration of *Clearant Process*<sup>®</sup> -treated tissues. In February 2006, Clearant ordered approximately \$240,000 of tissues treated with the *Clearant Process*<sup>®</sup>. During the second and third quarters of 2006, Clearant will act as a processor's representative by providing tissue to the marketplace to further demand for tissue treated with the *Clearant Process*<sup>®</sup>. These tissues will be considered inventory of Clearant from the date of receipt until depleted.

### **Employees**

As of December 31, 2005, we had approximately 30 full-time employees.

### **Executive Officers**

There are no family relationships among any of our directors, executive officers or key employees. We consider Alain Delongchamp and Jon Garfield to be our executive officers.

### **Code of Ethics**

We have adopted a Code of Conduct and Ethics that applies to all company directors, officers and employees. We have also adopted a Code of Ethics for CEO and Senior Financial Officers that applies to our chief executive officer and senior financial officers, including our principal financial officer and principal accounting officer.

### **Available Information**

We make our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K, and all amendments to these reports available free of charge on our corporate website as soon as reasonably practicable after such reports are filed with, or furnished to, the SEC. Our corporate website is located at [www.Clearant.com](http://www.Clearant.com). The information contained on our website is not part of this report or incorporated by reference herein.

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

You should carefully consider and evaluate all of the information in this report, including the risk factors listed below. 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.

**Table of Contents*****Risks Related to Our Business******Our limited operating history may make it difficult to evaluate our business to date and 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*<sup>®</sup>. We are in the early stage of operations and development, and have only a limited operating history on which to base an evaluation of our business 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, 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 be able to successfully develop our products and penetrate our target markets. Further, it is likely that significant losses will be incurred through at least the end of the year and possibly beyond, as we incur significant expenses associated with the further development, marketing and commercialization of the *Clearant Process*<sup>®</sup>. Our current cash burn rate is approximately \$0.7-\$1.2 million per month. If we do not raise any additional funds, our revenues do not meet expectations and we do not reduce our expenses, our cash reserves will be exhausted at approximately the end of 2006, and we will be required to seek additional funds.

***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<sup>®</sup> and sterilization services 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 at least the end of 2006 and possibly beyond.

Our ability to achieve meaningful near-term revenues is heavily dependent on meeting our current development schedule for proving the efficacy of the *Clearant Process*<sup>®</sup> in the tissue market and the successful licensing of such technology or providing sterilization services to third party tissue processors. 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*<sup>®</sup> in other markets. We may not successfully prove the efficacy of our pathogen inactivation processes for specific products according to our current development schedule, if at all.

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

***The Clearant Process<sup>®</sup> 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<sup>®</sup> 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*<sup>®</sup> in tissue;

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

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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*<sup>®</sup> for our target markets; and

Obtain (or have the users of the *Clearant Process*<sup>®</sup> obtain) required product regulatory approvals.

Research and development and commercialization efforts may not be successful or, if they are, the *Clearant Process*<sup>®</sup> 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 tracks the post-operative results of patients who received tissue that had been treated with the *Clearant Process*<sup>®</sup>. 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 six-month outcome results of this study, collected as of January 2006, are favorable. The occurrence of complications, stability and strength in the anterior cruciate ligament reconstructions using tissue treated with the *Clearant Process*<sup>®</sup> are comparable to the patient's non-operated contralateral 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*<sup>®</sup> and our revenues.

***Achieving market acceptance for the Clearant Process<sup>®</sup> will depend on our ability to demonstrate the efficacy of the Clearant Process<sup>®</sup> in our target markets, as well as how the Food and Drug Administration applies the Good Tissue Practice guidelines issued on November 18, 2004 and became effective on May 25, 2005.***

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*<sup>®</sup> in our target markets, on its willingness of potential users of the *Clearant Process*<sup>®</sup> to adopt the *Clearant Process*<sup>®</sup> and on the willingness of doctors and patients to utilize *Clearant Process*<sup>®</sup>-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*<sup>®</sup> 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 and became effective on May 25, 2005 are applied to tissue processors. The requirements may not provide sufficient incentive for tissue processors to adopt technologies that can provide validation for sterility label claims, the *Clearant Process*<sup>®</sup> 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*<sup>®</sup> for our target markets. We also collaborate with scientists and physicians at academic and other institutions, but these scientists and physicians may have other





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

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

***We 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. Clearant is currently conducting a multi-center clinical study at eight separate facilities across the U.S. The clinical study tracks the post-operative results of patients who received tissue that had been treated with the *Clearant Process®*. Study evaluations include failure rate, range of motions, and joint effusion (swelling) among other metrics which had been previously established by the clinical study committee prior to the start of the study. The six-month outcome results of this study, collected as of January 2006, are favorable. 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,



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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*<sup>®</sup> 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*<sup>®</sup> 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*<sup>®</sup>. If research and testing are not successful, the *Clearant Process*<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>.***

The *Clearant Process*<sup>®</sup> 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*<sup>®</sup> economically on a commercial scale for products other than those in which the *Clearant Process*<sup>®</sup> currently is being used. As part of commercialization of the *Clearant Process*<sup>®</sup>, we transfer the *Clearant Process*<sup>®</sup> 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*<sup>®</sup> conditions by us, however, to date only a very limited amount of such services have been provided. Under both a license agreement or sterilization service agreement the *Clearant Process*<sup>®</sup> 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*<sup>®</sup> 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*<sup>®</sup> 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*<sup>®</sup>, 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*<sup>®</sup> 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*<sup>®</sup> 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*<sup>®</sup> 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

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misappropriation of the *Clearant Process*<sup>®</sup> 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 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>.

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<sup>®</sup> 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

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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*<sup>®</sup> 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*<sup>®</sup>, delay, impede or otherwise reduce the licensing and use of the *Clearant Process*<sup>®</sup> by third parties and materially adversely affect our business, results of operation and financial condition.

In addition, successful product liability claims made against competitors could cause a perception that we are also vulnerable to similar claims and could negatively affect public perception of the technology and thus third parties' willingness to use the *Clearant Process*<sup>®</sup>, 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*<sup>®</sup> effectively will depend on the safety, efficacy and cost-effectiveness of the *Clearant Process*<sup>®</sup>, as well as the willingness of manufacturers of biological products to adopt new pathogen inactivation technologies. We believe that market acceptance will depend on the extent to which manufacturers and distributors of tissues and other biological products, as well as physicians, patients and health care payers, perceive the benefits of using the *Clearant Process*<sup>®</sup> and, if applicable, that such benefits outweigh any potential additional cost. As part of its strategy to obtain wide-spread acceptance of the *Clearant Process*<sup>®</sup>, we have entered into, and intend to continue to seek to enter into, sponsored research agreements with potential users of the *Clearant Process*<sup>®</sup> to support research on and validation of potential applications of the *Clearant Process*<sup>®</sup> to such products. While we expect that the *Clearant Process*<sup>®</sup>, when optimized for application to a particular product, will be capable of inactivating a broad range of known types of pathogenic microorganisms, a product processor or manufacturer may direct us, or may choose, not to optimize the *Clearant Process*<sup>®</sup> to inactivate the broad range of known types of pathogenic microorganisms in a particular application. If a product produced with such a process results in infections from pathogens that were not adequately inactivated, the marketplace's overall confidence in the *Clearant Process*<sup>®</sup> may be adversely affected both for that product and for other applications of the *Clearant Process*<sup>®</sup>.

Even if our processes and the third party products on which they will be used receive the necessary regulatory approvals, our processes may not achieve any significant degree of market acceptance among biological product manufacturers, physicians, patients and health care payers. For various reasons, such as implementation costs, ineffectiveness against all types of pathogens, differing regulatory requirements and logistical concerns, the biological products industry has not always integrated new inactivation technologies into their processes. Although we believe the *Clearant Process*<sup>®</sup> can significantly improve the safety of tissues and other biological products, we cannot provide

assurances that our technologies will be accepted rapidly or, other than in the tissue market, at all. If our processes fail to



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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.***

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 BioCleanse™ used by Regeneration Technologies, Inc.). Some of these technologies may have more animal and clinical data than we do to support the efficacy of their processes. There are currently no regulatory requirements that establish specific pathogen inactivation or sterility requirements for these products. If tissue processors choose to maintain their current processing methods or elect to adopt technologies other than the *Clearant Process®*, 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., Inactine™, riboflavin, psoralens), and applications of radiation other than the *Clearant Process®* (e.g., broad spectrum visible light, ultraviolet light and high energy electrons). If any of these technologies is successfully developed, it could have an adverse effect on our business, financial condition and results of operations.

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

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

Even though we do not receive payments directly from third-party health care payors, their reimbursement methods and policies impact demand 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



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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*<sup>®</sup> treated tissue could have a material adverse effect on Clearant. Significant uncertainty exists as to the reimbursement status of newly introduced health care products and services and there can be no assurance that adequate third-party coverage will be available for us to maintain price levels sufficient for realization of an appropriate return on our investment in developing new products.

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

***Risks Related To Our Industry***

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

The use of the *Clearant Process*<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>.***

New, planned and future third-party products which could utilize the *Clearant Process*<sup>®</sup> and anticipated future uses that result from the *Clearant Process*<sup>®</sup> 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*<sup>®</sup> 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*<sup>®</sup> 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*<sup>®</sup>, which would adversely affect our ability to generate licensing revenues and thus adversely affect our business, financial condition and results of operations.

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

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

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

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*<sup>®</sup>. Products enabled by or utilizing the *Clearant Process*<sup>®</sup> may not meet new regulations and use of the *Clearant Process*<sup>®</sup> 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*<sup>®</sup> 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*<sup>®</sup>, 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>.



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***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.



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

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

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

***Potential users of the Clearant Process<sup>®</sup> 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*<sup>®</sup> 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*<sup>®</sup> 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*<sup>®</sup> 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 Clearant's 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<sup>®</sup> 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.



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

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

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

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

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

difficulties in integrating operations, technologies, services and personnel;

diversion of financial and managerial resources from existing operations;

risk of entering new markets;

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 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. 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.***

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The sale of shares by our stockholders may significantly affect the market price of our stock. In December 2005, Clearant effected two registration statements for two groups of selling stockholders of the Company covering 3,693,334 shares (excluding shares underlying warrants) and 3,774,465 (excluding shares underlying warrants), respectively. Collectively, these two registration statements represent approximately 18.8% of our 39,758,550 shares of common stock outstanding as of January 23, 2006. Because the shares were registered on behalf of the selling stockholders, we have no control over which of the selling stockholders will actually sell all or any portion of their shares, or at what price.

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.

***We may need additional financing to fund our business.***

We may 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.

***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.

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

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

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***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.

**CAUTIONARY STATEMENT CONCERNING FORWARD LOOKING INFORMATION**

This prospectus contains forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to the financial condition, results of operations, business strategies, operating efficiencies or synergies, competitive positions, growth opportunities for existing products, plans and objectives of management, markets for stock of Clearant and other matters. Statements in this prospectus that are not historical facts are hereby identified as forward looking statements for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. Such forward looking statements, including, without limitation, those relating to the future business prospects, revenues and income of Clearant, wherever they occur, are necessarily estimates reflecting the best judgment of the senior management of Clearant on the date on which they were made, or if no date is stated, as of the date of this prospectus. These forward looking statements are subject to risks, uncertainties and assumptions, including those described in the section entitled Risk Factors, beginning on page 12 that may affect the operations, performance, development and results of our business. Because the factors discussed in this prospectus could cause actual results or outcomes to differ materially from those expressed in any forward looking statements made by us or on our behalf, you should not place undue reliance on any such forward looking statements. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward looking statements.

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

general economic conditions,

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

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

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

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

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



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

**Item 1B. Unresolved Staff Comments**

None

**Item 2. Properties**

Our principal executive offices, including all of our sales, marketing and administrative functions, are located in approximately 4,600 square feet of office space at 11111 Santa Monica Boulevard, Suite 650, in Los Angeles, California, under a lease which expires on January 31, 2007. We pay approximately \$12,000 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, 2007. We pay \$1,700 per month. We are currently consolidating our facility in Gaithersburg, Maryland and our office in Los Angeles, California and we are exploring the option to relocate within 20 miles of our current Los Angeles facility.

