ARQULE INC
Form 10-Q
November 04, 2015

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, 2015

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 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 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
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

Number of shares outstanding of the registrant’s Common Stock as of October 22, 2015:

Common Stock, par value $.01	62,891,548 shares outstanding

ARQULE, INC.

QUARTER ENDED SEPTEMBER 30, 2015

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ARQULE, INC.

CONDENSED BALANCE SHEETS (Unaudited)

	September 30, 2015	December 31, 2014
	(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)	
ASSETS		
Current assets:		
Cash and cash equivalents	$13,130	$12,525
Marketable securities-short term	30,629	46,683
Prepaid expenses and other current assets	193	1,893
Total current assets	43,952	61,101
Marketable securities-long term	—	2,058
Property and equipment, net	298	133
Other assets	251	102
Total assets	$44,501	$63,394
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$5,691	$6,947
Current portion of deferred revenue	7,373	11,098
Deferred gain on sale leaseback	—	232
Total current liabilities	13,064	18,277
Deferred revenue, net of current portion	—	4,572
Total liabilities	13,064	22,849
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; 62,891,548 and 62,821,781 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	629	628
Additional paid-in capital	510,072	508,270
Accumulated other comprehensive income (loss)	1	(10)
Accumulated deficit	(479,265)	(468,343)
Total stockholders' equity	31,437	40,545
Total liabilities and stockholders' equity	$44,501	$63,394

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,	
	2015	2014	2015	2014
	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
Research and development revenue	$2,653	$2,662	$8,442	$8,239
Costs and expenses:				
Research and development	3,180	5,014	11,920	17,981
General and administrative	1,839	2,997	7,802	9,318
Restructuring and other costs	—	1,099	—	1,099
Total costs and expenses	5,019	9,110	19,722	28,398
Loss from operations	(2,366)	(6,448)	(11,280)	(20,159)
Interest income	17	62	81	233
Interest expense	—	(11)	—	(28)
Other income (expense)	(5)	(2)	277	75
Net loss	(2,354)	(6,399)	(10,922)	(19,879)
Unrealized gain (loss) on marketable securities	8	(21)	11	(42)
Comprehensive loss	$(2,346)	$(6,420)	$(10,911)	$(19,921)
Basic and diluted net loss per share:				
Net loss per share	$(0.04)	$(0.10)	$(0.17)	$(0.32)
Weighted average basic and diluted common shares outstanding	62,827	62,652	62,753	62,621

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,	
	2015	2014
	(IN THOUSANDS)	
Cash flows from operating activities:		
Net loss	$(10,922)	$(19,879)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	129	532
Amortization of premium on marketable securities	406	893
Amortization of deferred gain on sale leaseback	(232)	(416)
Non-cash stock compensation	1,741	2,643
Gain on auction rate securities	—	(75)
Impairment of property and equipment	—	280
Gain on sale of property and equipment	(277)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,551	558
Accounts payable and accrued expenses	(1,256)	(1,275)
Deferred revenue	(8,297)	(8,228)
Net cash used in operating activities	(17,157)	(24,967)
Cash flows from investing activities:		
Purchases of marketable securities	(24,203)	(27,504)
Proceeds from sale or maturity of marketable securities	41,920	52,934
Additions to property and equipment	(315)	—
Proceeds from sale of property and equipment	298	—
Net cash provided by investing activities	17,700	25,430
Cash flows from financing activities:		
Proceeds from employee stock plan purchases	62	57
Net cash provided by financing activities	62	57
Net increase in cash and cash equivalents	605	520
Cash and cash equivalents, beginning of period	12,525	15,579
Cash and cash equivalents, end of period	$13,130	$16,099

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 clinical-stage biotechnology company organized as a Delaware corporation in 1993 engaged in the research and development of innovative therapeutics to treat cancers and rare diseases. Our mission is to produce novel drugs with differentiated mechanisms of action that will 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 prioritized clinical stage pipeline consists of four product candidates, all of which are in targeted, biomarker-defined populations. Our drug discovery efforts focus on a number of pre-clinical programs based on our insights into kinase biology and are derived from our extensive library of proprietary compounds.

Our lead product candidate is tivantinib (ARQ 197), an orally administered, small molecule inhibitor of the c-Met receptor tyrosine kinase ("c-MET") and its biological pathway. C-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 later-stage trials in additional indications.

