

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): August 7, 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 (see General Instruction A.2. below):

- 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 2.02. Results of Operations and Financial Condition.

On August 7, 2014, NeoStem issued a press release relating to, among other things, the results of the Company's second quarter ended June 30, 2014. A copy of this press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 2.02 by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 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 liability 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 specific reference in such a filing.

Forward Looking Statements

This Current Report on Form 8-K, including Exhibit 99.1, contains "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 August 7, 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: August 7, 2014

NeoStem Announces Second Quarter 2014 Financial Results and Provides Business Update

NEW YORK, Aug. 7, 2014 (GLOBE NEWSWIRE) -- NeoStem, Inc. (Nasdaq:NBS), a leader in the emerging cellular therapy industry, today provided an update on the progress of its business and reported second quarter 2014 financial results.

Notable achievements in 2014 year to date include:

- NeoStem's strategic acquisition of California Stem Cell, Inc. (CSC) which added a novel Phase 3 cancer immunotherapy platform to its pipeline.
- The appointment to its Board of Directors of Steven M. Klosk, President and CEO of Cambrex Corporation, a leading provider of active pharmaceutical ingredients, advanced intermediates and finished dosage form products to the branded and generic pharmaceutical markets.
- A substantial increase in the number of clinical service contracts and active clients at Progenitor Cell Therapy, LLC (PCT), NeoStem's revenue-generating, contract manufacturing subsidiary.
- The completion of the six month patient follow-up for the last patient enrolled in the PreSERVE AMI Phase 2 clinical trial of NBS10 (also referred to as AMR-001).
- Presentation of results by the University of California San Francisco (UCSF) of a Phase 1 trial using NeoStem's licensed T-regulatory technology in type 1 diabetes at the American Diabetes Association (ADA) annual meeting.
- With the acquisition of CSC, NeoStem now has three cGMP, state-of-the art, cell therapy manufacturing facilities located on both the East and West Coasts to support its internal R&D efforts and to serve the cell therapy community through PCT. CSC's Irvine facility will provide manufacturing support for the Intus Phase 3 melanoma clinical trial of NBS20, while PCT continues to pursue commercial expansion of its contract operations both in the U.S. and internationally.
- NeoStem's expansion of its intellectual property protection with the grant of two new European patents for its Ischemic Repair Program using CD34 cells.
- The inclusion of NeoStem in multiple Russell indexes.

"NeoStem has had an exciting first half as we make progress towards our goal of delivering transformative cell based therapies. We expect to continue to build on our progress through the rest of 2014 with a number of important programs," said Dr. Robin Smith, Chairman and CEO of NeoStem. These include:

- **Anticipated release of Phase 2 data from the PreSERVE AMI trial of NBS10:** This randomized, double-blind, placebo-controlled clinical trial is testing NBS10, the Company's second most advanced product candidate and lead candidate in its ischemic repair program, an autologous adult stem cell product, to treat patients with left ventricular dysfunction following acute ST segment elevation myocardial infarction (STEMI).
- If successful, NBS10 would address a significant unmet medical need as the indication currently has no effective treatment. For those suffering a STEMI this treatment has the potential to improve longevity and quality of life and positions NeoStem to capture a meaningful share of the worldwide market. The Company is evaluating other clinical indications that might benefit from this ischemic repair platform technology, including traumatic brain injury, chronic heart failure and critical limb ischemia.
- **Initiation of the Intus Phase 3 clinical trial of NBS20 for melanoma:** NeoStem's lead product candidate, NBS20, also referred to as DC/TC (dendritic cell/tumor cell), which targets malignant melanoma initiating cells, is designed to treat Stage IV or recurrent Stage III metastatic melanoma and is both the Company's lead product candidate in its targeted immunotherapy program for cancer as well as its overall lead product candidate in development. The immunotherapy has been granted fast track and orphan designation by the U.S. Food and Drug Administration (FDA) and the protocol is the subject of a Special Protocol Assessment (SPA). Under the SPA, the FDA is in agreement with the design, clinical endpoints, and planned clinical analyses of the Phase 3 trial that would serve as the basis for a Biologics License Application (BLA) that would be filed at the time NeoStem would request marketing approval. The protocol calls for enrolling 250 evaluable patients and is expected to be initiated in 2014.

- **Initiation of clinical trials in Immune Modulation Program using T regulatory cells:** NeoStem's immune modulation program is based on the premise that many autoimmune diseases are caused by an imbalance in the immune system between the T-effector cells and the T-regulatory cells. By expanding and re-infusing a patient's own T-regulatory cells, we believe the immune system can be brought into balance and the autoimmune attack can be suppressed. Presentation by UCSF on June 15th at the American Diabetes Association annual meeting of the results of a Phase 1 study of autologous T regulatory cells in adult patients with type 1 diabetes mellitus (T1DM) indicated safety and tolerability following administration, and complements recently published 12-month follow up data showing feasibility and preliminary evidence of efficacy in children with T1DM. Taken together, the results provide preliminary data that support developing a novel therapy for the treatment of T1DM with the goal of inducing immune tolerance and preserving pancreatic beta cell function.
- Subject to review and approval of the protocols by the appropriate regulatory authorities, NeoStem plans to initiate a Phase 2 study of NBS03D for the treatment of type 1 diabetes and a Phase 1 study of NBS03A in support of a steroid resistant asthma development program in 2014. The therapeutic opportunity is to down-regulate the production of inflammatory cytokines by the T cells instead of treating the cytokines after they have been produced, which is the approach of many current therapies.