We believe that the current leased space, with the addition of the lease under negotiations, 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.

**Item 3. Legal Proceedings**

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. 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, except for an arbitration action filed by a former employee for alleged breach of contract and recovery of benefits. In January 2006, the parties executed a settlement agreement thereby resolving the matter for full and final settlement of all claims under terms which remain confidential. Under the settlement agreement, we agree to pay \$212,000 in four equal payments which was fully accrued for as of December 31, 2005.

**Item 4. Submission Of Matters To A Vote Of Security Holders**

Not applicable.

**Table of Contents****PART II****Item 5. Market For Registrant's Common Equity And Related Stockholder Matters**

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 OTCBB, for the respective periods.

	<b>High</b>	<b>Low</b>
<b>Fiscal year ended December 31, 2004</b>		
First quarter	\$	\$
Second quarter		
Third quarter <sup>(1)</sup>		
Fourth quarter	0.23	0.14
<b>Fiscal year ended December 31, 2005</b>		
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

(1) We have no information concerning any trades reported on the OTC Bulletin Board prior to October 15, 2004. All listed share prices are post-split adjusted for an 8.67 for one stock split effective February 22, 2005.

(2) Clearant, Inc. merged with the registrant on March 31, 2005.

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.

As of January 23, 2006, there were approximately 190 holders of record representing approximately 6,300 beneficial owners of our common stock.

We have never declared or paid any dividends. We may, as our board of directors deems appropriate, continue to retain all earnings for use in our business or may consider paying dividends in the future.



**Table of Contents****Item 6. Selected Financial Data**

The following table sets forth selected financial data that is qualified by reference to, and should be read in conjunction with, Item 7. Management's Discussion and Analysis of Results of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data included elsewhere in this report.

<b>Statement of Operations Data:</b> <b>(In thousands, except per share data)</b>	Fiscal Year Ended December 31,				
	2005	2004	2003	2002	2001
Total revenues	541	1,006	408	108	123
Cost of sales	17	33	26	35	
Gross margin	524	973	382	73	123
Total operating expenses	11,643	14,935	12,831	11,188	6,764
Loss from operations	(11,119)	(13,962)	(12,449)	(11,115)	(6,641)
Other (expense) income, net	(471)	(867)	(254)	613	(92)
Net loss	(11,590)	(14,829)	(12,703)	(10,502)	(6,733)
Add: Preferred stock dividend and financing costs	(2,161)	(1,628)	(1,526)		
Net loss attributable to common stock	\$ (13,751)	\$ (16,457)	\$ (14,229)	\$ (10,502)	\$ (6,733)
Net loss per share Basic and diluted	\$ (0.47)	\$ (2.23)	\$ (1.93)	\$ (1.43)	\$ (0.95)
Number of shares Basic and diluted	29,498	7,370	7,369	7,368	7,052

**Balance Sheet Data:****(In thousands)**

Cash and cash equivalents	\$ 10,141	\$ 177	\$ 1,174	\$ 5,176	\$ 9,091
Working capital	7,620	(9,277)	2,738	(1,895)	6,905
Total assets	12,792	3,078	7,645	7,420	11,304
Stockholders' Equity (Deficit)	9,612	(24,995)	(11,167)	(14,614)	(2,900)
Long-term obligations and redeemable preferred stock	66	18,141	17,030	16,298	13,647

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations****Forward-Looking Statements**

*The forward-looking comments contained in the following 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 following discussion, as well as under the Risks Factors heading in Item 1. Business, above.*

**Overview**

We acquire, develop and market our pathogen inactivation technology, the *Clearant Process*<sup>®</sup>, to producers of biological products such as:

Devitalized musculoskeletal tissue allograft implants (tissue),

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Plasma protein therapeutics

Recombinant protein therapeutics,

Medical devices, and

Blood and blood-related products.

**The Merger**

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

**Our Business**

We develop and market a proprietary pathogen inactivation technology that reduces the risk of contamination to biological products by inactivating a broad range of pathogens. The *Clearant Process*<sup>®</sup> is based on exposing a biological product to gamma-irradiation under specialized, proprietary or patented conditions that deliver a predetermined amount of radiation to inactivate a desired level of pathogens, thereby reducing the risk of contamination, while preserving the functionality and integrity of the treated product. The *Clearant Process*<sup>®</sup> is designed to:

Inactivate a broad range of known pathogens irrespective of size, origin or structure,

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

Be used in both intermediate and final stages of production,

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

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

The *Clearant Process*<sup>®</sup> 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*<sup>®</sup> does not require the use of toxic chemicals. The advantage of gamma irradiation over currently available pathogen reduction 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*<sup>®</sup>, it was not possible to apply gamma radiation on biological products because the necessary 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*<sup>®</sup> on tissue used in surgical procedures such as anterior cruciate ligament (ACL) reconstruction, spinal fusion and general orthopedic repair procedures. We are also focusing on the application of the *Clearant Process*<sup>®</sup> on biotechnology recombinant protein products (including biotherapeutics, diagnostics and vaccines), plasma protein therapeutics and medical devices. We believe that the tissue market represents a continuing source of near-term product revenue and that the medical devices market, the

technology

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recombinant protein market and the plasma protein therapeutic market present an intermediate to longer-term opportunity.

To date, we have signed a total of 11 agreements with customers to utilize the *Clearant Process*<sup>®</sup> with their products. Through December 2005, we have signed 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 2005, four licensees have launched tissue products that were treated using the *Clearant Process*<sup>®</sup>. *Clearant Process*<sup>®</sup>-treated tissues produced by our licensees have been implanted by doctors in more than 6,000 patients since January 2004. 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*<sup>®</sup> conditions by us. To date in 2006, we have signed four such sterilization service agreements with tissue banks. Finally, we continue to work with various other companies at different stages of development with the anticipation that these companies incorporate the *Clearant Process*<sup>®</sup> into their manufacturing process.

Ten signed agreements with tissue banks.

Six signed license agreements with tissue banks.

Four signed sterilization service agreements with tissue banks.

One signed license agreement with a recombinant manufacturer.

In addition, we are assessing and implementing opportunities to be a processor representative for certain tissue products of our customers in order to facilitate market penetration of *Clearant Process*<sup>®</sup>-treated tissues. In February 2006, Clearant ordered approximately \$240,000 of tissues that will be treated with the *Clearant Process*<sup>®</sup>. During the second and third quarters of 2006, Clearant will act as a processor's representative by providing tissue to the marketplace to further demand for tissue treated with the *Clearant Process*<sup>®</sup>. These tissues will be considered inventory of Clearant from the date of receipt until depleted.

**Our Offices**

We are incorporated under the laws of the State of Delaware. Our principal executive offices are located at 11111 Santa Monica Boulevard, Suite 650, Los Angeles, California 90025, and our telephone number is (310) 479-4570.

**Results of Operations 2005 Compared to 2004*****Revenues***

Our total revenue decreased by \$465,000 or 46%, to \$541,000 for the year ended December 31, 2005, from \$1,006,000 for the year ended December 31, 2004. By contrast, revenues from licensing activities increased \$94,000 or 78%, to \$215,000 for the year ended December 31, 2005, from \$121,000 for the year ended December 31, 2004, as a result of greater implementation of the *Clearant Process*<sup>®</sup> into our customers' manufacturing processes and greater market acceptance of human tissue treated with the *Clearant Process*<sup>®</sup>. We expect licensing revenue to continue to increase as market acceptance of the *Clearant Process*<sup>®</sup> becomes greater and more of our licensees commercialize our technology. Revenues from contract research and milestones decreased \$384,000 or 62% to \$231,000 for the year ended December 31, 2005, from \$615,000 for the year ended December 31, 2004. The decrease is primarily related to non-recurring contract milestone payments and contract research completed during 2004. Grant revenue decreased by \$175,000 or 65%, to \$95,000 for the year ended December 31, 2005 from \$270,000 for the year ended December 31, 2004, as a result of the completion of a majority of our grant research projects in 2005. During 2005 we changed our emphasis from one-time, generally non-recurring research and grant revenue to obtaining license and sterilization service customers. We expect to continue this strategy and expect contract research and grant revenue to continue to decrease. We expect these license, sterilization and other revenue streams to be more characteristic of recurring revenue. In addition, we expect that the costs associated with sales through sterilization service to increase as the use of our sterilization service increases. In addition, we have ordered approximately \$240,000 of tissues that will be treated with the *Clearant Process*<sup>®</sup>. During the second and third quarters of 2006, Clearant will act as a processor's representative by providing tissue to the marketplace to further demand for tissue treated with the *Clearant Process*<sup>®</sup>. We may decide to acquire or act as a processor's representative by providing tissue to the marketplace of additional tissues that will be treated with the *Clearant Process*<sup>®</sup>.



**Table of Contents*****Sales, General and Administrative Expenses***

Sales, general and administrative expenses decreased by \$433,000 or 5%, to \$8,967,000 for the year ended December 31, 2005, from \$9,400,000 for the year ended December 31, 2004. The decrease was principally due to a \$755,000 decrease in public relations and advertising expenses, \$369,000 in decreased financing-related expenses and approximately \$270,000 in decreased patent-related costs, as compared to the same period last year. This decrease was partially offset by facility closing charges of \$305,000 associated with severance costs in conjunction with the relocation of the Maryland lab to Los Angeles. Additionally professional fees, such as accounting and investor relations expenses, increased \$817,000. We expect our sales, general and administrative expenses to increase gradually as we increase our efforts in the commercialization of the *Clearant Process*® through an increase in the sales force and market coverage. The timing of the increased sales expenses will be affected by the effort required to act as a processor's representative by providing tissue to the marketplace for such the tissues or future tissue orders (if any) among other factors.

***Research and Development Expenses***

Research and development expenses decreased by \$3,140,000 or 61%, to \$2,050,000 for the year ended December 31, 2005, from \$5,190,000 for the year ended December 31, 2004. This decrease was largely a result of reduced research and development personnel-related costs of \$1,948,000, research materials of \$598,000 and rent costs of \$353,000 during 2005 compared to 2004. During the fourth quarter of 2004 and first quarter of 2005, we reduced our R&D personnel and related expenses due to the limitations in our current cash position and our shift in focus from research and development to the commercialization of the *Clearant Process*®. Research and development headcount for the year ended December 31, 2005 and 2004 was 6 and 31 employees, respectively. 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.

***Stock-based Compensation***

Stock-based compensation increased by \$281,000 or 81% to \$626,000 for the year ended December 31, 2005, from \$345,000 for the year ended December 31, 2004. The increase is related to the issuance of common stock to non-employees for services rendered in 2005. From time to time, we may issue common stock to consultants for services rendered.

***Net Interest Expense***

Net interest expense increased by \$935,000 or 108% to \$1,802,000 for the year ended December 31, 2005, from \$867,000 for the year ended December 31, 2004. This increase 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. We do not expect to incur this bridge loan expense in 2006 and expect interest expense to significantly decrease. In addition, we have \$10,141,000 cash on hand as of December 31, 2005, which we are currently investing in short term conservative money market funds. We expect to earn interest income in 2006, although this amount will decrease as the cash is depleted.

***Preferred Stock Dividend and Financing Costs***

Preferred stock dividend and financing costs increased by \$533,000 or 33%, to \$2,161,000 for the year ended December 31, 2005, from \$1,628,000 for the year ended December 31, 2004. The increase was principally due to the conversion of preferred stock in conjunction with the reverse merger transaction during 2005. As of December 31, 2005, there were no shares of preferred stock outstanding.

**Results of Operations 2004 Compared to 2003*****Revenues***

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Our total revenue increased by \$598,000 or 147%, to \$1,006,000 for the year ended December 31, 2004, from \$408,000 for the year ended December 31, 2003. Revenues from licensing activities increased to \$121,000 for the year ended December 31, 2004, from \$0 for the year ended December 31, 2003, as a result of the introduction and subsequent sales of human tissue treated with the *Clearant Process*®. We expect licensing revenue to continue to increase as market acceptance of the *Clearant Process*® becomes greater and more of our licensees commercialize our technology. Revenues from contract research and milestones increased \$365,000 or 146% to \$615,000 for the year ended December 31, 2004, from \$250,000 for the year ended December 31, 2003. The increase is primarily related to non-recurring milestones reached during the year ended December 31, 2004. Grant revenue increased by \$112,000 or 71%, to \$270,000 for the year ended December 31, 2004 from \$158,000 for the year ended December 31, 2003, as a result of new grants obtained in 2004. We expect contract research and grant revenue to decrease as our customers move towards licensing activities.