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. During 2011, we received $25 million from Daiichi Sankyo resulting from the dosing of the first patient in the MARQUEE trial and $10 million from Kyowa Hakko Kirin resulting from dosing of the first patient in the ATTENTION trial. 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 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.

We regained worldwide rights for the development and commercialization of ARQ 092, designed to inhibit the AKT serine/threonine kinase, and all other compounds included under our AKT collaboration with Daiichi Sankyo pursuant to their formal notice to terminate our license and co-commercialization agreement received on March 26, 2013. Following the termination, we became responsible for funding the remainder of the Phase 1 trial with ARQ 092 beyond the contractual termination period, as well as any future clinical development and commercialization of this compound. The license agreement had provided exclusive rights to Daiichi Sankyo for the development, manufacturing and marketing of ARQ 092 on a worldwide basis. Under this agreement, we received a $10 million upfront fee from Daiichi Sankyo in November 2011. Following the termination of this agreement, ARQ 092 became our proprietary asset, and Daiichi Sankyo has no further financial or other obligations or rights related to this program. ARQ 092 is part of our proprietary pipeline of product candidates directed toward molecular targets and biological processes with demonstrated roles in the development of human cancers and rare diseases. Our priorities within this pipeline include ARQ 092, ARQ 087, a multi-kinase inhibitor designed to preferentially inhibit the fibroblast growth factor receptor (“FGFR”) family, and ARQ 761, a Beta lapachone analog being investigated in investigator-sponsored testing as a promoter of NQ01-mediated cancer cell necrosis.

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 month periods ended September 30, 2015 and 2014, our net use of cash was primarily driven by payments for operating expenses which resulted in net cash outflows of $17.2 million and $25.0 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, 2014 included in our annual report on Form 10-K filed with the SEC on March 4, 2015.

The unaudited condensed financial statements include, in our opinion, all adjustments (consisting only of normal recurring adjustments) necessary for a fair statement of our financial position as of September 30, 2015, and the results of our operations and cash flows for the nine months ended September 30, 2015 and September 30, 2014. The results of operations for such interim periods are not necessarily indicative of the results to be achieved for the full year.

2. COLLABORATIONS AND ALLIANCES

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 will jointly focus on the identification and preclinical development of inhibitors of PD-1 and PDL-1. We and Beryllium will each be responsible for our respective internal and outsourcing costs during pre-clinical development. Following lead optimization of any potential drug candidates, we and Beryllium will jointly decide whether to advance compounds into GLP/toxicology and clinical testing, initially on a shared cost basis, provided that we will have the right to advance compounds on our own should Beryllium vote against such advancement. The agreement also provides that we will be responsible for clinical development and commercialization of product candidates that are not out-licensed. Beryllium will have the right to participate financially throughout the program but will also have the option to opt out at certain times and receive a royalty. The agreement will terminate after the last payment obligation is satisfied, or prior to that upon 60-days' notice by either party.

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. Upon commercialization, we will receive tiered, double-digit royalties from Daiichi Sankyo on net sales of tivantinib commensurate with the magnitude of the transaction. We retain the option to participate in the commercialization of tivantinib in the U.S. 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.

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, 2015 totaled $99 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, 2015 by $59 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 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.

For the quarter ended September 30, 2014 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo and $102 was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue. For the nine months ended September 30, 2014, no research and development revenue was recognized related to our non-Phase 3 tivantinib collaboration as our costs incurred were offset by an equal amount of contra-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 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. For the three months and nine months ended September 30, 2015, $1.2 million and $4.2 million, respectively, were recognized as net revenue. For the three months and nine months ended September 30, 2014, $1.2 million and $4.0 million, respectively, were recognized as net revenue. At September 30, 2015, $4.1 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 with an estimated development period through April 2016.

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. The Company will recognize the payments, if any, as revenue in accordance with the contingency-adjusted performance model. As of September 30, 2015, 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.

Revenue for this agreement is recognized using the contingency-adjusted performance model with an estimated development period through April 2016. For both the three and nine months ended September 30, 2015 and 2014, $1.4 million and $4.3 million, respectively were recognized as revenue. At September 30, 2015, $3.3 million remains in deferred revenue.

