ARQULE INC
Form 8-K
May 17, 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): May 17, 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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 May 17, 2012, ArQule, Inc. ("ArQule" or the "Registrant") issued a press release announcing clinical data from a recent randomized, controlled Phase 2 clinical trial of its drug candidate, tivantinib, as a single agent in previously treated patients with hepatocellular carcinoma (HCC). Tivantinib is an oral, selective inhibitor of the c-MET receptor tyrosine kinase.

ArQule also announced that tivantinib will be the subject of five presentations at the Annual Meeting of the American Society of Clinical Oncology (ASCO). Abstracts of these presentations are available on www.asco.org. The presentations and the abstracts will include data from the Phase 2 clinical trial and ArQule's Phase 1 clinical trial evaluating tivantinib in combination with sorafenib in cohorts of patients with HCC, renal cell carcinoma and melanoma. These data regarding the Phase 2 trial supplement results of the trial previously reported by ArQule.

HCC Trial Summary: c-MET high patients

Data from the HCC trial demonstrated a statistically significant improvement in time-to-progression (HR=0.43, log rank p-value=0.03), accompanied by significant improvements in progression-free survival and disease control rate among second-line patients with c-MET high tumors who were treated with tivantinib. In addition, overall survival data were observed favoring tivantinib-treated patients in this population. Efficacy was similar in the two tivantinib dosing subgroups (360 milligrams twice daily and 240 milligrams twice daily), with less frequent neutropenia in the lower dose.

Previously announced top-line data from the HCC trial demonstrate that treatment with tivantinib produced a statistically significant 56 percent improvement in time-to-progression in the intent-to-treat population as determined by central radiology review, the primary endpoint (HR = 0.64, log rank p-value = 0.04) for this trial. Adverse events were reported at similar rates in the treatment and placebo arms, except for a higher incidence of fatigue and hematologic events, including neutropenia and anemia, in tivantinib-treated patients. The incidence of hematologic events declined following dose reduction of tivantinib from 360 milligrams twice daily to 240 milligrams twice daily.

ASCO Presentations

Beginning on June 2, 2012, ArQule will make the following presentations of clinical data for tivantinib at the 2012 American Society of Clinical Oncology (ASCO) Annual Meeting, which will be held from June 2 to June 8, 2010 in Chicago, Illinois:

Oral Presentation

Date and time: Saturday, June 2, 2012, 5:00 PM – 5:15 PM
Abstract number: 4006
Poster title: Tivantinib (ARQ 197) versus placebo in patients (Pts) with hepatocellular carcinoma (HCC) who failed one systemic therapy: Results of a randomized controlled phase II trial (RCT)
Presenter: Lorenza Rimassa, MD
Location: E Hall D1

Poster Discussion Sessions

Date and time: Saturday, June 2, 2012, 8:00 AM – 12:00 PM
Abstract number: 4545
Poster title: Safety and efficacy of MET inhibitor tivantinib (ARQ 197) combined with sorafenib in patients (pts) with renal cell carcinoma (RCC) from a phase 1 study
Poster board # 24
Presenter: Igor Puzanov, MD
Location: E450a

Date and time: Saturday, June 2, 2012, 1:15 PM – 5:15 PM
Abstract number: 8519
Poster title: Safety and efficacy of MET inhibitor tivantinib (ARQ 197) combined with sorafenib in patients (pts) with NRAS wild-type or mutant melanoma from a phase 1 study
Poster board # 8
Presenter: Julie A. Means-Powell, MD
Location: E450b

General Poster Session

Date and time: Monday, June 4, 2012, 8:00 AM – 12:00 PM
Abstract number: 4117
Poster title: Safety and efficacy of MET inhibitor tivantinib (ARQ 197) combined with sorafenib in patients (pts) with hepatocellular carcinoma (HCC) from a phase 1 study
Poster board # 50D
Presenter: Robert E. Martell, MD, PhD
Location: S Hall A2

Date and time: Monday, June 4, 2012, 8:00 AM – 12:00 PM
Abstract number: 4082
Poster title: A phase II study of tivantinib monotherapy in patients with previously treated advanced or recurrent gastric cancer
Poster board # 46A
Presenter: Kei Muro, MD
Location: S Hall A2

ArQule's press release dated May 17, 2012 is attached hereto as Exhibit 99.1 and incorporated herein by reference. Sections of the press release describing the presentations and providing additional information regarding presentation sites and times shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Section 9-Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. 99.1 Press release announcing clinical data to be presented at the 2012 American Society of Clinical Oncology (ASCO) Annual Meeting.

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

May 17, 2012

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