***Sales, General and Administrative Expenses***

Sales, general and administrative expenses increased by \$2,803,000 or 42%, to \$9,400,000 for the year ended December 31, 2004, from \$6,597,000 for the year ended December 31, 2003. The increase was principally due to a \$717,000 increase in marketing and advertising expenses as our efforts related to the commercialization and creating market awareness of the *Clearant Process*® increased. Additionally, professional fees such as outside legal and accounting expenses, increased by approximately \$1,235,000, along with approximately \$409,000 in increased salary-related expenses and approximately \$275,000 in increased amortization expenses related to the filing of additional patents, as compared to the same period last year. We expect our sales, general and administrative expenses to increase gradually as we increase our efforts in the commercialization of the *Clearant Process*® through an increase in the sales force and market coverage.

***Research and Development Expenses***

Research and development expenses decreased by \$952,000 or 16%, to \$5,190,000 for the year ended December 31, 2004, from \$6,142,000 for the year ended December 31, 2003. This decrease was largely a result of reduced research and development personnel-related and rent costs during 2004 compared to 2003. Throughout the latter part of 2004, we reduced our R&D personnel and related expenses due to the limitations in our current cash position. We anticipate we will continue to incur research and development costs, but at a reduced rate.

***Stock-based Compensation***

Stock-based compensation increased by \$253,000 or 275% to \$345,000 for the year ended December 31, 2004, from \$92,000 for the year ended December 31, 2003. The increase is primarily related to the exchange of warrants granted to an April 2004 bridge loan holder in connection with such holders additional participation in future bridge loans in October 2004. From time to time, we may issue common stock to consultants for services rendered.

***Net Interest Expense***

Net interest expense increased by \$613,000 or 241% to \$867,000 for the year ended December 31, 2004, from \$254,000 for the year ended December 31, 2003. This increase was primarily the result of the issuance of additional bridge loans and increased average debt balance during 2004.

***Preferred Stock Dividend and Financing Costs***

Preferred stock dividend and financing costs increased by \$102,000 or 7%, to \$1,628,000 for the year ended December 31, 2004, from \$1,526,000 for the year ended December 31, 2003. The increase was principally due to the issuance of additional preferred warrants in September 2004 with a fair value of approximately \$43,000 as of December 31, 2004. As of December 31, 2004 there were approximately 13,121,000 shares of preferred stock outstanding.

**Liquidity and Capital Resources**

Net cash used in operating activities was \$11,829,000 for the year ended December 31, 2005, compared to \$10,237,000 for the year ended December 31, 2004. During 2005, cash used by operations resulted in a \$11,590,000 net

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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.

Net cash used in operating activities was \$10,237,000 for the year ended December 31, 2004, compared to \$11,384,000 for the year ended December 31, 2003. During the year ended December 31, 2004, cash used by operations resulted in a \$14,829,000 net loss offset by a \$2,562,000 increase in accounts payable and accrued liabilities, which was related to unpaid wages as of December 31, 2004 and increased 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, 2004, included depreciation and amortization expense of \$694,000, non-cash charges of \$345,000 for stock-based compensation, and non cash interest expense of \$862,000.

Our net cash used in investing activities was \$236,000 for the year ended December 31, 2005 compared to net cash provided by investing activities of \$2,845,000 for the year ended December 31, 2004. During 2005, our investing activities consisted primarily of increasing our intellectual property portfolio and capital expenditures. Comparatively to 2004, we did not invest money in interest-bearing accounts but utilized cash to fund our operations and did not recognize any return on investments.

Our net cash provided by investing activities was \$2,845,000 for the year ended December 31, 2004 compared to net cash used in investing activities of \$4,238,000 for the year ended December 31, 2003. Our investing activities consisted primarily of intellectual property expenditures and investment purchases of and proceeds from marketable securities. During the year ended December 31, 2004, we received \$3,500,000 in proceeds from the disposal of marketable securities, partially offset by our investment in intellectual property of \$599,000.

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 \$22,042,000 for the year ended December 31, 2005, compared to \$6,411,000 for the year ended December 31, 2004. 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 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 \$6,411,000 for the year ended December 31, 2004, compared to \$11,644,000 for the year ended December 31, 2003. Cash provided by financing activities for the year ended December 31, 2004 consisted primarily of \$6,348,000 in net proceeds from issuance of bridge loans, leaving a balance of approximately \$177,000 in cash and cash equivalents at December 31, 2004.

We have been unprofitable since our inception and we expect to incur additional operating losses through at least the end of 2006 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, 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 2006.

Based upon our current plans, we believe that our existing capital resources will be sufficient to meet our operating expenses and capital requirements through at least the end of 2006. However, changes in our business





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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.

**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, 2005 are as follows (\$ in 000 s):

		Less than			More than
Contractual Obligations	Total	1 year	1 - 3 years	3 - 5 years	5 years
Lease obligations	\$ 407	\$ 341	\$ 64	\$ 2	\$
Other obligations facility closing	298	298			
	\$ 705	\$ 639	\$ 64	\$ 2	\$

**Off-Balance Sheet Arrangements**

Except for operating lease commitments disclosed above, as of December 31, 2005, 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 licensing fees, performance milestones and contract research activities, with additional revenues generated from government grants.

We license the *Clearant Process*<sup>®</sup> to third parties who intend to incorporate our technology into their product and manufacturing processes. Customers may require contract research or commercial scale-up activities to support and validate the commercial applicability and eventual licensing of the *Clearant Process*<sup>®</sup>. We recognize licensing revenue when a customer sells products incorporating the *Clearant Process*<sup>®</sup>. Revenue related to a performance milestone is recognized upon customer acceptance of the achievement of that milestone, as defined in the respective agreements and ability to pay. Revenue related to contract research activities is recognized on a percentage-of-completion basis, provided the customer has the ability to pay. In the event cash is received in advance of services performed, we will defer the related revenue recognition until the underlying performance milestone is achieved or the contract research activities commence. In the event advance cash payments are not attributable to any performance milestone or contract research activity, we will recognize the underlying amounts into revenue on a straight-line basis over the term of the underlying agreement or up to a maximum of fifteen years.

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We receive certain grants that support our research efforts in defined research projects, which are 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 are generally recognized ratably over each grant period and as costs under each grant are incurred.

We evaluate the collectability of accounts receivables and provide a reserve for credit losses, as appropriate.

***Cost of Revenues***

Cost of revenues consists of minimum royalties paid on certain contracting activities and are recognized when the related revenue is recognized.

***Cash Equivalents and Concentration of Credit Risk***

We consider all highly liquid investments with an original maturity of three months or less to be cash equivalents. Financial instruments that potentially subject us to a concentration of credit risk consist of cash and cash equivalents, short-term investments, and accounts receivable. Cash is deposited with what we believe are highly credited, quality financial institutions and may exceed FDIC insured limits.

***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. Amortization of such costs begins once the patent or trademark has been issued. We evaluate the recoverability of our patent costs and trademarks quarterly based on estimated undiscounted future cash flows.

***Research and Development Costs***

Research and development costs are expensed as incurred.

***Other Comprehensive Loss***

Other comprehensive loss in 2003 and 2004 consists of foreign currency translation adjustments recorded upon consolidation of our foreign subsidiaries. No such comprehensive loss was recorded in 2005.

***Marketable Securities***

Marketable securities consist of auction-rate securities purchased in 2003, which mature in January 2039. The auction-rate securities are liquid investments that provide us with the ability to draw down on the invested funds and reinvest in the security every 28 days, with no penalties. At December 31, 2003, the investment was classified as short-term as we intended to liquidate the entire investment over the next twelve months ended December 31, 2004. Consistent with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, we include all dividends and interest earned on the auction-rate securities in its statement of operations. The cost of our marketable securities approximated fair market value.

***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

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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***

In December 2002, the Financial Accounting Standards Board (FASB) issued SFAS No. 148, "*Accounting for Stock-Based Compensation-Transition and Disclosure*" (SFAS 148). SFAS 148 amended SFAS No. 123, "*Accounting for Stock-Based Compensation*" (SFAS 123), to provide alternative methods of transition for a voluntary change to the fair-value-based method of accounting for stock-based employee compensation. In addition, SFAS 148 amended the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The disclosure provisions of SFAS 148 have been adopted by us. SFAS 148 did not require us to change to the fair-value-based method of accounting for stock-based compensation.

We account for stock-based compensation arrangements in accordance with Accounting Principles Board Opinion No. 25, "*Accounting for Stock Issued to Employees*" (APB 25), and comply with the disclosure provisions of SFAS 123 and SFAS 148. Under APB 25, compensation expense is recognized over the vesting period based on the difference, if any, on the date of grant between the deemed fair value for accounting purposes of our stock and the exercise price on the date of grant.

***Net Loss Per Share***

We compute net loss per share in accordance with SFAS No. 128, "*Earnings Per Share*" (SFAS 128). Under the provisions of SFAS 128, basic loss per share is computed by dividing net loss, after deducting dividend requirements from the Series A Preferred Stock, 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, warrants and convertible preferred stock and accrued preferred stock dividends. 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. All convertible preferred stock and accrued dividends would be reflected on an as-if-converted basis. 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.

***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.

**Recent Accounting Pronouncements**

In December 2004, the FASB issued SFAS No. 123(R), "*Share-Based Payment*" (SFAS 123R). The statement requires all entities to recognize compensation expense in an amount equal to the fair value of share-based payments granted to employees. The statement eliminates the alternative method of accounting for employee share-based payments previously available under APB 25 and SFAS 123. The statement is effective for the Company beginning in the quarter ended September 30, 2005. In April 2005, the Securities and Exchange Commission amended the compliance dates to allow companies to implement SFAS 123R at the beginning of fiscal 2006. We are currently evaluating the provisions of SFAS 123R and its effect on our financial statements. We expect the effect of adopting this statement will be to increase the amounts reported as stock-based compensation expense in the future.

In December 2004, the FASB issued SFAS No. 153, "*Exchanges of Nonmonetary Assets*," (SFAS 153) an amendment to APB Opinion No. 29, "*Accounting for Nonmonetary Transactions*" (APB 29). SFAS 153 eliminates certain differences in the guidance in APB 29 as compared to the guidance contained in standards issued by the International Accounting Standards Board. The amendment to APB 29 eliminates the fair value exception for

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nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. Such an exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS 153 is effective for nonmonetary asset exchanges occurring in periods beginning after June 15, 2005. Earlier application is permitted for nonmonetary asset exchanges occurring in periods beginning after December 16, 2004. We do not expect adoption of SFAS 153 to have a material impact on our financial statements.

In March 2005, the FASB issued FASB Interpretation (FIN) No. 47, *Accounting for Conditional Asset Retirement Obligations* (FIN 47), which clarifies the meaning of the term *conditional asset retirement obligation* as used in SFAS 143, *Accounting for Asset Retirement Obligations* (SFAS 143) and clarifies when an entity would have sufficient information to reasonably estimate the fair value of an asset retirement obligation. This interpretation is effective no later than the end of fiscal years ending after December 15, 2005 (December 31, 2005 for calendar-year companies). Retrospective application of interim financial information is permitted but is not required. We do not expect adoption of FIN 47 to have a material impact on the Company's financial statements.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* (SFAS 154) an amendment to APB Opinion No. 20, *Accounting Changes* (APB 20), and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements* (SFAS 3) though SFAS 154 carries forward the guidance in APB 20 and SFAS 3 with respect to accounting for changes in estimates, changes in reporting entity, and the correction of errors. SFAS 154 establishes new standards on accounting for changes in accounting principles, whereby all such changes must be accounted for by retrospective application to the financial statements of prior periods unless it is impracticable to do so. SFAS 154 is effective for accounting changes and error corrections made in fiscal years beginning after December 15, 2005, with early adoption permitted for changes and corrections made in years beginning after May 2005.

