UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): **February 2, 2018**

ARQULE, INC.

(Exact name of registrant as specified in its 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 01803
(Address of principal executive offices) (Zip Code)

(781) 994-0300
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

☐ Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry into a Material Definitive Agreement.

On February 2, 2018, ArQule, Inc. ("ArQule" or the "Registrant"), Sinovant Sciences Ltd. ("Sinovant"), and Roivant Sciences Ltd. (Roivant), the parent of Sinovant, entered into a License Agreement (the "Agreement") pursuant to which ArQule granted Sinovant an exclusive license to develop, manufacture and commercialize its FGFR inhibitor, derazantinib (ARQ 087), in Greater China (including the People's Republic of China, Hong Kong, Macau and Taiwan).

The Agreement provides for an upfront payment to ArQule of $3 million and a guaranteed $2.5 million development milestone within the first year. ArQule is also eligible for an additional $82 million in regulatory and sales milestones. Upon commercialization, ArQule will receive double digit royalties in the low teens from Sinovant on net sales of derazantinib in the Greater China territory. Sinovant will be responsible for all costs and expenses of development, manufacture and commercialization.

A copy of the Agreement will be filed as an exhibit to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2017. A copy of the Registrant's February 7, 2018 press release announcing the transaction is filed as exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press release dated February 7, 2018

SIGNATURE

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)

By: /s/ Peter S. Lawrence
Peter S. Lawrence
President and Chief Operating Officer

Date: February 7, 2018

Exhibit 99.1

Contact:

Dawn Schottlandt
Vice President, Investor Relations/Corp. Communications
(781) 994-0300
www.ArQule.com

Roivant Sciences and ArQule Enter into License Agreement for Derazantinib in China

Collaboration will expand the clinical development of derazantinib

HONG KONG and BURLINGTON, Mass. February 7, 2018 – (Business Wire) – Roivant Sciences and ArQule, Inc. (NASDAQ: ARQL) today announced the initiation of a collaboration to pursue the development of derazantinib, a pan-FGFR (fibroblast growth factor receptor) inhibitor, in Greater China. As part of the collaboration, ArQule has granted a Roivant subsidiary an exclusive license to develop and commercialize derazantinib in the People's Republic of China, Hong Kong, Macau, and Taiwan. Deal terms include an upfront payment to ArQule of $3 million and an additional $2.5 million development milestone within the first year. ArQule is also eligible for regulatory and commercial milestones and royalties on future sales of derazantinib in Greater China.

ArQule is currently conducting a registrational trial for derazantinib in the United States and Europe as a potential treatment for intrahepatic cholangiocarcinoma (iCCA), a form of biliary tract cancer. The People's Republic of China has one of the world's highest incidences of iCCA, where it is the second most common form of liver cancer. Roivant intends to pursue the development of derazantinib in China for the treatment of iCCA while also pursuing further development in other tumor types with high rates of FGFR mutation.

"Intrahepatic cholangiocarcinoma is a devastating form of cancer, and there are no approved therapies globally," said Vivek Ramaswamy, Founder and CEO of Roivant Sciences. "The prevalence of this disease is exceptionally high in China and we will do our part to further the development of derazantinib in that region."

"We are pleased with Roivant's commitment to develop derazantinib in China, where the need for novel therapies is so pressing," said Paolo Pucci, CEO of ArQule. "We share their commitment to ensuring broad geographic access to new medicines, and we look forward to developing derazantinib in iCCA and other FGFR-driven cancers."

About Derazantinib

Derazantinib is a potent, orally administered inhibitor of the fibroblast growth factor receptor (FGFR) family, a key driver of cell proliferation, differentiation, and migration. In a Phase 1/2 study in patients with iCCA harboring FGFR2 gene fusions, treatment with derazantinib resulted in an objective response rate of 21%, nearly 3 times higher than standard-of-care chemotherapy. ArQule is currently conducting a registrational study with derazantinib in patients with FGFR2 fusion-positive second-line iCCA. The open-label single-arm trial is recruiting in both the United States and Europe with objective response rate as the primary endpoint. More information on that program is available here.

About Intrahepatic Cholangiocarcinoma

Cholangiocarcinoma (CCA) is the most common biliary malignancy and the second most common hepatic malignancy after hepatocellular carcinoma (HCC).[1] Depending on the anatomic location, CCA is classified as intrahepatic (iCCA), perihilar (pCCA), and extrahepatic (eCCA). iCCA originates from the intrahepatic biliary ductal system and forms an intrahepatic mass. iCCA is an aggressive cancer, with a median 5-year survival rate of 15% for patients diagnosed with early-stage disease.[2] In China, the incidence of cholangiocarcinoma is more than 7 cases per 100,000 people, and the majority of cases are intrahepatic.[3]

