

ARQULE INC
Form 8-K
December 06, 2007

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 29, 2007**

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

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(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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Section 8 Other Events

Item 8.01 Other Events.

On November 29, 2007, ArQule, Inc. (the Registrant) issued a press release updating the clinical status of ARQ 171, a second generation product candidate under development in the Registrant's E2F-1 Activated Checkpoint Therapy® (ACT) program. The press release is included as Exhibit 99.1 hereto and incorporated herein by reference.

As previously reported, under the terms of the Registrant's drug discovery and development agreement with F. Hoffmann-La Roche Ltd (Roche), Roche has an option to license worldwide rights for the development and commercialization of products from the Registrant's E2F-1 program following its review of certain information relating to that program. The Roche agreement requires the Registrant to provide a clinical data package that includes information from one of its ARQ 501 Phase 2 monotherapy trials and its ARQ 501 combination therapy trial, as well as information including a recommended Phase 2 dose for a second generation E2F-1 product candidate, such as ARQ 171.

The clinical data from the ARQ 501 trials are available. The ARQ 171 Phase 1 trial has been ongoing since December 2006. The Registrant has previously given guidance that a recommended Phase 2 dose for ARQ 171, based on data from the Phase 1 trial, could be available by the end of 2007. However, until the evaluation of cardiac function described in the press release is completed, the Registrant cannot predict when or whether a recommended Phase 2 dose will be achieved for ARQ 171.

Section 9 Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Text of press release announcing Phase 1 clinical trial status dated November 29, 2007.

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
Executive Vice President and Chief
Operating Officer

December 6, 2007