In February 2006, the FASB issued SFAS No. 155, *Accounting for Certain Hybrid Financial Instruments* (SFAS 155), which amends SFAS No. 133, *Accounting for Derivatives Instruments and Hedging Activities* (SFAS 133) and SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishment of Liabilities* (SFAS 140). SFAS 155 amends SFAS 133 to narrow the scope exception for interest-only and principal-only strips on debt instruments to include only such strips representing rights to receive a specified portion of the contractual interest or principle cash flows. SFAS 155 also amends SFAS 140 to allow qualifying special-purpose entities to hold a passive derivative financial instrument pertaining to beneficial interests that itself is a derivative instrument. We are currently evaluating the impact of this new Standard, but believe that it will not have a material impact on our financial position, results of operations or cash flows.

**Effects of Inflation**

Our most liquid assets are cash, cash equivalents and marketable securities. Because of their liquidity, these assets are not directly affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

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

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.

At December 31, 2005, 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.

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

See Financial Statements beginning on page F-1 of this Annual Report on Form 10-K.

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

Effective March 30, 2005, the Board of Directors of our then operating subsidiary Clearant Licensing, Inc., formerly Clearant, Inc., dismissed BDO Seidman LLP and appointed Singer Lewak Greenbaum & Goldstein LLP as its auditors.

During Clearant Licensing's two most recent fiscal years, and the subsequent interim period through March 30, 2005, it did not consult with Singer Lewak regarding any of the matters or events set forth in Item 304(2)(2)(i) and (ii) of Regulation S-K.

BDO Seidman's reports on Clearant Licensing's consolidated financial statements for the fiscal year ended December 31, 2003 did not contain any adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles, except as follows: As discussed in note 1 to the financial statements, Clearant Licensing had no established source of revenue and was dependent on its ability to raise equity funds, which raised substantial doubt about its ability to continue as a going concern.

In connection with the audits of the fiscal year ended December 31, 2003 and the interim period through March 30, 2005, there have been no disagreements between Clearant Licensing and BDO Seidman on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of BDO Seidman, would have caused it to make reference in connection with their opinion to the subject matter of the disagreements.

We provided BDO Seidman with a copy of the foregoing disclosures, and requested that it furnish a letter addressed to the Securities and Exchange Commission stating whether it agrees with the above statements, which it has provided.

**Item 9A. Controls and Procedures**

*Evaluation of disclosure controls and procedures*

We have evaluated, with the participation of our Chief Executive Officer and our Chief Financial 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 and our Chief Financial Officer have determined that our disclosure controls and procedures are effective in timely alerting them to material information required to be included in this report.

*Management's report on internal control over financial reporting*

Management's report on internal control over financial reporting, which appears on page F-2 of the financial statements, is incorporated by reference herein.

*Changes in internal control*

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

**Item 9B. Other Information**

Not applicable.

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**PART III**

The information required by Items 10 through 14 of Part III is incorporated by reference from Item 1 of this report and from registrant's proxy statement that will be mailed to stockholders in connection with the registrant's 2006 annual meeting of stockholders.

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**PART IV**

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

**(a) 1. Financial Statements**

See Financial Statements included as part of this Form 10-K

**2. Financial Statement Schedules**

All financial statement schedules are omitted because they are not applicable, not required, or the information is shown in the Financial Statements or Notes thereto.

**3. Exhibits**

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 of Clearant, Inc., a Delaware corporation <sup>(2)</sup>
3.2	By-Laws of Clearant, Inc., a Delaware corporation <sup>(2)</sup>
4.1	Specimen Common Stock Certificate <sup>(6)</sup>
10.1*	2005 Stock Award Plan <sup>(3)</sup>
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>(4)</sup>
10.5	Securities Purchase Agreement, dated November 7, 2005 <sup>(4)</sup>
10.6	Registration Rights Agreement, dated November 7, 2005 <sup>(4)</sup>
14.1	Code of Ethics for Financial Executives <sup>(5)</sup>
16.1	Letter from former accountant BDO Seidman, LLP <sup>(6)</sup>
21.1	Subsidiaries
23.1	Consent of Singer Lewak Greenbaum & Goldstein LLP, Independent Registered Accounting Firm
23.2	Consent of BDO Seidman LLP, Independent Registered Accounting Firm
31.1	Certification by the Chief Executive Officer, pursuant to Rule 13-a-14(a) and 15d-14(a), as adopted





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Exhibit No.	Description
	pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification by the Chief Financial Officer, pursuant to Rule 13-a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification by the Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification by the Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted 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 Securities and Exchange Commission on April 4, 2005.

(2) Incorporated by reference to Appendix G to our Proxy Statement on Form DEF14A for our annual meeting of stockholders held on June 30, 2005, filed with the Securities and Exchange Commission on April 4, 2005.

(3) 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 Securities and Exchange Commission on April 4, 2005.

(4) Incorporated by reference to our Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 10, 2005.

(5) Incorporated by reference to Appendix D to our Proxy Statement on Form DEF14A for our annual meeting of stockholders held on June 30, 2005, filed with the Securities and Exchange Commission on April 4, 2005.

(6) Incorporated by reference to our Registration Statement on Form S-3, filed with the Securities and Exchange Commission on November 23, 2005.



**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CLEARANT, INC.

Date: March 16, 2006

By: /s/ ALAIN DELONGCHAMP  
Alain Delongchamp  
Chief Executive Officer

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

Signature	Title(s)	Date
/s/ ALAIN DELONGCHAMP Alain Delongchamp	Chief Executive Officer (Principal Executive Officer) and Director	March 16, 2006
/s/ JON GARFIELD Jon Garfield	Secretary and Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2006
/s/ JOHN S. WEHRLE John S. Wehrle	Chairman of the Board of Directors	March 16, 2006
/s/ HERVÉ DE KERGROHEN Hervé de Kergrohen	Director	March 16, 2006
/s/ ALEXANDER MAN-KIT NGAN Alexander Man-Kit Ngan	Director	March 16, 2006
/s/ NOLAN H. SIGAL Nolan H. Sigal	Director	March 16, 2006

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**MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

Management of Clearant, Inc. (the Company) is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the SEC, internal control over financial reporting is a process designed by, or supervised by, the Company's principal executive and principal financial officers, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles in the United States.

The Company's internal control over financial reporting is supported by written policies and procedures, that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of the Company's management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that control may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In connection with the preparation of the Company's annual financial statements, management of the Company has undertaken an assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2005 based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO Framework). Management's assessment included an evaluation of the design of the Company's internal control over financial reporting and testing of the operational effectiveness of the Company's internal control over financial reporting.

Based on this assessment, management did not identify any material weakness in the Company's internal control over financial reporting, and management has concluded that the Company's internal control over financial reporting were effective as of December 31, 2005.

Singer Lewak Greenbaum & Goldstein LLP, the independent registered public accounting firm that audited the Company's financial statements included in this annual report, have issued an attestation report on management's assessment of internal control over financial reporting, a copy of which is included in this annual report on Form 10-K.

March 16, 2006

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders

Clearant, Inc.

Los Angeles, California

We have audited the balance sheets of Clearant, Inc. (the Company) as of December 31, 2005 and 2004, and the related statements of operations, stockholders' equity (deficits) and other comprehensive loss, and cash flows for each of the two years in the period ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provided a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Clearant, Inc. as of December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles. We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Clearant, Inc.'s internal control over financial reporting as of December 31, 2005, based on *criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)* and our report dated March 3, 2006 expressed an unqualified opinion on management's assessment of the effectiveness of Clearant, Inc.'s internal control over financial reporting and an unqualified opinion on the effectiveness of Clearant, Inc.'s internal control over financial reporting.

/s/ SINGER LEWAK GREENBAUM & GOLDSTEIN LLP

Los Angeles, California

March 3, 2006

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders

Clearant, Inc.

Los Angeles, California

We have audited management's assessment, included in the accompanying *Management's Report on Internal Control over Financial Reporting*, included on page F-2, that Clearant, Inc. (the Company) maintained effective internal control over financial reporting as of December 31, 2005, based on *criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)*. Clearant, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Clearant, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on *criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)*. Also in our opinion, Clearant, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on *criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)*.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the financial statements of Clearant, Inc. and our report dated March 3, 2006 expressed an unqualified opinion.

/s/ SINGER LEWAK GREENBAUM & GOLDSTEIN LLP

Los Angeles, California

March 3, 2006

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors  
Clearant, Inc. and Subsidiaries  
Los Angeles, California

We have audited the accompanying consolidated statements of operations, stockholders' equity (deficit) and other comprehensive loss and cash flows of Clearant, Inc., (a development stage enterprise) for the year ended December 31, 2003. 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 auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal controls over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements and 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 consolidated financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of Clearant, Inc. for the year ended December 31, 2003 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the consolidated financial statements, the Company is a development stage enterprise, has suffered recurring losses since inception and has an accumulated deficit as of December 31, 2003. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to this matter are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO SEIDMAN, LLP  
Los Angeles, California  
March 30, 2005

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

	December 31,	
	2005	2004
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 10,141	\$ 177
Accounts receivable, net	208	127
Prepays and other assets	381	502
Total current assets	10,730	806
Property and equipment, net	415	595
Identifiable intangibles, net	1,403	1,453
Deposits and other assets	244	224
Total assets	\$ 12,792	\$ 3,078
<b>Liabilities, Redeemable Preferred Stock and Stockholders Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,292	\$ 1,847
Accrued liabilities	1,664	3,061
Deferred revenue	48	178
Bridge loans, net	106	4,997
Total current liabilities	3,110	10,083
Deferred revenue noncurrent	60	91
Other liabilities	10	70
Total liabilities	3,180	10,244
Commitments and Contingencies		
Series A Redeemable Preferred stock:		
Series A redeemable convertible preferred stock (50,000 shares authorized; -0- and 6,454 shares issued and outstanding at December 31, 2005 and 2004,		17,829

respectively)

Stockholders' equity (deficit):

Series B preferred stock (-0- shares authorized; -0- and 6,630 shares issued and outstanding at December 31, 2005 and 2004, respectively)		16,386
Series C junior preferred stock (-0- shares authorized; -0- and 37 shares issued and outstanding at December 31, 2005 and 2004, respectively)		86
Common stock (\$0.0001 par value; 200,000 shares authorized; 39,759 and 7,372 issued and outstanding at December 31, 2005 and 2004, respectively)	4	1
Additional paid-in capital	82,179	17,398
Accumulated deficit	(72,571)	(58,820)
Other comprehensive loss		(46)
Total stockholders' equity (deficit)	9,612	(24,995)
Total liabilities, redeemable preferred stock and stockholders' equity (deficit)	\$ 12,792	\$ 3,078

*See accompanying notes to financial statements.*

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

	Fiscal Year Ended December 31,		
	2005	2004	2003
Revenues:			
Licensing	\$ 215	\$ 121	\$
Contract research and milestones	231	615	250
Grants	95	270	158
Total revenues	541	1,006	408
Cost of sales	17	33	26
Gross margin	524	973	382
Operating expenses:			
Sales, general and administrative	8,967	9,400	6,597
Research and development	2,050	5,190	6,142
Stock-based compensation	626	345	92
Total operating expenses	11,643	14,935	12,831
Loss from operations	(11,119)	(13,962)	(12,449)
Other income (expense):			
Interest expense, net	(1,802)	(867)	(254)
Gain on extinguishment of debt and other	1,331		
Loss before provision (benefit) for income taxes	(11,590)	(14,829)	(12,703)
Provision (benefit) for income taxes			
Net loss	(11,590)	(14,829)	(12,703)
Add: Preferred stock dividend and financing costs	(2,161)	(1,628)	(1,526)
Net loss attributable to common stock	\$ (13,751)	\$ (16,457)	\$ (14,229)
Net loss per share:			
Basic and diluted	\$ (0.47)	\$ (2.23)	\$ (1.93)

Number of shares used in per share calculation:

Basic and diluted	29,498	7,370	7,369
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*See accompanying notes to financial statements.*

