

Neuralstem, Inc.  
Form 10KSB  
April 02, 2007

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**U.S. SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

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**FORM 10-KSB**

**(Mark one)**

**Annual Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934**

**For the Fiscal Year Ended December 31, 2006**

**or**

**Transition Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Commission File Number 000-1357459**

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**Neuralstem, Inc.**  
**(Name of small business issuer in its charter)**

**Delaware**  
**(State or other jurisdiction**  
**of incorporation or organization)**

**52-2007292**  
**(I.R.S. Employer**  
**Identification No.)**

**9700 Great Seneca Highway**  
**Rockville, Maryland**  
**(Address of principal executive offices)**

**20850**  
**(Zip Code)**

**Issuer's telephone number: 301-366-4841**

**Securities registered under Section 12(b) of the Exchange Act:**

**None**

**Securities registered under Section 12(g) of the Exchange Act:**

**Common Stock**

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

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

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

The issuer's revenues for its most recent fiscal year is \$265,759.

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based upon the closing bid price of the Common Stock on March 30, 2007 was approximately \$90,259,512. Shares of Common Stock held by officers and directors and their affiliated entities have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily conclusive for other purposes.

The number of shares outstanding of Registrant's common stock, \$0.001 par value at March 29, 2007 was 28,884,605.

Transitional Small Business Disclosure Format (check one): Yes  No

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## Subsequent Event

On March 15, 2007, we completed the private placement of 2,054,000 units to institutional investors. The units consist of one share of common stock and one half common stock purchase warrant. An aggregate of 2,054,000 common shares and warrants to purchase an additional 1,027,000 common shares were issued. The units were priced at \$2.50 each and resulted in gross proceeds to the Company of \$5,135,000.00. The investors also received certain registration rights with regard to the underlying securities. The exercise price of the warrants is \$3.00.

On March 27, 2007, we sold an additional 400,000 units to an institutional investors. An additional 400,000 common shares and warrants to purchase as additional 200,000 common shares were issued. The offering resulted in gross proceeds of an additional \$1,000,000 to the Company.

In connection with the offerings, the Company paid fees and expenses totaling \$561,300.00 and issued its placement agent a warrant to purchase 294,480 common shares at \$3.00.

## FORWARD LOOKING STATEMENTS

In this annual report we make a number of statements, referred to as “forward-looking statements”, which are intended to convey our expectations or predictions regarding the occurrence of possible future events or the existence of trends and factors that may impact our future plans and operating results. These forward-looking statements are derived, in part, from various assumptions and analyses we have made in the context of our current business plan and information currently available to use and in light of our experience and perceptions of historical trends, current conditions and expected future developments and other factors we believe are appropriate in the circumstances. You can generally identify forward looking statements through words and phrases such as “*believe*”, “*expect*”, “*seek*”, “*estimate*”, “*anticipate*”, “*intend*”, “*plan*”, “*budget*”, “*project*”, “*may likely result*”, “*may be*”, “*may continue*” and other similar expressions. When reading any forward-looking statement you should remain mindful that actual results or developments may vary substantially from those expected as expressed in or implied by that statement for a number of reasons or factors, including but not limited to:

- the success of our research and development activities, the development of a viable commercial production model, and the speed with which regulatory authorizations and product launches may be achieved;
- whether or not a market for our product develops and, if a market develops, the rate at which it develops;
- our ability to successfully sell our products if a market develops;
- our ability to attract and retain qualified personnel to implement our growth strategies;
- our ability to develop sales marketing and distribution capabilities;
- our ability to obtain reimbursement from third party payers for the products that we sell;
- the accuracy of our estimates and projections;
- our ability to fund our short-term and long-term financing needs;
- changes in our business plan and corporate strategies; and

- other risks and uncertainties discussed in greater detail in the section captioned “Risk Factors”

Each forward-looking statement should be read in context with and in understanding of the various other disclosures concerning our company and our business made elsewhere in this annual report. You should not place undue reliance on any forward-looking statement as a prediction of actual results or developments. We are not obligated to update or revise any forward-looking statements contained in this annual report to reflect new events or circumstances unless and to the extent required by applicable law.

