CLEARANT INC
Form 10-Q
May 16, 2005

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United States
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For The Quarterly Period Ended **March 31, 2005**

Commission File Number 000-50309

Clearant, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**91-2190195**
(State or other jurisdiction of incorporation)	(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)

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 þ NO o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ

As of May 12, 2005, there were 35,829,350 shares of registrant s common stock, $0.001 par value, outstanding.

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PART I-FINANCIAL INFORMATION

ITEM 1. Financial Statements

CLEARANT, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except for per share data)

	March 31, 2005 (Unaudited)	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	$ 8,653	$ 177
Accounts receivable	138	127
Prepaids and other assets	334	502
Total current assets	9,125	806
Property and equipment, net	517	595
Identifiable intangibles, net	1,415	1,453
Restricted cash noncurrent	192	161
Other assets	54	63
Total assets	$ 11,303	$ 3,078
Liabilities, Redeemable Preferred Stock and Stockholders Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,871	$ 1,847
Accrued liabilities	2,444	3,061
Deferred revenue	151	178
Bridge Loans, net	463	4,997
Total current liabilities	4,929	10,083
Deferred revenue noncurrent	97	91
Other liabilities	57	70
Total liabilities	5,083	10,244
Commitments and Contingencies		
Series A Redeemable Preferred stock:		
Series A redeemable convertible preferred stock (-0- shares authorized; -0 and 6,454 shares issued and outstanding at March 31, 2005 and December 31, 2004, respectively)		17,829
Stockholders equity (deficit):		
Series B preferred stock (-0- shares authorized; -0- and 6,630 shares issued and outstanding at March 31, 2005 and December 31, 2004, respectively)		16,386

Series C junior preferred stock (-0- shares authorized; -0- and 37 shares issued and outstanding at March 31, 2005 and December 31, 2005, respectively)		86
Common stock $0.001 par value (100,000 shares authorized; 35,829 and 7,365 issued and outstanding at March 31, 2005 and December 31, 2004, respectively)	36	17,399
Additional paid-in capital	70,323	
Accumulated deficit	(64,086)	(58,820)
Other comprehensive loss	(53)	(46)
Total stockholder s equity (deficit)	6,220	(24,995)
Total liabilities, redeemable preferred stock and stockholders equity (deficit)	$ 11,303	$ 3,078

See accompanying notes to consolidated financial statements.

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CLEARANT, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except for per share data)

	Three Months Ended March 31,	
	2005 (Unaudited)	2004 (Unaudited)
Revenues:		
Licensing	$ 44	$ 18
Contract research and milestones	43	250
Grants	20	42
Total revenues	107	310
Cost of sales	4	8
Net revenues	103	302
Operating expenses:		
Sales and marketing	783	993
Research and development	754	1,402
General and administrative	1,209	826
Stock-based compensation		28
Total operating expenses	2,746	3,249
Loss from operations	(2,643)	(2,947)
Interest (expense) income, net	(1,786)	4
Gain on extinguishment of debt	1,290	
Gain on settlement of debt for stock	39	
Net loss	$ (3,100)	$ (2,943)
Add: Preferred stock dividend and financing costs	(2,161)	(401)
Net loss attributable to common stock	$ (5,261)	$ (3,344)
Net loss per share:		
Basic and diluted	$ (0.71)	$ (0.45)
Number of shares used in per share calculation:		
Basic and diluted	7,368	7,365

See accompanying notes to consolidated financial statements.

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CLEARANT, INC.
CONDENSED STATEMENT OF STOCKHOLDERS EQUITY
(in thousands, except for per share data)

	Series B Preferred Stock		Series C Preferred Stock		Common Stock, no par value		Common Stock, $0.001 par value		Additional Paid-in	Accumulated	Other Comprehensive	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Totals
Balance, December 31, 2004	6,630	$ 16,386	37	$ 86		$	7,372	$ 7	$ 17,392	$ (58,820)	$ (46)	(24,995)
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	12	30,555			14,095
Exchange of bridge loan warrants									(1,349)			(1,349)
Conversion of Series A Preferred dividend							2,141	2	3,792			3,794
Conversion of Series C							3		5	(5)		

Preferred dividend						
Conversion of 2004 bridge loans into common stock	3,834	4	6,721			6,725
Conversion of common stock (no par) to common stock ($.001 par)						
Bliss Essential, Corp. shares issued in connection with the merger transaction	7,136	7	10			17
Issuance of common stock in conjunction with Private Placement	2,910	3	8,410			8,413
Conversion of Publico Bridge Loans into common stock	783	1	2,372			2,373
Comprehensive loss:						
Net Loss				(3,100)		(3,100)
Other comprehensive loss					(7)	(7)
Total Comprehensive loss				(3,100)	(7)	(3,107)
Preferred stock dividend and financing costs				(2,161)		(2,161)
Balance at March 31, 2005 (unaudited)	35,829	$ 36	$ 70,323	$ (64,086)	$ (53)	6,220

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CLEARANT, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands, except for per share data)

