SENESCO TECHNOLOGIES INC
Form 8-K
December 09, 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): December 9, 2013

Senesco Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

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

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 December 9, 2013, Senesco Technologies, Inc. ("Senesco" or the "Company") issued a press release announcing the results of cohort 3 in its Phase 1b/2a clinical study of SNS01-T, the Company's drug candidate for the treatment of B-cell cancers, at the 55th American Society of Hematology Annual Meeting in New Orleans.

Senesco's drug candidate, SNS01-T, which is the subject of an on-going Phase 1b/2a clinical study in B-cell cancers, induces cell death in cancer cells by reducing the levels of a protective protein and replacing it with a protein that induces cell death.

Four heavily pre-treated, relapsed or refractory patients, two with diffuse large B-cell lymphoma (DLBCL) and two with multiple myeloma, who were enrolled in cohort 3 at a dosage of 0.2 mg/Kg, completed treatment. Three of the four patients were evaluable for safety. One patient had a dose reduction to 0.05 mg/kg due to pre-existing thrombocytopenia and was not evaluable for safety. No dose-limiting toxicities have been observed in any of the first three cohorts. As previously reported, based upon review of three patients treated at 0.2 mg/kg, the Data Review Committee recommended dose escalation to the 4^{th} dose level (0.375 mg/kg) and continued enrollment.

In addition to the absence of dose-limiting toxicity, since all patients in cohort 3 completed the full protocol-specified 6-week treatment period, the Company appears to be seeing longer treatment durations and fewer dropouts compared to cohorts 1 and 2. The most frequent adverse events are manageable infusion reactions, which decrease with repeated treatments and platelet count decreases, which recover over time. One myeloma patient had reductions in disease-related proteins in his blood and a second patient with DLBCL had evidence of tumor shrinkage in some lesions.

Like the previous treatment group, all four patients included at this dose level were refractory to, or had relapsed on, a significant number of previous treatments. Upon treatment with SNS01-T, three of the four patients exhibited stable disease at week 3 and two of the four were stable at week 6, the end of treatment.

The safety profile continues to be a positive feature of SNS01-T in this study. Since the Company's preclinical data in myeloma and lymphoma demonstrated significant tumor shrinkage at 0.375 mg/kg of SNS01-T, with a p-value of <0.01, the Company will be looking for evidence of clinical activity at this dose level in cohort 4.

The study is an open-label, multiple-dose, dose-escalation study to evaluate the safety and tolerability of SNS01-T when administered by intravenous infusion to approximately 15 relapsed or refractory multiple myeloma and B-cell

lymphoma patients. While the primary objective is to evaluate safety and tolerability, the effect of SNS01-T on tumor response and time to relapse or progression is assessed using multiple well-established metrics including measurement of monoclonal protein in multiple myeloma and CT imaging in B-cell lymphomas.

In the study, patients are dosed twice-weekly by intravenous infusion for six weeks followed by an observation period. The first and second cohorts of patients received 0.0125 mg/kg and 0.05 mg/kg per dose, respectively. The third cohort received 0.2 mg/kg and the planned dose level for cohort 4 is 0.375 mg/kg, which is 30 fold higher than the starting dose in group 1. It is expected that the study will enroll six to nine patients to complete 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 Senesco Technologies, Inc. dated December 9, 2013.

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: December 9, 2013 By: /s/ Leslie J. Browne, Ph.D.
Name: Leslie J. Browne, Ph.D.
Title: President and Chief Executive Officer