ARQULE INC
Form 10-Q
November 07, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

Quarterly report pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

For the Quarter Ended September 30, 2016

Commission File No. 000-21429

ArQule, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**04-3221586**
(State of Incorporation)	(I.R.S. Employer Identification Number)

One Wall Street, Burlington, Massachusetts 01803

(Address of Principal Executive Offices)

(781) 994-0300

(Registrant's Telephone Number, including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405) of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Number of shares outstanding of the registrant’s Common Stock as of October 24, 2016:

Common Stock, par value $.01 71,118,709 outstanding

ARQULE, INC.

QUARTER ENDED SEPTEMBER 30, 2016

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ARQULE, INC.

CONDENSED BALANCE SHEETS (Unaudited)

	September 30, 2016	December 31, 2015
	(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,998	$ 13,983
Marketable securities-short term	22,661	24,789
Prepaid expenses and other current assets	415	714
Total current assets	38,074	39,486
Property and equipment, net	204	266
Other assets	252	252
Total assets	$ 38,530	$ 40,004
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 7,296	$ 6,234
Deferred revenue	1,153	4,591
Total current liabilities	8,449	10,825
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 1,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.01 par value; 100,000,000 shares authorized; 71,118,709 and 62,939,780 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	711	629
Additional paid-in capital	527,363	510,664
Accumulated other comprehensive income	22	3
Accumulated deficit	(498,015)	(482,117)
Total stockholders' equity	30,081	29,179
Total liabilities and stockholders' equity	$ 38,530	$ 40,004

The accompanying notes are an integral part of these interim unaudited financial statements.

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ARQULE, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (Unaudited)

	THREE MONTHS ENDED September 30,		NINE MONTHS ENDED September 30,	
	2016	2015	2016	2015
	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
Research and development revenue	$ 1,223	$ 2,653	$ 3,522	$ 8,442
Costs and expenses:				
Research and development	5,265	3,180	13,800	11,920
General and administrative	1,824	1,839	5,755	7,802
Total costs and expenses	7,089	5,019	19,555	19,722
Loss from operations	(5,866)	(2,366)	(16,033)	(11,280)
Interest income	49	17	135	81
Other income (expense)	—	(5)	—	277
Net loss	(5,817)	(2,354)	(15,898)	(10,922)
Unrealized gain (loss) on marketable securities	(10)	8	19	11
Comprehensive loss	$ (5,827)	$ (2,346)	$ (15,879)	$ (10,911)
Basic and diluted net loss per share:				
Net loss per share	$ (0.08)	$ (0.04)	$ (0.23)	$ (0.17)
Weighted average basic and diluted common shares outstanding	71,083	62,827	69,247	62,753

The accompanying notes are an integral part of these interim unaudited financial statements.

ARQULE, INC.

CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2016	2015
	(IN THOUSANDS)	
Cash flows from operating activities:		
Net loss	$ (15,898)	$ (10,922)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	77	129
Amortization of premium on marketable securities	42	406
Amortization of deferred gain on sale leaseback	—	(232)
Non-cash stock compensation	1,444	1,741
Gain on sale of property and equipment	—	(277)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	299	1,551
Accounts payable and accrued expenses	1,062	(1,256)
Deferred revenue	(3,438)	(8,297)
Net cash used in operating activities	(16,412)	(17,157)
Cash flows from investing activities:		
Purchases of marketable securities	(28,445)	(24,203)
Proceeds from sale or maturity of marketable securities	30,550	41,920
Additions to property and equipment	(15)	(315)
Proceeds from sale of property and equipment	—	298
Net cash provided by investing activities	2,090	17,700
Cash flows from financing activities:		
Proceeds from stock offering, net	15,174	—
Proceeds from employee stock option exercises and employee stock purchase plan purchases	163	62
Net cash provided by financing activities	15,337	62
Net increase in cash and cash equivalents	1,015	605
Cash and cash equivalents, beginning of period	13,983	12,525
Cash and cash equivalents, end of period	$ 14,998	$ 13,130

The accompanying notes are an integral part of these interim unaudited financial statements.

ARQULE, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

We are a biopharmaceutical company engaged in the research and development of innovative therapeutics to treat cancers and rare diseases. Our 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. These drugs target biological pathways implicated in a wide range of cancers and certain non-oncology indications. Our discovery and development efforts are guided, when possible, by an understanding of the role of biomarkers, which are indicators of a particular biological condition or process and may predict the clinical benefit of our compounds in defined patient populations. Our clinical-stage pipeline consists of five drug candidates, all of which are in targeted patient populations, making ArQule a leader among companies our size in precision medicine.

Our lead product candidate is tivantinib (ARQ 197), an orally administered, small molecule inhibitor of the c-Met receptor tyrosine kinase ("MET") and its biological pathway. MET is a promising target for cancer therapy, based on its multiple roles in cancerous cell proliferation, tumor spread, new blood vessel formation and resistance to certain drug therapies. We and our partners, Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo") and Kyowa Hakko Kirin Co., Ltd. ("Kyowa Hakko Kirin"), are implementing a worldwide clinical development program with tivantinib. Our strategy is to focus on the most promising indications within our clinical programs based upon continually generated and updated clinical and pre-clinical data. Our lead indication is liver cancer ("hepatocellular carcinoma" or "HCC"), and we are currently conducting two Phase 3 trials with our partners. We have also completed earlier-stage single agent and combination therapy trials and pre-clinical experiments with tivantinib and other anti-cancer agents that may provide data to support trials in additional indications.

On March 22, 2016, we and Daiichi Sankyo announced that the independent data monitoring committee ("DMC") of the METIV-HCC study conducted the planned interim assessment, and it was determined the trial will continue to its final analysis. Accordingly, we reviewed the estimated development period and extended it to December 2016 for both the METIV-HCC trial and the JET-HCC trial.

We have licensed commercial rights to tivantinib for human cancer indications to Daiichi Sankyo in the U.S., Europe, South America and the rest of the world, excluding Japan and certain other Asian countries, where we have licensed commercial rights to Kyowa Hakko Kirin. Our agreements with these partners provide for possible future milestone payments, royalties on product sales, and development funding, in addition to significant payments that we have already received. To date we have received $100 million in upfront and milestone payments from Daiichi Sankyo, $15 million of which was related to the first patient enrolled in the METIV-HCC trial. That milestone was netted against our cumulative share of Phase 3 collaboration costs in 2013, and consequently we did not receive any cash proceeds from this milestone. To date, we have received $48 million in upfront and milestone payments from Kyowa Hakko Kirin.

Our proprietary pipeline of product candidates is directed toward molecular targets and biological processes with demonstrated roles in the development of both human cancers and rare, non-oncology diseases. Our clinical-stage candidates include: ARQ 087, a multi-kinase inhibitor designed to preferentially inhibit the fibroblast growth factor receptor (“FGFR”) family; ARQ 092, a selective inhibitor of the AKT serine/threonine kinase; ARQ 751, a next generation AKT inhibitor; and ARQ 761, a Beta lapachone analog being evaluated in investigator-sponsored testing as a promoter of NQO1-mediated programmed cancer cell necrosis. Specific tumor types and biomarkers have been identified to guide our clinical testing, based on analyses of Phase 1a anti-cancer activity in humans, preclinical findings and scientific literature. In addition, we have advanced ARQ 531, an investigational, orally bioavailable, potent and reversible inhibitor of both wild type and C481S-mutant BTK, into toxicology testing and plan to file an Investigational New Drug Application in early 2017.

Our uses of cash for operating activities have primarily consisted of salaries and wages for our employees, facility and facility-related costs for our offices and laboratories, fees paid in connection with preclinical and clinical studies, laboratory supplies and materials, and professional fees. The sources of our cash flow from operating activities have consisted primarily of payments received from our collaborators for services performed or upfront payments for future services. For the nine months ended September 30, 2016 and 2015, our net use of cash was primarily driven by payments for operating expenses which resulted in net cash outflows of $16.4 million and $17.2 million, respectively.

