

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

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 29, 2014

**NEOSTEM, INC.**  
(Exact Name of Registrant as Specified in Charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

001-33650  
(Commission  
File Number)

22-2343568  
(IRS Employer  
Identification No.)

420 Lexington Avenue, Suite 350, New York, New York 10170  
(Address of Principal Executive Offices)(Zip Code)

(212) 584-4180  
Registrant's Telephone Number

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

## Item 7.01 Regulation FD Disclosure.

On May 29, 2014, NeoStem, Inc., a Delaware corporation (the “Company” or “NeoStem”), issued a press release announcing results of a pooled analysis indicating that Melapuldencel-T, an investigational patient-specific immunotherapy for metastatic melanoma, may significantly increase survival rates for patients with advanced stages of the disease. A copy of this press release is attached as Exhibit 99.1

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing.

### *Forward Looking Statements*

This Current Report on Form 8-K, including Exhibit 99.1 hereto, contain “forward-looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are typically preceded by words such as “believes,” “expects,” “anticipates,” “intends,” “will,” “may,” “should,” or similar expressions, although some forward-looking statements are expressed differently. Forward-looking statements represent the Company’s management’s judgment regarding future events. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company can give no assurance that such expectations will prove to be correct. All statement other than statements of historical fact included in the Current Report on Form 8-K are forward-looking statements. The Company cannot guarantee the accuracy of the forward-looking statements, and you should be aware that the Company’s actual results could differ materially from those contained in the forward-looking statements due to a number of factors, including the statements under “Risk Factors” contained in the Company’s reports filed with the Securities and Exchange Commission.

## Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 29, 2014*

\*Exhibit 99.1 is furnished as part of this Current Report on Form 8-K.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**NEOSTEM, INC.**

By: /s/ Catherine M. Vaczy  
Name: Catherine M. Vaczy, Esq.  
Title: General Counsel

Dated: May 29, 2014

**NeoStem Presents Five-Year Survival Data for Autologous Melanoma Immunotherapy Targeting Cancer Stem Cells at American Society of Clinical Oncology Annual Meeting**

***-- Pooled Analysis of Early-Phase Studies Indicates Melapuldencel-T, an Investigational Immunotherapy for Metastatic Melanoma Targeting Cancer Initiating (Stem) Cells, May Increase Survival Rates Significantly for Patients With***

***Advanced-Stage Disease --***

***-- 5-Year Overall Survival of Melapuldencel-T Cohort Was 33 Percent vs. 20 Percent for Patients Treated With Irradiated Autologous Tumor Cells for This Subset of Patients --***

***-- Phase 3 Study Planned for 2014, With Special Protocol Assessment --***

NEW YORK, May 29, 2014 (GLOBE NEWSWIRE) -- NeoStem, Inc. (Nasdaq:NBS) ("NeoStem" or the "Company"), a leader in the emerging cellular therapy industry, today announced results of a pooled analysis indicating that Melapuldencel-T, an investigational patient-specific immunotherapy for metastatic melanoma, may increase survival rates significantly for patients at the most advanced stages of the disease. The findings will be presented on Sunday, June 1 in a poster by Robert O. Dillman, MD, study author and Vice-President, NeoStem Oncology, at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO), taking place in Chicago.

The analysis to be presented at ASCO includes a subset of pooled data from three melanoma clinical trials, conducted successively from 1990-2011. Two of these trials (one of which was controlled and one of which was not) studied Melapuldencel-T. The new pooled analysis indicates significantly better five-year overall survival rates in patients treated with Melapuldencel-T than those treated with the comparator therapy (autologous tumor cells that had been irradiated to render them inactive) for the subset of patients who still had evidence of disease after prior treatment with one or more standard therapies.

"This subset analysis lends further support to the view that tumor-initiating cells are viable targets for therapeutic interventions like Melapuldencel-T, aiming for better overall survival, even for patients in the most advanced stages of malignant melanoma," said Dr. Dillman. "In addition, the product may have significant safety and tolerability advantages over existing therapies."

Melapuldencel-T is an autologous immunotherapy intended to eliminate cancer-initiating (stem) cells capable of causing disease recurrence. The therapy employs the patient's own tumor cells and dendritic cells (a type of immune cell), along with granulocyte-macrophage colony stimulating factor (GM-CSF, a natural growth factor that stimulates white blood cells in the body). The patient's dendritic cells are mixed with the patient's tumor cells to create the therapeutic agent, which is then suspended in GM-CSF for injection into the patient.

