ARQULE INC
Form 10-Q
May 05, 2011
Table of Contents

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 March 31, 2011

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)

19 Presidential Way, Woburn, Massachusetts 01801

(Address of Principal Executive Offices)

(781) 994-0300

(Registrant s Telephone Number, including Area Code)

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

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 o No o

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 o

Accelerated filer x

Non-accelerated filer o
(Do not check if a smaller reporting company)

Smaller reporting company o

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

Number of shares outstanding of the registrant s Common Stock as of April 27, 2011:

Common Stock, par value $.01 53,378,286 shares outstanding

Table of Contents

ARQULE, INC.

QUARTER ENDED MARCH 31, 2011

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

Condensed Consolidated Balance Sheets (Unaudited) March 31, 2011 and December 31, 2010 3

Condensed Consolidated Statements of Operations (Unaudited) three months ended March 31, 2011 and 2010 4

Condensed Consolidated Statements of Cash Flows (Unaudited) three months ended March 31, 2011 and 2010 5

Notes to Unaudited Condensed Consolidated Financial Statements 6

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations 15

Item 3. Quantitative and Qualitative Disclosures about Market Risk 22

Item 4. Controls and Procedures 23

PART II - OTHER INFORMATION

Item 1. Legal Proceedings 23

Item 1A. Risk Factors 23

Item 2. Unregistered Sales of Equity Securities and Use Of Proceeds 23

Item 3. Defaults Upon Senior Securities 23

Item 4. (Removed and Reserved) 23

Item 5. Other Information 23

Item 6. Exhibits 23

SIGNATURES 24

Table of Contents

ARQULE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	March 31, 2011	December 31, 2010
	(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 63,474	$ 20,457
Marketable securities-short term	46,593	60,238
Prepaid expenses and other current assets	1,233	1,119
Total current assets	111,300	81,814
Marketable securities-long term	27,685	2,154
Property and equipment, net	3,506	3,517
Other assets	1,376	1,381
Total assets	$ 143,867	$ 88,866
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	$ 18,195	$ 16,836
Note payable	1,700	1,700
Current portion of deferred revenue	32,825	27,825
Current portion of deferred gain on sale leaseback	552	552
Total current liabilities	53,272	46,913
Deferred revenue, net of current portion	56,231	54,627
Deferred gain on sale leaseback, net of current portion	1,749	1,888
Total liabilities	111,252	103,428
Commitments and contingencies		
Stockholders equity (deficit) :		
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; 53,158,513 and 44,973,335 shares issued and outstanding at March 31, 2011 and December 31, 2010, respectively	532	450
Additional paid-in capital	432,311	383,713
Accumulated other comprehensive loss	(44)	(7)
Accumulated deficit	(400,184)	(398,718)
Total stockholders equity (deficit)	32,615	(14,562)
Total liabilities and stockholders equity (deficit)	$ 143,867	$ 88,866

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

Table of Contents

ARQULE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	THREE MONTHS ENDED MARCH 31,	
	2011	2010
	(IN THOUSANDS, EXCEPT PER SHARE DATA)	
Revenue:		
Research and development revenue	$ 13,405	$ 6,325
Costs and expenses:		
Research and development	11,393	12,444
General and administrative	3,543	3,329
Total costs and expenses	14,936	15,773
Loss from operations	(1,531)	(9,448)
Interest income	55	310
Interest expense	(6)	(122)
Other income (expense)	16	(492)
Net loss	$ (1,466)	$ (9,752)
Basic and diluted net loss per share:		
Net loss per share	$ (0.03)	$ (0.22)
Weighted average basic and diluted common shares outstanding	50,623	44, 388

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

Table of Contents

ARQULE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	THREE MONTHS ENDED March 31,	
	2011	2010
	(IN THOUSANDS)	
Cash flows from operating activities:		
Net loss	$ (1,466)	$ (9,752)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	288	376
Amortization of premium/discount on marketable securities	214	316
Amortization of deferred gain on sale leaseback	(139)	(139)
Non-cash stock compensation	1,092	866
Loss on auction rate securities put option		762
Gain on auction rate securities	(16)	(270)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(114)	1,187
Other assets	5	7
Accounts payable and accrued expenses	1,359	1,716
Deferred revenue	6,604	(4,625)
Net cash provided by (used in) operating activities	7,827	(9,556)
Cash flows from investing activities:		
Purchases of marketable securities	(44,622)	(17,096)
Proceeds from sale or maturity of marketable securities	32,501	19,900
Purchases of property and equipment	(277)	(36)
Net cash provided by (used in) investing activities	(12,398)	2,768
Cash flows from financing activities:		
Payment of notes payable		(6,300)
Proceeds from stock offering, net	46,756	
Proceeds from stock option exercises	832	
Net cash provided by (used in) financing activities	47,588	(6,300)
Net increase (decrease) in cash and cash equivalents	43,017	(13,088)
Cash and cash equivalents, beginning of period	20,457	36,551
Cash and cash equivalents, end of period	$ 63,474	$ 23,463

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

Table of Contents

ARQULE, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED 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 and engaged in the research and development of innovative cancer therapeutics. Our mission is to produce novel medicines with differentiated mechanisms of action that target specific biological pathways implicated in a wide range of cancers.