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

	Series B Preferred		Series C Preferred		Common Stock, \$0.0001 par value		Additional Paid-in Capital	Accumulated Deficit	Comprehensive Loss	Stock-holders Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
<b>Balance, December 31, 2002</b>		\$		\$	7,368	\$ 1	\$ 13,473	\$ (28,082)	\$ (6)	\$ (14,614)
Exercise of common stock options					1		1			1
Issuance of warrants in connection with 2003 bridge loans							4			4
Conversion of 2002 and 2003 bridge loans and related interest to Series B preferred stock	2,301	6,328								6,328
Issuance of Series B Preferred Stock, net of costs	4,329	11,275								11,275
Issuance of warrants in connection with Series B Preferred Stock		(1,217)					1,217			
Stock compensation expense							92			92
Comprehensive loss:										
Net loss								(12,703)		(12,703)
Other comprehensive loss									(24)	(24)
Total comprehensive loss								(12,703)	(24)	(12,727)
Accumulated Series A								(1,526)		(1,526)

Preferred Stock  
dividend and  
amortization of  
financing costs

**Balance at  
December 31,  
2003**

	<b>6,630</b>	<b>\$ 16,386</b>	<b>\$</b>	<b>7,369</b>	<b>\$ 1</b>	<b>\$ 14,787</b>	<b>\$ (42,311)</b>	<b>\$ (30)</b>	<b>\$ (11,167)</b>
Exercise of common stock options				3		1			1
Issuance of warrants in connection with 2004 bridge loans						1,862			1,862
Issuance of Series C Preferred Stock, net of costs			37	86					86
Issuance of warrants in connection with Series C Preferred Stock						43	(43)		
Beneficial conversion feature recorded on 2004 bridge loans financing						351			351
Beneficial conversion feature recorded on Series C Preferred Stock issuance						9	(9)		
Stock compensation expense						345			345
Comprehensive loss:									
Net Loss							(14,829)		(14,829)
Other comprehensive loss								(16)	(16)
Total Comprehensive loss							(14,829)	(16)	(14,845)
Accumulated Series A Preferred Stock							(1,628)		(1,628)



dividend and  
amortization of  
financing costs

**Balance at  
December 31,  
2004**

**6,630 \$ 16,386 37 \$ 86 7,372 \$ 1 \$ 17,398 \$ (58,820) \$ (46) \$ (24,995)**

*See accompanying notes to financial statements*

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

	Series B Preferred Stock		Series C Preferred Stock		Common Stock, \$0.0001 par value		Additional Paid-in Capital	Accumulated Deficit	Other Comprehensive Loss	Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
<b>Balance, December 31, 2004</b>	<b>6,630</b>	<b>\$ 16,386</b>	<b>37</b>	<b>\$ 86</b>	<b>7,372</b>	<b>\$ 1</b>	<b>\$ 17,398</b>	<b>\$ (58,820)</b>	<b>\$ (46)</b>	<b>\$ (24,995)</b>
Issuance of warrants to January 2005 Bridge Holders							93			93
Settlement of debt for common stock					31		64			64
Exchange of warrants for common stock					77		158			158
Beneficial return to preferred shareholders from allocation of shares from common to preferred stockholders							2,100			2,100
Conversion of preferred stock into common stock	(6,630)	(16,386)	(37)	(86)	11,542	1	30,566			14,095
Exchange of bridge loan warrants							(1,349)			(1,349)
Conversion of Series A Preferred dividend					2,141		3,794			3,794
Conversion of Series C Preferred dividend					3		5			5
Conversion of 2004 bridge loans into					3,834	1	6,724			6,725

common 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 services	73		278	278
Compensation expenses incurred in connection with issuance of options and warrants to non-employees			458	458
Secondary placement	3,774		11,036	11,036
Comprehensive loss: Net Loss			(11,590)	(11,590)
Other comprehensive loss			(13)	(13)
Cumulative translation loss attributable to the dissolution of foreign subsidiaries			59	59
Total Comprehensive loss			(11,590)	46 (11,544)
Preferred stock dividend and			(2,161)	(2,161)

financing costs

**Balance at  
December 31,  
2005**

**\$                    \$            39,759 \$ 4 \$ 82,179 \$ (72,571) \$            \$ 9,612**

*See accompanying notes to financial statements.*

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

	<b>Year Ended December 31,</b>		
	2005	2004	2003
<b>Operating activities</b>			
Net loss	\$ (11,590)	\$ (14,829)	\$ (12,703)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	470	694	325
Stock-based compensation	626	345	92
Non-cash interest expense associated with convertible debt financings (Note 12)	1,795	862	309
Gain on extinguishment of debt and other	(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:			
Receivables and prepaids	142	(32)	(131)
Payable to related parties, net			(23)
Accounts payable	(555)	1,201	77
Accrued liabilities	(1,360)	1,361	492
Deferred revenue	(161)	144	125
Other assets and liabilities	(82)	17	53
Net cash used in operating activities	(11,829)	(10,237)	(11,384)
<b>Investing activities</b>			
Cost of identified intangibles	(129)	(599)	(486)
Capital expenditures	(132)	(56)	(252)
Proceeds from sales of fixed assets, net	25		
Purchases of marketable securities			(6,500)
Proceeds from disposals of marketable securities		3,500	3,000
Net cash provided by (used in) investing activities	(236)	2,845	(4,238)
<b>Financing activities</b>			
Issuance of common stock, net of costs	19,554		
Issuance of Series B preferred stock, net of costs			11,319
Issuance of Series C preferred stock, net of costs		86	
Issuance of convertible notes payable, net of costs	2,811	6,348	403
Exercise of common stock options	50	1	1
Payments on bridge loans	(366)		
Principal payments on capital lease obligations	(7)	(24)	(79)

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Net cash provided by financing activities	22,042	6,411	11,644
<b>Effect of translation adjustments on cash and cash equivalents</b>	(13)	(16)	(24)
<b>Change in cash and cash equivalents</b>	9,964	(997)	(4,002)
<b>Cash and cash equivalents, beginning of period</b>	177	1,174	5,176
<b>Cash and cash equivalents, end of period</b>	\$ 10,141	\$ 177	\$ 1,174

**Supplemental Disclosure of Cash Flow Information:**

Cash paid for interest	\$ 9	\$	\$
Cash paid for taxes	\$ 1	\$ 1	\$ 1

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

	<b>Year Ended December 31,</b>		
	2005	2004	2003
<b>Supplemental Disclosure of Non-cash Financing Activities:</b>			
Accumulated preferred stock dividend and amortization of financing costs	\$ 2,161	\$ 1,628	\$ 1,526
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 loans 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 2005 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		5
Warrants issued to purchase common stock in conjunction with the 2004 and 2003 bridge loan financings into common stock		1,862	4
Beneficial conversion feature recorded in conjunction with the 2004 bridge loan financings		351	
Warrants issued to purchase common stock in conjunction with the 2004 Series C Preferred financings		43	
Beneficial conversion feature recorded in conjunction with the 2004 Series C financings		9	
Conversion of bridge loans and related interest into Series A and Series B Preferred Stock			6,328
Warrants issued to purchase Series B Preferred Stock in conjunction with the 2003 Series B Preferred financing			1,217

*See accompanying notes to financial statements.*

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**CLEARANT, INC.**  
**NOTES TO THE 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*<sup>®</sup> that inactivates pathogens that may contaminate biological products such as tissue allograft implants, recombinant protein therapeutics, plasma protein therapeutics, blood and blood-related products. The *Clearant Process*<sup>®</sup> enables customers to meet the medical need for safer biological products and to satisfy current and future product safety guidelines. The Company's primary business model is to provide customers the ability to apply the *Clearant Process*<sup>®</sup> 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. The Company's ability to achieve a profitable level of operations will depend on continuing to increase customer acceptance of the *Clearant Process*<sup>®</sup> and increased recognition by end users of the value of the *Clearant Process*<sup>®</sup> in assuring sterile products.

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States 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.

As described more fully in Note 8, 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., (the Company) changed its state of incorporation from Nevada to Delaware. In conjunction with the reincorporation, Clearant now has authorized common stock consisting of 200 million shares, \$0.0001 par value, of which 39,758,500 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. We 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 placement agent.

At December 31, 2004 the consolidated financial statements include the accounts of Clearant, Inc. and Clearant Europe. At December 31, 2005 the financial statements include only the accounts of Clearant, Inc. as all of the accounts and operations in Clearant Europe were transferred to Clearant, Inc. effective October 1, 2005. For purposes of presentation, the balances as of and the results of operations for the year ended December 31, 2004 were consolidated, but the balances as of and the results of operations for the year ended December 31, 2005 were not



consolidated.

For purposes of the consolidated financial statements during the year ended, and, at December 31, 2004, all significant intercompany balances and transaction have been eliminated in consolidation.

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

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, 2003, these conditions raised substantial doubt as to the Company's ability to continue as a going concern. The Company's ability to continue as a going concern was dependent upon its ability to raise additional capital and generate sufficient cash flows to meet its obligations as they become due. Management believes that sufficient cash flows from product sales and equity funding will be available to meet its planned business objectives for a reasonable period of time; however, there can be no assurance that the Company will be successful in its efforts to generate sufficient revenue or raise additional capital on terms acceptable to the Company. 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 2 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 (SAB 104), *Revenue Recognition*. The Company's revenue sources are licensing fees and services to customers who incorporate the *Clearant Process*<sup>®</sup> 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 licensing revenue when a customer sells products incorporating the *Clearant Process*<sup>®</sup>. 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 evaluates the collectability of accounts receivables and provides a reserve for credit losses, as appropriate. As of December 31, 2005 and 2004, the Company reserved for credit losses of \$20 and \$0, 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.

**Cost of Revenues**

Cost of revenues consists of minimum royalties paid on certain contracting activities and are recognized when the related revenue is recognized.

**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

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

the years ended December 31, 2005, 2004 and 2003, three customers accounted for approximately 59%, 60% and 89% of revenues, respectively, and three customers accounted for approximately 38%, 90% and 89% of accounts receivable, respectively.

**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. 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.

**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.

**Stock-Based Compensation**

We account for stock-based compensation arrangements in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and comply with the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123) and SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure* (SFAS 148). Under APB 25, compensation expense is recognized over the vesting period based on the difference, if any, on the date of grant between the deemed fair value for accounting purposes of our stock and the exercise price on the date of grant.

SFAS 123 requires disclosure of pro forma net loss based upon the fair value of the options issued to employees, had the Company elected to account for such options under the provisions of SFAS 123. The Company calculates the fair value of each option granted on the date of the grant using the Black-Scholes option pricing model for employees as prescribed by SFAS 123 and the following assumptions:

Risk-free interest rate	3.0%-5.5%
Expected life in years	3-5
Dividend yield	0%
Expected volatility	70%-75%

The weighted average deemed fair value of options granted to employees for the years ended December 31, 2005, 2004 and 2003 was \$2.53, \$2.27 and \$2.60, respectively.

Had the Company determined compensation expense for its stock options based on the fair value at the grant date under SFAS 123, the Company's pro forma net loss for the years ended December 31, 2005, 2004 and 2003 would have been as follows:

	For the year ended December 31,		
	2005	2004	2003
Net loss attributable to common stock, as reported	\$ (13,751)	\$ (16,457)	\$ (14,229)
Add: stock-based compensation expense included in reported net loss	554	345	92
Deduct: stock-based compensation expense determined under the fair value method for all awards	(1,236)	(1,921)	(3,110)
Net loss attributable to common stock pro forma	\$ (14,433)	\$ (18,033)	\$ (17,247)
Net loss per share:			
As reported, basic and diluted	\$ (0.47)	\$ (2.23)	\$ (1.93)
Pro forma, basic and diluted	\$ (0.49)	\$ (2.45)	\$ (2.34)

Because the Company's stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its stock options.