Our cash requirements may vary materially from those now planned depending upon the results of our drug discovery and development strategies, our ability to enter into additional corporate collaborations and the terms of such collaborations, results of research and development, unanticipated required capital expenditures, competitive and technological advances, acquisitions and other factors. We cannot guarantee that we will be able to develop any of our drug candidates into a commercial product. It is likely we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our ability to raise additional funds will depend on financial, economic and market conditions, and due to global capital and credit market conditions or for other reasons, we may be unable to raise capital when needed, or on terms favorable to us. If necessary funds are not available, we may have to delay, reduce the scope of, or eliminate some of our development programs, potentially delaying the time to market for any of our product candidates.

We have prepared the accompanying condensed financial statements pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to these rules and regulations. These condensed financial statements should be read in conjunction with our audited financial statements and footnotes related thereto for the year ended December 31, 2015 included in our annual report on Form 10-K filed with the SEC on February 29, 2016.

In the opinion of the Company, the accompanying unaudited condensed financial statements contain all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of its financial position as of September 30, 2016, its results of operations for the three and nine months ended September 30, 2016 and September 30, 2015, and its cash flows for the nine months ended September 30, 2016 and September 30, 2015. The results of operations for such interim periods are not necessarily indicative of the results to be achieved for the full year. The condensed balance sheet at December 31, 2015 was derived from audited annual financial statements, but does not contain all of the footnote disclosures from the annual financial statements.

2. COLLABORATIONS AND ALLIANCES

Daiichi Sankyo Tivantinib Agreement

On December 18, 2008, we entered into a license, co-development and co-commercialization agreement with Daiichi Sankyo to conduct research, clinical trials and the commercialization of tivantinib in human cancer indications 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 has exclusive rights for development and commercialization.

The agreement provides for a $60 million cash upfront licensing payment from Daiichi Sankyo to us, which we received in December 2008, and an additional $560 million in potential development and sales milestone payments offset by our share of Phase 3 costs. On November 3, 2015, the Company announced that it had exercised its option with Daiichi Sankyo to co-commercialize tivantinib in the United States (the "Co-Commercialization Option"), pursuant to the agreement. Subject to the receipt of regulatory approvals, the first commercial indication for tivantinib under the Co-Commercialization Option is anticipated to be second line HCC. The parties have a prescribed period to conclude a co-commercialization agreement in accordance with the terms of the agreement which is expected to occur in 2016. If the METIV-HCC trial is successful, and tivantinib is approved in second line HCC, the agreement provides that the Company will receive a total of $55 million in milestone payments for the official acceptance of drug approval applications by FDA and the European Medicines Agency ("EMA") in this first indication, plus an additional $100 million in combined milestones tied to receipt of commercialization regulatory approval by the FDA and the first commercial sale in the UK, Germany, France, Italy or Spain. These milestones, totaling $155 million, will be partially offset by Phase 3 costs owed to Daiichi Sankyo by the Company at the time of approval in the US or EU. At September 30, 2016, the Company's share of these Phase 3 costs totaled $65.9 million. The agreement also provides that the Company will receive tiered double digit royalties on net sales of tivantinib throughout the territory. Given the anticipated commercial market for second line HCC, the Company expects to earn royalties on net sales for this indication at the baseline contractual rate of 20 percent.

We and Daiichi Sankyo will share equally the costs of Phase 2 and Phase 3 clinical studies, with our share of Phase 3 costs payable solely from milestone and royalty payments by Daiichi Sankyo. Under the terms of our tivantinib collaboration agreement with Daiichi Sankyo we share development costs equally with our share of Phase 3 costs funded solely from milestones and royalties. In each quarter the tivantinib collaboration costs we incur are compared with those of Daiichi Sankyo. If our costs for the quarter exceed Daiichi Sankyo's, we recognize revenue on the amounts due to us under the contingency adjusted performance model. Revenue is calculated on a pro-rata basis using the time elapsed from inception of the agreement over the estimated duration of the development period under the agreement. If our costs for the quarter are less than those of Daiichi Sankyo's, we report the amount due to Daiichi Sankyo as contra-revenue in that quarter. To the extent that our share of Phase 3 collaboration costs exceeds the amount of milestones and royalties received, that excess is netted against future milestones and royalties if and when earned and is not reported as contra-revenue.

Our cumulative share of the Daiichi Sankyo Phase 3 costs through September 30, 2016 totaled $105.9 million. We received a milestone of $25 million in February 2011 upon enrolling the first patient in the MARQUEE trial, the cash proceeds of which were subsequently applied to our share of Phase 3 collaboration costs. On January 31, 2013, we announced that the first patient had been enrolled in the pivotal Phase 3 METIV trial of tivantinib, entitling us to a $15 million milestone. That $15 million milestone was also netted against our cumulative share of Phase 3 collaboration costs in 2013, and consequently we did not receive any cash proceeds from this milestone. Our cumulative share of Phase 3 collaboration costs has exceeded the amount of milestones received through September 30, 2016 by $65.9 million which will be netted against future milestones and royalties, if any, when earned and has not been reported as contra-revenue.

For the quarter and nine months ended September 30, 2016, our non-Phase 3 tivantinib collaboration costs incurred exceeded those of Daiichi Sankyo's and $73 and $79, respectively, were recognized as research and development revenue

For the quarter ended September 30, 2015 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo and $130 was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue. For the nine months ended September 30, 2015, our non-Phase 3 tivantinib collaboration costs incurred exceeded those of Daiichi Sankyo and $119 was recognized as tivantinib Daiichi Sankyo net research and development revenue.

The duration and termination of the agreement are tied to future events. Unless earlier terminated due to breach, insolvency or upon 90 days' notice if prior to Phase 3 clinical trials or 180 days' notice if on or after the beginning of Phase 3 clinical trials by Daiichi Sankyo, the agreement shall continue until the later of (i) such time as Daiichi Sankyo is no longer developing at least one licensed product or (ii) if Daiichi Sankyo has commercialized a licensed product or products, such time as all royalty terms for all licensed products have ended. The royalty term, on a country-by-country basis for a product, ends as of the later of (i) the expiration of the last valid claim under a patent covering the manufacture, use, or sale of a licensed product or (ii) a certain number of years from the date of the commercial sale of the licensed product in such country.

Revenue for this agreement is recognized using the contingency-adjusted performance model. Through September 30, 2012, revenue was recognized based upon an estimated development period through December 2013. As a result of the October 2012 decision to discontinue the MARQUEE trial, the development period as of October 1, 2012 was extended to June 2015. Commencing with the fourth quarter of 2012 and through the third quarter of 2013 revenue was recognized over that development period. In the fourth quarter of 2013, following a recommendation by the DMC that the METIV-HCC trial continue with patients receiving a lower dose of tivantinib than the dose originally employed in the trial, we reviewed the estimated development period and extended it to June 2016. On March 22, 2016, we and Daiichi Sankyo announced that the DMC of the METIV-HCC study conducted the planned interim assessment, and it was determined the trial will continue to its final analysis. Accordingly, we reviewed the estimated development period and extended it to December 2016.

For the three months and nine months ended September 30, 2016, $0.8 million and $2.1 million, respectively, were recognized as net revenue. For the three months and nine months ended September 30, 2015, $1.2 million and $4.2 million, respectively, were recognized as net revenue. At September 30, 2016, $0.7 million remains in deferred revenue.

Kyowa Hakko Kirin Licensing Agreement

On April 27, 2007, we entered into an exclusive license agreement with Kyowa Hakko Kirin to develop and commercialize tivantinib in Japan and parts of Asia. A $3 million portion of an upfront licensing fee was received by the Company under this agreement in the first quarter of 2007, and an additional $27 million in upfront licensing fees was received on May 7, 2007. The agreement includes $123 million in upfront and potential development milestone payments from Kyowa Hakko Kirin to ArQule, including the $30 million cash upfront licensing payments. In February 2008, we received a $3 million milestone payment from Kyowa Hakko Kirin. Upon commercialization, ArQule will receive tiered royalties in the mid-teen to low-twenty percent range from Kyowa Hakko Kirin on net sales of tivantinib. Kyowa Hakko Kirin will be responsible for all clinical development costs and commercialization of the compound in certain Asian countries, consisting of Japan, China (including Hong Kong), South Korea and Taiwan. In July 2010, we announced the initiation of a Phase 2 trial with tivantinib by Kyowa Hakko Kirin in gastric cancer, for which we received a $5 million milestone payment in September 2010.