## **RISK FACTORS**

An investment in Neuralstem, Inc. involves significant risks. You should read these risk factors carefully before deciding whether to invest in our company. The following is a description of what we consider our key challenges and risks.

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## **Risks Relating to the Company's Stage of Development**

***Since the Company has a limited operating history and has significantly shifted its operations and strategies since inception, you cannot rely upon the Company's limited historical performance to make an investment decision.***

Since inception in 1996 and through December 31, 2006, the Company has raised in aggregate, approximately \$39,994,994 in capital and recorded accumulated losses totaling \$38,592,725 as of December 31, 2006. The Company had a working capital of \$1,485,024 and stockholder's equity of \$1,552,269. Our net losses for the two most recent fiscal years have been \$3,147,488 and \$1,651,507 for 2006 and 2005 respectively. During this period, we have generated only marginal revenue from licensing and grants in the amount of \$265,759 and \$309,142 for the 2006 and 2005 fiscal years, respectively.

The Company's ability to generate revenues and achieve profitability depends upon its ability to complete the development of its stem cell products, obtain the required regulatory approvals, manufacture, market and sell its products. In part because of the Company's past operating results, no assurances can be given that the Company will be able to accomplish all or any these goals.

Although the Company has generated some revenue to date, the Company has not generated any revenue from the commercial sale of its proposed stem cell products. Since inception, the Company has engaged in several related lines of business and has discontinued operations in certain areas. For example, in 2002, the Company lost a material contract with the Department of Defense and was forced to close its principal facility and lay off almost all of its employees in an attempt to focus the Company's strategy on its stem cell technology. This limited and changing history may not be adequate to enable you to fully assess the Company's current ability to develop and commercialize its technologies and proposed products, obtain approval from the U.S. Food and Drug Administration ("FDA"), achieve market acceptance of its proposed products and respond to competition. No assurances can be given as to exactly when, if at all, the Company will be able to fully develop, commercialize, market, sell and derive material revenues from its proposed products in development.

***The Company will need to raise additional capital to continue operations, and failure to do so will impair the Company's ability to fund operations, develop its technologies or promote its products.***

The Company has relied almost entirely on external financing to fund operations. Such financing has historically come primarily from the sale of common and preferred stock and convertible debt to third parties and to a lesser degree from grants, loans and revenue from license and royalty fees. The Company anticipates, based on current proposed plans and assumptions relating to its operations (including the timetable of, and costs associated with, new product development) and financings the Company has undertaken prior to the date of this annual report, that its current working capital will be sufficient to satisfy contemplated cash requirements for approximately 24 months, assuming that the Company does not engage in an extraordinary transaction or otherwise face unexpected events or contingencies, any of which could effect cash requirements. As of March 29, 2007, the Company has cash and cash equivalents on hand of \$6,713,296. Presently, the Company has a monthly cash burn rate of \$260,000. Accordingly, the Company will need to raise additional capital to fund anticipated operating expenses and future expansion after such 24 month period. Among other things, external financing will be required to cover the further development of the Company's technologies and products and other operating costs. The Company cannot assure you that financing whether from external sources or related parties will be available if needed or on favorable terms. If additional financing is not available when required or is not available on acceptable terms, the Company may be unable to fund operations and planned growth, develop or enhance its technologies, take advantage of business opportunities or respond to competitive market pressures. Any negative impact on the Company's operations may make capital raising more difficult and may also result in a lower price for the Company's securities.

*The Company may have difficulty raising needed capital in the future as a result of, among other factors, the Company's limited operating history and business risks associated with the Company.*

The Company's business currently generates limited amounts of cash which will not be sufficient to meet its future capital requirements. The Company's management does not know when this will change. The Company has expended and will continue to expend substantial funds in the research, development and clinical and pre-clinical testing of the Company's stem cell technologies and products. The Company will require additional funds to conduct research and development, establish and conduct clinical and pre-clinical trials, commercial-scale manufacturing arrangements and to provide for the marketing and distribution. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable from any available source, the Company may have to delay, reduce the scope of or eliminate one or more of its research, development or commercialization programs or product launches or marketing efforts which may materially harm the Company's business, financial condition and results of operations.