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, 2015 and December 31, 2014:

September 30, 2015	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Security type				
Corporate debt securities-short term	$30,628	$6	$(5)	$30,629
Corporate debt securities-long term	—	—	—	—
Total available-for-sale marketable securities	$30,628	$6	$(5)	$30,629

December 31, 2014	**Amortized Cost**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Fair Value**
Security type				
Corporate debt securities-short term	$46,690	$16	$(23)	$46,683
Corporate debt securities-long term	2,061	—	(3)	2,058
Total available-for-sale marketable securities	$48,751	$16	$(26)	$48,741

The fair value of our available-for-sale marketable securities in a continuous unrealized loss position for more than 12 months was $1,126 at September 30, 2015. The unrealized loss on these marketable securities was under $1 at September 30, 2015. None of our available-for-sale marketable securities were in a continuous unrealized loss position for more than 12 months at December 31, 2014.

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, 2015	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 11,935	$ 11,935	$ —	$ —
Corporate debt securities-short term	30,629	—	30,629	—
Corporate debt securities-long term	—	—	—	—
Total	$ 42,564	$ 11,935	$ 30,629	$ —

	December 31, 2014	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 10,740	$ 10,740	$ —	$ —
Corporate debt securities-short term	46,683	—	46,683	—
Corporate debt securities-long term	2,058	—	2,058	—
Total	$ 59,481	$ 10,740	$ 48,741	$ —

4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses include the following at September 30, 2015 and December 31, 2014:

	2015	2014
Accounts payable	$346	$259
Accrued payroll	1,537	2,130
Accrued outsourced pre-clinical and clinical fees	3,173	3,753
Accrued professional fees	355	157

Other accrued expenses	280	648
	$5,691	$6,947

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, the shares that would be issued upon the exercise of outstanding stock options, were 8,342,725 and 7,999,284 for the three and nine months ended September 30, 2015 and 2014, respectively.

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, 2015 and 2014.

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,	
	2015	2014	2015	2014
Research and development	$142	$186	$538	$854
General and administrative	359	494	1,203	1,706
Restructuring	—	83	—	83
Total stock-based compensation expense	$501	$763	$1,741	$2,643

In the three and nine months ended September 30, 2015 and 2014, 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, 2015 was as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2014	7,724,614	$ 4.89
Granted	1,513,850	1.25
Cancelled	(895,739)	4.79
Outstanding as of September 30, 2015	8,342,725	$ 4.24
Exercisable as of September 30, 2015	5,793,400	$ 5.12

The aggregate intrinsic value of options outstanding at September 30, 2015 was $908, and $51 related to exercisable options. The weighted average grant date fair value of options granted in the nine months ended September 30, 2015 and 2014 was $0.77 and $1.65 per share, respectively. No options were exercised in the nine months ended September 30, 2015 or 2014.

Shares vested, expected to vest and exercisable at September 30, 2015 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, 2015	8,156,021	$ 4.24	5.44	$ 843
Exercisable at September 30, 2015	5,793,400	$ 5.12	4.04	$ 51

The total compensation cost not yet recognized as of September 30, 2015 related to non-vested option awards was $3.1 million, which will be recognized over a weighted-average period of 2.5 years. During the nine months ended September 30, 2015, 689,759 shares expired and 205,980 shares were forfeited. The weighted average remaining contractual life for options exercisable at September 30, 2015 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, 2015, 82,564 shares have been forfeited, and 101,498 shares have vested. We recognized share-based compensation expense related to restricted stock of $59 and $77 for the nine months ended September 30, 2015 and 2014, respectively.

Restricted stock activity under the Plan for the nine months ended September 30, 2015 was as follows:

Restricted Stock	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2014	105,665	$ 2.51
Vested	(36,101)	2.51
Cancelled	(10,929)	2.51
Unvested as of September 30, 2015	58,635	$ 2.51

The fair value of restricted stock vested in the nine months ended September 30, 2015 and 2014 was $68 and $55 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, 2015, no expense has been recorded for any performance-based stock units granted to the CEO, COO, or CMO.

7. 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 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 beginning 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 are currently evaluating the potential impact that this ASU may have on our financial position and 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.

8. INCOME TAXES

As of December 31, 2014, we had federal NOL, state NOL, and research and development credit carryforwards of approximately $331,909, $152,434 and $27,761, respectively, which expire at various dates through 2034, which can be used to offset future income tax liabilities. Federal capital loss carry forwards of approximately $571 can be used to offset future federal capital gain income and expire in 2015. Approximately $15,014 of our federal NOL and $863 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. We have determined that it is more likely than not that we will not recognize the benefits of our federal and state deferred tax assets and, as a result, we have a full valuation allowance against our net deferred tax assets.