#### **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 December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123(R), *Share-Based Payment* (SFAS 123R). The statement requires all entities to recognize compensation expense in an amount equal to the fair value of share-based payments granted to employees. The statement eliminates the alternative method of accounting for employee share-based payments previously available under APB 25 and SFAS 123. In April 2005, the

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

Securities and Exchange Commission amended the compliance dates to allow companies to implement SFAS 123R at the beginning of fiscal 2006. The Company has not completed the process of evaluating the impact that will result from adopting SFAS 123R, but believes the impact upon adoption will be an increase to compensation expense.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets* (SFAS 153) an amendment to APB Opinion No. 29, *Accounting for Nonmonetary Transactions* (APB 29). SFAS 153 eliminates certain differences in the guidance in APB 29 as compared to the guidance contained in standards issued by the International Accounting Standards Board. The amendment to APB 29 eliminates the fair value exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. Such an exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS 153 is effective for nonmonetary asset exchanges occurring in periods beginning after June 15, 2005. Earlier application is permitted for nonmonetary asset exchanges occurring in periods beginning after December 16, 2004. Management does not expect adoption of SFAS 153 to have a material impact on the Company's financial statements or results of operations.

In March 2005, the FASB issued FASB Interpretation (FIN) No. 47, *Accounting for Conditional Asset Retirement Obligations* (FIN 47), which clarifies the meaning of the term *conditional asset retirement obligation* as used in SFAS 143, *Accounting for Asset Retirement Obligations* (SFAS 143) and clarifies when an entity would have sufficient information to reasonably estimate the fair value of an asset retirement obligation. This interpretation is effective no later than the end of fiscal years ending after December 15, 2005 (December 31, 2005 for calendar-year companies). Retrospective application of interim financial information is permitted but is not required. Management does not expect adoption of FIN 47 to have a material impact on the Company's financial statements.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* (SFAS 154) an amendment to APB Opinion No. 20, *Accounting Changes* (APB 20), and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements* (SFAS 3) though SFAS 154 carries forward the guidance in APB 20 and SFAS 3 with respect to accounting for changes in estimates, changes in reporting entity, and the correction of errors. SFAS 154 establishes new standards on accounting for changes in accounting principles, whereby all such changes must be accounted for by retrospective application to the financial statements of prior periods unless it is impracticable to do so. SFAS 154 is effective for accounting changes and error corrections made in fiscal years beginning after December 15, 2005, with early adoption permitted for changes and corrections made in years beginning after May 2005. The Company will implement SFAS No. 154 in its fiscal year beginning January 1, 2006. We are currently evaluating the impact of this new standard, but believe that it will not have a material impact upon the Company's financial position, results of operations or cash flows.

In February 2006, the FASB issued SFAS No. 155, *Accounting for Certain Hybrid Financial Instruments* (SFAS 155), which amends SFAS No. 133, *Accounting for Derivatives Instruments and Hedging Activities* (SFAS 133) and SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishment of Liabilities* (SFAS 140). SFAS 155 amends SFAS 133 to narrow the scope exception for interest-only and principal-only strips on debt instruments to include only such strips representing rights to receive a specified portion of the contractual interest or principle cash flows. SFAS 155 also amends SFAS 140 to allow qualifying special-purpose entities to hold a passive derivative financial instrument pertaining to beneficial interests that itself is a derivative instrument. The Company is currently evaluating the impact of this new Standard, but believes that it will not have a material impact on the Company's financial position, results of operations or cash flows.

**NOTE 3 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, after deducting dividend requirements from the Series A Preferred Stock (Note 9), 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, warrants and convertible preferred stock and accrued

preferred stock dividends. 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. All convertible preferred stock and accrued dividends would be reflected on an as-if-converted basis. For the periods presented, the computation of

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

diluted loss per share equaled basic loss per share as the inclusion of any dilutive instruments would have had an antidilutive effect on the earnings per share calculation in the periods presented.

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

	For the Year Ended December 31,		
	2005	2004	2003
Convertible preferred stock (and related accrued dividends) and convertible bridge loans		19,063,000	13,233,000
Stock Options	2,776,000	4,999,000	5,060,000
Warrants	5,179,000	4,119,000	1,372,000

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

	For the year ended December 31,		
	2005	2004	2003
Basic and diluted net loss per share:			
Numerator:			
Net loss attributable to common stock	\$ (13,751)	\$ (16,457)	\$ (14,229)
Denominator:			
Weighted average common stock shares outstanding	29,498	7,370	7,369
Net loss per share, basic and diluted	\$ (0.47)	\$ (2.23)	\$ (1.93)

**NOTE 4 PROPERTY AND EQUIPMENT**

Property and equipment consists of the following at December 31:

	2005	2004
Equipment	\$ 975	\$ 1,126
Computer equipment and software	496	446
Furniture and fixtures	69	70
Leasehold improvements	23	13
	1,563	1,655
Less accumulated depreciation	(1,148)	(1,060)
	\$ 415	\$ 595

Included in property and equipment is equipment leased under capital leases of \$42 and \$141 at December 31, 2005 and 2004. Accumulated depreciation relating to these capital leases for the years ended December 31, 2005 and 2004 was \$2 and \$72, respectively. Depreciation expense was \$282, \$342 and \$310 for the years ended December 31, 2005, 2004 and 2003, respectively.

**NOTE 5 IDENTIFIABLE INTANGIBLES**

Identifiable intangibles consist of the following at December 31:

	2005	2004
Trademarks	\$ 37	\$ 36
Patents	1,911	1,782

	1,948	1,818
Less accumulated amortization	(545)	(365)
	\$ 1,403	\$ 1,453

Over the period January 1, 2006 to December 31, 2010, the Company projects cumulative amortization expense related to its patents and trademarks issued at December 31, 2005 to be approximately \$180. Because the Company evaluates the recoverability of its intangibles on a quarterly basis, and anticipates that new patents will be granted

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and issued in 2006 throughout 2010, actual amortization expense recorded over December 31, 2006 to December 31, 2010 could fluctuate significantly from the projected amount over the same period.

During the year ended December 31, 2005, 2004 and 2003, the Company recorded approximately \$148, \$313 and \$0, respectively, of expense associated with patent impairment.

**NOTE 6 RESTRICTED CASH**

The Company is required to maintain restricted cash deposits in certificate of deposit accounts in connection with various lease arrangements. As of December 31, 2005 and 2004, the Company had cash deposits of approximately \$191 and \$252, respectively, which is included in deposits and other cash assets on the balance sheet.

**NOTE 7 INCOME TAXES**

The significant components of the provision for income taxes for the years ended December 31, 2005, 2004 and 2003 were \$1, \$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, 2005 and 2004 are as follows:

	2005	2004	2003
Deferred tax assets (liabilities):			
Net operating loss carryforwards	\$ 23,178	\$ 19,407	\$ 13,492
Purchase in-process research and development	548	698	757
Research and development credits	1,338	1,325	1,194
Depreciation, accrued expenses and other	462	517	226
Net deferred tax assets	25,527	21,947	15,669
Less valuation allowance	(25,527)	(21,947)	(15,669)
	\$	\$	\$

During 2005, the Company's valuation allowance on deferred tax assets increased from \$21,947 as of December 31, 2004 to \$25,527 as of December 31, 2005, 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, 2005, 2004 and 2003 was approximately \$11,160 and \$430, respectively, \$14,057 and \$772, respectively, and \$11,996 and \$707, 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:

	2005	2004	2003
Federal statutory rate	(34%)	(34%)	(34%)
State taxes	(5%)	(5%)	(5%)
Tax credits	(1%)	(2%)	(3%)
Foreign loss with no benefit	7%	%	%
Valuation allowance	33%	41%	42%

At December 31, 2005 and 2004, the Company had net operating losses (NOL) for federal and state income tax purposes of approximately \$123,237 and \$102,279, which begin expiring in 2019 and 2006, 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 8), 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, 2005, the Company has not performed an analysis in order to determine whether such limitations exist.

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The Company also has federal and state research and development tax credit carryforwards as of December 31, 2005 and 2004, of approximately \$1,401 and \$1,137, respectively, which begin to expire in 2022 and 2018, respectively.

**NOTE 8 REVERSE MERGER TRANSACTION**

In June 2005, the Company changed the par value of the common stock from \$0.001 to \$0.0001, however for presentation purposes, the following footnote and the values contained therein are shown at \$0.001 par value. 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 convertible 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.

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The following is an analysis of the capital transactions and adjustments recorded to the Company's balance sheet in conjunction with the transaction:

	<b>Opening balance</b>	<b>Adjusting</b>	<b>Ending Balance (Post Merger)</b>
<b>At March 31, 2005 (in \$000s):</b>	<b>(Pre Merger)</b>	<b>Entries</b>	
<b>Assets</b>			
Cash and cash equivalents	\$ 116	8,520 (a)	\$ 8,653
Other assets	2,682	\$ 17 (b) (32) (a)	2,650
<b>Total assets</b>	<b>\$ 2,798</b>	<b>\$ 8,505</b>	<b>\$ 11,303</b>
<b>Liabilities, redeemable preferred stock and stockholders' (deficit) equity</b>			
Convertible notes, net	\$ 8,478	\$ (6,793) (c) 68 (c) 1,024 (d) (2,350) (e) (23) (e) 59 (d)	\$ 463
Other liabilities	4,545	75 (a)	4,620
Total liabilities	13,023	(7,940)	5,083
Series A redeemable preferred stock, net	17,889	(17,889) (f),(g)	
Stockholders' (deficit) equity:			
Series B preferred stock	16,386	(16,386) (h)	
Series C junior preferred stock	91	(91) (i),(j)	
Common stock, no par value	17,714	(17,714) (k)	
Common stock, \$0.001 par value		12 (f),(h),(i) 2 (g) 4 (c) 7 (k) 7 (b) 3 (a) 1 (e)	36
Additional paid-in capital		30,555 (f),(h),(i) 3,792 (g) 5 (j) 6,721 (c) 17,707 (k) (59) (d) 10 (b) 8,410 (a)	70,323

		2,372	(e)	
		(1,290)	(d)	
		(2,100)	(l)	
Accumulated deficit	(62,252)	(1,024)	(d)	(64,086)
		1,290	(d)	
		(2,100)	(l)	
Other comprehensive loss	(53)			(53)
Total shareholders (deficit) equity	(28,114)	34,334		6,220
<b>Total liabilities, redeemable preferred stock and stockholders (deficit) equity</b>	<b>\$ 2,798</b>	<b>\$ 8,505</b>		<b>\$ 11,303</b>

**Explanation of Adjusting Entries**

- (a) Entry to record proceeds received from private placement of 2,910,000 shares of Company common stock at \$3.00 per share. Cash proceeds of \$8,520 represent gross proceeds of \$8,730 less approximately \$210 in costs associated with the placement. Total costs of the transaction include approximately \$242 in direct legal fees, of which \$167 were paid at closing and the remaining \$75 were recorded in accrued liabilities. Following the

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merger and private placement, the Company had 35,829,350 shares of common stock, par value \$.001, issued and outstanding.

- (b) Entry to record the merger. Upon completion of the transaction and effective March 31, 2005, prior stockholders continue to own 7,136,000 shares of Company common stock. The registrant had no operations as of March 31, 2005, and approximately \$17 in cash.
- (c) Entry to record the conversion of approximately \$6,793 of Clearant convertible promissory notes outstanding as of March 31, 2005 into approximately 3,834,000 shares of common stock. In conjunction with the conversion, net unamortized costs remaining at March 31, 2005 of \$68 were included as an adjustment to additional paid in capital.
- (d) Entry to record unamortized portion of Clearant convertible note warrants and beneficial conversion features to interest expense upon conversion of the notes into common stock. At the date of the conversion and immediately prior to the merger, Clearant exchanged all warrants outstanding and issued in conjunction with 2004 and 2005 bridge loan financings two-year warrants to purchase approximately 2,477,000 shares of common stock at \$4.00 per share. The fair value of the warrants exchanged was re-measured and resulted in the recording of a one-time gain of \$1,290 and a \$59 adjustment to additional paid-in capital. Remaining warrants outstanding immediately prior to the merger were cancelled except as set forth herein.
- (e) Entry to record the conversion of approximately \$2,350 of Company convertible notes into approximately 783,000 shares of common stock at \$3.00 per share. Related accrued interest of \$23 was forgiven and recorded as an adjustment to additional paid-in capital. The Company issued note holders two-year warrants to purchase approximately 839,000 shares of common stock at \$4.00 per share. The fair value of the warrants of \$849 (calculated using a Black-Scholes model) had no impact on the financial statements at March 31, 2005 (net adjustment of \$0 to additional paid-in capital).
- (f) Entry to record the conversion of Clearant Series A preferred stock into 5,677,000 shares of the common stock. Immediately prior to the conversion, Series A preferred stock was comprised of original investment of \$14,521, accrued Series A preferred dividends of \$3,794 and net unamortized costs of \$426. The net unamortized costs of \$426 were reclassified against additional paid-in capital.
- (g) Entry to record the conversion of \$3,794 of accrued Series A preferred dividends into 2,141,000 shares of common stock.
- (h) Entry to record the conversion of Clearant Series B preferred stock into 5,832,000 shares of common stock. Immediately prior to the conversion, Series B preferred stock was comprised of original investment of \$18,233 and costs of \$1,847. The cost of \$1,847 was reclassified against original paid-in capital.
- (i) Entry to record the conversion of Clearant Series C preferred stock into 33,000 shares of common stock. Immediately prior to the conversion, Series C preferred stock was comprised of original investment of \$102, accrued Series C preferred dividends of \$5, and net unamortized costs of \$16. The net unamortized costs of \$16 were reclassified against additional paid-in capital.
- (j) Entry to record the conversion of \$5 of accrued Series C preferred dividends into 3,000 shares of common stock.