The Company's long term capital requirements are expected to depend on many factors, including:

- continued progress and cost of its research and development programs;
- progress with pre-clinical studies and clinical trials;
- time and costs involved in obtaining regulatory clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- costs of developing sales, marketing and distribution channels and its ability to sell the Company's stem cell products;

- costs involved in establishing manufacturing capabilities for commercial quantities of its products;
- competing technological and market developments;
- market acceptance of its stem cell products;
- costs for recruiting and retaining employees and consultants; and
- costs for educating and training physicians about its stem cell products.

The Company may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. The Company may seek to raise any necessary additional funds through the exercising of warrants, options, equity or debt financings, collaborative arrangements with corporate partners or other sources, which may be dilutive to existing stockholders or otherwise have a material effect on the Company's current or future business prospects. If adequate funds are not available, the Company may be required to significantly reduce or refocus its development and commercialization efforts.

***The Company relies on stem cell technologies that it may not be able to commercially develop, which will prevent the Company from generating revenues, operating profitably or providing investors any return on their investment.***

The Company has concentrated its research on its stem cell technologies, and the Company's ability to generate revenue and operate profitably will depend on it being able to develop these technologies for human applications. These are emerging technologies with, as yet, limited human applications. The Company cannot guarantee that it will be able to develop its stem cell technologies or that such development will result in products or services with any significant commercial utility. The Company anticipates that the commercial sale of such products or services, and royalty/licensing fees related to its technology, will be the Company's primary sources of revenues. If the Company is unable to develop its technologies, investors will likely lose their entire investment.

***Inability to complete pre-clinical and clinical testing and trials will impair the viability of the Company.***

The Company is in its development stage and has not yet applied for approval by the FDA to conduct clinical trials. Even if the Company successfully files an IND and receives approval from the FDA to commence trials, the outcome of pre-clinical, clinical and product testing of the Company's products is uncertain, and if the Company is unable to satisfactorily complete such testing, or if such testing yields unsatisfactory results, the Company will be unable to commercially produce its proposed products. Before obtaining regulatory approvals for the commercial sale of any potential human products, the Company's products will be subjected to extensive pre-clinical and clinical testing to demonstrate their safety and efficacy in humans. No assurances can be given that the clinical trials of the Company's products, or those of licensees or collaborators, will demonstrate the safety and efficacy of such products at all, or to the extent necessary to obtain appropriate regulatory approvals, or that the testing of such products will be completed in a timely manner, if at all, or without significant increases in costs, program delays or both, all of which could harm the Company's ability to generate revenues. In addition, the Company's proposed products may not prove to be more effective for treating disease or injury than current therapies. Accordingly, the Company may have to delay or abandon efforts to research, develop or obtain regulatory approval to market its proposed products. Many companies involved in biotechnology research and development have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and efficacy of a therapeutic product under development could delay or prevent regulatory approval of the product and could harm the Company's ability to generate revenues, operate profitably or produce any return on an investment in the Company.

***The Company's additional financing requirements could result in dilution to existing stockholders.***

The additional financings which the Company will require may in the future be obtained through one or more transactions which will effectively dilute the ownership interests of stockholders. The Company has the authority to issue additional shares of common stock and preferred stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. The Company is authorized to issue 75,000,000 shares of common stock and 7,000,000 shares of preferred stock. Such securities may be issued without the approval or other consent of the Company's stockholders.