Dr. Smith continued, "A review of the current status of the cell therapy sector reveals NeoStem as a standout enterprise given its multi-dimensional and diversified approach to accelerating its clinical pipeline by acquisition, internal executive hires and pursuing multiple independent platforms so as not to limit our capacity to grow shareholder value. The key drivers of our near and longer term growth will relate to the generation of clinical data and the diversity of our platforms."

Financial Results for the Second Quarter of 2014 (all comparisons are with the Second Quarter of 2013):

Total revenue for the three months ended June 30, 2014 was \$4.5 million, up 3 percent from \$4.4 million for the prior year period. Clinical services and reimbursable revenue, representing approximately 80% of total revenues, increased slightly compared with the prior year period. Of note, the number of clinical service contracts for process development in the current year nearly doubled, resulting in \$2.1 million of deferred revenue as of June 30, 2014. This revenue will be recognized in future periods upon completion of the associated contracts.

For the three months ended June 30, 2014, research and development expenses were \$5.8 million compared with \$4.0 million for the quarter ended June 30, 2013, an increase of \$1.8 million. The increase was primarily comprised of the following:

- Targeted Cancer Immunotherapy Program: \$2.0 million increase in expenses associated with the cancer immunotherapy program, and specifically efforts to initiate the Phase 3 clinical trial of NeoStem's lead product candidate NBS20, which targets malignant melanoma initiating cells. The oncology platform was acquired in the CSC merger on May 8, 2014.
- Immune Modulation Program using T regulatory cells: \$1.4 million increase in expenses associated with the immune modulation program, primarily due to efforts to develop Tregs for the treatment of type 1 diabetes, steroid resistant asthma, and organ transplant rejection.
- The above increases were partially offset by a \$1.6 million decrease in expenses related to the Company's PreSERVE AMI clinical trial of NBS10, which completed enrollment in 2013.

Selling, general and administrative expenses were \$7.4 million, up from \$4.3 million a year ago. The increase was related to increased corporate development activities, including those associated with the acquisition of CSC, expenses associated with the additional CSC operating activities since the acquisition date, increased corporate infrastructure needed to support the Company's expanded clinical activities, and higher equity-based compensation paid in exchange for services.

Net loss for the three months ended June 30, 2014 was \$12.8 million compared with \$8.6 million for the three months ended June 30, 2013. Net loss for the six months ended June 30, 2014 was \$26.6 million (or \$19.4 million when excluding non-cash charges - see appendix for reconciliation) compared with \$17.5 million for the six months ended June 30, 2013 (or \$13.1 million when excluding non-cash charges - see appendix for reconciliation).

At June 30, 2014 NeoStem's cash and cash equivalents, and marketable securities totaled \$33.8 million. This compares with cash and cash equivalents of \$46.1 million at December 31, 2013.

Appendix

Use of Non-GAAP Financial Measures

The Company uses Net Loss Excluding Non-Cash Charges as a non-GAAP financial measure in evaluating its performance. This measure represents net loss, less equity-based compensation, depreciation and amortization, and other non-cash adjustments included in net loss. The Company believes that providing this measure to investors provides important

supplemental information of its performance and permits investors and management to evaluate the core operating performance and cash utilization of the Company by excluding the use of these non-cash adjustments. Additionally, the Company believes this information is frequently used by securities analysts, investors and other interested parties in the evaluation of performance. Management uses, and believes that investors benefit from, this non-GAAP financial measure in assessing the Company's operating results, as well as in planning, forecasting and analyzing future periods.

Net Loss Excluding Non-Cash Charges has limitations as an analytical tool, and investors should not consider this measure in isolation, or as a substitute for analysis of the Company's results as reported under generally accepted accounting principles in the United States ("U.S. GAAP"). For example, this measure does not reflect the Company's cash expenditures, future requirements for capital expenditures, contractual commitments, or cash requirements for working capital needs. Although depreciation and amortization are non-cash charges, the assets being depreciated or amortized often will have to be replaced in the future, and Net Loss Excluding Non-Cash Charges does not reflect any cash requirements for such replacements. Given these limitations, the Company relies primarily on its U.S. GAAP results and uses the Net Loss Excluding Non-Cash Charges measure only as a supplemental measure of its financial performance and cash utilization.

GAAP to Non-GAAP Reconciliation

(in millions)	Six Months Ended	
	June 30, 2014	June 30, 2013
<u>Net Loss Excluding Non-Cash Charges Reconciliation</u>		
Net loss	(\$26.6)	(\$17.5)
Equity-based compensation	5.7	3.3
Depreciation and amortization	1.0	0.8
Changes in fair value of derivative liability	(0.0)	(0.1)
Changes in acquisition-related contingent consideration	0.4	---
Bad debt recovery	(0.0)	(0.0)
Deferred income taxes	0.1	0.4
Net Loss Excluding Non-Cash Charges	<u>(\$19.4)</u>	<u>(\$13.1)</u>

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, including with respect to the Company's ability to develop and grow its business, the successful development of cellular therapies, including with respect to the Company's research and development and clinical evaluation efforts in connection with the Company's Targeted Cancer Immunotherapy Program, Ischemic Repair Program and Immune Modulation Program, 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 on March 13, 2014 and Current Report on Form 8-K filed with the Securities and Exchange Commission on May 8, 2014 and in the Company's 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.

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