- (k) Entry to record the conversion of approximately 7,371,000 shares of Clearant's common stock, no par value, into approximately 7,371,000 shares of the Company's common stock, \$0.001 par value.
- (l) Entry to record share exchange of 1.5 million shares from common stockholders to preferred stockholders to consummate the merger. The share exchange was valued at \$2,100 and is treated as a beneficial impact of the transaction to the preferred stockholders and included in net loss attributable to common stock in the quarter ended March 31, 2005.

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**NOTE 9 CAPITALIZATION****Common Stock Transactions and Non-cash Financing Activities**

During 2005, the Company settled certain debts of approximately \$103 in exchange for 31,000 shares of common stock at a price per share of \$2.25 (the Settlement Price). In connection with the debt settlement, the Company recorded a one-time gain of \$39, which represented the difference between the deemed fair value of the Company's common stock and the Settlement Price at the settlement date.

During 2005 and prior to the March 31, 2005 reverse merger, Clearant exchanged certain warrants for 77,000 shares of the Company's common stock. The exchange resulted in a one-time expense of \$158, which is included in general and administrative costs in 2005.

During 2005 and immediately prior to the March 31, 2005 reverse merger, Clearant's common stockholders exchanged 1,500,000 shares (pre share split) of common stock to the then-holders of Series A, B and C preferred stock in order to consummate the transaction. The 1,500,000 shares were allocated pro-rata amongst the then-preferred holders and valued at \$2,100. The share exchange was treated as a beneficial impact of the transaction to preferred shareholders and included in net loss attributable to common stock in 2005.

During 2005, the Company issued 57,979 shares of common stock with a fair value of \$235 as compensation 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, \$168 is reflected in stock-based compensation in 2005.

In December 2005, the Company issued 14,950 shares of common stock with a fair value of \$43 as a settlement of outstanding debt from services rendered in 2004. As such, no stock-based compensation was recognized in 2005.

**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 8) 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 March 25, 2007, there shall be no further transfer restrictions except as provided by law.

**Preferred Stock**

For the years ended December 31, 2005, 2004 and 2003, the Company recognized \$61, \$250 and \$249, respectively, of amortization expense associated with the Series A Preferred issuance costs.

The following table summarizes the Series A Preferred activity for the periods ended December 31, 2005, 2004 and 2003:

	Series A Preferred	
	Shares	Amount
<b>Balance at December 31, 2002</b>	6,454,000	\$ 14,723
Accrued dividends, amortization of financing costs and other		1,461
<b>Balance at December 31, 2003</b>	6,454,000	\$ 16,184
Accrued dividends, amortization of financing costs and other		1,645
<b>Balance at December 31, 2004</b>	6,454,000	17,829
Conversion of preferred stock into common stock	(6,454,000)	(17,829)



**Balance at December 31, 2005**

\$

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The following table summarizes the Series B Preferred activity for the periods ended December 31, 2005, 2004 and 2003:

	Series B Preferred	
	Shares	Amount
<b>Balance at December 31, 2002</b>		\$
Conversion of Series B bridge loans and related interest	2,301,000	6,328
Issuance of Series B Preferred, net of costs	4,329,000	10,058
<b>Balance at December 31, 2003</b>	6,630,000	\$ 16,386
No activity		
<b>Balance at December 31, 2004</b>	6,630,000	\$ 16,386
Conversion of preferred stock into common stock	(6,630,000)	(16,386)
<b>Balance at December 31, 2005</b>		\$

In September 2004, the Company issued 37,000 shares of Series C Preferred and warrants for an aggregate purchase price of \$102 to one investor (the Series C Preferred Holder). In connection with the issuance of the Series C Preferred, the Company incurred issuance and warrant costs (Note 11) of \$16 and \$43, respectively. Proceeds from the sale, net of costs of \$16, were \$86. In addition, the Company recorded an adjustment to retained earnings of \$9 from a beneficial conversion option on the Series C Preferred (calculated in accordance with EITF No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instrument* as the effective conversion price of the Series C Preferred multiplied by the number of shares convertible into common stock at the date the Series C Preferred was issued).

The following table summarizes the Series C Preferred activity for the year ended December 31, 2005 and 2004:

	Series C Preferred	
	Shares	Amount
<b>Balance at December 31, 2003</b>		\$
Issuance of Series C Preferred, net of costs	37,000	86
<b>Balance at December 31, 2004</b>	37,000	\$ 86
Conversion of preferred stock into common stock	(37,000)	(86)
<b>Balance at December 31, 2005</b>		\$

**Preferred Stock Preferences and Rights**

Beginning in June 2002, the Series A Preferred holders, in preference to the holders of Common Stock, are entitled to receive cumulative semiannual dividends. The dividends compound semiannually and are payable on June 30 and December 31 in each year, if declared by the Board of Directors, but only out of funds that are legally available therefore. If dividends are paid on any shares of Common Stock, the Company must pay such dividends to the holders of Series A Preferred on an as-if converted basis. As of December 31, 2005 and 2004, accumulated, but undeclared Series A Preferred dividends totaled \$0 and \$3,794, respectively.

Beginning in July 2003, the Series B Preferred holders, in preference to the holders of Common Stock, are entitled to receive non-cumulative semiannual dividends. The dividends compound semiannually and are payable on June 30 and December 31 in each year, if declared by the Board of Directors, but only out of funds that are legally available therefore. If dividends are paid on any shares of Common Stock, the Company must pay such dividends to the holders

of Series B Preferred on an as-if converted basis. No Series B Preferred dividends have been declared. The Series C Preferred holder shall be entitled to receive non-cumulative annual dividends. The dividends compound annually and are payable on September 30 in each year, if declared by the Board of Directors, but only out of funds that are legally available therefore. If dividends are paid on any shares of Common Stock, the Company must pay such dividends to the holders of Series C Preferred on an as-if converted basis. No Series C Preferred dividends have been declared.

Each share of Series A Preferred may, at the option of the holder, be converted at any time prior to the fifth day prior to the redemption date (as defined) into shares of Common Stock at the then-effective conversion price. Each share of Series B Preferred and Series C Preferred may, at the option of the holder, be converted at any time into shares of

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Common Stock at the then-effective conversion rate for the stock. The initial conversion rate for the Series A Preferred, Series B Preferred and Series C Preferred is one-for-one. Any accrued and unpaid dividends are payable in cash, or, at the election of the Company, in Common Stock, at the time of conversion.

Each share of Series A and Series B Preferred will be automatically converted into shares of Common Stock based upon the then-effective conversion price (i) at any time upon the affirmative election of the majority holders (as defined), or (ii) immediately upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act covering the offer and sale of Common Stock for account of the Company in which the per share price is at least \$5.50 and the net proceeds to the Company are at least \$20,000. Each share of Series C Preferred will be automatically converted into either (i) the next round of equity security issued in the next round of equity financing consummated by the Company or (ii) shares of Common Stock based upon the then-effective conversion price at any time upon the affirmative election or written consent of the majority holders of the outstanding shares of Series C Preferred.

Upon any liquidation, dissolution or winding up of the Company (including an acquisition or an asset transfer, as defined), each holder of shares of Series A and Series B Preferred will be entitled to receive, prior and in preference to any distribution to the holders of shares of Series C Preferred and Common Stock, an amount per share equal to the original issue price (as defined) for each share of Series A Preferred (as defined) and Series B Preferred (as defined), plus all accrued and unpaid dividends. The Series C Preferred has senior liquidation preferences to the holders of Common Stock, but junior in right and time of payment to dividends and liquidation to the Series A Preferred, the Series B Preferred and any other securities which rank senior to the Series C Preferred with respect to dividends and liquidation preference. Thereafter, any remaining assets will be distributed ratably to the holders of Common Stock. Except as otherwise provided or as required by law, the holders of shares of Series A Preferred, Series B Preferred and Series C Preferred have voting rights and powers equal to those of holders of Common Stock and are entitled to vote, together with the holders of Common Stock and not as a separate class, on all matters upon which the holders of Common Stock are entitled to vote. Each holder of shares of Series A Preferred and Series B Preferred is entitled to such number of votes as shall be equal to the numbers of shares of Common Stock into which such shares could then be converted. The Company holds the proxy to vote on all matters related to the Series C Preferred Stock.

For so long as at least 25% of the total shares of Series A Preferred issued remain outstanding, the company may not, without first obtaining the affirmative vote or written consent of the holders of at least a majority of the shares of Series A Preferred: (i) amend, alter or repeal any provision of the Company's Articles of Incorporation to alter or change the rights, preferences, privileges or restrictions of the Series A Preferred so as to affect adversely the shares as such series; (ii) authorize or designate, whether by reclassification or otherwise, any new class or series of shares having rights, preferences or privileges prior to the shares of Series A Preferred to increase the rights, preferences or privileges or the number of authorized shares of any class or series having rights, preferences or privileges prior to the shares of Series A Preferred; and (iii) increase or decrease the aggregate number of authorized shares of Series A Preferred.

For so long as at least 25% of the total shares of Series B Preferred issued remain outstanding, the company may not, without first obtaining the affirmative vote or written consent of the holders of at least 60% of the shares of Series B Preferred: (i) amend, alter or repeal any provision of the Company's Articles of Incorporation to alter or change the rights, preferences, privileges or restrictions of the Series B Preferred so as to affect adversely the shares as such series; (ii) authorize or designate, whether by reclassification or otherwise, any new class or series of shares having rights, preferences or privileges prior to the shares of Series B Preferred to increase the rights, preferences or privileges or the number of authorized shares of any class or series having rights, preferences or privileges prior to the shares of Series B Preferred; and (iii) increase or decrease the aggregate number of authorized shares of Series B Preferred.

The majority of Series A holders, as defined, voting together as a separate class, have the right to require the Company, to the extent it may lawfully do so, to redeem the Series A Preferred in three (3) equal annual installments

(redemption) beginning on December 31, 2006 (the Redemption Date). If, subsequent to a redemption, the Company is in material default of any of its material financing or loan agreements, any installment payments not yet made to

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the Majority Holders of outstanding Series A Preferred will become immediately due (or if the Company is in such default at the time the holders request redemption, all shares of Series A Preferred will be redeemed immediately in one installment on the fifth anniversary of the original issue date). The redemption price for a share of Series A Preferred will be a sum equal to the greater of (i) the fair market value of a share of Series A Preferred (to be determined by a mutually acceptable third-party) on an as-if-converted basis and (ii) the Series A Preference.

**NOTE 10 STOCK OPTIONS**

Effective March 31, 2005 and in conjunction with the merger (Note 8), 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 Option 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 Clearant, Inc. 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. Options granted to an individual who, at the time of grant of such option, owns stock representing more than 10% of the voting power of all classes of 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.