Our lead product candidate is tivantinib (ARQ 197), an orally administered, small molecule inhibitor of the c-Met receptor tyrosine kinase that is currently being evaluated in Phase 2 and Phase 3 clinical trials in a number of indications. In January 2011, we enrolled the first patient in the Phase 3 trial of tivantinib in non-small cell lung cancer (NSCLC) in combination with erlotinib, and in February 2011, we received a $25 million payment from Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) resulting from the achievement of this clinical milestone. 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 Co., Ltd. (Kyowa Hakko Kirin).

Our proprietary pipeline is directed toward molecular targets and biological processes with demonstrated roles in the development of human cancers. The most advanced candidates in this pipeline are ARQ 621, an inhibitor of the Eg5 kinesin motor protein, and ARQ 736, an inhibitor of the RAF kinases, both of which are in Phase 1 clinical testing. A third pipeline program, focused on small molecule inhibitors of fibroblast growth factor receptor, is in pre-clinical development. Our drug discovery efforts are focused primarily on the ArQule Kinase Inhibitor Platform, which we are using to generate compounds designed to inhibit kinases without competing with adenosine triphosphate (ATP) for binding to the target kinase, as well as other types of kinase inhibitors. We have assessed the potential of ArQule Kinase Inhibitor Platform (AKIP) to target multiple kinases in oncology and other therapeutic areas, and we are generating and validating compounds that inhibit these kinase targets.

We have prepared the accompanying condensed consolidated 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 consolidated financial statements should be read in conjunction with our audited financial statements and footnotes related thereto for the year ended December 31, 2010 included in our annual report on Form 10-K filed with the SEC on March 2, 2011.

The unaudited condensed consolidated 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 March 31, 2011, and the results of our operations and cash flows for the three months ended March 31, 2011 and March 31, 2010. 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

Daiichi Sankyo Kinase Inhibitor Discovery Agreement

On November 7, 2008, we entered into a research collaboration, exclusive license and co-commercialization agreement with Daiichi Sankyo under which we are applying our proprietary technology and know-how using our AKIP technology for the discovery of therapeutic compounds that selectively inhibit certain kinases in the field of oncology. The agreement defines two such kinase targets, and Daiichi Sankyo will have an option to license compounds directed to these targets following the completion of certain pre-clinical studies. The agreement provides for a $15 million upfront payment, which we received in November 2008, research support payments for the first and second years of the collaboration, 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. We retain the option to co-commercialize licensed products developed under this agreement in the U.S. In May 2009, we entered into an agreement with Daiichi Sankyo related to potential future milestones and royalties for our AKIP collaboration, under which we could receive up to $265 million in potential development and sales milestone payments for each product selected for clinical development. Upon commercialization of a licensed product, we would also receive tiered, double-digit royalties on its net

Table of Contents

sales. On October 12, 2010, we and Daiichi Sankyo announced the expansion of this agreement, establishing a third target, with an option for a fourth, in oncology, and including a two-year extension through November 2012.

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 Daiichi Sankyo, the agreement terminates on the later of (i) the expiration of the research collaboration period, or (ii) various periods specified in the agreement for development and commercialization of products. If Daiichi Sankyo has commercialized a licensed product or products, the agreement will continue in force until 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 with an estimated performance period through November 2012. For the quarters ended March 31, 2011 and 2010, $2.4 million and $2.5 million, respectively were recognized as revenue. At March 31, 2011, $15.1 million remains in deferred revenue.

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. 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 that we incur are compared with those of Daiichi Sankyo. If our costs for the quarter exceed Daiichi Sankyo s, we recognize revenue on the amounts due to us under the contingency adjusted performance model. Revenue is calculated on a pro-rata basis using the time elapsed from inception of the agreement over the estimated duration of the development period under the agreement. If our costs for the quarter are less than those of Daiichi Sankyo s, we report the amount due to Daiichi Sankyo as contra-revenue in that quarter. In the quarter ended March 31, 2011, our tivantinib collaboration costs incurred were less than those of Daiichi Sankyo s by $5.0 million and accordingly that amount was recognized as contra-revenue and was netted against our tivantinib Daiichi Sankyo research and development revenue. The dosing of the first patient in a Phase 3 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. We determined that the milestone is not considered substantive under FASB guidance related to multiple element arrangements. Accordingly, 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 December 2013. For the quarter ended March 31, 2011, $11.4 million was recognized as revenue from the milestone.