In August 2011, Kyowa Hakko Kirin announced the initiation of the Phase 3 ATTENTION trial. Dosing of the first patient in this trial triggered a $10 million milestone payment, which we received in August 2011. The milestone payment was recorded as deferred revenue and is being recognized as revenue using the contingency-adjusted performance model. On February 4, 2014, Kyowa Hakko Kirin announced the initiation of the Phase 3 JET-HCC trial. There were no milestone payments associated with the initiation of this trial.

In addition to the upfront and possible regulatory milestone payments totaling $123 million, the Company will be eligible for future milestone payments based on the achievement of certain levels of net sales. The Company will recognize the payments, if any, as revenue in accordance with the contingency-adjusted performance model. As of September 30, 2016, the Company had not recognized any revenue from these sales milestone payments, and there can be no assurance that it will do so in the future.

The duration and termination of the agreement are tied to future events. Unless earlier terminated due to breach, insolvency or upon 90 days' notice by Kyowa Hakko Kirin, the agreement terminates on the date that the last royalty term expires in all countries in the territory. The royalty term ends as of the later of (i) the expiration of the last pending patent application or expiration of the patent in the country covering the manufacture, use, or sale of a licensed product or (ii) a certain number of years from the date of the commercial launch in such country of such license product.

Through December 2015, revenue for this agreement was recognized using the contingency-adjusted performance model with an estimated development period through April 2016. As noted for the Daiichi Sankyo tivantinib program, the estimated development period for the METIV-HCC study was reviewed and extended to December 2016 in the first quarter of 2016. Similarly, the estimated development period for the Kyowa Hakko Kirin Phase 3 JET-HCC trial was reviewed and also extended to December 2016.

For the three months and nine months ended September 30, 2016, $0.5 million and $1.4 million respectively, were recognized as revenue. For the three months and nine months ended September 30, 2015, $1.4 million and $4.3 million respectively, were recognized as revenue. At September 30, 2016, $0.5 million remains in deferred revenue.

Beryllium Discovery Corp. Agreement

In May 2015, we entered into a collaborative research and development agreement with Beryllium Discovery Corp. ("Beryllium"). Pursuant to the agreement, we agreed to focus on the identification and preclinical development of inhibitors of PD-1 and PDL-1.

As a result of a change in our research and development priorities, including with respect to our emphasis on accelerating pre-clinical development of ARQ531, our BTK inhibitor, we entered into an agreement with Beryllium pursuant to which we jointly terminated the collaborative research and development agreement effective November 4, 2016.

3. MARKETABLE SECURITIES AND FAIR VALUE MEASUREMENTS

We generally classify our marketable securities as available-for-sale at the time of purchase and re-evaluate such designation as of each balance sheet date. Since we generally intend to convert them into cash as necessary to meet our liquidity requirements our marketable securities are classified as cash equivalents if the original maturity, from the

date of purchase, is ninety days or less and as short-term investments if the original maturity, from the date of purchase, is in excess of ninety days but less than one year. Our marketable securities are classified as long-term investments if the maturity date is in excess of one year of the balance sheet date.

We report available-for-sale investments at fair value as of each balance sheet date and include any unrealized gains and, to the extent deemed temporary, unrealized losses in stockholders' equity. Realized gains and losses are determined using the specific identification method and are included in other income (expense) in the statement of operations and comprehensive loss.

We conduct quarterly reviews to determine the fair value of our investment portfolio and to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. In the event that the cost basis of a security exceeds its fair value, we evaluate, among other factors, the duration of the period that, and extent to which, the fair value is less than cost basis, the financial health of and business outlook for the issuer, including industry and sector performance, and operational and financing cash flow factors, overall market conditions and trends, our intent to sell the investment and if it is more likely than not that we would be required to sell the investment before its anticipated recovery. Unrealized losses on available-for-sale securities that are determined to be temporary, and not related to credit loss, are recorded in accumulated other comprehensive income (loss).

For available-for-sale debt securities with unrealized losses, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is reflected in the statement of operations and comprehensive loss as an impairment loss.

Regardless of our intent to sell a security, we perform additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

The following is a summary of the fair value of available-for-sale marketable securities we held at September 30, 2016 and December 31, 2015:

September 30, 2016	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
Corporate debt securities-short term	$ 22,639	$ 27	$ (5)	$ 22,661
Total available-for-sale marketable securities	$ 22,639	$ 27	$ (5)	$ 22,661

December 31, 2015	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
Corporate debt securities-short term	$ 24,786	$ 13	$ (10)	$ 24,789
Total available-for-sale marketable securities	$ 24,786	$ 13	$ (10)	$ 24,789

Our available-for-sale marketable securities in a loss position at September 30, 2016, and December 31, 2015 were in a continuous unrealized loss position for less than 12 months.

The following tables present information about our assets that are measured at fair value on a recurring basis for the periods presented and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves. We value our level 2 investments using quoted prices for identical assets in the markets where they are traded, although such trades may not occur daily. These quoted prices are based on observable inputs, primarily interest rates. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability. There were no transfers in or out of Level 1 or Level 2 measurements for the periods presented:

	September 30, 2016	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 14,093	$ 14,093	$ —	$ —
Corporate debt securities-short term	22,661	—	22,661	—
Total	$ 36,754	$ 14,093	$ 22,661	$ —

	December 31, 2015	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 11,800	$ 11,800	$ —	$ —
Corporate debt securities-short term	24,789	—	24,789	—
Total	$ 36,589	$ 11,800	$ 24,789	$ —

4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses include the following at September 30, 2016 and December 31, 2015:

	September 30, 2016	December 31, 2015
Accounts payable	$ 90	$ 186
Accrued payroll	1,732	1,956
Accrued outsourced pre-clinical and clinical fees	4,890	3,273
Accrued professional fees	331	516
Other accrued expenses	253	303
	$ 7,296	$ 6,234

5. NET LOSS PER SHARE

Net loss per share is computed using the weighted average number of common shares outstanding. Basic and diluted net loss per share amounts are equivalent for the periods presented as the inclusion of potential common shares in the number of shares used for the diluted computation would be anti-dilutive to loss per share. Potential common shares, for the three and nine months ended September 30, 2016, include 9,187,698 shares that would be issued upon the exercise of outstanding employee stock options and 3,567,956 shares that would be issued upon exercise of the stock options issued in our February 26, 2016 stock offering. Potential common shares, for the three months and nine months ended September 30, 2015, include 8,342,725 shares that would be issued upon the exercise of outstanding employee stock options.

6. STOCK-BASED COMPENSATION AND STOCK PLANS

Our stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the employees' requisite service period (generally the vesting period of the equity grant). We estimate the fair value of stock options using the Black-Scholes valuation model. Key input assumptions used to estimate the fair value of stock options include the exercise price of the award, expected option term, expected volatility of our stock over the option's expected term, risk-free interest rate over the option's expected term, and the expected annual dividend yield. We believe that the valuation technique and approach utilized to develop the underlying assumptions are appropriate in calculating the fair values of our stock options granted in the nine months ended September 30, 2016 and 2015.

The following table presents stock-based compensation expense included in our Condensed Statements of Operations and Comprehensive Loss:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	$ 107	$ 142	$ 407	$ 538
General and administrative	322	359	1,037	1,203
Total stock-based compensation expense	$ 429	$ 501	$ 1,444	$ 1,741

In the three and nine months ended September 30, 2016 and 2015, no stock-based compensation expense was capitalized and there were no recognized tax benefits associated with the stock-based compensation expense.

Option activity under our stock plans for the nine months ended September 30, 2016 was as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2015	8,305,950	$ 4.24
Granted	1,609,000	1.78
Exercised	(97,498)	1.16
Cancelled	(629,754)	5.31
Outstanding as of September 30, 2016	9,187,698	$ 3.77
Exercisable as of September 30, 2016	6,102,042	$ 4.78

The aggregate intrinsic value of options outstanding at September 30, 2016 was $703 and $157 related to exercisable options. The weighted average grant date fair value of options granted in the nine months ended September 30, 2016 and 2015 was $1.10 and $0.77 per share, respectively.

