ARQULE INC
Form 8-K
November 03, 2015

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): November 3, 2015

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.)

One Wall Street

Burlington, MA

(Address of principal executive offices)

01803

(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 7 – Regulation FD

Item 7.01 Regulation FD Disclosure

On November 3, 2015, ArQule, Inc. (the "Registrant") announced that it had exercised its option with Daiichi Sankyo to co-commercialize tivantinib in the United States (the "Co-Commercialization Option"), pursuant to the License, Co-Development and Co-Commercialization Agreement by and between Registrant and Daiichi Sankyo Co., Ltd. dated December 18, 2008 (the "Agreement"). Subject to the receipt of regulatory approvals, the first commercial indication for tivantinib under the Co-Commercialization Option is anticipated to be second line hepatocellular carcinoma ("HCC"). As previously reported, the Registrant and Daiichi Sankyo are currently conducting METIV-HCC, a pivotal Phase 3 trial in that indication. The parties have a prescribed period to conclude a co-commercialization agreement in accordance with the terms of the Agreement which is expected to occur in the first quarter of 2016.

If the METIV-HCC trial is successful, and tivantinib is approved in second line HCC, the Agreement provides that the Registrant will receive a total of $55 million in milestone payments for the official acceptance of drug approval applications by FDA and EMA in this first indication, plus an additional $100 million in combined milestones tied to receipt of commercialization regulatory approval by the FDA and the first commercial sale in the UK, Germany, France, Italy or Spain. These milestones, totaling $155 million, will be partially offset by Phase 3 costs owed to Daiichi Sankyo by the Registrant which the Company expects to total approximately $75-$85 million at the time of approval in the US or EU. The Agreement also provides that Registrant will receive tiered double-digit royalties on net sales of tivantinib throughout the territory, and given the anticipated commercial market for second line HCC Registrant expects to earn royalties on net sales for this indication at the baseline contractual rate of 20 percent.

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 METIV-HCC trial and potential milestones and royalties that the Company would be entitled to receive under the Agreement if METIV-HCC were successful, and tivantinib were approved by the FDA and EMEA. 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

November 3, 2015