Neuralstem, Inc. Form S-3/A April 27, 2010

As filed with the Securities and Exchange Commission on April 27, 2010

Registration No. 333-165973

**UNITED STATES** 

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

Amendment No. 1 to 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 Silvestre Law Group, P.C. 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 (8)
Common Stock, par value \$0.01	786,551	\$	2.01(2)	1,577,034	112.44
Common Stock, par value \$0.01(4)	400,000	\$	2.01(3)	804,000	57.33
Common Stock, par value \$0.01(5)	3,481,405	\$	2.13(3)	7,415,393	528.72
Common Stock, par value \$0.01(6)	400,000	\$	2.01(3)	804,000	57.33
Common Stock, par value \$0.01(7)	96,000	\$	2.01(3)	192,960	13.76
Total	5,163,956			10,793,387	769.57

- (1) Pursuant to SEC Rule 416, also covers additional common shares that may be offered to prevent dilution as a result of stock splits or stock dividends.
- (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 2, 2010.
- (3) Fee based on exercise price of applicable to shares issuable upon exercise of warrants in accordance with Rule 457(g)
- (4) Represents common shares issuable upon the exercise (at a price of \$1.85 per share) of outstanding warrants.
- (5) Represents common shares issuable upon the exercise (at a price of \$2.13 per share) of outstanding warrants.
- (6) Represents common shares issuable upon the exercise (at a price of \$1.70 per share) of outstanding warrants issued to a consultant as compensation.
- (7) Represents common shares issuable upon the exercise (at a price of \$1.25 per share) of outstanding warrants issued to a consultant as compensation.
- (8) The Registrant previously paid the Registration Fee in connection with the initial filing of this registration statement (File No. 333-165973) filed with the Securities and Exchange Commission on April 9, 2010.

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 said Section 8(a), may determine.

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 27, 2010

#### **PROSPECTUS**

#### NEURALSTEM, INC.

#### 5,163,956 Shares of Common Stock

This prospectus relates to the resale of up to 5,163,956 shares of our common stock being offered by the selling shareholders listed on page 11. We will not receive any proceeds from the sale of the shares of common stock by the selling shareholders.

Our shares of common stock are quoted on the NYSE: AMEX under the symbol "CUR." On April 2, 2010, the last reported sales price of our common stock was, was \$2.02.

Our principal	executive	offices are	located at 97	'00 Great S	leneca Highway,	, Rockville, MD,	telephone number
301-366-4841.							

Investing in our common stock involves a high degree of risk. You are urged to read the section entitled "Risk Factors" beginning on page 3; of this prospectus, which describes specific risks and other information that should be considered before you make an investment decision.

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.

The Date of this Prospectus is [\_\_], 2010

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#### PROSPECTUS SUMMARY

The summary below 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, 2009, filed with the Securities and Exchange Commission ("SEC") on March 31, 2010. As used in this prospectus, unless context otherwise requires, the words "we," "us," "our," "the Company" and "Neuralstem" refer to Neuralstem, Inc. Al any reference to "common shares," or "common stock," refers to our \$.01 par value common stock.

#### **Our Business**

We are focused on the development and commercialization of treatments for central nervous system disease based on transplanting human neural stem cells and small molecule drugs.

We have developed and maintain a portfolio of patents and patent applications that form the proprietary base of our research and development efforts in the areas of neural stem cell research, small molecule research, and related technologies. We believe our patented technology, in combination with our know-how, and collaborative projects with major research institutions, provide a competitive advantage and will enable us to develop and commercialize products for use in treatment of a number of neurodegenerative conditions and in regenerative repair of acute disease.

Regenerative medicine 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 either the level of research or pre-clinical stage of development, or at the clinical stage of development. On December 18, 2008 we filed our first Investigational New Drug Application ("IND") with the U.S. Food and Drug Administration ("FDA") to begin a clinical trial to treat Amyotrophic Lateral Sclerosis ("ALS" or "Lou Gehrig's disease"). On September 21, 2009, the FDA approved our IND. The first patient in our study was dosed on January 21, 2010.

