Neuralstem, Inc. Form S-3 May 01, 2008

As filed with the Securities and Exchange Commission on April \_\_\_\_, 2008

Registration No. 333-\_\_

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

# FORM S-3 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Neuralstem, Inc. (Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization) 52-2007292

(I.R.S. Employer Identification Number)

Neuralstem, Inc. 9700 Great Seneca Highway Rockville, Maryland 20850 (301) 366-4841

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Paracorp Inc 40 E. Division Street Suite A Dover, DE 19901 (888)-372-7273

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

With a copy to:
Raul Silvestre
Law Offices of Raul Silvestre & Associates, APLC
31200 Via Colinas, Suite 200
Westlake Village, CA 91362
(818)597-7552

**Approximate date of commencement of proposed sale to the public:** From time to time after this registration statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box."

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

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

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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box."

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box."

# **CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Offering Price Per Share	Proposed Aggregate Offering Price	Amount Of Registration Fee
Common Stock	615,309	1.9(2)	1,169,087	\$ 45.95
Common Stock underlying Warrant	1,227,000	1.9(2)	2,331,300	\$ 91.62
Total	1,842,309			\$ 137.57

- (1) Pursuant to SEC Rule 416(a), also covers additional common shares that may be offered to prevent dilution as a result of stock splits, stock dividends or similar transactions relating to these securities.
- (2) 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 28, 2008 on the American Stock Exchange.

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The information in this prospectus is not complete and may be changed. A registration statement relating to the securities has been filed with the Securities and Exchange Commission. We may not sell these securities 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.

#### SUBJECT TO COMPLETION, DATED APRIL 30, 2008

#### **PROSPECTUS**

#### **NEURALSTEM, INC.**

1,842,309 Shares of Common Stock

This prospectus relates to the resale of up to 1,842,309 shares of our common stock being offered by the selling stockholders. We will not receive any proceeds from the sale of the shares of common stock by the selling stockholders.

Our shares of common stock are quoted on The American Stock Exchange under the symbol "CUR" The average of the high and low price of our common stock on April 28, 2008, was \$1.90.

THIS INVESTMENT INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD PURCHASE SHARES ONLY IF YOU CAN AFFORD A COMPLETE LOSS OF YOUR INVESTMENT. SEE "RISK FACTORS" BEGINNING ON PAGE 3 FOR A DISCUSSION OF RISKS APPLICABLE TO US AND AN INVESTMENT IN OUR COMMON STOCK.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED THESE SECURITIES, OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

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#### PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding to invest in our securities. We urge you to read this entire prospectus carefully, including the" Risk Factors" section and the consolidated financial statements and related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, filed with the Securities and Exchange Commission ("SEC") on March 27, 2008. As used in this prospectus, unless context otherwise requires, the words "we," "us," "our," "the Company" and "Neuralstem" refer to Neuralstem, Inc.

#### FORWARD LOOKING STATEMENTS

This prospectus, and the documents incorporated into it by reference, contains forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), 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 such 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 Prospectus as well as our public filings with the Securities and Exchange Commission. 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 Prospectus or any other filing to reflect new events or circumstances unless and to the extent required by applicable law.

#### **SUMMARY**

#### Overview

Neuralstem is focused on the development and commercialization of treatments based on transplanting human neural stem cells.

We have developed and maintain a portfolio of patents and patent applications that form the proprietary base for our research and development efforts in the area of neural stem cell research. We own or exclusively license four (4) issued patents and thirteen (13) patent pending applications in the field of regenerative medicine and related technologies. We believe our technology base, in combination with our know-how, and collaborative projects with major research institutions provides a competitive advantage and will facilitate the successful development and commercialization of products for use in the treatment of a wide array of neurodegenerative conditions and in regenerative repair of acute disease.

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This is a young and emerging field. There can be no assurances that our intellectual property portfolio will ultimately produce viable commercialized products and processes. Even if we are able to produce a commercially viable product, there are strong competitors in this field and our product may not be able to successfully compete against them.