About ArQule

ArQule is a biopharmaceutical company engaged in the research and development of targeted therapeutics to treat cancers and rare diseases. ArQule's mission is to discover, develop and commercialize novel small molecule drugs in areas of high unmet need that will dramatically extend and improve the lives of our patients. Our clinical-stage pipeline consists of five drug candidates, all of which are in targeted, biomarker-defined patient populations, making ArQule a leader among companies our size in precision medicine. ArQule's proprietary pipeline includes: Derazantinib, a multi-kinase inhibitor designed to preferentially inhibit the fibroblast growth factor receptor (FGFR) family, in a registrational trial for iCCA and in phase 1b for multiple oncology indications; Miransertib (ARQ 092), a selective inhibitor of the AKT serine/threonine kinase, in a phase 1/2 company sponsored study for Overgrowth Diseases, in a phase 1 study for ultra-rare Proteus syndrome conducted by the National Institutes of Health (NIH), as well as in multiple oncology indications; ARQ 751, a next generation AKT inhibitor, in phase 1 for patients with AKT1 and PI3K mutations; and ARQ 761, a β-lapachone analog being evaluated as a promoter of NQO1-mediated programmed cancer cell necrosis, in phase 1/2 in multiple oncology indications in partnership with the University of Texas Southwestern Medical Center. In addition, we have advanced ARQ 531, an investigational, orally bioavailable, potent and reversible inhibitor of both wild type and C481S-mutant BTK, in phase 1 for patients with B-cell malignancies refractory to other therapeutic options. ArQule's current discovery efforts are focused on the identification and development of novel kinase inhibitors, leveraging the Company's proprietary library of compounds. You can follow us on Twitter and LinkedIn.

About Roivant

Roivant is dedicated to transformative innovation in healthcare. Roivant focuses on realizing the full potential of promising biomedical research by developing and commercializing novel therapies across diverse therapeutic areas. Roivant partners with innovative biopharmaceutical companies and academic institutions to ensure that important medicines are rapidly developed and delivered to patients.

Roivant advances its drug pipelines through wholly- or majority-owned subsidiary companies, including Axovant (neurology), Myovant (women’s health and endocrine diseases), Dermavant (dermatology), Enzyvant (rare diseases), and Urovant (urology). Roivant also pursues its mission by incubating and launching innovative healthcare companies operating outside of traditional biopharmaceutical development. Roivant’s long-range mission is to reduce the time and cost of developing and delivering new medicines for patients. For more information, please visit www.roivant.com.

Forward Looking Statements

This press release contains forward-looking statements regarding the Company's clinical trials with derazantinib as well as the potential for future milestone and royalty payments under its License Agreement with Roivant and its subsidiary. These statements are based on the Company's current beliefs and expectations, and are subject to risks and uncertainties that could cause actual results to differ materially. Positive information about pre-clinical and early stage clinical trial results does not ensure that later stage or larger scale clinical trials will be successful. For example, derazantinib may not demonstrate promising therapeutic effect. In addition, derazantinib may not demonstrate an acceptable safety profile in current or later stage or larger scale clinical trials as a result of known or as yet unanticipated side effects. The results achieved in later stage trials may not be sufficient to meet applicable regulatory standards or to justify further development. Problems or delays may arise during clinical trials or in the course of developing, testing or manufacturing derazantinib that could lead the Company or Roivant and its subsidiary to discontinue its development. Even if later stage clinical trials are successful, unexpected concerns may arise from subsequent analysis of data or from additional data. Obstacles may arise or issues may be identified in connection with review of clinical data with regulatory authorities. Regulatory authorities may disagree with the Company's or Roivant's and its subsidiary's view of the data or require additional data or information or additional studies. In addition, we plan to develop and use a companion diagnostic to identify patients with FGFR2 fusions and possibly other fusions for our future derazantinib clinical trials. We intend to outsource the development of such companion diagnostics to one or more third party collaborators. Such collaborators may encounter difficulties in developing and obtaining approval for such companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, concordance or clinical validation. Any delay or failure to develop or obtain regulatory approval of such companion diagnostics could delay or prevent approval of derazantinib. Moreover, the subsidiary of Roivant to which derazantinib has been licensed is a new entity with no track record of drug development or commercialization. If derazantinib is not successfully developed and commercialized in Greater China as a result of any of the foregoing or other issues, risks or uncertainties, ArQule may not receive any future milestones or royalties under the License Agreement. Drug development involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Furthermore, ArQule may not have the financial or human resources to successfully pursue drug discovery in the future. For more detailed information on the risks and uncertainties associated with the Company's drug development and other activities, see the Company's periodic reports filed with the Securities and Exchange Commission. The Company does not undertake any obligation to publicly update any forward-looking statements.

[1] Welzel TM, et al. Impact of classification of hilar cholangiocarcinomas (Klatskin tumors) on the incidence of intra- and extrahepatic cholangiocarcinoma in the United States. *Journal of the National Cancer Institute* 2006; 98(12), 873-875.

[2] American Cancer Society

[3] Banales JM, et al. Cholangiocarcinoma: current knowledge and future perspectives consensus statement from the European Network for the Study of Cholangiocarcinoma (ENS-CCA). *Nature Reviews: Gastroenterology & Hepatology* 2016; 13, 261-280.

Related links

www.arqule.com

www.roivant.com

SOURCE ArQule, Inc.