#### **Risks Relating to Intellectual Property and Government Regulation**

*The Company may not be able to withstand challenges to its intellectual property rights, such as patents, should contests be initiated in court or at the U.S Patent and Trademark Office.*

The Company relies on its intellectual property, including its issued and applied for patents, as the foundation of its business. The intellectual property rights of the Company may come under challenge, and no assurances can be given that, even though issued, the Company's current and potential future patents will survive claims commencing in the court system alleging invalidity or infringement on other patents. For example, in 2005, the Company's neural stem cell technology was challenged in the U.S. Patent and Trademark Office by a competitor. Although the Company prevailed in this particular matter upon re-examination by the patent office, these cases are complex, lengthy and expensive, and could potentially be adjudicated adversely to the Company, removing the protection afforded by an issued patent. The viability of the Company's business would suffer if such patent protection were limited or eliminated. Moreover, the costs associated with defending or settling intellectual property claims would likely have a material adverse effect on the Company.

***The Company may not be able to adequately protect against piracy of intellectual property in foreign jurisdictions.***

Considerable research in the area of stem cell therapies is being performed in countries outside of the United States, and a number of the Company's competitors are located in those countries. The laws protecting intellectual property in some of those countries may not provide protection for the Company's trade secrets and intellectual property adequate to prevent its competitors from misappropriating the Company's trade secrets or intellectual property. If the Company's trade secrets or intellectual property are misappropriated in those countries, the Company may be without adequate remedies to address the issue.

***The Company's products may not receive FDA approval, which would prevent the Company from commercially marketing its products and producing revenues.***

The FDA and comparable government agencies in foreign countries impose substantial regulations on the manufacture and marketing of pharmaceutical products through lengthy and detailed laboratory, pre-clinical and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these regulations typically takes several years or more and varies substantially based upon the type, complexity and novelty of the proposed product. The Company cannot yet accurately predict when it might first submit any Investigational New Drug, or IND, application to the FDA, or whether any such IND application would be granted on a timely basis, if at all, nor can the Company assure you that it will successfully complete any clinical trials in connection with any such IND application. Further, the Company cannot yet accurately predict when it might first submit any product license application for FDA approval or whether any such product license application would be granted on a timely basis, if at all. As a result, the Company cannot assure you that FDA approvals for any products developed by it will be granted on a timely basis, if at all. Any such delay in obtaining, or failure to obtain, such approvals could have a material adverse effect on the marketing of the Company's products and its ability to generate product revenue.

***Because the Company or its collaborators must obtain regulatory approval to market its products in the United States and other countries, the Company cannot predict whether or when it will be permitted to commercialize its products.***

Federal, state and local governments and agencies in the United States (including the FDA) and governments in other countries have significant regulations in place that govern many of the Company's activities. The Company is or may become subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances used in connection with its research and development work. The preclinical testing and clinical trials of the products that the Company or its collaborators develop are subject to extensive government regulation that may prevent the Company from creating commercially viable products from its discoveries. In addition, the sale by the Company or its collaborators of any commercially viable product will be subject to government regulation from several standpoints, including manufacturing, advertising and promoting, selling and marketing, labeling, and distributing. If, and to the extent that, the Company is unable to comply with these regulations, its ability to earn revenues will be materially and negatively impacted.

## **Risks Relating to Competition**

*The Company's competition includes both public and private organizations and collaborations among academic institutions and large pharmaceutical companies, most of which have significantly greater experience and financial resources than the Company does.*

The biotechnology industry is characterized by intense competition. The Company competes against numerous companies, many of which have substantially greater financial and other resources than it has. Several such enterprises have initiated cell therapy research programs and/or efforts to treat the same diseases targeted by the Company. Companies such as Geron Corporation, Genzyme Corporation, StemCells, Inc., Advanced Cell Technology, Inc., Aastrom Biosciences, Inc. and Viacell, Inc., as well as others, have substantially greater resources and experience in the Company's fields than it does, and are well situated to compete with us effectively. Of course, any of the world's largest pharmaceutical companies represent a significant actual or potential competitor with vastly greater resources than the Company's.