At September 30, 2015 and December 31, 2014, 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 September 30, 2015 and December 31, 2014, we had no accrued interest or penalties related to uncertain tax positions. Our U.S. federal tax returns for the tax years 2011 through 2014 and our state tax returns for the tax years 2010 through 2014 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, 2015, 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.

9. RESTRUCTURING AND OTHER COSTS

On July 30, 2014, we approved plans to restructure our operations to better align our human and financial resources with our primary focus on clinical stage development programs and to extend our cash runway beyond the anticipated time for achievement of key milestones, such as the completion of the METIV-HCC trial. Commencing on August 4,

2014, we began to reduce our current workforce from 62 to approximately 40 employees by the end of 2014. Most of this reduction came from our Discovery Group, which had been engaged primarily in early-stage, pre-clinical research. The costs associated with this action were comprised of severance payments of $662 and benefits continuation costs of $74. In the year ended December 31, 2014, $319 of these costs was paid and the remaining amount of $417 was paid by March 31, 2015. In addition, in the three months ended September 30, 2014, we incurred non-cash charges of $83 related to the modification of employee stock options, and $280 for impairment of property and equipment impacted by the restructuring.

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

The following discussion should be read in conjunction with our financial statements and related notes contained in this report.

We are a clinical-stage biotechnology company engaged in the research and development of innovative therapeutics to treat cancers and rare diseases. Our mission is to produce novel drugs with differentiated mechanisms of action that will 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 prioritized clinical stage pipeline consists of four product candidates, all of which are in targeted, biomarker-defined populations. Our drug discovery efforts focus on a number of pre-clinical programs based on our insights into kinase biology and are derived from our extensive library of proprietary compounds.

Our product candidates and programs are based on our understanding of biological processes that lead to the proliferation and metastasis of cancer cells, combined with our ability to generate product candidates possessing certain pre-selected, drug-like properties. We believe that these qualities, when present from the earliest stages of product development, increase the likelihood of producing safe, effective and marketable drugs. Our discovery and development efforts are also 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 lead product candidate is tivantinib (ARQ 197), an orally administered, small molecule inhibitor of the c-Met receptor tyrosine kinase ("c-MET" or "MET") and its biological pathway. C-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.

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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. A dose reduction in the METIV-HCC trial from 240 mg twice daily ("BID") tablets to 120 mg BID tablets was implemented in September 2013 following the observation of a higher incidence of neutropenia in the initial phase of the METIV-HCC trial than was observed in the Phase 2 trial in the same patient population, which employed a 240 mg BID capsule dose, and in other trials with tivantinib. Certain enhanced patient monitoring procedures were temporarily instituted to confirm the safety profile of the lower dose. Following a review of data analyses from a predefined number of patients who received this lower dose, the Data Monitoring Committee ("DMC") of the METIV-HCC trial recommended in January 2014 continuation of the ongoing trial, with patients receiving the lower dose. Pharmacokinetic analyses among a predefined number of patients treated with the 120 mg BID tablet dose showed that the incidence of neutropenia was reduced with this lower dose and that the plasma exposure of the lower dose was comparable to the 240 mg BID capsule dose in the Phase 2 trial with similar medians and overlapping ranges.

Approximately 300 patients are being enrolled in the METIV-HCC trial at more than 100 clinical sites worldwide. Our current estimate of the time frame for completion of patient accrual is the end of 2015. We define patient accrual as the process of screening and identifying patients for subsequent randomization into the treatment arms of the trial. This trial is being conducted under a Special Protocol Assessment ("SPA") agreement with the U.S. Food and Drug Administration ("FDA"). An SPA is an agreement establishing the design, endpoints and statistical analysis of a clinical trial intended to provide the necessary data, depending on the outcome of the trial, which could support the filing of a New Drug Application ("NDA"). Final marketing approval depends on the results of the trial. Because the METIV-HCC trial is enrolling patients with MET-diagnostic high HCC whom we believe are likely to benefit from treatment with tivantinib, the SPA also includes an immunohistochemistry ("IHC")-based companion diagnostic ("CDx") under development by a third party provider of such tests in collaboration with Daiichi Sankyo and ourselves. The CDx is being developed to enable the identification of the MET status of patients seeking to be enrolled in this trial. Our collaborator for the companion diagnostic test and our collaborator for a second test will each need to submit a Premarket Approval ("PMA") application to FDA that establishes the predictive value of the respective CDx in connection with the registration and commercialization of tivantinib in the U.S., and additional regulatory applications will need to be made in other geographic areas.