Melapuldencel-T was developed by California Stem Cell, Inc., which was acquired by NeoStem in May 2014. NeoStem is initiating a Phase 3 study of Melapuldencel-T later this year under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration (FDA), and the therapy has been granted fast-track designation by the agency as well.

"Melapuldencel-T has the clear potential to advance immunotherapy for melanoma patients who urgently need new options for extending survival," said Douglas W. Losordo, MD, FACC, FAHA, Chief Medical Officer, NeoStem. "NeoStem is excited to continue investigating this promising therapy in a large-scale Phase 3 study beginning this year."

"Presentation as a vaccine (Melapuldencel-T) of a large array of patient-specific, cancer-initiating (stem) cell antigens appear to enable the immune system to respond to the very cells capable of causing disease progression resulting in the observed improved survival. These data further support investigation of Melapuldencel-T and the need to personalize therapy because the relevant cancer initiating cell antigens appear to differ from patient to patient," said Andrew L. Pecora, MD, FACP, CPE, Director and Chief Visionary Officer, NeoStem and a melanoma therapy clinical investigator.

**Pooled Analysis Details and Results**

The ASCO poster is based on further analysis of previously published data from 170 patients enrolled in three studies: a single-arm Phase 2 trial of irradiated, proliferating, autologous tumor cells<sup>1</sup>, a single-arm Phase 2 trial of Melapuldencel-T<sup>2</sup>, and a randomized trial directly comparing the two treatments.<sup>3</sup> Twenty-seven comparator-treated patients were excluded to decrease interpatient differences associated with poor survival. Remaining patients were classified as NED or non-NED.

A previously published pooled analysis of these studies showed that metastatic melanoma patients treated with autologous dendritic cells loaded with antigens from autologous proliferating tumor cells (Melapuldencel-T) had better overall survival than patients injected with irradiated, proliferating, autologous tumor cells.<sup>4</sup> A survival benefit for Melapuldencel-T was also seen in the subset of patients who had no evidence of disease (NED) at the time of treatment. Five-year overall survival for all patients was 50 percent for the Melapuldencel-T group vs. 32 percent for patients receiving irradiated, proliferating, autologous tumor cells (p=0.004). In the subset of patients with NED, five-year overall survival was 73 percent for the

Melapuldencel-T group vs. 43 percent for patients receiving irradiated, proliferating, autologous tumor cells ( $p=0.015$ ).<sup>4</sup> The toxicity data demonstrated no Grade IV (life threatening toxicity) and only one Grade III (allergic reaction attributed to the GM-CSF) event in the pooled data. No significant adverse effects were reported regarding hematopoietic cells or renal function, hepatic function, or patient performance status.

The analysis described in the ASCO poster addresses whether better survival was also associated with Melapuldencel-T in the non-NED patients ( $n=73$ ). Survival curves were generated for 39 patients treated with Melapuldencel-T and 34 patients treated with the comparator, and compared by log-rank test. Five-year overall survival for all 73 non-NED patients was 27 percent (median 25.5 months). No patients were lost to follow up; 15/23 survivors had been followed for at least 5 years. A higher proportion of patients in the Melapuldencel-T cohort than in the comparator cohort had M1c disease (the most advanced subclass of stage IV melanoma, in which the tumor has metastasized to vital organs other than the lungs) (44 percent vs 35 percent,  $p=0.071$ ). Overall 5-year survival was better in the Melapuldencel-T cohort than in the comparator cohort (33 percent vs 20 percent,  $p=0.025$ ). In the further subset of patients who had measurable disease by RECIST (Response Evaluation Criteria In Solid Tumors) ( $n=32$ ), overall five-year survival was better for Melapuldencel-T (20 percent vs 10 percent,  $p=0.039$ ).

### **About Melapuldencel-T**

Melapuldencel-T, developed by California Stem Cell, Inc. and now NeoStem's most advanced product candidate and foundation for its Targeted Immunotherapy Program in oncology, is a late stage novel proprietary cancer cell therapy. NeoStem plans to initiate, before the end of 2014, a pivotal Phase 3 trial of Melapuldencel-T, an autologous, melanoma initiating (stem) cell immune based therapy intended to eliminate the tumor cells capable of causing disease recurrence. Melapuldencel-T has been approved to enter this trial with a Special Protocol Assessment ("SPA") from the Food and Drug Administration ("FDA") and has received Fast Track designation for metastatic melanoma, as well as Orphan Drug designation. The pooled results may not be predicative of our future Phase 3 results, in part because all patients will be treated using current day standards of care, and the Phase 3 study design will not include any uncontrolled data or cross-study comparisons, allow patients to be excluded from the analysis after data are collected, or permit pooling of different studies.