All of our research efforts to date are at the level of basic research or in the pre-clinical stage of development. We are focused on leveraging our key assets, including our intellectual property, our scientific team, our facilities and our capital, to accelerate the advancement of our stem cell technologies. In addition, we are pursuing strategic collaborations with members of academia. We are headquartered in Rockville, Maryland.

In addition to our core tissue based technology we have begun developing a Small-Molecule compound. The company has performed preliminary *in vitro* and *in vivo* tests on the compound with regard to neurogenesis. Based on the results of these tests we have applied for a U.S. patent on the compound.

#### **Technology**

Our technology is the ability to isolate human neural stem cells from most areas of the developing human brain and spinal cord and our technology includes the ability to grow them into physiologically relevant human neurons of all types. Our two issued core patents entitled: (i) *Isolation, Propagation, and Directed Differentiation of Stem Cell from Embryonic and Adult Central Nervous System of Mammals*; and (ii) *In Vitro Generation of Differentiated Neurons from Cultures of Mammalian Multi-potential CNS Stem Cell* contain claims which cover the process of deriving the cells and the cells created from such process.

What differentiates our stem cell technology from others is that our patented processes do not require us to "push" the cells towards a certain fate by adding specific growth factors. Our cells actually "become" the type of cell they are fated to be. We believe this process and the resulting cells create a technology platform that allows for the efficient isolation and ability to produce, in commercially reasonable quantities, neural stem cells from the human brain and spinal cord.

Our technology allows for cells to grow in cultured dishes, also known as *in vitro* growth, without mutations or other adverse events that would compromise their usefulness.

#### Research

We have devoted substantial resources to our research programs in order to isolate and develop a series of neural stem cell banks that we believe can serve as a basis for therapeutic products. Our efforts to date have been directed at methods to identify, isolate and culture large varieties of stem cells of the human nervous system, and to develop therapies utilizing these stem cells. This research is conducted both internally and through the use of third party laboratory consulting companies under our direct supervision.

As of December 31, 2007, we had 7 full-time employees. Of these employees three work on Research and development and four in administration. We also use the services of numerous outside consultants in business and scientific matters. We believe that we have good relations with our employees and consultants.

#### THE OFFERING

Common stock being offered by Selling

Up to 1,842,309 shares

Stockholders

American Stock Exchange Symbol CUR

Risk Factors The securities offered by this prospectus are speculative

and involve a high degree of risk and investors

purchasing securities should not purchase the securities unless they can afford the loss of their entire investment. See "Risk Factors" beginning on page 3.

#### **RISK FACTORS**

We have described below a number of uncertainties and risks which, in addition to uncertainties and risks presented elsewhere in this Prospectus, may adversely affect our business, operating results and financial condition. The uncertainties and risks enumerated below as well as those presented elsewhere in this Prospectus should be considered carefully in evaluating our company and our business and the value of our securities.

#### 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, 2007, the Company has recorded accumulated losses totaling \$45,655,997. On December 31, 2007, the Company had a working capital surplus of \$6,517,757 and stockholders' equity of \$6,809,354. Our net losses for the two most recent fiscal years have been (\$7,603,272) and (\$3,147,487) for 2007 and 2006 respectively. Revenues for the twelve months ended December 31, 2007 were \$306,057.

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, and 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, the exercise of investor warrants 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 11 months, assuming that the Company does not engage in an extraordinary transaction or otherwise face unexpected events or contingencies, any of which could affect cash requirements. As of December 31, 2007, the Company had cash equivalents on hand of \$7,403,737. Presently, the Company has a monthly cash burn rate of approximately \$400,000. Accordingly, the Company will need to raise additional capital to fund anticipated operating expenses and future expansion after such 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 resulting 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.

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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 Investigational New Drug Application (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.

At present, the Company is not able to finance it operations through the sales of its product. Accordingly, the Company will be required to secure additional financing. If the Company is able to obtain such additional financings such financing may be dilutive to current shareholders. 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.

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# 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 n