

SENESCO TECHNOLOGIES INC

Form 8-K

June 19, 2013

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): June 19, 2013

Senesco Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

001-31326

84-1368850

(Commission File Number) (IRS Employer Identification No.)

Edgar Filing: SENESCO TECHNOLOGIES INC - Form 8-K

(State or Other Jurisdiction
of Incorporation)

721 Route 202-206, Suite 130, Bridgewater, NJ 08807
(Address of Principal Executive Offices) (Zip Code)

(908) 864-4444
(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 June 19, 2013, Senesco Technologies, Inc. (“Senesco”) issued a press release announcing the results of cohort 2 in its Phase 1b/2a clinical study of SNS01-T.

In cohort 2, the requisite number of 3 patients was evaluable for the primary safety endpoint from the total of 4 enrolled. Two multiple myeloma patients and one diffuse large B-cell lymphoma patient completed the required number of doses to be evaluable. As with the previous dose level, there were no drug-related serious adverse events or dose-limiting toxicities in either the evaluable patients or in the one patient who received only 5 infusions before being withdrawn. Over cohorts 1 and 2 at the two lowest dose levels, stabilization of serum monoclonal protein levels has been observed in three of the five evaluable multiple myeloma patients, and, in three of nine patients overall.

Like the previous group, all four patients included at this dose level were refractory to, or had relapsed on, a significant number of previous treatments, including bone marrow transplant in 3 of the 4 patients. One of the 3 myeloma patients at this dose level showed stabilization of their serum monoclonal protein levels at weeks 3 and 6, while 2 patients progressed during treatment. The single DLBCL patient treated at this dose level had progressive disease at week 6.

The study is an open-label, multiple-dose, dose-escalation study, which is evaluating the safety and tolerability of SNS01-T when administered by intravenous infusion to approximately 15 relapsed or refractory multiple myeloma, mantle cell (MCL) or diffuse large B-cell lymphoma (DLBCL) patients. While the primary objective of this study is to evaluate safety and tolerability, the effect of SNS01-T on tumor response and time to relapse or progression will be assessed using multiple well-established metrics including measurement of monoclonal protein in multiple myeloma and CT imaging in MCL and DLBCL .

In the study, patients are dosed twice-weekly for 6 weeks followed by an observation period. The first group of patients received 0.0125 mg/kg per dose by intravenous infusion. The second group received 0.05 mg/kg and the planned dose levels for the third and fourth groups are 0.2 and 0.375 mg/kg, respectively. The top dose planned is 30 fold higher than the starting dose in cohort 1.

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 Senesco Technologies, Inc. dated June 19, 2013.

2

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.

SENESCO TECHNOLOGIES, INC.

Dated: June 19, 2013 By: /s/ Leslie J. Browne, Ph.D.
Name: Leslie J. Browne, Ph.D.
Title: President and Chief Executive Officer