	Three Months Ended March 31,	
	2005 (Unaudited)	2004 (Unaudited)
Operating activities		
Net loss	$ (3,100)	$ (2,943)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	166	92
Stock-based compensation		28
Non-cash interest expense associated with convertible debt financings (Note 6)	1,786	
Gain on extinguishment of debt	(1,290)	
Gain on settlement of debt for stock	(39)	
Warrant exchange for common stock	158	
Changes in operating assets and liabilities:		
Changes in operating assets and liabilities:		
Receivables and prepaids	98	(101)
Accounts payable	24	525
Accrued liabilities	(588)	(275)
Deferred revenue	(21)	(1)
Other assets and liabilities	56	37
Net cash used in operating activities	(2,750)	(2,638)
Investing activities		
Cost of identified intangibles	(51)	(230)
Capital expenditures		(17)
Cash received in 2005 merger activities	17	
Marketable securities investment:		
Purchases		
Proceeds from Disposals		2,341
Net cash (used in) provided by investing activities	(34)	2,094
Financing activities		
Issuance of common stock, net of costs	8,455	
Issuance of convertible notes payable, net of costs	2,811	
Exercise of common stock options	2	
Principal payments on capital lease obligations	(1)	(8)
Net cash provided by (used in) financing activities	11,267	(8)
Effect of translation adjustments on cash	(7)	3
Change in cash and cash equivalents	8,476	(549)
Cash and cash equivalents, beginning of period	177	1,174

Cash and cash equivalents, end of period	$ 8,653	$ 625

See accompanying notes to consolidated financial statements

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CLEARANT, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except for per share data)
(Unaudited)

NOTE 1 BASIS OF PRESENTATION

The accompanying unaudited interim condensed consolidated 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 for these interim periods. 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. The results of operations for the three months ended March 31, 2005 are not necessarily indicative of the results that may be expected for the entire 2005 fiscal year.

The registrant, Clearant, Inc., a Nevada corporation, formerly known as Bliss Essentials Corp., (the Company) has omitted footnote disclosures that would substantially duplicate the disclosures contained in the audited financial statements of the Company and should be read in conjunction with the financial statements for the fiscal years ended December 31, 2004 and 2003 and notes thereto in the Company s amended Current Report on Form 8-K/A dated March 31, 2005, filed with the Securities and Exchange Commission as of May 13, 2005. The December 31, 2004 consolidated balance sheet has been derived from the audited financial statements on Form 8-K/A. All share data has been restated to reflect any reverse stock splits that took place following the periods presented. Certain reclassifications, where needed, were made in prior periods to be consistent with current period presentation. These unaudited condensed financial statements should be read together with the financial statements for the year ended December 31, 2004, and footnotes thereto.

During the quarter ended March 31, 2005 and as described more fully in Note 5, the Company acquired all of the outstanding common stock of Clearant, Inc., a Delaware corporation, formerly a California corporation (Clearant), though a reverse triangular merger. For accounting purposes, the merger is treated as a recapitalization of Clearant with Clearant deemed the acquirer (i.e., a reverse acquisition). The historical financial statements prior to March 31, 2005 are those of Clearant.

NOTE 2 NEW ACCOUNTING PRONOUNCEMENTS

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 123®, *Share-Based Payment* (FAS 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 Accounting Principles Board Opinion No. 25 and FAS 123R. 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 FAS 123R at the beginning of fiscal 2006. The Company has not completed the process of evaluating the impact that will result from adopting FAS 123R, but believes the impact will be to increase compensation expense.

In December 2004, the FASB issued SFAS No. 153, Exchanges of Nonmonetary Assets (FAS 153), an amendment to Opinion No. 29, Accounting for Nonmonetary Transactions . FAS 153 eliminates certain differences in the guidance in Opinion No. 29 as compared to the guidance contained in standards issued by the International Accounting Standards Board. The amendment to Opinion No. 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. FAS 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 No. 153 to have a material impact on the Company s financial statements.

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

NOTE 3 NET LOSS PER SHARE

The Company computes net loss per share in accordance with SFAS No. 128, *Earnings Per Share* (FAS 128). Under the provisions of FAS 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 FAS No. 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. Antidilutive weighted average shares outstanding and excluded from the earnings per share calculation for the quarters ended March 31, 2005 and 2004 were -0- and 13,233, respectively shares from the assumed conversion of convertible preferred stock and cumulative preferred dividends, at an as-if-converted price of $1.40 of preferred to common stock (as adjusted for stock splits, if any), and 848 and 414 common shares, respectively issuable upon the exercise of stock options.

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

	Three Months Ended March 31, 2005	Three Months Ended March 31, 2004
Basic and diluted net loss per share:		
Numerator:		
Net loss attributable to common stock	$ (5,261)	$ (3,344)
Denominator:		
Weighted average common stock shares outstanding	7,368	7,365
Net loss per share, basic and diluted	$ (0.71)	$ (0.45)

NOTE 4 STOCK OPTIONS AND STOCK-BASED COMPENSATION

The Company accounts for its stock-based compensation arrangements in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and complies with the disclosure provisions of FAS 123 and FAS 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 the Company s stock and the exercise price on the date of grant.