Initially directed at patients with metastatic melanoma, Melapuldencel-T uses the patient's isolated and purified tumor stem cells to train the immune system to identify and eliminate cancer stem cells, the root cause of tumor formation and the key drivers of tumor escape, tumor genesis, self-renewal and recurrence in a broad spectrum of solid tumor cancers.

The platform on which Melapuldencel-T is created, in which autologous dendritic cells are pulsed with irradiated tumor cells (DC/TC), is also being investigated for other indications including hepatocellular carcinoma and other immune responsive tumor types.

### **About Melanoma**

Melanoma is the most lethal form of skin cancer, and is most often caused by unrepaired DNA damage to skin cells from UV radiation. Rates of melanoma have been rising for at least 30 years. It is estimated that approximately 76,100 new cases of melanoma will be diagnosed in the U.S. in 2014, and that 9,710 people will die from the disease.<sup>5</sup>

### **About NeoStem, Inc.**

NeoStem is a leader in the emerging cellular therapy industry, pursuing the preservation and enhancement of human health globally through the development of cell based therapeutics that prevent, treat or cure disease by repairing and replacing damaged or aged tissue, cells and organs and restoring their normal function. The business includes the development of novel proprietary cell therapy products as well as a revenue-generating contract development and manufacturing service business. This combination has created an organization with unique capabilities for cost effective in-house product development and immediate revenue and cash flow generation. [www.neostem.com](http://www.neostem.com)

### **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management's current expectations, as of the date of this press release, and involve certain risks and uncertainties. Forward-looking statements include statements herein with respect to the successful execution of the Company's business strategy, the Company's ability to develop and grow its business, the successful development of cellular therapies with respect to the Company's research and development and clinical evaluation efforts in connection with the Company's Targeted Immunotherapy Program (including whether or not Melapuldencel-T will successfully be developed to treat metastatic melanoma or any other cancer indicator), CD34 Cell Program, T Regulatory Cell Program and other cell therapies, the future of the regenerative medicine industry and the role of stem cells and cellular therapy in that industry and the performance and planned expansion of the Company's contract development and manufacturing business. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors. Factors that could cause future results to materially differ from the recent results or those projected in forward-looking statements include the "Risk Factors" described in the Company's Annual Report on Form 10-K filed with the Securities and

Exchange Commission ("SEC") on March 13, 2014, the Company's Current Report on Form 8-K filed with the SEC on May 8, 2014 and in the Company's other periodic filings with the SEC. The Company's further development is highly dependent on future medical and research developments and market acceptance, which is outside its control.

**References:**

1. Dillman RO, DePriest C, DeLeon C, et al. Patient-specific vaccines derived from autologous tumor cell lines as active specific immunotherapy: results of exploratory phase I/II trials in patients with metastatic melanoma. *Cancer Biother Radiopharm.* 2007 Jun;22(3):309-21.
2. Dillman RO, Selvan SR, Schiltz PM, et al. Phase II trial of dendritic cells loaded with antigens from self-renewing, proliferating autologous tumor cells as patient-specific antitumor vaccines in patients with metastatic melanoma: final report. *Cancer Biother Radiopharm.* 2009 Jun;24(3):311-9.
3. Dillman RO, Cornforth AN, Depriest C, et al. Tumor stem cell antigens as consolidative active specific immunotherapy: a randomized phase II trial of dendritic cells versus tumor cells in patients with metastatic melanoma. *J Immunother.* 2012 Oct;35(8):641-9.
4. Dillman RO, Depriest C, Ellis R, Cornforth AN, DeLeon C. 5-year survival for patients with metastatic melanoma who had no evidence of disease at time of treatment with patient specific tumor stem cell vaccines. In: *Proceedings of the 105th Annual Meeting of the American Association for Cancer Research*; 2014 Apr 5-9; San Diego, CA. Philadelphia (PA): AACR; 2014. Abstract nr 197.
5. American Cancer Society. What are the key statistics about melanoma skin cancer? Available at <http://www.cancer.org/cancer/skincancer-melanoma/detailedguide/melanoma-skin-cancer-key-statistics>.

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