

SENESCO TECHNOLOGIES INC
Form 8-K
December 10, 2012

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 10, 2012

Senesco Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Edgar Filing: SENESCO TECHNOLOGIES INC - Form 8-K

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 10, 2012, Senesco Technologies, Inc. (“Senesco”) issued a press release to report that the interim results from the on-going Phase 1b/2a study were presented yesterday by Dr. John Lust, the PI at Mayo Clinic, Rochester, MN at the 54th American Society of Hematology (ASH) Annual Meeting and Exposition in Atlanta, Georgia. As previously disclosed, cohort 1 was completed in August, 2012 and currently two of the planned three patients in cohort 2 have completed dosing. No drug-related serious adverse events or disease limiting toxicities have been recorded to date.

In multiple myeloma, normal plasma cells have transformed into malignant myeloma cells that accumulate in the bone marrow, where they produce large quantities of a protein called monoclonal (M) protein that is released into the blood stream. A high level of M-protein in the blood is an important characteristic of multiple myeloma. Progressively increasing M-protein levels is a marker of worsening disease and a reduction in M-protein is an indicator of a tumor response. Normally plasma cells account for approximately 5% of the cells in the bone marrow. In multiple myeloma, plasma cell content of the bone marrow typically exceeds 10%. Reductions in the percent of plasma cells in the bone marrow are representative of the partial elimination of tumor cells and provide an estimate of drug-induced apoptosis (death) of myeloma cells.

Blood levels of M-protein were measured using serum protein electrophoresis. For patients 41-002 and 42-002 in cohort 1, serum levels of monoclonal (M) protein remained within 25% of the baseline values (3.6, 3.0 g/dL respectively) at weeks 3 (3.9, 2.8 g/dL) and 6 (4.2, 2.8 g/dL), stable disease. For patient 42-002 M-protein stayed within 25% of baseline at week 10 (3.2 g/dL), i.e., 4 weeks after the end of treatment. M-protein levels for patient 43-001 increased from baseline to week 3 by 26% and from baseline to week 6 by 30%. Bone marrow plasma cells were measured by morphologic assessment of bone marrow samples at baseline and the end of treatment. Indicative of the partial disappearance of cancer cells, the plasma cell levels for patients 41-002 and 42-002 declined from 70% to 50% (a 29% reduction), and from 50% to 15% (a 70% reduction) respectively. Plasma cell levels for patient 43-001 increased from 70% at baseline to 97% at end of treatment.

In cohort 2, one multiple myeloma patient and one diffuse large B-cell lymphoma patient have completed 6 weeks of dosing. For the multiple myeloma patient, serum levels of M-protein remained within 25% of the baseline value (1.5 g/dL) at weeks 3 (1.2 g/dL) and 6 (1.2 g/dL). The plasma cell level in this patient declined from 95% to 90%. Tumor response in the DLBCL patient will be assessed by tumor imaging and is not yet completed.

The study is an open-label, multiple-dose, dose-escalation study, which will evaluate 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 is now receiving 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.

<u>Exhibit No.</u>	<u>Description</u>
--------------------	--------------------

99.1	Press Release of Senesco Technologies, Inc. dated Decmeber 10, 2012.
------	----------------------------------------------------------------------

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 10, 2012

By: /s/ Leslie J. Browne, Ph.D.

Name: Leslie J. Browne, Ph.D.

Title: President and Chief Executive Officer