Effective March 31, 2005 and in conjunction with the Transaction (Note 5), 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 1.9 million shares (the Existing Options), which are grandfathered under the Company s 2000 Stock Option Plan, as amended (the 2000 Plan). There are no future grants available under the 2000 Plan.

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CLEARANT, INC.
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(Unaudited)

FAS No. 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 FAS No. 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 FAS No. 123 and the following assumptions:

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

Had the Company determined compensation expense for its stock options based on the fair value at the grant date under FAS No. 123, the Company s pro forma net loss for the quarters ended March 31, 2005 and March 31, 2004 would have been as follows**:**

	Three Months Ended March 31, 2005	Three Months Ended March 31, 2004
Net loss attributable to common stock, as reported	$ (5,261)	$ (3,344)
Add: stock-based compensation expense included in reported net loss		28
Deduct: stock-based compensation expense determined under the fair value method for all awards	(132)	(735)
Net loss attributable to common stock pro forma	$ (5,393)	$ (4,051)
Net loss per share:		
As reported, basic and diluted	$ (0.71)	$ (0.45)
Pro forma, basic and diluted	$ (0.73)	$ (0.55)

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.

NOTE 5 REVERSE MERGER TRANSACTION

Merger and Private Placement

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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CLEARANT, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except for per share data)
(Unaudited)

The following is an analysis of the capital transactions and adjustments recorded to the Company s balance sheet in conjunction with the transaction (amounts are unaudited):

At March 31, 2005 (in $000s):	Opening balance (Pre Merger)	Adjusting Entries	Ending Balance (Post Merger)
Assets			
Cash and cash equivalents	$ 116	8,520(a) $ 17(b)	$ 8,653
Other assets	2,682	(32)(a)	2,650
Total assets	**$ 2,798**	**$ 8,505**	**$ 11,303**
Liabilities, redeemable preferred stock and stockholders (deficit) equity			
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)	70,323

		10(b)	
		8,410(a)	
		2,372(e)	
		(1,290)(d)	
		2,100(l)	
Accumulated deficit	(62,252)	(1,024)(d)	(64,086)
		1,290(d)	
		(2,100)(l)	(53)
Other comprehensive loss	(53)		(53)
Total shareholders (deficit) equity	(28,114)	$ 34,334	6,220
Total liabilities, redeemable preferred stock and stockholders (deficit) equity	**$ 2,798**	**$ 8,505**	**$ 11,303**

Explanation of Adjusting Entries

(a) Entry to record proceeds received from private placement of 2,910 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 merger and private placement, the Company had 35,829 shares of common stock, par value $.001, issued and outstanding.

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(b) Entry to record the merger. Upon completion of the transaction and effective March 31, 2005, prior stockholders continue to own 7,136 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 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 its 2004 and 2005 bridge loan financings with two-year warrants to purchase approximately 2,477 shares of common stock at $4.00 per share. The fair value of the warrants exchanged was remeasured 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 the Company s convertible notes into approximately 783 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 noteholders two-year warrants to purchase approximately 839 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 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 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 were reclassified against original paid-in capital.

(i) Entry to record the conversion of Clearant Series C preferred stock into 33 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 shares of common stock.

(k)

Entry to record the conversion of approximately 7,371 shares of Clearant s common stock, no par value, into approximately 7,371 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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CLEARANT, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except for per share data)
(Unaudited)

NOTE 6 COMMON STOCK

Common Stock Transactions

During the quarter ended March 31, 2005, the Company settled certain debts of approximately $103 in exchange for 31 shares of common stock at a price per share of $2.25. 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 $2.25 at the settlement date.

During the quarter ended March 31, 2005 and prior to the merger, Clearant exchanged certain warrants for 77 shares of common stock. The exchange resulted in a one-time expense of $157, which is included in general and administrative costs in the Company s Condensed Consolidated Statements of Operations for the three months ended March 31, 2005.

During the quarter ended March 31, 2005 and immediately prior to the March 2005 reverse merger transaction, Clearant s common stockholders exchanged 1.5 million 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 1.5 million 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 the Company s March 31, 2005 quarterly Condensed Consolidated Statements of Operations.

Lock-up Period

For a period beginning on March 25, 2005 and ending on March 25, 2006, the holders of Clearant s Common Stock immediately prior to the merger (Note 5) 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.

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ITEM 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes, and the other financial information included in this report.

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 in Item 5 below.

Overview

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

Tissue allograft implants

Recombinant products

Plasma therapeutics

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. We entered into a reverse triangular merger with Clearant, Inc., which was incorporated in the state of California on April 30, 1999, and reincorporated in Delaware on March 31, 2005, and is now our wholly-owned subsidiary through whom we conduct our business operations. 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.

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*® 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*® 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 four to thirteen logs of pathogen reduction

Be used in both intermediate and final stages of production

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

The *Clearant Process*® is designed to be effective against a wider spectrum of pathogens than many competing sterilization technologies, including the inactivation of bacteria, fungi, spores and lipid-enveloped and non-enveloped

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viruses. The *Clearant Process*® will enable our customers, who offer a wide variety of biological products, to meet the medical need for safer biological products and to satisfy current and future product safety guidelines. We believe the *Clearant Process*® is a cost-effective technology applicable across multiple market segments, with minimal capital requirements to implement.

