

ARQULE INC
Form 8-K
November 10, 2008

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 7, 2008

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)

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(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))
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Section 1 Registrant's Business and Operations

Item 1.01 Entry into a Material Definitive Agreement.

On November 10, 2008, ArQule, Inc. ("ArQule" or the "Registrant") announced that it has entered into the two agreements described below with Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo"). The agreements form the basis of a strategic relationship for the development and discovery of novel oncology therapeutics.

(i) On November 7, 2008, ArQule and Daiichi Sankyo entered into a binding letter of intent for an agreement to co-develop and co-commercialize ARQ 197, a small molecule, selective inhibitor of the c-Met receptor tyrosine kinase, in human cancer indications. The agreement will cover the U.S., Europe, South America and the rest of the world, excluding Japan, China (including Hong Kong), South Korea and Taiwan, where, as previously disclosed, Kyowa Hakko Kirin Co., Ltd. has obtained exclusive rights from ArQule for development and commercialization of ARQ 197.

The binding letter of intent provides for a \$60 million cash upfront licensing payment and an additional \$560 million in potential development and sales milestone payments from Daiichi Sankyo to ArQule. Upon commercialization, ArQule will receive tiered, double digit royalties from Daiichi Sankyo on net sales of ARQ 197 commensurate with the magnitude of the transaction. ArQule and Daiichi Sankyo will share equally the costs of Phase 2 and Phase 3 clinical studies, with ArQule's share of Phase 3 costs payable solely from milestone and royalty payments. Daiichi Sankyo will fund the costs of commercialization. ArQule retains the option to participate in the commercialization of ARQ 197 in the U.S. The definitive contract based on the binding letter of intent, which will include the terms set forth above, is expected to be signed in December 2008. The upfront payment provided for in the binding letter of intent will be paid upon the later of: (i) December 8, 2008 or (ii) the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

A copy of the Registrant's November 10, 2008 press release announcing the transaction is filed as exhibit 99.1 to this report and is incorporated herein by reference.

(ii) On November 7, 2008, ArQule and Daiichi Sankyo entered into a research collaboration, exclusive license and co-commercialization agreement under which ArQule will apply its proprietary technology and know-how to the discovery of therapeutic compounds that selectively inhibit certain kinases.

The agreement provides for a \$15 million upfront payment, payments for research support in the first and second years of the collaboration, and licensing fees for compounds discovered as a result of this research. ArQule will also receive milestone payments related to clinical development, regulatory review and sales, and royalty payments on net sales of compounds from the collaboration. Milestone amounts and the percentages for tiered royalties payable on net sales amounts will be determined within the 6-month period following execution of the agreement. ArQule retains the option to co-commercialize licensed products in the U.S., and Daiichi Sankyo will fund the costs of worldwide development, commercialization and manufacturing.

A copy of the Registrant's November 10, 2008 press release announcing the transaction is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Section 9 Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Text of press release announcing transactions referred to herein dated November 10, 2008

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 10, 2008