

Neuralstem, Inc.
Form SB-2
April 30, 2007

Filed with the Securities and Exchange Commission on April 30, 2007
Registration No. [_____]

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

FORM SB-2

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

NEURALSTEM, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware <i>(State of Incorporation)</i>	2836 <i>(Primary Standard Industrial Code No.)</i>	52-2007292 <i>(IRS Employer Identification No.)</i>
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9700 Great Seneca Highway, Rockville, Maryland 20850
(301) 366-4841
(Address and telephone number of principal executive offices)

Paracorp Inc
40 E. Division Street Suite A
Dover, DE 19901
888-372-7273
(Name, address and telephone number of agent for service)

Copies to:

Raul Silvestre
Law Offices of Raul Silvestre & Associates, APLC
31200 Via Colinas, Suite 200
Westlake Village, CA 91362

Approximate date of commencement of proposed sale to the public: From time-to-time after the effective date of this Registration Statement.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

offering.

If delivery of the Prospectus is expected to be made pursuant to Rule 434, please check the following box.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Offering Price Per Share	Proposed Aggregate Offering Price	Amount Of Registration Fee
Common Stock	2,454,000	\$ 3.95 ⁽¹⁾	\$ 9,693,300	\$ 297.58
Common Stock underlying warrants	1,227,000	\$ 3.95	\$ 4,846,650	\$ 148.79
Common Stock underlying Placement Agent Warrant	294,480	\$ 3.95	\$ 1,163,196	\$ 35.71
Total	3,975,480		\$ 15,703,146	\$ 482.08

- (1) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457 under the Securities Act of 1933 based upon the average of the high and low prices of the registrant's common stock on April 27, 2007 on the over the counter stock market.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

The information in this Prospectus is not complete and may be changed. We have filed a registration statement containing this prospectus with the Securities and Exchange Commission. The securities offered for sale under this prospectus may not be offered for sale or sold until the registration statement filed with the Securities and Exchange Commission is effective. This Prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

OFFERING PROSPECTUS
Subject to completion, dated April 30, 2007

NEURALSTEM, INC.
A DELAWARE CORPORATION

3,975,480
Common Shares

The selling stockholders identified on pages 34 of this prospectus are offering on a resale basis a total of 3,975,480 shares of our common stock. Although we will incur expenses in connection with the registration of the common stock, we will not receive any of the proceeds from the sale of the shares of common stock by the selling stockholders. We will receive gross proceeds of up to \$6,762,000 from the exercise of the warrants, if and when they are exercised.

Our common stock is listed on the OTC Bulletin Board and traded under the symbol "NRLS.OB." On April 27, 2007, the closing price of the common stock quoted on the OTC Bulletin Board was \$3.95 per share.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read this entire prospectus and any amendments or supplements carefully before you make your investment decision.

The securities offered by this prospectus involve a high degree of risk.
See "Risk Factors" beginning on page

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined that this prospectus is truthful or complete. A representation to the contrary is a criminal offense.

The date of this Prospectus is April 30, 2007

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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.

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 \$1,486,154 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 prospectus, that its current working capital will be sufficient to satisfy contemplated cash requirements for approximately 20 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 the date of this prospectus, the Company has cash and cash equivalents on hand of approximately \$6,400,000. 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 20 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 prospectus captioned “ *Our Business--Our Research and Programs*”