ARQULE INC
Form 8-K
August 29, 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 and Exchange Act of 1934

Date of Report: August 28, 2012
(Date of earliest event reported)

ArQule, Inc.
(Exact Name of Registrant as Specified in Its Charter)

| Delaware | 000-21429 | 04-3221586 |
|---|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (Commission File Number) | (I.R.S. Employer Identification Number) |

19 Presidential Way,
Woburn, MA 01801
(address of Principal Executive Offices) (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))

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Item 8.01. — Other Events.

ArQule, Inc. (ArQule) has been informed by Kyowa Hakko Kirin Co., Ltd. (Kyowa), which has exclusive development rights to tivantinib in Japan and certain parts of Asia, of Kyowa's decision to temporarily suspend patient enrollment in its ongoing Phase 3 ATTENTION (Asian Trial of Tivantinib plus Erlotinib for NSCLC without EGFR Mutation) trial. The ATTENTION trial investigates the use of tivantinib and erlotinib versus erlotinib and placebo in second line non-squamous non-small cell lung cancer (NSCLC). This trial is being conducted by Kyowa in Japan, South Korea and Taiwan.

Kyowa has taken this action following the recommendation of an independent Safety Review Committee (SRC) in Japan after the reporting of suspected cases of interstitial lung disease (ILD) in the study. The SRC has requested additional information and analyses regarding these cases of ILD which showed an imbalance between the arms of the trial.

During review of the additional information, treatment of patients already enrolled in the study is continuing pursuant to the protocol for the study. Updates on the status of this review and a determination regarding whether to restart patient enrollment will be provided as warranted.

Daiichi Sankyo, Inc. (Daiichi Sankyo) and ArQule are developing tivantinib in the Americas, Europe and certain other regions of the world. The partners are conducting in those regions the Phase 3 MARQUEE trial (Met Inhibitor ARQ 197 plus Erlotinib vs Erlotinib plus Placebo in NSCLC) that completed recruitment of approximately 1,000 patients in May 2012. Kyowa's decision regarding the ATTENTION trial is unrelated to the MARQUEE trial.

Erlotinib (Tarceva™) was approved by the U.S. Food and Drug Administration (FDA) in November, 2004 for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen. Tivantinib is an investigational selective c-MET inhibitor in Phase 3 clinical development in combination with erlotinib for non-squamous NSCLC in the U.S. under a Special Protocol Assessment agreed upon with the FDA. Clinical trials of tivantinib and erlotinib reported to date have demonstrated that this combination was well tolerated by patients, without apparent drug-drug interaction.

In April, 2007, ArQule entered into an exclusive license agreement with Kyowa to develop and commercialize tivantinib in Japan and parts of Asia, including South Korea, Taiwan and China (including Hong Kong). In December 2008, ArQule and Daiichi Sankyo signed a license, co-development and co-commercialization agreement to co-develop tivantinib in the U.S., Europe, South America and the rest of the world excluding territories covered by ArQule's agreement with Kyowa.

Forward Looking Statements

This Form 8-K contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are generally identified by the words "will," "expects," "anticipates," "believes," "estimates" or similar expressions. These forward-looking statements reflect management's view of future events and are subject to risks, uncertainties, assumptions and other important factors, many of which may be beyond our control, and could cause actual results to differ materially from those expressed or implied in these forward-looking statements. Factors that could cause actual results to differ from such statements include, but are not limited to: an adverse decision or decisions following a review of additional safety information, or findings regarding a clinical benefit that are inconsistent with those of recent publications. The forward- looking statements contained herein represent management's judgment of ArQule as of the date hereof. We disclaim any intent or obligation to update any forward-looking statement except to the extent required by law.

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)

By: /s/ Peter S. Lawrence
Peter S. Lawrence
President & Chief Operating Officer

August 29, 2012