Shares vested, expected to vest and exercisable at September 30, 2016 are as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Vested and unvested expected to vest at September 30, 2016	9,019,305	$ 3.76	5.53	$ 674
Exercisable at September 30, 2016	6,102,042	$ 4.78	3.98	$ 157

The total compensation cost not yet recognized as of September 30, 2016 related to non-vested option awards was $3.0 million, which will be recognized over a weighted-average period of 2.4 years. During the nine months ended September 30, 2016, 2,218 shares were forfeited. The weighted average remaining contractual life for options exercisable at September 30, 2016 was 4.0 years.

In 2013, we granted 242,697 shares of restricted stock to employees, vesting annually over a four year period. The weighted average fair value of the restricted stock at the time of grant in 2013 was $2.51 per share, and is being expensed ratably over the vesting period. Through September 30, 2016, 82,617 shares have been forfeited, and 130,804 shares have vested. We recognized share-based compensation expense related to restricted stock of $56 and $59 for the nine months ended September 30, 2016 and 2015, respectively.

Restricted stock activity under the Plan for the nine months ended September 30, 2016 was as follows:

Restricted Stock	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2015	58,635	$ 2.51
Vested	(29,306)	2.51
Cancelled	(53)	2.51
Unvested as of September 30, 2016	29,276	$ 2.51

The fair value of restricted stock vested in the nine months ended September 30, 2016 and 2015 was $52 and $68 respectively.

In July 2010, the Company amended its chief executive officer's (the "CEO's") employment agreement to grant the CEO 100,000 stock options, of which 25% vested upon grant and 25% vested annually over the next three years, and a maximum of 390,000 performance-based stock units that vest upon the achievement of certain performance and market based targets. In March 2013, the Company amended its CEO's employment agreement to modify the performance and market based targets.

In February 2012, the Company amended its chief medical officer's (the "CMO's") employment agreement to grant the CMO 50,000 performance-based stock units that vest upon the achievement of certain performance based targets.

In March 2013, the Company amended its chief operating officer's (the "COO's") employment agreement to grant the COO 125,000 performance-based stock units that vest upon the achievement of certain performance based targets. In March 2013, the Company amended its CMO's employment agreement to grant the CMO 120,000 performance-based stock units that vest upon the achievement of certain performance based targets.

Through September 30, 2016, no expense has been recorded for any performance-based stock units granted to the CEO, COO, or CMO.

7. STOCK OFFERING

On February 26, 2016 the Company entered into definitive stock purchase agreements with certain institutional and accredited investors. In conjunction with this stock offering we issued 8,027,900 shares of our common stock and non-transferable options for 3,567,956 shares of our common stock for aggregate net proceeds of $15.2 million. Each option is exercisable for $2.50 per share and expires on March 22, 2017. If all options were to be exercised it would result in additional proceeds of approximately $8.9 million.

8. RECENT ACCOUNTING PRONOUNCEMENTS

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The new standard will be effective for us on January 1, 2017. We are currently evaluating the potential impact that this standard may have on our financial position, results of operations and statement of cash flows.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for us on January 1, 2019. We are currently evaluating the potential impact that this standard may have on our financial position and results of operations.

In August 2014, the FASB issued Accounting Standard Update ("ASU") 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Under the new guidance, management will be required to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The provisions of this ASU are effective for annual periods ending after December 15, 2016, and for annual and interim periods thereafter. We are currently evaluating the potential impact that this ASU may have on our disclosures.

In June 2014, the FASB issued ASU No. 2014-12, "Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period." This ASU requires a reporting entity to treat a performance target that affects vesting and that could be achieved after the requisite service period as a performance condition, and apply existing guidance under the Stock Compensation Topic of the ASC as it relates to awards with performance conditions that affect vesting to account for such awards. The provisions of this ASU are effective for interim and annual periods beginning after December 15, 2015. We evaluated this ASU and determined that it did not have a material impact on our financial position or results of operations.

During the quarter ended June 30, 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers” (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. We are currently evaluating the method of adoption and the potential impact that Topic 606 may have on our financial position and results of operations.

9. INCOME TAXES

As of December 31, 2015, we had federal NOL, state NOL, and research and development credit carryforwards of approximately $357,122, $176,712 and $27,750 respectively, which expire at various dates through 2035. Approximately $15,020 of our federal NOL and $868 of our state NOL were generated from excess tax deductions from share-based awards, the tax benefit of which will be credited to additional paid-in-capital when the deductions reduce current taxes payable.

At September 30, 2016 and December 31, 2015, we had no unrecognized tax benefits. We do not expect that the total amount of unrecognized tax benefits will significantly increase in the next twelve months. Our policy is to recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2015 and 2014, we had no accrued interest or penalties related to uncertain tax positions. Our U.S. federal tax returns for the tax years 2012 through 2015 and our state tax returns for the tax years 2012 through 2015 remain open to examination. Prior tax years remain open to the extent of net operating loss and tax credit carryforwards.

Utilization of NOL and research and development credit carryforwards may be subject to a substantial annual limitation in the event of an ownership change that has occurred previously or could occur in the future pursuant to Section 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions. An ownership change may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income, and may, in turn, result in the expiration of a portion of those carryforwards before utilization. In general, an ownership change, as defined by Section 382, results from transactions that increase the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three year period. We undertook a detailed study of our NOL and research and development credit carryforwards through January 31, 2016, to determine whether such amounts are likely to be limited by Sections 382 or 383. As a result of this analysis, we currently do not believe any Sections 382 or 383 limitations will significantly impact our ability to offset income with available NOL and research and development credit carryforwards. However, future ownership changes under Section 382 may limit our ability to fully utilize these tax benefits.

10. SUBSEQUENT EVENT

On October 25, 2016, the Company entered into a Sales Agreement with JonesTrading Institutional Services LLC ("Jones") to sell, from time to time, shares of the Company's common stock having an aggregate sales price of up to $30 million through an "at the market offering" program under which Jones will act as sales agent.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our condensed financial statements and accompanying notes contained in this quarterly report on Form 10-Q and our audited financial statements and related notes included in our Annual Report on Form 10-K for the year ended December 31, 2015.

We are a biopharmaceutical company engaged in the research and development of innovative therapeutics to treat cancers and rare diseases. Our 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. These drugs target biological pathways implicated in a wide range of cancers and certain non-oncology indications. Our discovery and development efforts are guided, when possible, by an understanding of the role of biomarkers, which are indicators of a particular biological condition or process and may predict the clinical benefit of our compounds in defined patient populations. Our clinical-stage pipeline consists of five drug candidates, all of which are in targeted patient populations, making ArQule a leader among companies our size in precision medicine.

ArQule has a long history of kinase drug discovery and development, having discovered and introduced nine kinase inhibitors into human clinical trials. Our drug discovery efforts have been informed by our historical expertise in chemistry, our work in rational drug design and by our insight into kinase binding and regulation. We have applied this knowledge to produce significant chemical matter for a number of kinase targets and to build an extensive library of proprietary compounds with the potential to target multiple kinases in oncology and other therapeutic areas, such as rare diseases. We expect to bring further preclinical programs forward either directly or with collaborators and to interrogate our library against new targets beyond kinases.

Our lead product candidate is tivantinib (ARQ 197), an orally administered, small molecule inhibitor of the c-Met receptor tyrosine kinase ("MET") and its biological pathway. MET is a promising target for cancer therapy, based on its multiple roles in cancerous cell proliferation, tumor spread, new blood vessel formation and resistance to certain drug therapies. We and our partners, Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo") and Kyowa Hakko Kirin Co., Ltd. ("Kyowa Hakko Kirin"), are implementing a worldwide clinical development program with tivantinib. Our strategy is to focus

on the most promising indications within our clinical programs based upon continually generated and updated clinical and pre-clinical data. Our lead indication is liver cancer ("hepatocellular carcinoma" or "HCC"), and we are currently conducting two Phase 3 trials with our partners. We have also completed earlier-stage single agent and combination therapy trials and pre-clinical experiments with tivantinib and other anti-cancer agents that may provide data to support trials in additional indications.

Our most advanced ongoing clinical trial, the METIV-HCC trial, is a pivotal Phase 3 randomized, double-blind, controlled study of tivantinib as single agent therapy in previously treated patients with MET diagnostic-high, inoperable HCC conducted by Daiichi Sankyo and us. The primary endpoint is overall survival ("OS") in the intent-to-treat ("ITT") population, and the secondary endpoint is progression-free survival ("PFS") in the same population.

