SENESCO TECHNOLOGIES INC
Form 8-K
August 15, 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): August 13, 2012

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 August 13, 2012, Senesco Technologies, Inc. ("Senesco") issued a press release announcing that the results from its completed non-clinical study of SNS01-T in combination of lenalidomide in a model of multiple myeloma. Combining SNS01-T treatment with lenalidomide (the active ingredient in REVLIMID® marketed by Celgene Corporation) inhibits tumor growth more effectively than either drug alone. All mice treated with the combination survived over 100 days to the end of the study. Tumors were eradicated after a single 6-week cycle of the combination in two thirds of the animals, and there was no regrowth after an additional 8 weeks without further treatment.

Mice implanted with human myeloma tumors derived from RPMI 8226 cells were randomized into 4 groups and treated with control nanoparticles, or, either SNS01-T (0.375 mg/kg; i.v., 2x per week), lenalidomide (50 mg/kg; i.p., 5x per week), or both. The mice received 2 cycles of treatment, 6 weeks and 5 weeks respectively, with an 11 day rest period between cycles. Mice, whose tumors were undetectable at the end of cycle 1, received no drug treatment in cycle 2 unless tumor reappeared. The mice were monitored for 2 weeks after the end of the second cycle of treatment. The total length of the study was 102 days.

At the end of the second cycle of dosing, tumor growth was inhibited compared to control nanoparticles by 84 % ($p < 0.0001$), 34 % ($p = 0.05$), and 98.1 % ($p << 0.0001$) in animals treated with SNS01-T, 50 mg/kg of lenalidomide, and SNS01-T plus 50 mg/kg of lenalidomide, respectively. The median survival of mice treated with control nanoparticles or 50 mg/kg of lenalidomide was 48 days and 95 days, respectively. Mice treated with SNS01-T or SNS01-T in combination with lenalidomide had 60 % and 100 % survival, respectively, and thus median survival could not be determined in these groups.

In conclusion, SNS01-T alone and in combination with 50 mg/kg of lenalidomide demonstrated significantly improved efficacy compared to lenalidomide alone. Tumors were eradicated in 4 out of 6 animals receiving SNS01-T plus lenalidomide and did not reappear during 8 weeks with no further treatment.

Also, on August 15, 2012 Senesco issued a press release announcing that that it has completed the first cohort of patients in its Phase 1b/2a clinical trial for the treatment of multiple myeloma in which SNS01-T was safe and well tolerated and met the criteria for Stable Disease in 2 of the 3 evaluable patients that comprised cohort 1.

The safety data for the group were provided to the Data Review Committee (DRC) which advised Senesco that SNS01-T was safe and well tolerated and that it is appropriate to proceed with cohort 2 and to escalate the dose level to 0.05 mg/kg, a four-fold increase. No drug-related serious adverse events or dose limiting toxicities were recorded

for any patients.

The requisite number of 3 patients was evaluable from a total of 6 patients enrolled in the cohort. In two of these three patients their disease had not progressed on treatment, based on several criteria including the monoclonal protein, and was considered stable at week 3 and week 6, the end of the dosing regimen. Three patients were withdrawn from the study by their physicians due to disease progression before completing treatment. One of the responding patients has continued to have Stable Disease at week 10, a month after the end of treatment with SNS01-T.

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 patients. Patients are dosed twice-weekly for 6 weeks followed by an observation period. The first group of patients received 0.0125 mg/kg, approximately 1 mg per patient by intravenous infusion. The planned dose levels for the second, third and fourth groups are 0.05, 0.2 and 0.375 mg/kg, respectively.

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.

A copy of the press releases are filed as Exhibits 99.1 and 99.2 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 August 13, 2012.
99.2	Press Release of Senesco Technologies, Inc. dated August 15, 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: August 15, 2012 By: /s/ Leslie J. Browne, Ph.D.
Name: Leslie J. Browne, Ph.D.
Title: President and Chief Executive Officer