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, our partner for the development of tivantinib in Asian territories, announced the initiation of this trial in Japanese patients with MET diagnostic-high, inoperable HCC treated with one prior therapy 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. Kyowa Hakko Kirin is also developing a CDx for the JET-HCC trial to enable the identification of the MET status of patients to be enrolled in this trial. There are no milestone payments associated with the initiation of this trial.

Two Phase 3 clinical trials have been conducted evaluating the combination of tivantinib and erlotinib in second-line patients with advanced or metastatic non-squamous non-small cell lung cancer ("NSCLC"). We and our partner, Daiichi Sankyo, conducted the first of these, named MARQUEE, in Western territories. MARQUEE was a randomized, double-blind, controlled pivotal Phase 3 trial conducted under an SPA. At the time of the interim analysis of MARQUEE, the independent DMC recommended that the study be discontinued early after concluding that it would not meet its primary endpoint of improved OS, although the interim analysis showed a statistically significant improvement in PFS in the ITT population. Final data from the trial demonstrated particular clinical benefits in a sub-group of patients with non-squamous NSCLC whose tumors expressed high levels of MET protein. No safety concerns were identified by the DMC at the interim analysis, and this did not change in the final data analysis. We are awaiting the results of the MARQUEE trial with respect to a sub-population of approximately 100 patients with EGFR mutant NSCLC. OS and PFS in these patients have been designated as secondary efficacy endpoints in the trial.

The second Phase 3 trial in NSCLC, named ATTENTION, was a randomized, double-blind, controlled pivotal trial conducted in non-squamous NSCLC patients with wild-type epidermal growth factor receptor ("EGFR") in Asia by Kyowa Hakko Kirin, our partner for the development of tivantinib in Asian territories. Recruitment of new patients in ATTENTION was permanently suspended before the target patient recruitment goal was completed based on a recommendation by the trial's Safety Review Committee following an observed imbalance in interstitial lung disease ("ILD") cases as a drug-related adverse event. Patients already recruited were allowed to continue in the trial after being re-consented. The safety profile observed in ATTENTION was in line with what was previously observed in other NSCLC trials with tivantinib, with the exception of ILD, which is a known adverse event observed in Japanese patients treated with EGFR inhibitors such as erlotinib. In the ITT population, OS favored the treatment arm of tivantinib plus erlotinib compared to the erlotinib only control arm, but it was not statistically significant. PFS and overall response rate ("ORR") results also showed a trend toward improvement favoring the treatment arm.

On January 11, 2013, we announced the top-line results of a randomized Phase 2 signal generation trial of tivantinib used in combination with irinotecan and cetuximab in patients with refractory or relapsed colorectal cancer ("CRC"). The trial did not meet its primary endpoint of PFS. The PFS and ORR results obtained in both the control arm and the treatment arm were longer than expected compared to previously published historical norms. Additional data and analyses from this trial were presented at the American Society of Clinical Oncology ("ASCO") Annual Meeting in June 2013, showing that the median PFS in the treatment arm was 8.3 months, compared with 7.3 months in the control arm. Median OS in the treatment arm was 19.8 months, compared with 16.9 months in the control arm. ORR in the treatment arm was 45 percent versus 33 percent in the control arm. Adverse events were reported at similar rates in the treatment and control arms of the trial, except for increased neutropenia observed in the treatment arm, with no discontinuations of treatment for this reason. Tivantinib was generally well tolerated in combination with the approved doses of irinotecan and cetuximab studied in this 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. During 2011, we received $25 million from Daiichi Sankyo resulting from the dosing of the first patient in the MARQUEE trial and $10 million from Kyowa Hakko Kirin resulting from dosing of the first patient in the ATTENTION trial. On January 31, 2013, we announced that the first patient had been enrolled in the pivotal Phase 3 METIV trial, entitling us to a $15 million milestone from Daiichi Sankyo. 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. The terms of our tivantinib licensing agreements with Daiichi Sankyo and Kyowa Hakko Kirin remain in effect following the recent developments in these trials.

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 include 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).

The NCI has reported to us that the randomized, double blind, placebo-controlled CTEP Phase 2 clinical trial of tivantinib as a single agent in prostate cancer met its primary endpoint of PFS. Data from this trial were presented at the 2015 Genitourinary Cancers Symposium (ASCO GU). We and our partner, Daiichi Sankyo, intend to discuss with the NIH the potential for additional trials in this indication. In addition, in the uncontrolled single agent, signal generation CTEP studies in breast cancer, multiple myeloma and mesothelioma, the primary endpoint of response rate was not met. The Phase 2 trials in kidney cancer and head and neck cancer also did not meet their end points. As a result, we do not plan to prioritize development in these indications at this time.