We completed patient accrual in the METIV-HCC trial in December 2015 and have randomized over 300 patients at more than 100 clinical sites worldwide. On March 22, 2016, we and Daiichi Sankyo announced that the independent data monitoring committee ("DMC") of the METIV-HCC study conducted the planned interim assessment, and it was determined that the trial will continue to its final analysis. The interim assessment was triggered when at least 60 percent of the target number of events occurred. The final analysis will take place when 100 percent of the target number of events occurs, which we currently expect to be in late 2016 or early 2017. The METIV-HCC trial is being conducted under a Special Protocol Assessment ("SPA") agreement with the U.S. Food and Drug Administration ("FDA").

In addition to METIV-HCC, a second Phase 3 clinical trial in HCC with tivantinib known as JET-HCC is ongoing in Japan. On February 4, 2014, Kyowa Hakko Kirin announced the initiation of this trial in Japanese patients with MET diagnostic-high, inoperable HCC previously treated with sorafenib. The trial is a randomized, double-blind placebo-controlled study to compare PFS in patients treated with tivantinib with those treated with placebo. Kyowa Hakko Kirin plans to enroll approximately 160 patients in this study.

We have licensed commercial rights to tivantinib for human cancer indications to Daiichi Sankyo in the U.S., Europe, South America and the rest of the world, excluding Japan and certain other Asian countries, where we have licensed commercial rights to Kyowa Hakko Kirin. Our agreements with these partners provide for possible future milestone payments, royalties on product sales, and development funding, in addition to significant payments that we have already received. To date we have received $100 million in upfront and milestone payments from Daiichi Sankyo, $15 million of which was related to the first patient enrolled in the METIV-HCC trial. That milestone was netted against our cumulative share of Phase 3 collaboration costs in 2013, and consequently we did not receive any cash proceeds from this milestone. To date, we have received $48 million in upfront and milestone payments from Kyowa Hakko Kirin.

We have collaborated with the National Cancer Institute (“NCI”) through its Cancer Therapy Evaluation Program (“CTEP”) to explore the clinical potential of tivantinib in a variety of tumor indications while we focus our internal efforts on the two Phase 3 programs in HCC. These CTEP-sponsored trials included Phase 2 single agent trials in prostate cancer (randomized), multiple myeloma, breast cancer and malignant mesothelioma, and Phase 2 combination therapy trials in kidney cancer (with or without erlotinib, randomized) and head and neck cancer (with or without cetuximab, randomized).

Our proprietary pipeline of product candidates is directed toward molecular targets and biological processes with demonstrated roles in the development of both human cancers and rare, non-oncology diseases. Our clinical-stage candidates include: ARQ 087, a multi-kinase inhibitor designed to preferentially inhibit the fibroblast growth factor receptor (“FGFR”) family; ARQ 092, a selective inhibitor of the AKT serine/threonine kinase; ARQ 751, a next generation AKT inhibitor; and ARQ 761, a Beta lapachone analog being evaluated in investigator-sponsored testing as a promoter of NQO1-mediated programmed cancer cell necrosis. Specific tumor types and biomarkers have been identified to guide our clinical testing, based on analyses of Phase 1a anti-cancer activity in humans, preclinical findings and scientific literature. In addition, we have advanced ARQ 531, an investigational, orally bioavailable, potent and reversible inhibitor of both wild type and C481S-mutant BTK, into toxicology testing and plan to file an Investigational New Drug Application in early 2017.

Under our agreement with the National Human Genome Research Institute of the NIH, a Phase 1 clinical trial investigating ARQ 092 as a potential treatment for Proteus syndrome, a rare overgrowth disorder caused by a mutation in the AKT 1 gene, began enrolling patients in November 2015. A Phase 1b clinical trial for ARQ 092 has completed enrollment in lymphoma, endometrial cancers and in cancers harboring AKT 1 and PI3K mutations. Thus far in this enriched cohort of the trial, we have observed five patients with confirmed responses, three of which had the

same AKT 1 mutation that occurs in Proteus syndrome and one of which had a PI3k mutation. Clinical development of ARQ 087 has advanced into Phase 2 for intrahepatic cholangiocarcinoma ("iCCA") following the observation of two confirmed partial responses in this patient population in the Phase 1 portion of the trial. Additional testing is on-going in solid tumors as part of a Phase 1b expansion cohort of this trial. ARQ 761 is currently in a Phase 1b clinical trial for solid tumors and Phase 1b/2 for pancreatic cancer.

We have incurred a cumulative deficit of approximately $498 million from inception through September 30, 2016. We recorded a net loss for 2014 and 2015 and expect a net loss for 2016.

Our revenue consists primarily of development funding from our alliances with Daiichi Sankyo and Kyowa Hakko Kirin. Revenue and expenses fluctuate from quarter to quarter based upon a number of factors, notably the timing and extent of our cancer-related research and development activities together with the length and outcome of our clinical trials.

In May 2015, we entered into a Collaborative Research and Development Agreement with Beryllium Discovery Corp. ("Beryllium"). Pursuant to the agreement, we will jointly focus on the identification and preclinical development of inhibitors of PD-1 and PDL-1.

As a result of a change in our research and development priorities, including with respect to our emphasis on accelerating pre-clinical development of ARQ531, our BTK inhibitor, we entered into an agreement with Beryllium pursuant to which we jointly terminated the collaborative research and development agreement effective November 4, 2016.

On December 18, 2008, we entered into a license, co-development and co-commercialization agreement with Daiichi Sankyo to conduct research, clinical trials and commercialization of tivantinib in human cancer indications. The agreement provides for a $60 million cash upfront licensing payment from Daiichi Sankyo to us, which we received in December 2008, and an additional $560 million in potential development and sales milestone payments offset by our share of the Phase 3 costs. Upon commercialization, we will receive tiered, double-digit royalties from Daiichi Sankyo on net sales of tivantinib commensurate with the magnitude of the transaction. On November 3, 2015, the Company announced that it had exercised its option with Daiichi Sankyo to co-commercialize tivantinib in the United States (the "Co-Commercialization Option"), pursuant to the Agreement. Subject to the receipt of regulatory approvals, the first commercial indication for tivantinib under the Co-Commercialization Option is anticipated to be second line HCC. The parties have a prescribed period to conclude a co-commercialization agreement in accordance with the terms of the Agreement which is expected to occur in 2016. If the METIV-HCC trial is successful, and tivantinib is approved in second line HCC, the Agreement provides that the Company will receive a total of $55 million in milestone payments for the official acceptance of drug approval applications by FDA and the European Medicines Agency ("EMA") in this first indication, plus an additional $100 million in combined milestones tied to receipt of commercialization regulatory approval by the FDA and the first commercial sale in the UK, Germany, France, Italy or Spain. These milestones, totaling $155 million, will be partially offset by Phase 3 costs owed to Daiichi Sankyo by the Company which the Company expects to total approximately $75 million to $85 million at the time of approval in the US or EU. The Agreement also provides that the Company will receive tiered double digit royalties on net sales of tivantinib throughout the territory. Given the anticipated commercial market for second line HCC, the Company expects to earn royalties on net sales for this indication at the baseline contractual rate of 20 percent.

We and Daiichi Sankyo will share equally the costs of Phase 2 and Phase 3 clinical studies, with our share of Phase 3 costs payable solely from milestone and royalty payments by Daiichi Sankyo.

The dosing of the first patient in the Phase 3 MARQUEE clinical trial of tivantinib in NSCLC, announced in January 2011, triggered the payment of a $25 million development milestone from Daiichi Sankyo that was received in February 2011. Revenue for this agreement is recognized using the contingency-adjusted performance model. Through September 30, 2012, revenue was recognized based upon an estimated development period through December 2013. As a result of the October 2012 decision to discontinue the MARQUEE trial, the development period as of October 1, 2012 was extended to June 2015. Commencing with the fourth quarter of 2012 and through the third quarter of 2013 revenue was recognized over that development period. In the fourth quarter of 2013, following a recommendation by the independent data monitoring committee that the METIV-HCC trial continue with patients receiving a lower dose of tivantinib than the dose originally employed in the trial, we reviewed the estimated development period and extended it to June 2016. On March 22, 2016, we and Daiichi Sankyo announced that the independent data monitoring committee ("DMC") of the METIV-HCC study conducted the planned interim assessment, and it was determined the trial will continue to its final analysis. Accordingly, we reviewed the estimated development period and extended it to December 2016.