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

Our initial area of focus is the application of the *Clearant Process*® on devitalized human tissue implants used in surgical procedures. We are also focusing on the application of the *Clearant Process*® on in-process intermediates used in the production of recombinant protein products (e.g., serum) and biotechnology recombinant protein products (including biotherapeutics, diagnostics and vaccines). We believe that the devitalized human tissue market represents a source of near-term product revenue, while the protein-based pharmaceuticals markets present an intermediate to longer-term opportunity.

We have signed six licensing agreements with devitalized human tissue banks, and one with a manufacturer of recombinant protein products, in return for milestone payments and royalties on end-product sales. During 2004, two of our licensees launched devitalized human tissue products that were treated using the *Clearant Process*®. *Clearant Process*®-treated allografts produced by our licensees have been implanted by doctors in more than 2,500 patients since January 2004. Additionally, four of our licensees are anticipated to begin marketing *Clearant Process*®-treated products during 2005.

Asia License

On April 8, 2005, we entered into a twenty-year license agreement with TriStar Bioventures International, granting exclusive rights to commercialize the *Clearant Process*® in designated countries in Asia. TriStar and its Asian sublicensees will have the right to manufacture specified products using the *Clearant Process*® and distribute them worldwide. In return, TriStar agreed to pay non-recoupable, non-refundable payments totaling $5 million, of which $500,000 will be paid by October 31, 2005, $1 million by each January 31st and October 31st in 2006 and 2007, and the final $500,000 by October 31, 2008, as well as a royalty of 7.5% of gross revenues which increases to 12.5% over eleven years. We were also granted a 10% preferred equity interest in TriStar, as well as first refusal, purchase and board observation rights.

Results of Operations

Revenues

Revenues from licensing activities increased 140% to $44,000 in the quarter ended March 31, 2005, from $18,000 in the quarter ended March 31, 2004, as a result of increased sales of human tissue treated with the *Clearant Process*®. We had license agreements with seven companies at March 31, 2005 compared to six at March 31, 2004. Revenues from contract research and grants declined 80% to $63,000 in the quarter ended March 31, 2005, from $292,000 in the same quarter last year. This decline largely resulted from a non-recurring $250,000 milestone payment from a single customer in the quarter ended March 31, 2004.

Marketing, General and Administrative Expenses

Marketing, general and administrative expenses increased by $173,000, or 9.5%, to $1,992,000 for the quarter ended March 31, 2005, from $1,819,000 for the quarter ended March 31, 2004. The increase was principally due to increased expenses of approximately $170,000 associated with our March 31, 2004 merger, a non-recurring expense of

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approximately $160,000 resulting from the exchange of warrants for common stock, and increased patent amortization of approximately $100,000 as compared to the same period last year. Offsetting these expenses were a $230,000 decrease in outside legal and marketing expenses in the first quarter of this year as compared to the quarter ended March 31, 2004.

Research and Development Expenses

Research and development expenses decreased by $648,000, or 46.2%, to $754,000 for the quarter ended March 31, 2005, from $1,402,000 for the quarter ended March 31, 2004. This decrease was largely a result of reduced research and development personnel-related costs during the quarter compared to the same period in 2004. Throughout the latter part of 2004 and during the first quarter of 2005, we reduced our R&D personnel and related expenses as the principal research and development required to support the *Clearant Process*® in the tissue market was substantially complete. We anticipate we will continue to incur research and development costs to as we continue to further develop the *Clearant Process*® for other markets.

Net Interest Expense

Net interest expense increased by $1,790,000 to $1,786,000 for the quarter ended March 31, 2005, compared to net interest income of $4,000 for the quarter ended March 31, 2004. This increase was primarily the result of increased interest expense associated with bridge loan borrowing from April 2004 through March 31, 2005. Comparatively, we had no bridge loans outstanding during the quarter ended March 31, 2004.

Preferred Stock Dividend and Financing Costs

Preferred stock dividend and financing costs increased by $1,760,000 or from $401,000 to $2,161,000 for the quarters ended March 31, 2005 and 2004, respectively. The increase was principally due to a $2,100,000 deemed preferred dividend as a result of our exchanging 1.5 million shares of common stock to preferred stockholders of Clearant in order to consummate the March 31, 2005 merger.

Liquidity and Capital Resources

Net cash used in operating activities was $2,750,000 for the quarter ended March 31, 2005, compared to $2,638,000 for the quarter ended March 31, 2004. During the quarter ended March 31, 2005, cash was used by a $3,100,000 net loss from operations and a $564,000 decrease in accounts payable and accrued liabilities, primarily employee related. Primary sources of cash during the quarter were a decrease in prepaid and other current assets and a $154,000 net decrease in other assets and long-term liabilities. Significant non-cash adjustments to operating activities for the quarter included depreciation and amortization expense of $166,000, a non-cash gain on extinguishment of debt of $1,290,000, and non cash interest expense of $1,786,000.