## **Risks Relating to the Company's Reliance on Third Parties**

*The Company's outsource model depends on collaborators, non-employee consultants, research institutions, and scientific contractors to help it develop and test its proposed products. Our ability to develop such relationships could impair or delay our ability to develop products.*

The Company's strategy for the development, clinical testing and commercialization of its proposed products is based on an outsource model. This model requires that the Company enter into collaborations with corporate partners, research institutions, scientific contractors and licensors, licensees and others in order to further develop its technology and develop products. In the event the Company is not able to enter into such relationships in the future, our ability to develop products may be seriously hindered; or we would be required to expend considerable money and research to bring such research and development functions in house. Either outcome could result in our inability to develop a commercially feasible product or in the need for substantially more working capital to complete the research in-house. Also, we are currently dependent on collaborators for a substantial portion of our research and development. Although our collaborative agreements do not impose any duties or obligations on us other than the licensing of our technology, the failure of any of these collaborations may hinder our ability to develop products in a timely fashion. By way of example, our collaboration with John Hopkins University, School of Medicine yielded findings that contributed to our patent application entitled Transplantation of Human Cells for Treatment of Neurological Disorder. Had the collaboration not have existed, our ability to apply for such patent would have been greatly hindered. We currently have 4 key collaborations. They are with:

- The University of California, San Diego;
- University of South Florida;
- University of Central Florida; and
- John Hopkins University.

As we are under no financial obligation to provide additional funding under any of these collaborations, our primary risk is that no results are derived from their research. For further information relating to our collaborations, see that section of this annual report captioned “ *Our Business--Our Research and Programs*”.

*We intend to rely upon the third-party FDA-approved manufacturers for our stem cells. Should these manufacturers fail to perform as expected, we will need to develop or procure other manufacturing sources, which*

*would cause delays or interruptions in our product supply and result in the loss of significant sales and customers.*

We currently have no internal manufacturing capability, and will rely extensively on FDA-approved licensees, strategic partners or third party contract manufacturers or suppliers. We current have an agreement with Charles River Laboratories for the manufacturing and storage of our cells. The agreement is a paid for services agreement and does not require us to purchase a minimum amount of cells. In the event Charles River Laboratories fails to provide suitable cells, we would be forced to either manufacture the cells ourselves or seek other third party vendors. Should we be forced to manufacture our stem cells, we cannot give you any assurance that we will be able to develop an internal manufacturing capability or procure third party suppliers. In the event we must seek alternative third party suppliers, they may require us to purchase a minimum amount of cells, could be significantly more expensive than our current supplier, or could require other unfavorable terms. Any such event would materially impact our prospects and could delay our development. Moreover, we cannot give you any assurance that any contract manufacturers or suppliers we procure will be able to supply our product in a timely or cost effective manner or in accordance with applicable regulatory requirements or our specifications.

### **General Risks Relating to the Company's Business**

*The Company may be subject to litigation that will be costly to defend or pursue and uncertain in its outcome.*

The Company's business may bring it into conflict with its licensees, licensors, or others with whom it has contractual or other business relationships or with its competitors or others whose interests differ from the Company's. If the Company is unable to resolve those conflicts on terms that are satisfactory to all parties, the Company may become involved in litigation brought by or against it. That litigation is likely to be expensive and may require a significant amount of management's time and attention, at the expense of other aspects of the Company's business. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require the Company to pay damages, enjoin it from certain activities, or otherwise affect its legal or contractual rights, which could have a significant adverse effect on its business.

*The Company may not be able to obtain third-party patient reimbursement or favorable product pricing, which would reduce its ability to operate profitably.*

The Company's ability to successfully commercialize certain of its proposed products in the human therapeutic field may depend to a significant degree on patient reimbursement of the costs of such products and related treatments at acceptable levels from government authorities, private health insurers and other organizations, such as health maintenance organizations. The Company cannot assure you that reimbursement in the United States or foreign countries will be available for any products it may develop or, if available, will not be decreased in the future, or that reimbursement amounts will not reduce the demand for, or the price of, its products with a consequent harm to the Company's business. The Company cannot predict what additional regulation or legislation relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such regulation or legislation may have on the Company's business. If additional regulations are overly onerous or expensive or if health care related legislation makes its business more expensive or burdensome than originally anticipated, the Company may be forced to significantly downsize its business plans or completely abandon its business model.