Under the terms of our tivantinib collaboration agreement with Daiichi Sankyo we share development costs equally with our share of Phase 3 costs funded solely from milestones and royalties. In each quarter the tivantinib collaboration costs we incur are compared with those of Daiichi Sankyo. If our costs for the quarter exceed Daiichi

Sankyo's, we recognize revenue on the amounts due to us under the contingency adjusted performance model. Revenue is calculated on a pro-rata basis using the time elapsed from inception of the agreement over the estimated duration of the development period under the agreement. If our costs for the quarter are less than those of Daiichi Sankyo, we report the amount due to Daiichi Sankyo as contra-revenue in that quarter. To the extent that our share of Phase 3 collaboration costs exceeds the amount of milestones and royalties received, that excess is netted against future milestones and royalties if and when earned and is not reported as contra-revenue.

Our cumulative share of the Daiichi Sankyo Phase 3 costs through September 30, 2016 totaled $105.9 million. We received a milestone of $25 million in February 2011 upon enrolling the first patient in the MARQUEE trial, the cash proceeds of which were subsequently applied to our share of Phase 3 collaboration costs. On January 31, 2013, we announced that the first patient had been enrolled in the pivotal Phase 3 METIV trial of tivantinib, entitling us to a $15 million milestone. That $15 million milestone was also netted against our cumulative share of Phase 3 collaboration costs in 2013, and consequently we did not receive any cash proceeds from this milestone. Our cumulative share of Phase 3 collaboration costs has exceeded the amount of milestones received through September 30, 2016 by $65.9 million which will be netted against future milestones and royalties, if any, when earned and has not been reported as contra-revenue.

For the quarter ended and nine months September 30, 2016, our non-Phase 3 tivantinib collaboration costs incurred exceeded those of Daiichi Sankyo's and $73 thousand and $79 thousand, respectively, were recognized as research and development revenue.

For the quarter ended September 30, 2015 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo and $130 was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue. For the nine months ended September 30, 2015, our non-Phase 3 tivantinib collaboration costs incurred exceeded those of Daiichi Sankyo and $119 was recognized as tivantinib Daiichi Sankyo net research and development revenue.

On April 27, 2007, we entered into an exclusive license agreement with Kyowa Hakko Kirin to develop and commercialize tivantinib in Japan and parts of Asia. The agreement includes $123 million in upfront and potential development milestone payments from Kyowa Hakko Kirin to ArQule, including $30 million cash upfront licensing payments that we received in 2007. In addition to the upfront and possible development milestone payments totaling $123 million, the Company will be eligible for future milestone payments based on the achievement of certain levels of net sales. To date, we have received $48 million in upfront and milestones payments.

Through December 2015, revenue for this agreement was recognized using the contingency-adjusted performance model with an estimated development period through April 2016. As noted for the Daiichi Sankyo tivantinib program, the estimated development period for the METIV-HCC study was reviewed and extended to December 2016 in the first quarter of 2016. Similarly, the estimated development period for the Kyowa Hakko Kirin Phase 3 JET-HCC trial was reviewed and also extended to December 2016.

The Company will recognize the payments, if any, as revenue in accordance with its revenue recognition policies. As of September 30, 2016, the Company has not recognized any revenue from these potential sales milestone payments, and there can be no assurance that it will do so in the future.

Upon commercialization, ArQule will receive tiered royalties in the mid-teen to low-twenty percent range from Kyowa Hakko Kirin on net sales of tivantinib. Kyowa Hakko Kirin will be responsible for all clinical development costs and commercialization of the compound in certain Asian countries, consisting of Japan, China (including Hong Kong), South Korea and Taiwan.

LIQUIDITY AND CAPITAL RESOURCES

	September 30, 2016	December 31, 2015	Increase (decrease) $	Increase (decrease) %
	(in millions)			
Cash, cash equivalents and marketable securities-short term	$37.7	$ 38.8	$ (1.1)	(3)%
Working capital	29.6	28.7	0.9	3 %

	Nine Months Ended September 30, 2016	**September 30, 2015**	**Increase (decrease)**
	(in millions)		
Cash flow from:			
Operating activities	$(16.4)	$ (17.2)	$ 0.8
Investing activities	2.1	17.7	(15.6)
Financing activities	15.3	0.1	15.2

Cash flow from operating activities. Our uses of cash for operating activities have primarily consisted of salaries and wages for our employees, facility and facility-related costs for our offices and laboratories, fees paid in connection

with preclinical and clinical studies, laboratory supplies and materials, and professional fees. The sources of our cash flow from operating activities have consisted primarily of payments received from our collaborators for services performed or upfront payments for future services. For the nine months ended September 30, 2016 and 2015, our net use of cash was primarily driven by payments for operating expenses which resulted in net cash outflows of $16.4 million and $17.2 million, respectively.

Cash flow from investing activities. Our net cash provided by investing activities of $2.1 million for the nine months ended September 30, 2016, was comprised primarily of net sales of marketable securities. Our net cash provided by investing activities of $17.7 million for the nine months ended September 30, 2015, was comprised of net sales of marketable securities of $17.7 million, proceeds from sale of equipment of $0.3 million offset by additions to property and equipment of $0.3 million. The composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of the Company’s constant evaluation of conditions in financial markets, the maturity of specific investments, and our near term liquidity needs.

Cash flow from financing activities. Our net cash provided by financing activities of $15.3 million for the nine months ended September 30, 2016, was comprised of net proceeds from our February 26, 2016 stock offering of $15.2 million and $0.1 million from stock option exercises and employee stock plan purchases. Our net cash provided by financing activities for the nine months ended September 30, 2015 of $ 0.1 million were from employee stock plan purchases.

Our cash equivalents and marketable securities typically include U.S. Treasury bill funds, money market funds, commercial paper, and U.S. federal and state agency backed certificates that have investment grade ratings. Our cash equivalents and our portfolio of marketable securities are subject to market risk due to changes in interest rates. Fixed rate interest securities may have their market value adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in market value due to changes in interest rates.

Our cash requirements may vary materially from those now planned depending upon the results of our drug discovery and development strategies, our ability to enter into additional corporate collaborations and the terms of such collaborations, results of research and development, unanticipated required capital expenditures, competitive and technological advances, acquisitions and other factors. We cannot guarantee that we will be able to develop any of our drug candidates into a commercial product. It is likely we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our ability to raise additional funds will depend on financial, economic and market conditions, and due to global capital and credit market conditions or for other reasons, we may be unable to raise capital when needed, or on terms favorable to us. If necessary funds are not available, we may have to delay, reduce the scope of, or eliminate some of our development programs, potentially delaying the time to market for any of our product candidates.

On February 26, 2016 the Company entered into definitive stock purchase agreements with certain institutional and accredited investors. In conjunction with this stock offering we issued 8,027,900 shares of our common stock and non-transferable options for 3,567,956 shares of our common stock for aggregate net proceeds of $15.2 million. Each option is exercisable for $2.50 per share and expires on March 22, 2017. If all options were to be exercised it would result in additional proceeds of approximately $8.9 million.

In light of the $15.2 million we received from the February 26, 2016 stock purchase agreements, we anticipate that our cash, cash equivalents and marketable securities on hand at September 30, 2016, and financial support from our collaboration agreements will be sufficient to finance our working capital and capital requirements into 2018.

Our contractual obligations were comprised of the following as of September 30, 2016 (in thousands):

	Payment due by period				
Contractual Obligations	**Total**	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating lease obligations	$1,938	541	$ 1,397	$ —	$ —
Purchase obligations	4,890	4,890	—	—	—
Total	$6,828	$ 5,431	$ 1,397	$ —	$ —

In January 2015, we entered into a lease agreement for a new headquarters facility. The lease commenced on May 1, 2015 for a term of five years and three months with an average annual rental rate of $455 thousand. The obligations for this new facility are included in the table above.