Our net cash used in investing activities was $50,000 for the quarter ended March 31, 2005 compared to net cash provided by investing activities of $2,094,000 for the quarter ended March 31, 2004. Our investing activities consist primarily of intellectual property expenditures and investment purchases and proceeds from marketable securities. Compared to the first quarter of March 2004, there were no marketable securities purchases or disposals during the quarter ended March 31, 2005.

We have financed our operations since inception primarily through the sale of shares of our stock. Our net cash provided by financing activities was $11,267,000 for the quarter ended March 31, 2005, compared to net cash used in financing activities of $8,000 for the quarter ended March 31, 2004. Cash provided by financing activities for the quarter ended March 31, 2005 consisted of a $11,266,000 in net proceeds from issuance of commercial notes and sales

of common stock in connection with the merger, leaving a balance of approximately $8,653,000 in cash and cash equivalents at March 31, 2005.

We have been unprofitable since our inception and we expect to incur additional operating losses for at least the next twelve months as we incur expenditures on research and development, commercial operations, sales and marketing. Our activities to date are not as broad in depth or scope as the activities we may undertake in the future, and

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our historical operations and financial information are not necessarily indicative of the future operating results or 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 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 for at least the next twelve months. Based upon our current plans, we believe that our existing capital resources will be sufficient to meet our operating expenses and capital requirements for the next twelve months. However, changes in our business strategy, technology development or marketing plans or other events affecting our operating plans and expenses may result in the expenditure of existing cash before that time. If this occurs, our ability to meet our cash obligations as they become due and payable will depend on our ability to sell securities, borrow funds or some combination thereof. We may not be successful in raising necessary funds on acceptable terms, or at all.

We may seek to raise additional funding through public or private financing or through collaborative arrangements with strategic partners. We may also seek to raise additional capital through public or private placement of shares of equity securities, in order to increase the amount of our cash reserves on hand.

Contractual Obligations and Commercial Commitments

We lease facilities and equipment under noncancelable operating leases with various expirations through 2006. The future minimum lease payments under these leases and other contractual obligations as of March 31, 2005 are as follows ($ in 000 s):

Contractual Obligations	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating lease obligations	$ 990	$ 702	$ 288		
Other obligations	$ 935	$ 925			
	$ 1,925	$ 1,627	$ 288		

Off-Balance Sheet Arrangements

As of March 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 (SAB 104), *Revenue Recognition*. Our revenue sources are licensing fees, performance milestones and contract research activities, with additional revenues generated from government grants.

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We license the Clearant Process® 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®. We recognize licensing revenue when a customer sells products incorporating the Clearant Process®. 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.

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 evaluates the recoverability of our patent costs and trademarks quarterly based on estimated undiscounted future cash flows.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (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 Accounting Principles Board Opinion No. 25 and SFAS 123R. 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 FAS 123R at the beginning of fiscal 2006. We are currently evaluating the provisions of SFAS 123R and its effect on our financial statements. The effect of adopting this statement will be to increase our compensation expense in the future.

In December 2004, the FASB issued SFAS No. 153, Exchanges of Nonmonetary Assets (FAS 153), an amendment to Opinion No. 29, Accounting for Nonmonetary Transactions . FAS 153 eliminates certain differences in the guidance in Opinion No. 29 as compared to the guidance contained in standards issued by the International Accounting Standards Board. The amendment to Opinion No. 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. FAS 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 No. 153 to have a material impact on our financial statements.

ITEM 3. 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 March 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. Investments in both fixed rate and floating rate interest earning instruments carry a degree of interest rate risk. Fixed rate securities may have their fair market value adversely impacted due to a rise in interest rates, while floating rate securities with shorter maturities may

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produce less income if interest rates fall. The market risk associated with our investments in debt securities is substantially mitigated by the frequent turnover of the portfolio.

ITEM 4. 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.

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PART II OTHER INFORMATION

ITEM 1. 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 prospectus, 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.

ITEM 5. Other Information

Risk Factors

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

Risks Related to Our Business

Our limited operating history may make it difficult to evaluate our business to date and our future viability.

We were incorporated in April 1999 in order to acquire certain of the assets of Puresource and Sterways, including certain patents that comprise a portion of the *Clearant Process*®. We are in the early stage of operations and development, and have only a limited operating history on which to base an evaluation 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 2005 and possibly beyond, as we incur significant expenses associated with the further development, marketing and commercialization of the *Clearant Process*®.

We have a history of and expects to continue to generate substantial losses, may not become profitable and will need to expand our licensing of the Clearant Process® to generate significant revenues.

To date, we have generated only limited revenues, and have had limited marketing activities. We expect that we will have significant operating losses and accumulated losses and will record significant net operating cash outflows at least through the end of 2005 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*® in the devitalized human tissue market and the successful licensing of such technology to third party tissue processors. Our longer term financial performance, on the other hand, is heavily dependent on timely and cost effectively proving the efficacy of and successfully licensing the *Clearant Process*® in the serum and recombinant products markets. We may not successfully prove the efficacy of our pathogen inactivation processes for specific products according to our current development schedule, if at all.

