ARQULE INC
Form 8-K
October 16, 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): October 16, 2012

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):

¨ 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))

Section 8 — Other Events

Item 8.01 Other Events.

On October 16, 2012, ArQule, Inc. (the "Registrant") announced a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) for the design of a pivotal Phase 3 trial of tivantinib in patients with hepatocellular carcinoma (HCC).

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 study of tivantinib as single agent therapy in previously treated patients with MET diagnostic-high inoperable HCC. The primary endpoint is overall survival in the intent-to-treat population, and the secondary endpoint is progression free survival in the same population. Approximately 300 patients are planned to be enrolled at approximately 120 centers worldwide.

A copy of the press release dated October 16, 2012 announcing the SPA is filed as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 — SPA Press release dated October 16, 2012

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 16, 2012