The following table sets forth the activity of the 2000 and 2005 Plan and Non-Plan Options issued for the years ended December 31, 2005, 2004 and 2003:

	Employees		Non-Employees		Total	
	Shares	Exercise Price	Shares	Exercise Price	Shares	Exercise Price
<b>Outstanding at December 31, 2002</b>	4,495,000	\$ 0.60-\$7.94	100,000	\$ 2.30-\$7.22	4,595,000	\$ 0.60-\$7.94
Granted	800,000	\$ 2.75	10,000	\$ 2.80	810,000	\$ 2.75-\$2.80
Exercised	(2,000)	\$ 0.60		\$	(2,000)	\$ 0.60
Canceled	(232,000)	\$ 0.60-\$7.22		\$	(232,000)	\$ 0.60-\$7.22
<b>Outstanding at December 31, 2003</b>	5,061,000	\$ 0.60-\$7.94	110,000	\$ 2.30-\$7.22	5,171,000	\$ 0.60-\$7.94
Granted	474,000	\$ 2.80	40,000	\$ 7.22	514,000	\$ 2.80-\$7.22
Exercised	(2,000)	\$ 0.60-\$2.30		\$	(2,000)	\$ 0.60-\$2.30
Change in status	(199,000)	\$ 0.60-\$7.22	199,000	\$ 0.60-\$7.22		
Canceled	(81,000)	\$ 0.60-\$7.22	(30,000)	\$ 7.22	(111,000)	\$ 0.60-\$7.22

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<b>Outstanding at 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
<b>Outstanding at December 31, 2005</b>	2,396,000	\$ 0.60-\$7.94	380,000	\$ 0.60-\$7.22	2,776,000	\$ 0.60-\$7.94

Options available under the 2005 Plan for future grants, which exclude the Non-Plan Options, totaled 4,002,297 at December 31, 2005.

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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 was as follows:

	Options Outstanding			Options Exercisable	
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Number of Shares	Weighted Average Exercise Price
Range of Exercise Price:					
Employees:					
\$0.60 to \$0.66	467,000	\$ 0.64	6.56	467,000	\$ 0.64
\$2.25 to \$2.30	371,000	\$ 2.27	4.85	335,000	\$ 2.27
\$2.80 to \$3.17	614,000	\$ 2.92	6.98	566,000	\$ 2.93
\$3.86 to \$4.51	944,000	\$ 4.08	9.54	195,000	\$ 4.12
Total Employees (\$0.60 to \$4.51)	2,396,000	\$ 2.83	7.69	1,563,000	\$ 2.25
Non-employees	380,000	\$ 2.04	4.06	380,000	\$ 2.04

The exercise price of options granted to employees is at least the deemed fair value of the Company's Common Stock. Therefore, no amount is recorded as deferred compensation.

On July 1, 2005, the Board of Directors approved awarding stock options for 1,011,665 shares to employees & directors. All awards were at \$4.12, the fair market value at the date of grant based on the closing price of the Company's common stock on July 1, 2005. The Company valued the shares using the Black-Scholes option-pricing model and the following assumptions: risk-free interest rate 3.84%, expected life 5 years, dividend yield 0% and volatility 72%.

On July 29, 2005, the Company granted 42,500 stock options to employees under the 2005 Stock Option Plan. All awards were at \$4.51, the fair market value at the date of grant based on the closing price of the Company's common stock on July 29, 2005. The Company valued the options using the Black-Scholes option pricing model and the following assumptions: risk-free interest rate 4.12%, expected life 5 years, dividend yield 0% and volatility 72%.

On August 30, 2005, the Company granted 200,000 stock options to an Officer of the Company under the 2005 Stock Option Plan. The award was at \$3.86, the fair market value at the date of grant based on the closing price of the Company's common stock on August 30, 2005. The Company valued the options using the Black-Scholes option pricing model and the following assumptions: risk-free interest rate 4.03%, expected life 5 years, dividend yield 0% and volatility 72%.



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**NOTE 11 WARRANTS**

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 8) all of the Company's 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's 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's bridge loan financings in 2005 (Note 12), the Company issued five-year warrants to such holders to purchase an aggregate 167,547 shares of the Company's 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 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.

In conjunction with the Company's bridge loan financings in 2004 (Note 12), the Company issued five-year warrants to such holders to purchase an aggregate 3,085,323 shares of the Company's common stock at prices ranging from \$2.75 to \$3.25 per share (collectively, the 2004 Bridge Warrants). The aggregate fair value of the 2004 Bridge Warrants was approximately \$1,862 (calculated in accordance with APB Opinion No 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants*) and is presented as a discount to the bridge loan payable at December 31, 2004. For the year ended December 31, 2004, the Company recognized approximately \$547 of related interest expense associated with the 2004 Bridge Loan Warrants. As of December 31, 2004, none of the 2004 Bridge Loan Warrants were exercised. Both the number of shares purchasable under the 2004 Bridge Loan Warrants and the exercise prices are subject to adjustment based upon the price per share of the Company's next equity round of financing.

In September 2004 and in conjunction with the Company's Series C Preferred financing (Note 9), the Company issued a five-year warrant to its Series C preferred holder to purchase an aggregate 74,000 shares of the Company's common stock at \$2.75 per share (the Series C Preferred Warrant). The fair value of the Series C Preferred Warrants was approximately \$43 and is presented as an adjustment to retained earnings for the year ended December 31, 2004. Both the number of shares purchasable under the Series C Preferred Warrant and the exercise price are subject to adjustment based upon the price per share of the Company's next equity round of financing.

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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, 2005 were as follows:

Number of Shares	Warrants Outstanding Exercise Price	Weighted Average of Remaining Contractual Life (Years)
3,316,645	\$ 4.00	1.25
1,862,698	\$ 4.96	4.85

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. 123 and the following assumptions:

Risk-free interest rate	3.0%-5.5%
Expected life in years	3-5
Dividend yield	0%
Expected volatility	70% to 75%

The weighted average deemed fair value of warrants granted to non-employees for the years ended December 31, 2005, 2004 and 2003 was \$1.66, \$1.22 and \$1.93 per share, respectively.

**NOTE 12 BRIDGE LOANS**

In January 2005, the Company issued convertible promissory notes in the aggregate principal amount of \$461, to certain investors (the January Bridge Loans). The January Bridge Loans bear simple interest at a rate of 10% per annum and mature on the earlier of the next equity round of financing or one year from the original issuance date. The January Bridge Loans were issued under the same terms as the September Bridge Loans. In connection with the issuance of the January Bridge Loans, the Company issued five-year warrants (Note 11). At the time of issuance, both the number of shares purchasable under the January 2005 Warrants and the exercise price of the January 2005 Warrants were subject to adjustment based upon the price per share of the Company's next equity round of financing. From January through March 2005 the Company issued convertible promissory notes in the amount of \$2,350 to a certain investor (Publico) (collectively, the Publico Bridge Loans). The Publico Bridge Loans bear simple interest at a rate of 6% per annum and matures on the earlier of the next equity round of financing (as defined) or six months from the original issuance date.

From April to December 2004, the Company issued convertible promissory notes in the aggregate principal amount of \$6,476, in favor of certain investors and in connection with certain bridge financing (collectively, the 2004 Bridge Loans). In conjunction with the issuance of the 2004 Bridge Loans, the Company incurred aggregate issuance and warrant costs of \$128 and \$1,862, respectively. In addition, the Company recorded a discount of \$351 from a beneficial conversion option on certain 2004 Bridge Loans (calculated in accordance with EITF No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instrument* as the effective conversion price of certain 2004 Bridge Loans multiplied by the number of shares convertible into common stock at the date such 2004 Bridge Loans were issued). The issuance costs were capitalized and are being amortized to interest expense over the term of the 2004 Bridge Loans. The value of the warrants and beneficial conversion option is presented as a discount on 2004 Bridge Loans and are being amortized to interest expense over the term of the 2004 Bridge Loans. The 2004 Bridge Loans bear simple interest rates of 6% to 10% per annum, and mature on the earlier of the next equity round of financing or one year from the date of issuance.

The 2004 Bridge Loans provide that upon the first closing of the next equity round, the holders shall convert all principal and accrued interest into a number of next equity round securities having an aggregate agreed value equal to the sum of the outstanding principal balance plus accrued interest as of the date of conversion. In addition, the

agreements provide that prior to closing of the next equity round, the holders shall have the option to convert all outstanding principal and accrued interest into a number of shares of common stock equal to the sum of the outstanding principal balance plus accrued interest as of the date of conversion, divided by the share price of the next

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equity round security. As of December 31, 2004, none of the convertible notes were converted. The agreed value is contingent upon the price per share at which the Company issues securities in its next equity round of financing. For the years ended December 31, 2005 and 2004, the Company recorded \$1,795 and \$862 of interest expense associated with the 2005 and 2004 Bridge Loans.

**NOTE 13 COMMITMENTS AND CONTINGENCIES****Leases and Commitments**

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, 2005, are as follows:

2006	\$ 639
2007	44
2008	20
2009 and thereafter	2
Net minimum lease payments	\$ 705

Rental expense on non-cancelable operating leases for the years ended December 31, 2005, 2004 and 2003 was \$744, \$881 and \$773, respectively.

The Company has obligations under capital leases for the years ended December 31, 2005 and 2004 of \$42 and \$3, respectively. As of December 31, 2005, the Company has one capital lease for equipment with a monthly payment including interest, of approximately \$1, that expires in three 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, except for an arbitration action filed by a former employee for alleged breach of contract and recovery of benefits. In January 2006, the parties executed a settlement agreement thereby resolving the matter for full and final settlement of all claims under terms which remain confidential. Under the settlement agreement, the Company agrees to pay \$212,000 in four equal payments which was fully accrued for as of December 31, 2005.

**NOTE 14 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, 2005, 2004 and 2003.

**NOTE 15 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 will be additional period costs incurred in 2006 in connection with the closing of the lab and moving of the equipment; however as of December 31, 2005, these costs are not quantifiable. The plan was approved by the Company's executive management team and the Board of Directors and the Company expects the plan to be substantially complete by March 31, 2006.



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**NOTE 16 SELECTED QUARTERLY FINANCIAL DATA (Unaudited)**

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

	Quarter ended			
	Mar. 31,	Jun. 30,	Sept. 30,	Dec. 31,
<b>2005</b>				
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)
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
<b>2004</b>				
Total revenues	\$ 310	\$ 110	\$ 269	\$ 317
Gross margin	302	102	260	309
Total operating expenses	3,249	3,926	3,599	4,161
Loss from operations	(2,947)	(3,824)	(3,339)	(3,852)
Other income (expense), net	4	(80)	(98)	(693)
Net loss	\$(2,943)	\$ (3,904)	\$ (3,437)	\$ (4,545)
Preferred stock dividend and financing costs	(401)	(401)	(413)	(413)
Net loss attributable to common stock	\$(3,344)	\$ (4,305)	\$ (3,850)	\$ (4,958)
Net loss per share Basic and diluted	\$ (0.45)	\$ (0.58)	\$ (0.52)	\$ (0.67)
Number of shares Basic and diluted	7,369	7,369	7,369	7,370

**NOTE 17 SUBSEQUENT EVENTS**

In February 2006, the Company ordered approximately \$240 of tissues treated with the *Clearant Process*<sup>®</sup>. During the second and third quarters of 2006, the Company will act as a processor's representative by providing tissue to the marketplace to further demand for tissue treated with the *Clearant Process*<sup>®</sup>. These tissues will be considered inventory of the Company from the date of receipt until depleted.

Pursuant to the License Agreement (Agreement) with Tristar Bioventures International (Tristar), dated April 1, 2005, in consideration for the access to and use of the *Clearant Process*<sup>®</sup> the Company was due a one-time, non-recoupable, non-refundable payment in the amount of \$500 on October 31, 2005. As of February 23, 2006, the breach remained uncured by Tristar and the license agreement automatically terminated under its terms. In 2005, the Company has not recognized any revenue from Tristar, and therefore no bad debt expense will be incurred related to the termination. The Company, however, continues to have ongoing discussions with Tristar regarding a resolution.

In February 2006 and in connection with delay in the required registration of the shares of common stock for the March 2005 investors, the Company at its discretion entered into a settlement agreement whereby the Company issued five-year warrants to such holders to purchase an aggregate 332,220 shares of the Company's common stock at an exercise price of \$4.96 per share.