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. These product candidates include: ARQ 092, designed to inhibit the AKT serine/threonine kinase; ARQ 087, a multi-kinase inhibitor designed to preferentially inhibit the fibroblast growth factor receptor ("FGFR") family; and ARQ 761, a Beta lapachone analog being evaluated in investigator-sponsored testing as a promoter of NQ01-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 the scientific literature.

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, is expected to dose the first patient in the fourth quarter of 2015. A Phase 1b clinical trial for ARQ 092 is on-going in lymphoma, endometrial and other cancers harboring the AKT 1 mutation. Thus far in this enriched cohort of the trial, we have observed four patients with confirmed responses, two of which had the same AKT 1 mutation which occurs in Proteus syndrome. 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 program. Additional testing is on-going in solid tumors as part of a Phase 1b clinical trial. ARQ 761 is currently in a Phase 1b clinical trial for solid tumors.

We regained worldwide rights for the development and commercialization of ARQ 092 and all other compounds included under our AKT collaboration with Daiichi Sankyo pursuant to their formal notice to terminate our license and commercialization agreement received on March 26, 2013. Following the termination, we became responsible for funding the remainder of the Phase 1 trial with ARQ 092 beyond the contractual termination period, as well as any future clinical development and commercialization of this compound. The license agreement had provided exclusive rights to Daiichi Sankyo for the development, manufacturing and marketing of ARQ 092 on a worldwide basis. Under this agreement, we received a $10 million upfront fee from Daiichi Sankyo in November 2011. Following the termination of this agreement, ARQ 092 became our proprietary asset, and Daiichi Sankyo has no further financial or other obligations or rights related to this program.

On July 30, 2014, we approved plans to restructure our operations to better align our human and financial resources with our primary focus on clinical stage development programs and to extend our cash runway beyond the anticipated time frame for achievement of key milestones, such as the completion of the METIV-HCC trial. Commencing on August 4, 2014, we began to reduce our workforce from 62 to approximately 40 employees by the end of 2014. Most of this reduction came from our Discovery Group, which had been engaged primarily in early-stage, pre-clinical research. As a result of this near-term focus on our proprietary clinical pipeline, including ARQ 092 and ARQ 087, we will concentrate our discovery efforts on the development of a number of preclinical programs derived from our insights into kinase biology and library of proprietary compounds, as well as the enhancement and preservation of such library. We plan to achieve progress in these areas through greater reliance on academic and other collaborations and on outsourcing strategies.

We have incurred a cumulative deficit of approximately $479 million from inception through September 30, 2015. We recorded a net loss for 2012, 2013 and 2014 and expect a net loss for 2015.

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. We and Beryllium will each be responsible for our respective internal and outsourcing costs during pre-clinical development. Following lead optimization of any potential drug candidates, we and Beryllium will jointly decide whether to advance compounds into GLP/toxicology and clinical testing, initially on a shared cost basis, provided that we will have the right to advance compounds on our own should Beryllium vote against such advancement. The agreement also provides that we will be responsible for clinical development and commercialization of product candidates that are not out-licensed. Beryllium will have the right to participate financially throughout the program but will also have the option to opt out at certain times and receive a royalty. The agreement will terminate after the last payment obligation is satisfied, or prior to that upon 60-days’ notice by either party.

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. We retain the option to participate in the commercialization of tivantinib in the U.S. 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 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.

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, 2015 totaled $99.0 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, 2015 by $59.0 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 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.

For the quarter ended September 30, 2014 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo and $102 thousand was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue. For the nine months ended September 30, 2014, no research and development revenue was recognized related to our non-Phase 3 tivantinib collaboration as our costs incurred were offset by an equal amount of contra-revenue.

In November 2012, we completed our ARQ 092 research collaboration with Daiichi Sankyo entered into on November 7, 2008 for the discovery of therapeutic compounds that selectively inhibit certain kinases in the field of oncology. The agreement provided for a $15 million upfront payment, which we received in November 2008, research support payments for the first two years of the collaboration (which was extended for an additional two years in 2010), licensing fees for compounds discovered as a result of this research, milestone payments related to clinical development, regulatory review and sales, and royalty payments on net sales of compounds from the collaboration. Daiichi Sankyo’s obligation to provide further research funding to ArQule under this agreement terminated in November 2012.