Even if we successfully prove the efficacy of the *Clearant Process*® for specific products, there can be no assurance that we will be able to successfully market that process to third party manufacturers or that our marketing efforts will result in significant revenues. Various other factors could have material, negative impacts on our results of operations, including difficulties encountered by third parties in obtaining governmental approvals for products which are treated with our pathogen inactivation processes; adverse changes in government regulations; the timing of the introduction of

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

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

Successfully demonstrate the efficacy of the *Clearant Process®* in sterilizing biological products, including devitalized human tissue, serum and recombinant proteins;

Enter into additional license agreements with manufacturers and providers of biological products;

Develop and protect our intellectual property rights;

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

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

These research and development efforts may not be successful or, if they are, the *Clearant Process®* may not obtain market acceptance among major manufacturers and providers of tissues and other biological products.

Achieving market acceptance for the Clearant Process® will depend on our ability to demonstrate the efficacy of the Clearant Process® in our target markets, as well as how the FDA applies the Good Tissue Practice guidelines issued on November 18, 2004.

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

In addition, adoption of the *Clearant Process®* by potential users may depend, in part, on how the GTP regulations issued by the FDA on November 18, 2004 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®* 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 licensees to claim sterility. If the FDA requires additional data from our licensees 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 licensees 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 highly skilled scientific and managerial personnel and to attract additional personnel.

Our success will depend largely on our ability to attract and retain highly skilled scientific and managerial personnel. Competition for desirable scientific and managerial personnel is intense, and we cannot guarantee that we

will be able to attract and retain the necessary staff.

The loss of members of managerial or scientific staff could have a material adverse effect on our future operations and on successful development of the *Clearant Process*® for our target markets. We also collaborate with scientists at

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academic and other institutions, but these scientists and academics may have other commitments or conflicts of interest that limit their availability. The failure to maintain our management 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 will need to expand our finance, administrative, scientific and operations staff. Further, 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.

The Clearant Process® has been commercialized only in the devitalized human 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 devitalized human 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 the *Clearant Process®* for all of our target products. The inability to optimize 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 licensees 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 licensees are unable 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.

To compete effectively with other pathogen inactivation or removal technologies, our processes must be easy to use, regulatorily compliant and cost-effective on a commercial scale. We may not be able to achieve any of these objectives. The *Clearant Process*® or third-party products using it may fail in one or more testing phases or may not attain market acceptance. Third parties may develop superior products or have proprietary rights that preclude us from marketing the

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Clearant Process®. If research and testing are not successful, the *Clearant Process*® will not be commercially viable, and our business, financial condition and results of operation will be materially adversely affected.

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

The *Clearant Process*® has been used in a limited manner on a commercial scale only in the devitalized human tissue market. It may be difficult or impossible to use the *Clearant Process*® economically on a commercial scale for products other than those in which the *Clearant Process*® currently is being used. As part of commercialization of the *Clearant Process*®, we transfer the *Clearant Process*® technology to our licensees in order to allow the licensees to practice the technology and integrate the technology into our facility and/or manufacturing processes. This 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 devitalized human tissue processors. 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 licensee is dependent upon several factors, including the licensee s current manufacturing processes, facilities, personnel, product and packaging. In addition, as a result of limitations associated with product-specific requirements for particular applications of the *Clearant Process*® or otherwise, we may face future situations which could require greater cost and time than anticipated to transfer the technology or where it is unable to effectively transfer the technology at all for use on a commercial scale.

In such case, we would be required to modify the parameters pursuant to which the *Clearant Process*® is applied to the applicable product, which could lead to the need for additional testing and clinical trials by the third party user. If we were required to modify the *Clearant Process*®, our development costs would increase and our programs could be delayed significantly, with a similar delay in receipt of potential licensing revenues. In any such circumstance, we may not be able to successfully modify the *Clearant Process*® at all for use on a particular product on a commercial scale. If we are unable to timely and cost-effectively develop successful technology transfer procedures for its target markets, including appropriate procedures, packaging and specifications, our ability to market and license the *Clearant Process*® and to generate licensing revenues, and its business, financial condition and results of operations, will be adversely affected.

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

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

We cannot be certain that our patents or patents that we license from others will be enforceable and afford protection against competitors. Our patents or patent applications, if issued, may be challenged, invalidated or circumvented. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Even if our patents are valid, we cannot guarantee that competitors will not independently develop alternative technologies that duplicate the functionality of our technology. Due to the extensive time required for development, testing and regulatory review of licensees 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

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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*®.

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, would, if granted) prohibit us from protecting our intellectual property. If there are interfering patents or other intellectual property and we are unable to license such interfering patents or other intellectual property on commercially reasonable terms or to modify the *Clearant Process*® in a cost-effective manner that does not (i) infringe on such intellectual property and (ii) materially impact the viability of the *Clearant Process*®, our business, results of operations and financial condition could be adversely affected.