Purchase obligations are comprised primarily of outsourced preclinical and clinical trial expenses and payments to license certain intellectual property to support the Company’s research efforts. Under our tivantinib collaboration with Daiichi Sankyo, our share of Phase 3 costs are payable solely from future milestones and royalties. As of September 30, 2016 our portion of these costs was $65.9 million and is excluded from the table above. These costs are netted against any future milestones and royalties due to us. Daiichi Sankyo has the right to offset future milestone and royalty payments by this amount.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

A “critical accounting policy” is one which is both important to the portrayal of the Company’s financial condition and results and requires management’s most difficult, subjective or complex judgments, often as a result of the need to

make estimates about the effect of matters that are inherently uncertain. For additional information, please see the discussion of our significant accounting policies in Note 2 to the Financial Statements included in our Annual Report for the fiscal year ended December 31, 2015 on Form 10-K filed with the SEC on February 29, 2016.

RESULTS OF OPERATIONS

The following are the results of operations for the three and nine months ended September 30, 2016 and 2015:

Revenue

			Increase (decrease)	
	2016	2015	$	%
	(in millions)			
For the three months ended September 30:				
Research and development revenue	$ 1.2	$ 2.7	$ (1.5)	(54)%
For the nine months ended September 30:				
Research and development revenue	$ 3.5	$ 8.4	$ (4.9)	(58)%

Research and development revenue in the three and nine months ended September 30, 2016 and 2015 is comprised of revenue from the Daiichi Sankyo tivantinib development agreement and the Kyowa Hakko Kirin exclusive license agreement. The revenue decreases in the three months ended September 30, 2016 of $0.5 million from our Daiichi Sankyo METIV-HCC trial and $1.0 million from our Kyowa Hakko Kirin JET-HCC trial were principally due to the March 2016 extension of the development period through December 31, 2016 for both programs. The revenue decreases in the nine months ended September 30, 2016 of $2.0 million from our Daiichi Sankyo METIV-HCC trial and $2.9 million from our Kyowa Hakko Kirin JET-HCC trial were also principally due to the extension of the development period through December 31, 2016.

Under the terms of our tivantinib collaboration agreement with Daiichi Sankyo we share development costs equally with our share of Phase 3 costs funded solely from milestones and royalties. In each quarter the tivantinib collaboration costs that we incur are compared with those of Daiichi Sankyo. If our costs for the quarter exceed Daiichi Sankyo's, we recognize revenue on the amounts due to us under the contingency adjusted performance model. Revenue is calculated on a pro-rata basis using the time elapsed from inception of the agreement over the estimated duration of the development period under the agreement. If our costs for the quarter are less than those of Daiichi Sankyo, we report the amount due to Daiichi Sankyo as contra-revenue in that quarter. To the extent that our share of Phase 3 collaboration costs exceeds the amount of milestones and royalties received, that excess is netted against future milestones and royalties if and when earned and is not reported as contra-revenue.

Revenue for this agreement is recognized using the contingency-adjusted performance model. Through September 30, 2012, revenue was recognized based upon an estimated development period through December 2013. As a result of the October 2012 decision to discontinue the MARQUEE trial, the development period as of October 1, 2012 was extended to June 2015. Commencing with the fourth quarter of 2012 and through the third quarter of 2013 revenue was recognized over that development period. In the fourth quarter of 2013, following a recommendation by the DMC that the METIV-HCC trial continue with patients receiving a lower dose of tivantinib than the dose originally employed in the trial, we reviewed the estimated development period and extended it to June 2016. On March 22, 2016, we and Daiichi Sankyo announced that the DMC of the METIV-HCC study conducted the planned interim assessment, and it was determined the trial will continue to its final analysis. Accordingly, we reviewed the estimated development period and extended it to December 2016.

Our cumulative share of the Daiichi Sankyo Phase 3 costs through September 30, 2016 totaled $105.9 million. We received a milestone of $25 million in February 2011 upon enrolling the first patient in the MARQUEE trial, the cash proceeds of which were subsequently applied to our share of Phase 3 collaboration costs. On January 31, 2013, we announced that the first patient had been enrolled in the pivotal Phase 3 METIV trial of tivantinib, entitling us to a $15 million milestone. That $15 million milestone was also netted against our cumulative share of Phase 3 collaboration costs in 2013, and consequently we did not receive any cash proceeds from this milestone. Our cumulative share of Phase 3 collaboration costs has exceeded the amount of milestones received through September 30, 2016 by $65.9 million which will be netted against future milestones and royalties, if any, when earned and has not been reported as contra-revenue.

For the quarter and nine months ended September 30, 2016, our non-Phase 3 tivantinib collaboration costs incurred exceeded those of Daiichi Sankyo's and $73 thousand and $79 thousand, respectively, were recognized as research and development revenue.

For the quarter ended September 30, 2015 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo and $130 thousand was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue. For the nine months ended September 30, 2015, our non-Phase 3 tivantinib collaboration costs incurred exceeded those of Daiichi Sankyo and $119 thousand was recognized as

tivantinib Daiichi Sankyo net research and development revenue.

Research and development

			Increase (decrease)	
	2016	2015	$	%
	(in millions)			
For the three months ended September 30:				
Research and development	$5.3	$3.2	$ 2.1	66 %
For the nine months ended September 30:				
Research and development	$13.8	$11.9	$ 1.9	16 %

Research and development expense in the three months ended September 30, 2016 increased by $2.1 million principally due to increased outsourced clinical and product development costs of $1.9 million and professional fees of $0.2 million.

Research and development expense in the nine months ended September 30, 2016 increased by $1.9 million principally due to increased outsourced clinical and product development costs of $2.6 million and professional fees of $0.2 million. These cost increases were partially offset by decreased labor and related costs of $0.4 million and facility costs of $0.5 million.

At September 30, 2016 and 2015 we had 21 employees dedicated to our research and development program.

Overview

Our research and development expense consists primarily of salaries and related expenses for personnel, costs of contract manufacturing services, costs of facilities and equipment, fees paid to professional service providers in conjunction with our clinical trials, fees paid to research organizations in conjunction with pre-clinical animal studies, costs of materials used in research and development, consulting, license, and sponsored research fees paid to third parties and depreciation of associated laboratory equipment. We expect that our research and development expense will remain significant as we continue to develop our portfolio of oncology programs.

We have not accumulated and tracked our internal historical research and development costs or our personnel and personnel-related costs on a program-by-program basis. Our employee and infrastructure resources are allocated across several projects, and many of our costs are directed to broadly applicable research endeavors. As a result, we cannot state the costs incurred for each of our oncology programs on a program-by-program basis.

The expenses incurred by us to third parties for pre-clinical and clinical trials in the current year and since inception of our lead clinical stage program were as follows (in millions):

Oncology program	Current status	Nine Months Ended September 30, 2016	Program-to-date
c-Met program—tivantinib	Phase 3	$ 0.1	$ 84.7

Under the terms of our tivantinib collaboration agreement with Daiichi Sankyo we share development costs equally with our share of Phase 3 costs funded solely from milestones and royalties. Our cumulative share of Phase 3 collaboration costs has exceeded the amount of milestones received through September 30, 2016 by $65.9 million and is not reflected in the above table.

Our future research and development expenses in support of our current and future oncology programs will be subject to numerous uncertainties in timing and cost to completion. We test potential products in numerous pre-clinical studies for safety, toxicology, and efficacy. We may conduct multiple clinical trials for each product. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain products in order to focus our resources on more promising products. Completion of clinical trials may take several years or more, and the length of time generally varies substantially according to the type, complexity, novelty, and intended use of a product. It is not unusual for the pre-clinical and clinical development of each of these types of products to take nine years or more, and for total development costs to exceed $500 million for each product.

We estimate that clinical trials of the type generally needed to secure new drug approval are typically completed over the following timelines:

Clinical Phase	**Estimated Completion Period**
Phase 1	1 – 2 years
Phase 2	2 – 3 years
Phase 3	2 – 4 years

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others, the following:

the number of clinical sites included in the trials;

the length of time required to enroll suitable patients;

the number of patients that ultimately participate in the trials;

the duration of patient follow-up to ensure the absence of long-term product-related adverse events; and

the efficacy and safety profile of the product.