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, and in September 2010, we received a $5 million milestone payment. 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 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.

The Company will recognize the payments, if any, as revenue in accordance with its revenue recognition policies. As of September 30, 2015, 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. Revenue for this agreement is recognized using the contingency-adjusted performance model with an estimated development period through April 2016.

LIQUIDITY AND CAPITAL RESOURCES

	September 30, 2015	December 31, 2014	Increase (decrease)	
	(in millions)		$	%
Cash, cash equivalents and marketable securities-short term	$43.8	$ 59.2	$(15.4)	(26)%
Marketable securities-long term	—	2.1	(2.1)	(100)%
Working capital	31.0	42.8	(11.8)	(28)%

	Nine Months Ended September 30, 2015	September 30, 2014	Increase (decrease)
	(in millions)		
Cash flow from:			
Operating activities	$(17.2)	$ (25.0)	$ 7.8
Investing activities	17.7	25.4	(7.7)
Financing activities	0.1	0.1	—

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, 2015 and 2014, our net use of cash was primarily driven by our net loss and the difference between cash receipts from our collaborators and payments for operating expenses which resulted in net cash outflows of $17.2 million and $25.0 million, respectively.

Cash flow from investing activities. 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. Our net cash provided by investing activities of $25.4 million for the nine months ended September 30, 2014, was comprised of net sales of marketable securities. 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 for both the nine months ended September 30, 2015 and 2014 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 and commercial paper. 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 July 30, 2014, we approved plans to restructure our operations to better align our human and financial resources with our primary focus on clinical stage development programs and to extend our cash runway beyond the anticipated time for achievement of key milestones, such as the completion of the METIV-HCC trial. Commencing on August 4, 2014, we began to reduce our current workforce from 62 to approximately 40 employees by the end of the year. Most of this reduction came from our Discovery Group, which has been engaged primarily in early-stage, pre-clinical research. The costs associated with this action were comprised of severance payments of $662 thousand and benefits continuation costs of $74 thousand. In addition, in the year ended December 31, 2014, we incurred non-cash charges of $83 thousand related to the modification of employee stock options, and $280 thousand for impairment of property and equipment impacted by the restructuring. In the year ended December 31, 2014, $319 of these costs was paid and the remaining amount of $417 was paid by March 31, 2015. The restructuring actions for which charges were incurred in the year ended December 31, 2014 are expected to result in annual cost savings of approximately $2.5 to $3.0

million commencing in 2015.

We anticipate that our cash, cash equivalents and marketable securities on hand at September 30, 2015, financial support from our collaboration agreements, and savings from our workforce reduction described above, will be sufficient to finance our working capital and capital requirements into 2017.

Our contractual obligations were comprised of the following as of September 30, 2015 (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	$2,426	$524	$1,479	$423	$ —
Purchase obligations	3,173	3,173	—	—	—
Total	$5,599	$3,697	$1,479	$423	$ —

Operating lease obligations are for our facilities under non-cancelable operating leases. 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, 2015 our portion of these costs was $59.0 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, 2014 on Form 10-K filed with the SEC on March 4, 2015.

RESULTS OF OPERATIONS

The following are the results of operations for the three and nine months ended September 30, 2015 and 2014:

Revenue

			Increase (decrease)	
	2015	2014	$	%
	(in millions)			
For the three months ended September 30:				
Research and development revenue	$2.7	$2.7	$ —	—
For the nine months ended September 30:				
Research and development revenue	$8.4	$8.2	$ 0.2	2 %

Research and development revenue in the three and nine months ended September 30, 2015 and 2014 is comprised of revenue from the Daiichi Sankyo tivantinib development agreement and the Kyowa Hakko Kirin exclusive license agreement. The revenue increase in the nine month period is due to higher revenue from our Daichii Sankyo tivantinib program.

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, 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 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.

Our cumulative share of the Daiichi Sankyo Phase 3 costs through September 30, 2015 totaled $99 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, 2015 by $59 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 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.

For the quarter ended September 30, 2014 our non-Phase 3 tivantinib collaboration costs incurred were less than those of Daiichi Sankyo and $102 thousand was recognized as contra-revenue and netted against our tivantinib Daiichi Sankyo research and development revenue. For the nine months ended September 30, 2014, no research and development revenue was recognized related to our non-Phase 3 tivantinib collaboration as our costs incurred were offset by an equal amount of contra-revenue.