We may face litigation to defend against claims of infringement, assert claims of infringement, enforce our patents, protect our trade secrets or know-how, or determine the scope and validity of others proprietary rights. Patent and other intellectual property litigation is costly. In addition, we may be required to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine the priority of inventions relating to our patent applications. 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 contacts will not be breached. Further, confidentiality agreements may conflict with other agreements 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® and which cause harm to others, 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 and marketing of biotherapeutics and tissue products treated with the *Clearant Process*®. 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. 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 licensees with the *Clearant Process*® and achieve levels of pathogen inactivation sufficient to meet regulatory standards for sterilization or viral inactivation, yet still contain sufficient pathogens to be harmful to humans.

We have obtained product liability insurance covering the commercial introduction of any product that utilizes our pathogen inactivation processes, but we do not know whether it will be able to maintain such insurance on acceptable terms, if at all. Any insurance we have or may obtain in the future may not provide adequate coverage against potential liabilities. A liability claim, regardless of merit or eventual outcome, and regardless of whether the user of the *Clearant Process*® complied with our standards and procedures for its proper use, could affect manufacturers and the public s

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

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

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

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

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

We believe that our ability to commercialize the *Clearant Process*® effectively will depend on the safety, efficacy and cost-effectiveness of the *Clearant Process*®, as well as the willingness of manufacturers of biological products to adopt new pathogen inactivation technologies. We believe that market acceptance will depend on the extent to which manufacturers and distributors of tissues and other biological products, as well as physicians, patients and health care payors, perceive the benefits of using the *Clearant Process*® and, if applicable, that such benefits outweigh any potential additional cost. As part of its strategy to obtain wide-spread acceptance of the *Clearant Process*®, we have entered into, and intend to continue to seek to enter into, sponsored research agreements with potential users of the *Clearant Process*® to support research on and validation of potential applications of the *Clearant Process*® to such products. While we expect that the *Clearant Process*®, when optimized for application to a particular product, will be capable of inactivating a broad range of known types of pathogenic microorganisms, a product processor or manufacturer may direct us, or may choose, not to optimize the *Clearant Process*® to inactivate the broad range of known types of pathogenic microorganisms in a particular application. If a product produced with such a process results in infections from pathogens that were not adequately inactivated, the marketplace s overall confidence in the *Clearant Process*® may be adversely affected both for that product and for other applications of the *Clearant Process*®.

Even if our processes and the third party products on which they will be used receive the necessary regulatory approvals, our processes may not achieve any significant degree of market acceptance among biological product manufacturers, physicians, patients and health care payors. For various reasons, such as implementation costs, ineffectiveness against all types of pathogens, differing regulatory requirements and logistical concerns, the biological products industry has not always integrated new inactivation technologies into their processes. Although we believe the *Clearant Process*® can significantly improve the safety of devitalized human tissues and other biological products, we cannot provide assurances that our technologies will be accepted rapidly or, other than in the devitalized human tissue market, at all. If our processes fail to achieve market acceptance, we will be unable to implement successfully our licensing strategy and our business, results of operations and financial condition would be materially adversely affected.

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

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

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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, 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 devitalized human 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 other technologies or combinations of existing technologies (including BioCleanse™ used by Regeneration Technologies). 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 devitalized human 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.

Risks Related To Our Industry

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

The use of the *Clearant Process*® on a commercial scale requires the use of commercial gamma irradiation facilities. While there are a number of commercial gamma irradiation service providers in the United States and internationally, the vast majority of U.S. facilities are owned and operated by two commercial gamma irradiation service providers. If customers are not able to negotiate favorable terms with such service providers to treat their

products, our efforts to commercialize the process with additional customers may be hindered.

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

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New, planned and future third-party products which could utilize the *Clearant Process*® and anticipated future uses that result from the *Clearant Process*® are subject to extensive and rigorous regulation by local, state, federal and foreign regulatory authorities. These regulations are wide-ranging and govern, among other things, product development, product testing, product manufacturing, product labeling, product storage, product pre-market clearance or approval, product sales and distribution, product advertising and promotion. The irradiation facilities in which the *Clearant Process*® will be carried out commercially are also subject to state and federal safety, environmental and licensing requirements. Failure by manufacturers and processors to meet any of these regulatory requirements could prevent the manufacturing and/or marketing of a product made with the *Clearant Process*® and could adversely affect our future royalty revenues.

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

Sponsors of innovative biotherapeutic products or medical devices incorporating biological materials must obtain biological products licenses or premarket approvals before legally marketing these products, regardless of whether the *Clearant Process*® is used in their manufacture. Future royalties from the use of the *Clearant Process*® for innovative biotherapeutic products will depend on the sponsors success and timeliness in obtaining initial FDA and/or other required regulatory approval for these products. Manufacturers of existing, approved products would have to submit supplements to their licenses or premarket approvals in order to incorporate the *Clearant Process*® into the manufacturing processes for these products. In most cases, the FDA would have to review and approve these supplements prior to marketing an already approved product made with the *Clearant Process*®. These requirements or FDA and/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 human tissue products for surgical implantation have been exempted by the FDA from the requirements for licensing new products or having manufacturing changes approved prior to implementation. While this may expedite adoption of the *Clearant Process*® for these products by eliminating the regulatory review period, distributors must nevertheless satisfy themselves of the safety and effectiveness of tissue manufactured using the *Clearant Process*®, and tissue processors and distributors must still meet the other regulatory requirements discussed below.