In addition to our core stem cell based technologies, we have developed and patented a series of small molecule compounds (low molecular weight organic compounds which can efficiently cross the blood/brain barrier). The Company expects to file an IND to commence a human safety trial of its lead compound to treat major depression in late 2010 or early 2011.

#### 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. These two core patents form the foundation of our proposed stem cell products.

#### Research

We have devoted substantial resources to our research programs 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.

#### **Employees and Location**

As of March 13, 2010, we had eight full-time employees and six full time independent contractors. Of these employees, ten work on research and development and four in administration. We also use the services of numerous outside consultants in business and scientific matters.

#### Where to Find More Information

We make our public filings with the SEC, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all exhibits and amendments to these reports. Also our executive officers, directors and holders of more than 10% of our common stock, file reports with the SEC on Forms 3, 4 and 5 regarding their ownership of our securities. These materials are available on the SEC's web site, http://www.sec.gov. You may also read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Alternatively, you may obtain copies of these filings, including exhibits, by writing or telephoning us at:

NEURALSTEM, INC 9700 Great Seneca Highway, Rockville, Maryland 20850 Attn: Chief Financial Officer Tel: (301) 366-4841

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#### THE OFFERING

Common stock being offered by Selling

Shareholders

Up to 5,163,956 shares

NYSE: AMEX 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.

Use of Proceeds

We will not receive any proceeds from the sale of the common shares by the Selling Shareholders. In the event the warrants held by the Selling Shareholders are exercised for cash, we will receive approximately 5,163,956. The proceeds, if any, will be used for general working capital.

#### 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 us 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 cont similar expressions.

When reading any forward-looking statement, you should remain mindful that actual results or developments may vary substantially from those 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 product, 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 or license our products if a market develops;
- our ability to attract and retain qualified personnel to implement our business plan and corporate growth strategies;
- our ability to develop sales, marketing, and distribution capabilities;
- our ability to obtain reimbursement from third party payers for our proposed products if they are developed;

•	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 SEC. 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.

### RISK FACTORS THAT MAY AFFECT OUR FUTURE RESULTS AND FINANCIAL CONDITION

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 Our Stage of Development

We have a limited operating history and have significantly shifted our operations and strategies since inception.

Since inception in 1996 and through December 31, 2009, we have raised \$62,551,375 of capital and recorded accumulated losses totaling \$67,566,831. On December 31, 2009, we had a working capital surplus of \$892,552 and stockholders' deficit of \$5,015,456. Our net losses for the two most recent fiscal years have been \$10,364,363 and \$11,830,798 for 2009 and 2008 respectively. We had no revenues for the twelve months ended December 31, 2009.

Our ability to generate revenues and achieve profitability will depend upon our ability to complete the development of our proposed stem cell products, obtain the required regulatory approvals, manufacture, and market and sell our proposed products. In part because of our past operating results, no assurances can be given that we will be able to accomplish any of these goals.

Although we have generated some revenue in prior years, we have not generated any revenue from the commercial sale of our proposed stem cell products. Since inception, we have engaged in several related lines of business and have discontinued operations in certain areas. For example, in 2002, we lost a material contract with the Department of Defense and were forced to close our principal facility and lay off almost all of our employees in an attempt to focus our development strategy on stem cell technologies. This limited and changing history may not be adequate to enable you to fully assess our future prospects. No assurances can be given as to exactly when, if at all, we will be able to fully develop, commercialize, market, sell and/or derive material revenues from our proposed products

We will need to raise additional capital to continue operations.

Since inception, we have relied almost entirely on external financing to fund operations. Such financing has come primarily from the sale of common stock and the exercise of investor warrants. As of December 31, 2009, we had cash and cash equivalents on hand of \$2,309,774. Presently, we have a monthly cash burn rate of approximately \$600,000. We will need to raise additional capital to fund anticipated operating expenses and future expansion. Among other things, external financing will be required to further develop our technologies and products, as well as to pay general operating costs. On September 21, 2009, the FDA approved our IND application to commence Phase I trials for ALS. The first patient was dosed on January 21, 2010.