An element of our business strategy is to pursue the research and development of a broad pipeline of products. This is intended to allow us to diversify the risks associated with our research and development expenditures. As a result, we believe our future capital requirements and future financial success do not substantially depend on any one product. To the extent we are unable to build and maintain a broad pipeline of products, our dependence on the success of one or a few products increases.

Our strategy includes entering into alliance arrangements with third parties to participate in the development and commercialization of our products, such as our collaboration agreements with Daiichi Sankyo and Kyowa Hakko Kirin. In the event that third parties have control over the clinical trial process for a product, the estimated completion date would be under control of that third party rather than under our control. We cannot forecast with any degree of certainty whether our products will be subject to future collaborative arrangements or how such arrangements would affect our development plans or capital requirements.

As a result of the uncertainties discussed above, we make significant estimates in determining the duration and completion costs of our oncology programs or when and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our oncology programs in a timely manner or our failure to enter into appropriate collaborative agreements could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time-to-time in order to continue with our product development strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

General and administrative

			Increase (decrease)	
	2016	2015	$	%
	(in millions)			
For the three months ended September 30:				
General and administrative	$1.8	$1.8	$ —	—
For the nine months ended September 30:				
General and administrative	$5.8	$7.8	$ (2.0)	(26)%

General and administrative expense of $1.8 million in the quarter ended September 30, 2016 was essentially unchanged from September 30, 2015.

General and administrative expense decreased in the nine months ended September 30, 2016 principally due to lower facility costs of $1.6 million, labor related costs of $0.2 million and professional fees of $0.2 million.

General and administrative headcount was 14 at September 30, 2016, compared to 15 at September 30, 2015.

Interest income and other income (expense)

			Increase (decrease)	
	2016	2015	$	%
	(in thousands)			
For the three months ended September 30:				
Interest income	$49	$17	$ 32	188 %
Other income (expense)	—	(5)	(5)	(100)%
For the nine months ended September 30:				
Interest income	$135	$81	$ 54	67 %
Other income (expense)	—	277	(277)	(100)%

Interest income is derived from our portfolio of cash, cash equivalents and investments and increased in the three and nine month periods ended September 30, 2016 primarily due to an increase in our portfolio balance resulting from our $15.2 million stock offering on February 26, 2016. Other income (expense) in the three and nine month periods ended September 30, 2015 includes a loss of $5 thousand and a gain of $277 thousand, respectively, from the sale of property and equipment.

RECENT ACCOUNTING PRONOUNCEMENTS

For a discussion of new accounting pronouncements please read Note 8, *Recent Accounting Pronouncements* to our financial statements included in this report.

FORWARD LOOKING STATEMENTS

In addition to historical information, this report contains forward-looking statements. You can identify these forward-looking statements by their use of words such as “anticipate,” “assume,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “project,” “target,” “will” and other words and terms of similar meaning. You also can identify them b the fact that they do not relate strictly to historical or current facts. All statements which address operating performance, events or developments that the Company expects or anticipates will occur in the future, such as projections about its future results of operations, its financial condition, research, development and commercialization of its products and anticipated trends in its business are forward-looking statements.

In this report we make forward-looking statements regarding our drug development pipeline and our clinical trials involving tivantinib. Additional forward-looking statements relate to our agreements with Kyowa Hakko Kirin and Daiichi Sankyo, including potential future milestones and royalty payments that could result from the future development of tivantinib.

Drug development involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. For example, pre-clinical efforts associated with our product pipeline may fail or prove disappointing because our technology platform did not produce candidates with the desired characteristics. Animal xenograft pre-clinical studies may be unpredictive of human response. Positive information about early stage clinical trial results will not ensure that later stage or larger scale clinical trials will be successful.

Furthermore, our drugs may not demonstrate promising therapeutic effects; in addition, they may not demonstrate appropriate safety profiles in ongoing or later stage or larger scale clinical trials as a result of known or as yet unidentified side effects. The results achieved in later stage trials may not be sufficient to meet applicable regulatory standards. Problems or delays may arise during clinical trials or in the course of developing, testing or manufacturing our drugs that could lead us or our partner to discontinue development.

Even if later stage clinical trials are successful, the risk exists that unexpected concerns may arise from analysis of data or from additional data or that obstacles may arise or issues be identified in connection with review of clinical data with regulatory authorities or that regulatory authorities may disagree with the Company's view of the data or require additional data or information or additional studies. Also, the planned timing of initiation of clinical trials and the duration and conclusion of such trials for our drugs are subject to the ability of the company to enroll patients, enter into agreements with clinical trial sites and investigators, and other technical hurdles and issues that may not be resolved.

We also make forward-looking statements regarding the adequacy of our financial resources. Our capital resources may not be adequate because our cash requirements may vary materially from those now planned depending upon the results of our drug discovery and development strategies, the outcomes of our clinical trials, our ability to enter into additional corporate collaborations in the future and the terms of such collaborations, results of research and development, the need for currently unanticipated capital expenditures, competitive and technological advances, acquisitions, financial market conditions and other factors. Additionally, our corporate collaborators may terminate their agreements with us, thereby eliminating that source of funding, because we may fail to satisfy the prescribed terms of the collaborations or for other reasons.

We cannot guarantee that we will be able to develop any of our drug candidates into a commercial product generating revenues. If we experience increased losses, we may have to seek additional financing from public and private sales of our securities, including equity securities. There can be no assurance that additional funding will be available when needed or on acceptable terms.

The factors, risks and uncertainties referred to above and others are more fully described under the heading "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 filed with the SEC on February 29, 2016, as updated from time to time in our subsequent Quarterly Reports on Form 10-Q and Current

Reports on Form 8-K. The forward-looking statements contained herein represent the judgment of the Company as of the date of this report. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We own financial instruments that are sensitive to market risk as part of our investment portfolio. We have implemented policies regarding the amount and credit ratings of investments. Our investment portfolio is used to preserve our capital until it is used to fund operations, including our research and development activities. Our investments are evaluated quarterly to determine the fair value of the portfolio.

Our cash equivalents and marketable securities typically include commercial paper, money market funds, and U.S. Treasury bill funds that have investment grade ratings.

Our cash equivalents and our portfolio of marketable securities are subject to market risk due to changes in interest rates. Fixed rate interest securities may have their market value adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in market value due to changes in interest rates. Based on the type of securities we hold, we do not believe a change in interest rates would have a material impact on our financial statements. If interest rates were to increase or decrease by 1%, this would not result in a material change in the fair value of our investment portfolio.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer (Principal Executive Officer) and President and Chief Operating Officer (Principal Financial Officer), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2016, our Chief Executive Officer (Principal Executive Officer) and President and Chief Operating Officer (Principal Financial Officer) concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

There have been no changes in the Company's internal control over financial reporting during the most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. — LEGAL PROCEEDINGS. None.

ITEM 1A. — RISK FACTORS. For information regarding factors that could affect the Company's results of operations, financial condition and liquidity, see the risk factors discussion provided under "Risk Factors" in Item 1A of ArQule's Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC on February 29, 2016, as updated from time to time in our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. See also, "Forward-Looking Statements" included in this Quarterly Report on Form 10-Q.

ITEM 2. — UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS. None.

ITEM 3. — DEFAULTS UPON SENIOR SECURITIES. None.

ITEM 4. — MINE SAFETY DISCLOSURES. Not applicable.

ITEM 5. — OTHERS INFORMATION. None.

ITEM 6. — EXHIBITS.

EXHIBIT NO.	DESCRIPTION
31.1	Rule 13a-14(a) Certificate of Chief Executive Officer, filed herewith.
31.2	Rule 13a-14(a) Certificate of Principal Financial Officer, filed herewith.
32	Rule 13a-14(b) Certificate of Chief Executive Officer and Principal Financial Officer, filed herewith.
101	Interactive Data File

ARQULE, INC.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ArQule, Inc.

Date: November 7, 2016 /s/ PETER S. LAWRENCE
Peter S. Lawrence
President and Chief Operating Officer
(Principal Financial Officer)

/s/ ROBERT J. WEISKOPF
Robert J. Weiskopf
Chief Financial Officer and Treasurer
(Principal Accounting Officer)