ARQULE INC
Form 8-K
October 12, 2010

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): **October 11, 2010**

ARQULE, INC.

(Exact Name of Issuer as Specified in Charter)

Delaware	**000-21429**	**04-3221586**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

19 Presidential Way

Woburn, MA

(Address of principal executive offices)

01801

(Zip code)

(781) 994-0300

(Registrant s telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Section 8 Other Events

Item 8.01 Other Events.

On October 11, 2010, ArQule, Inc. (the Registrant) announced a Special Protocol Assessment (SPA) agreement with the FDA for the design of a Phase 3 trial of ARQ 197 in patients with non-small cell lung cancer (NSCLC) of non-squamous histology. The trial is planned for initiation later this year.

The SPA process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application. Final marketing approval depends on the results of the trial.

The Phase 3 trial will be a randomized, double-blinded, placebo-controlled study of erlotinib plus ARQ 197 versus erlotinib plus placebo in patients with locally advanced or metastatic NSCLC of non-squamous histology. The primary endpoint is overall survival in the intent-to-treat population. Key secondary objectives include overall survival in the epidermal growth factor wild-type sub-population and progression-free survival in the intent-to-treat population. Approximately 1,000 patients will be enrolled from 150 sites in the U.S., Canada, Europe, Russia, Australia and Latin America.

Also, on October 11, 2010 the Registrant announced the presentation of final results from a Phase 2 clinical trial in NSCLC of ARQ 197 at the annual meeting of the European Society for Medical Oncology (ESMO).

Copies of the press releases dated October 11, 2010 announcing the SPA and the ESMO presentation are filed as Exhibits 99.1 and 99.2, respectively, and are incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 SPA Press release dated October 11, 2010

99.2 ESMO Press release dated October 11, 2010

SIGNATURES

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.

ARQULE, INC.
(Registrant)

/s/ Peter S. Lawrence
Peter S. Lawrence
President and Chief Operating Officer

October 12, 2010