We have expended and expect to continue to expend substantial cash in the research, development, clinical and pre-clinical testing of our stem cell technologies with the goal of ultimately obtaining FDA approval to market our proposed products. We will require additional capital to conduct research and development, establish and conduct

clinical and pre-clinical trials, enter into commercial-scale manufacturing arrangements and to provide for marketing and distribution of our products.

Our long term capital requirements are expected to depend on many factors, including:

- the continued progress and costs of our research and development programs;
  - the progress of pre-clinical studies and clinical trials;
  - the time and costs involved in obtaining regulatory clearance;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
  - The cost of defending any patent litigation;
- •the costs of developing sales, marketing and distribution channels and our ability to sell our products if developed;

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- the costs involved in establishing manufacturing capabilities for commercial quantities of our proposed products;
  - competing technological and market developments;
    - market acceptance of our proposed products;
  - the costs of recruiting and retaining employees and consultants; and
  - the costs associated with educating and training physicians about our proposed products.

We cannot assure you that financing will be available if needed. If additional financing is not available, we may not be able to fund operations and planned growth, develop or enhance our technologies, take advantage of business opportunities or respond to competitive market pressures. If we exhaust our cash reserves and are unable to realize adequate additional financing, we may be unable to meet operating obligations which could result in us initiating bankruptcy proceedings or delaying, or eliminating some or all of our research and product development programs.

Additional financing requirements could result in dilution to existing stockholders.

We are not able to finance our operations by generating revenue. Accordingly, we will be required to secure additional financing which may be dilutive to current shareholders. We are authorized to issue 150,000,000 shares of common stock and 7,000,000 shares of preferred stock. Such securities may generally be issued without the approval or consent of our stockholders. The issuance of such securities may result in substantial dilution.

#### Risks Relating to Our Business

Our business is dependent on a single product candidate.

At present our ability to progress as a company is significantly dependent on a single product candidate for ALS which is entering Phase I clinical trials. Any clinical, regulatory or other development that significantly delays or prevents us from completing any of our trials, any material safety issue or adverse side effect to any study participant in any of these trials, or the failure of these trials to show the results expected would likely depress our stock price significantly and could prevent us from raising the substantial additional capital we will need to further develop our cellular technologies. Moreover, any material adverse occurrence in our first clinical trials could substantially impair our ability to initiate clinical trials to test our stem cell therapies in other potential indications. This, in turn, could adversely impact our ability to raise additional capital and pursue our planned research and development efforts.

Our business relies on stem cell technologies that we may not be able to commercially develop.

We have concentrated the majority of our research on stem cell technologies. Our ability to generate revenue and operate profitably will depend on being able to develop these technologies for human applications. These are emerging technologies and have limited human applications. We cannot guarantee that we will be able to develop our technologies or that such development will result in products with any commercial utility or value. We anticipate that the commercial sale of such products and royalty/licensing fees related to the technology, will be our primary sources of revenues. If we are unable to develop the technologies, we may never realize any revenue.

Our product development programs are based on novel technologies and are inherently risky.

We are subject to the risks of failure inherent in the development of products based on new technologies. The novel nature of these therapies creates significant challenges in regard to product development and optimization,

manufacturing, government regulation, third party reimbursement, and market acceptance. For example, the pathway to regulatory approval for cell-based therapies, including our product candidates, may be more complex and lengthy than the pathway for conventional drugs. These challenges may prevent us from developing and commercializing products on a timely or profitable basis or at all.

Our inability to complete pre-clinical and clinical testing and trials will impair our viability.

On September 21, 2009, we received approval from the FDA for our first IND in order to commence clinical trials. We commenced the trials on January 21, 2010 with the dosing of our first patient. Although we have commenced the trials, the outcome of the trials is uncertain, and if we are unable to satisfactorily complete such trials, or if such trials yield unsatisfactory results, we will be unable to commercialize our proposed products. No assurances can be given that the clinical trials will be completed or result in a successful outcome.

If regulatory authorities do not approve our products or if we fail to maintain regulatory compliance, we would be unable to commercia