Research and development

			Increase (decrease)	
	2015	2014	$	%
	(in millions)			
For the three months ended September 30:				
Research and development	$3.2	$5.0	$(1.8)	(37)%
For the nine months ended September 30:				
Research and development	$11.9	$18.0	$(6.1)	(34)%

Research and development expense in the quarter ended September 30, 2015 decreased by $1.8 million primarily due to lower labor related costs of $0.5 million from reduced headcount, outsourced clinical and product development costs of $0.6 million, facility costs of $0.6 million and lab expenses of $0.1 million.

Research and development expense in the nine months ended September 30, 2015 decreased by $6.1 million primarily due to lower labor related costs of $2.2 million from reduced headcount, outsourced clinical and product development costs of $1.7 million, facility costs of $1.4 million and lab expenses of $0.7 million. At September 30, 2015 we had 21 employees dedicated to our research and development program compared to 27 at September 30, 2014.

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 quarter and since inception of our lead clinical stage program were as follows (in millions):

Oncology program	Current status	**Nine Months Ended September 30, 2015**	**Program-to-date**
c-Met program—tivantinib	Phase 3	$ 0.7	$ 84.5

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, 2015 by $59.0 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)	
	2015	2014	$	%
	(in millions)			
For the three months ended September 30:				
General and administrative	$1.8	$3.0	$(1.2)	(39)%
For the nine months ended September 30:				
General and administrative	$7.8	$9.3	$(1.5)	(16)%

General and administrative expense decreased by $1.2 million in the three months ended September 30, 2015, principally due to lower facility costs of $0.9 million, labor related costs from reduced headcount of $0.2 million, and professional fees of $0.1 million.

General and administrative expense decreased by $1.5 million in the nine months ended September 30, 2015, principally due to lower facility costs of $0.7 million, labor related costs from reduced headcount of $0.6 million, and professional fees of $0.2 million. General and administrative headcount was 15 at September 30, 2015, compared to 19 at September 30, 2014.

Restructuring and other costs

On July 30, 2014, we approved plans to restructure our operations to better align our human and financial resources with our primary focus on clinical stage development programs and to extend our cash runway beyond the anticipated time for achievement of key milestones, such as the completion of the METIV-HCC trial. Commencing on August 4, 2014, we began to reduce our current workforce from 62 to approximately 40 employees by the end of 2014. Most of this reduction came from our Discovery Group, which had been engaged primarily in early-stage, pre-clinical research. The costs associated with this action were comprised of severance payments of $662 thousand and benefits continuation costs of $74 thousand. In the year ended December 31, 2014, $319 thousand of these costs was paid and the remaining amount of $417 thousand was paid by March 31, 2015. In addition, in the three months ended September 30, 2014, we incurred non-cash charges of $83 thousand related to the modification of employee stock options, and $280 thousand for impairment of property and equipment impacted by the restructuring.

The restructuring actions for which charges were incurred in the quarter ended September 30, 2014 are expected to result in annual cost savings of approximately $2.5 to $3.0 million commencing in 2015.

There were no restructuring expenses incurred in the three or nine month periods ended September 30, 2015.

Interest income, interest expense and other income (expense)

			Increase (decrease)	
	2015	2014	$	%
	(in thousands)			
For the three months ended September 30:				
Interest income	$17	$62	$(45)	(73)%
Interest expense	—	(11)	(11)	(100)%
Other income (expense)	(5)	(2)	3	150 %
For the nine months ended September 30:				
Interest income	$81	$233	$(152)	(65)%
Interest expense	—	(28)	(28)	(100)%
Other income (expense)	277	75	202	269 %

Interest income is derived from our portfolio of cash, cash equivalents and investments and decreased in the three and nine month periods ended September 30, 2015 primarily due to a decrease in our portfolio balance. We had no interest expense in the three and nine month periods ended September 30, 2015 because our notes payable were repaid in full

in 2014. 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. Other income (expense) in the three and nine-month periods ended September 30, 2014 includes a loss of $2 thousand and a gain of $75 thousand, respectively from the change in fair value of our auction rate securities.

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 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 beginning 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 are currently evaluating the potential impact that this ASU may have on our financial position and 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.

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, 2014 filed with the SEC on March 4, 2015, 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, 2015. 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, 2015, 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, 2014 filed with the SEC on March 4, 2015, 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 4, 2015 /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)