

ARQULE INC
Form 8-K
January 31, 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): January 31, 2013

ARQULE, INC.
(Exact Name of Issuer as Specified in Charter)

Delaware
(State or other jurisdiction
of incorporation)

000-21429
(Commission File Number)

04-3221586
(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 January 31, 2013, ArQule, Inc. (the “Registrant”) and Daiichi Sankyo Co., Ltd. (Daiichi Sankyo”) announced that the first patient has been enrolled in their pivotal Phase 3 METIV-HCC clinical trial of tivantinib (ARQ 197), an investigational selective inhibitor of MET, in patients diagnosed with hepatocellular carcinoma (HCC) who have received one or two prior systemic anti-cancer therapies.

As a result, the Registrant will receive a \$15 million milestone payment from Daiichi Sankyo. This payment is provided for under the terms of the license, co-development and co-commercialization agreement with Daiichi Sankyo previously disclosed by the Registrant (the “Agreement”). The Agreement covers the co-development and commercialization of tivantinib by the parties in the U.S., Europe, South America and the rest of the world, excluding Japan, China (including Hong Kong), South Korea and Taiwan, where Kyowa Hakko Kirin Co., Ltd. has exclusive rights for tivantinib’s development and commercialization.

Under the terms of the agreement, Daiichi Sankyo and the Registrant share the costs of development of tivantinib. The Registrant’s share of Phase 3 development costs are payable exclusively out of milestones and royalties received from Daiichi Sankyo under the Agreement. Because the Registrant’s cumulative share of Phase 3 costs incurred but not yet paid exceeds the milestone amount, the full \$15 million will be repaid to Daiichi Sankyo.

Section 9 — Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. 99.1 Text of press release describing announcement of enrollment of patient and payment of milestone dated January 31, 2013.

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

January 31, 2013