***The Company's products may be expensive to manufacture, and they may not be profitable if the Company is unable to control the costs to manufacture them.***

The Company's products may be significantly more expensive to manufacture than most other drugs currently on the market today due to a fewer number of potential manufactures, greater level of needed expertise, and other general market conditions affecting manufacturers of stem cell based products. The Company would hope to substantially reduce manufacturing costs through process improvements, development of new science, increases in manufacturing scale and outsourcing to experienced manufacturers. If the Company is not able to make these, or other improvements, and depending on the pricing of the product, its profit margins may be significantly less than that of most drugs on the market today. In addition, the Company may not be able to charge a high enough price for any cell therapy product it develops, even if they are safe and effective, to make a profit. If the Company is unable to realize significant profits from its potential product candidates, its business would be materially harmed.

***In order to secure market share and generate revenues, the Company's proposed products must be accepted by the health care community, which can be very slow to adopt or unreceptive to new technologies and products.***

The Company's proposed products and those developed by its collaborative partners, if approved for marketing, may not achieve market acceptance since hospitals, physicians, patients or the medical community in general may decide not to accept and utilize these products. The products that the Company is attempting to develop represents substantial departures from established treatment methods and will compete with a number of more conventional drugs and therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any of the Company's developed products will depend on a number of factors, including:

- the Company's establishment and demonstration to the medical community of the clinical efficacy and safety of its proposed products;
- the Company's ability to create products that are superior to alternatives currently on the market;
- the Company's ability to establish in the medical community the potential advantage of its treatments over alternative treatment methods; and
- reimbursement policies of government and third-party payors.

If the health care community does not accept the Company's products for any of the foregoing reasons, or for any other reason, the Company's business would be materially harmed.

***We depend on two key employees for our continued operations and future success. A loss of either employee could significantly hinder our ability to move forward with our business plan.***

The loss of either of our key executive officers, Richard Garr and Karl Johe, would be significantly detrimental to us.

- We currently do not maintain “key person” life insurance on the life of Mr. Garr. As a result, the Company will not receive any compensation upon the death or incapacity of this key individuals;
- We currently do maintain “key person” line insurance on the life of Mr. Johe. As a result, the Company will receive approximately \$1,000,000 in the event of his death or incapacity.

In addition, the Company's anticipated growth and expansion into areas and activities requiring additional expertise, such as clinical testing, regulatory compliance, manufacturing and marketing, will require the addition of new

management personnel and the development of additional expertise by existing management personnel. There is intense competition for qualified personnel in the areas of the Company's present and planned activities, and there can be no assurance that the Company will be able to continue to attract and retain the qualified personnel necessary for the development of its business. The failure to attract and retain such personnel or to develop such expertise would adversely affect the Company's business.

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***The Company has entered into long-term contracts with key personnel and stockholders, with significant anti-termination provisions, which could make future changes in management difficult or expensive.***

Messrs. Garr and Johe have entered into seven (7) year employment agreements with the Company which expire on November 1, 2012 and which include termination provisions stating that if either employee is terminated for any reason other than a voluntary resignation, then all compensation due to such employee under the terms of the respective agreement shall become due and payable immediately. These provisions will make the replacement of either of these employees very costly to the Company, and could cause difficulty in effecting a change in control of the Company. Termination prior to full term on the contracts would cost the Company \$240,000 per year unserved, or as much as \$1,680,000 per contract, and immediate vesting of all outstanding options (1,200,000 shares each). *Executive Compensation--Employment Agreements and Change in Control Arrangements*".

***The Company has no product liability insurance, which may leave it vulnerable to future claims that the Company will be unable to satisfy.***

The testing, manufacturing, marketing and sale of human therapeutic products entails an inherent risk of product liability claims, and the Company cannot assure you that substantial product liability claims will not be asserted against it. The Company has no product liability insurance. In the event the Company is forced to expend significant funds on defending product liability actio