

Sevion Therapeutics, Inc.
Form 8-K
December 09, 2014

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): December 8, 2014

Sevion Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Edgar Filing: Sevion Therapeutics, Inc. - Form 8-K

Delaware 001-31326 84-1368850
(State or Other Jurisdiction of Incorporation) (Commission File Number) (IRS Employer Identification No.)

4045 Sorrento Valley Boulevard, San Diego, California 92121
(Address of Principal Executive Offices) (Zip Code)

(858) 909-0749
(Registrant's telephone number,
including area code)

Not applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K 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 8.01 Other Events.

On December 8, 2014, Sevion Therapeutics, Inc. (the “Company”) issued a press release announcing the presentation of results from its Phase 1b/2a clinical trial of its product candidate, SNS01-T, for the treatment of multiple myeloma and lymphoma. The results were presented in a poster session titled “Lymphoma: Therapy with Biologic Agents, excluding Pre-Clinical Models: Poster III” at the 56th American Society of Hematology (ASH) Annual Meeting and Exposition in San Francisco.

The study, “Mature Results of a Phase 1-2 Open-Label, Dose-Escalation Study of Intravenous SNS01-T in Patients with Relapsed or Refractory B Cell Malignancies,” was an open-label, multiple-dose, dose-escalation study to evaluate the safety and tolerability of SNS01-T when administered by intravenous infusion to patients with relapsed or refractory multiple myeloma, mantle cell (MCL) or diffuse large B-cell lymphoma (DLBCL). The primary objective of the study was to evaluate safety and tolerability. Secondary objectives included pharmacokinetics, tumor response markers, and time to relapse or progression.

Of 22 patients treated, 14 patients were evaluable for dose limiting toxicity. Of four dose cohorts tested, the maximum tolerated dose was determined to be the third dose group, at 0.2 mg/Kg. The most frequent adverse events were fatigue, infusion reaction, nausea, thrombocytopenia and chills, with no treatment related deaths. Two dose limited toxicities were observed in the fourth dose group (0.375 mg/Kg), including Grade 4 infusion reaction and Grade 4 neutropenia. Potential treatment effects were observed in cohorts 3 and 4, with a 44% reduction in sum of product of tumor diameter in 1 of 3 lymphoma patients lasting 30 weeks; a 15% and 33% reduction in serum and urine monoclonal proteins (SPEP and UPEP), and a 19% free light chain (FLC) ratio decrease lasting 10 weeks in one of two patients with multiple myeloma enrolled in cohort 3; and a 21-30% UPEP reduction and 0-42% FLC ratio decrease lasting 3 to 6 weeks in 2 of 6 evaluable patients with multiple myeloma in cohort 4.

A copy of the press release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 Press Release of Sevion Therapeutics, Inc. dated December 8, 2014.

SIGNATURE

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.

**SEVION THERAPEUTICS,
INC.**

Dated: December 9, 2014 By: /s/ Ronald A. Martell
Name: Ronald A. Martell
Title: Chief Executive Officer