ARQULE INC
Form 8-K
September 03, 2013

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): September 3, 2013

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 40.14d-2(b))
¨Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 40.13e-4(c))

Section 8 — Other Events

Item 8.01 Other Events.

ArQule, Inc. (“ArQule” or the “Company”) and its partner, Daiichi Sankyo, Inc. (“Daiichi Sankyo”) are currently sponsoring a Phase 3 trial of tivantinib in the treatment of hepatocellular cancer (“HCC”). This trial is known as the METIV-HCC study. Recently the Company and Daiichi Sankyo received a letter from the trial Data Monitoring Committee (“DMC”) recommending that the study dosage be reduced from 240 mg twice daily (“BID”) to 120 mg BID and that certain enhanced patient monitoring procedures be instituted to confirm the safety profile of the lower dose. This recommendation resulted from the observation of a higher incidence of neutropenia in the METIV-HCC trial than was observed in the Company’s and Daiichi Sankyo’s Phase 2 trial in the same patient population.

The Company and Daiichi Sankyo have accepted the recommendation of the DMC to implement the lower dose and will be filing a protocol amendment with regulatory authorities and related parties. After a prescribed number of patients have been dosed at 120 mg BID, the DMC will review data from that patient cohort to determine the safety profile of the lower dose and whether to recommend any further action. Because the trial is still in the early stages of recruitment, the Company and Daiichi Sankyo are not able to comment at this time on whether the timeline for recruitment of the trial may be delayed compared with original estimates as a result of the proposed amendment and subsequent data review.

The Company and Daiichi Sankyo expect that the dose reduction will reduce the incidence of neutropenia observed to date in the METIV-HCC trial, resulting in greater patient safety and fewer early patient terminations. The Companies also believe they have now selected a dose that will offer the best possibility for a favorable benefit-risk ratio.

The Company and Daiichi Sankyo will continue to review available data from this and other studies to better understand the increased incidence of neutropenia observed in the METIV-HCC trial compared with the Phase 2 HCC trial, including any possible impact from a change in dosage form. The incidence of neutropenia seen in the METIV-HCC trial to date has not been observed in other trials with tivantinib, which continue to employ a dose of 360 mg BID.

The METIV-HCC trial is a randomized, double-blinded study of tivantinib as single agent therapy in previously treated patients with MET diagnostic-high inoperable HCC. It is being conducted under a Special Protocol Assessment with the FDA. The primary endpoint of the study is overall survival in the intent-to-treat population, and the secondary endpoint is progression free survival in the same population.

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Forward-Looking Statements

This report contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “could,” “will,” “would,” “should,” “expect,” “plan,” “anticipate,” “estimate,” “intend,” “predict,” “seek,” “contemplate,” “potential” or “continue” or the negative of these terms or other compar terminology. These forward-looking statements include, but are not limited to, statements about: the Company’s expectations that the dose reduction will reduce the incidence of neutropenia in the METIV-HCC trial and that enhanced patient monitoring procedures will confirm the safety profile of the lower dose and its belief that the lower dose offers patients in the trial the best possibility for a favorable benefit-risk ratio. Such forward-looking statements are based upon management's current expectations and are subject to known and unknown risks and uncertainties that could cause actual results, events or developments to be materially different from those indicated in such forward-looking statements Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under “Risk Factors” in the Company’s annual report on Form 10-K and other filings with the Securities and Exchange Commission. The Company expressly disclaims any intent or obligation to update these forward-looking statements, except as 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)

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

September 3, 2013

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