The products enabled by or utilizing the *Clearant Process*® may not receive FDA or other required regulatory approval in a timely manner, if at all. Even if approvals are obtained, the marketing and manufacturing of such products are subject to continuing FDA and other regulatory requirements, such as requirements to comply with good manufacturing practices. The failure to comply with such requirements could result in enforcement action against third party manufacturers which utilize our processes, which could adversely affect our business because our revenues

from licensing the *Clearant Process*® would be reduced or eliminated. Later discovery of problems with a product, manufacturer or facility may result in additional restrictions on the product or manufacturer, including withdrawal of the product from the market or a prohibition against the use of the *Clearant Process*®. Problems with a product, manufacturer or facility which utilizes the *Clearant Process*® may harm other manufacturers and the public s perception of the safety of the *Clearant Process*® generally, which would result in decreased utilization of the *Clearant*

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Process® and a decrease or elimination of our licensing revenues, which would adversely affect our business, financial condition and results of operations.

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

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

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

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

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

We cannot provide assurances that planned trials will begin on time or be completed on schedule or at all, that any trials will result in marketable products or that the *Clearant Process*® will be commercially successful in one or more applications even if they have been approved by the FDA for marketing. Our process development costs will increase

if any third party incorporating our processes has delays in testing or approvals. Similarly, our process development costs will increase if we experience any delays in any testing or studies 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.

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To date, we have commercialized the *Clearant Process®* only for the devitalized human tissue market, for which neither we nor the tissue processors were required to obtain any regulatory approval. Accordingly, we do not have any 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 on the receipt of royalties 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 on receiving royalties from the licensing of the *Clearant Process®* to customers in our target markets. The success of that model depends on our ability to successfully optimize 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 licensing revenues and thus our business, financial condition and results of operations. We will not have control over any such events or developments.

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

Our success will also be subject to the widespread acceptance of the licensees end products. Negative publicity, both in the United States and internationally, concerning improperly sterilized biological products leading to transmission of disease or death, whether or not those products were treated by the *Clearant Process®*, could limit widespread market acceptance of those products, and thus reduce the ability of users of the *Clearant Process®* to sell such products and thus generate licensing revenue for us. For example, recent instances of bacterial transmission through traditionally-processed tissue allografts, one of which resulted in death, resulted in the withdrawal of tissue allografts from the market by one major processor, and may affect the willingness of patients and surgeons to use allografts. Thus, our licensees in the devitalized human 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®*. If our licensees are unable to overcome such a perception, our ability to generate licensing 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®* and thus reduce our current and potential future revenue streams. For example, if synthetic technologies are successfully developed which stimulate the growth of tissue surrounding an implant, it could result in a decline in demand for tissue allografts, which is one of our target markets.

Potential users of the Clearant Process® may depend on third party payors 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 royalty payments.

Potential users of the *Clearant Process*® may depend on third party payors for reimbursement for the use of their products by the end consumer. To the extent that users of the *Clearant Process*® depend on reimbursement of patients medical expenses by government health care programs and private health insurers, the willingness of governments and private insurers to cover the applicable procedure and if so, the level of payment which may apply will affect the

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revenues they receive for their products and thus the royalty revenues that we ultimately receive. Third-party payors may not reimburse users of the users of the *Clearant Process*® at levels which will, in turn, be profitable to us.

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 royalty revenue.

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

Our target markets are generally characterized by a small number of market participants. For example, the devitalized human 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 devitalized human tissue market.

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

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

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.

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.

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

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

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

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the SEC and the 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 regulations and/or laws. If we fail to comply with any of these regulations and/or laws, a range of actions could result, including, but not limited to, the termination of clinical trials, restrictions on products made with the *Clearant Process*®, including withdrawal of products made with the *Clearant Process*® from the market, significant fines, exclusion from government healthcare programs, or other sanctions or litigation.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING INFORMATION

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to the financial condition, results of operations, business strategies, operating efficiencies or synergies, competitive positions, growth opportunities for existing products, plans and objectives of management, markets for stock of Clearant and other matters. Statements in this report that are not historical facts are forward-looking statements for the purpose of the safe harbor provided by Section 21E of the 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 report. These forward-looking statements are subject to risks, uncertainties and assumptions, including those described in the Risk Factors described below, that may affect the operations, performance, development and results of our business. Because the factors discussed in this report could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any such forward-looking statements. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should understand that the following important factors, in addition to those discussed above and in the Risk Factors 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,

competition among addiction treatment centers,

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

development of new treatment modalities,

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.

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 the Company or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this report may not occur.

ITEM 6. Exhibits

(a) Exhibits

Exhibit 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

Exhibit 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

Exhibit 32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Exhibit 32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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SIGNATURES

Pursuant to the requirements 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: May 16, 2005

By: /S/ ALAIN DELONGCHAMP

Alain Delongchamp
Chief Executive Officer

Date: May 16, 2005

By: /S/ DONALD J. LEWIS

Donald J. Lewis
Chief Financial Officer