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 with an estimated development period through December 2013. For the quarters ended March 31, 2011 and 2010, $9.9 million and $2.8 million, respectively, were recognized as net revenue. At March 31, 2011, $51.1 million remains in deferred revenue.

Table of Contents

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. 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 regulatory milestone payments totaling $123 million, the Company will be eligible for future milestone payments based on the achievement of certain levels of net sales. The Company will recognize the payments, if any, as revenue in accordance with its revenue recognition policies. As of March 31, 2011, 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 the quarters ended March 31, 2011 and 2010 $1.1 million and $1.0 million, respectively, were recognized as revenue. At March 31, 2011 $22.8 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 consolidated 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. Certain of our marketable securities are classified as trading securities and any changes in the fair value of those securities are recorded as other income (expense) in the statement of operations.

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).

Table of Contents

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 consolidated statement of operations 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.

We invest our available cash primarily in U.S. Treasury bill funds, money market funds, commercial paper fully guaranteed by the FDIC under the Temporary Liquidity Guarantee Program, commercial paper, and U.S. federal and state agency backed certificates, including auction rate securities that have investment grade ratings. Auction rate securities are structured with short-term interest reset dates of generally less than 90 days, but with contractual maturities that can be well in excess of ten years. At the end of each reset period, which occurs every seven to twenty-eight days, investors can sell or continue to hold the securities at par value. If auction rate securities fail an auction, due to sell orders exceeding buy orders, the funds associated with a failed auction would not be accessible until a successful auction occurred, a buyer was found outside the auction process, the underlying securities matured or a settlement with the underwriter is reached. ArQule s marketable securities portfolio includes auction rate securities of $2.5 million (at cost) at March 31, 2011 and $2.6 million (at cost) at December 31, 2010. These auction rate securities failed at auction due to sell orders exceeding buy orders.

The following is a summary of the fair value of available-for-sale marketable securities we held at March 31, 2011 and December 31, 2010:

March 31, 2011	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
U.S. Federal Treasury and U.S. government agencies securities-short term	$ 10,460	$ 3	$	$ 10,463
Corporate debt securities-short term	36,130	14	(14)	36,130
	46,590	17	(14)	46,593
U.S. Federal Treasury and U.S. government agencies securities -long term	25,660	1	(48)	25,613
Total available-for-sale marketable securities	$ 72,250	$ 18	$ (62)	$ 72,206

December 31, 2010	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
U.S. Federal Treasury and U.S. government agencies securities	$ 12,184	$ 2	$ (1)	$ 12,185
Corporate debt securities-short term	48,061	12	(20)	48,053
Total available-for-sale marketable securities	$ 60,245	$ 14	$ (21)	$ 60,238

The Company s available-for-sale marketable securities in a loss position at March 31, 2011 and December 31, 2010 were in a continuous unrealized loss position for less than 12 months.

The following is a summary of the fair value of trading securities we held at March 31, 2011 and December 31, 2010:

March 31, 2011	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
Auction rate securities	$ 2,500	$	$ (428)	$ 2,072
Total trading securities	$ 2,500	$	$ (428)	$ 2,072

Table of Contents

December 31, 2010	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Security type				
Auction rate securities	$ 2,600	$	$ (446)	$ 2,154
Total trading securities	$ 2,600	$	$ (446)	$ 2,154

The underlying collateral of our auction rate securities consists of student loans, supported by the federal government as part of the Federal Family Education Loan Program (FFELP).

At March 31, 2011 and December 31, 2010, the Company s auction rate securities are included in marketable securities-long term and total $2,072 and $2,154, respectively. The increase in fair value of our auction rate securities totaling $16 in the quarter ended March 31, 2011 was recorded as a gain in other income (expense) in the statement of operations. The net decrease in fair value of our auction rate securities put option and auction rate securities totaling $492 in the quarter ended March 31, 2010 was recorded as a loss in other income (expense) in the statement of operations.

In January 2011, we adopted a newly issued accounting standard which requires additional disclosure about the amounts of and reasons for significant transfers in and out of Level 1 and Level 2 fair value measurements. This standard also clarified existing disclosure requirements related to the level of disaggregation of fair value measurements for each class of assets and liabilities and requires disclosures about inputs and valuation techniques used to measure fair value for both recurring and nonrecurring Level 2 and Level 3 measurements. In addition, effective for interim and annual periods beginning after December 15, 2010, this standard further requires an entity to present disaggregated information about activity in Level 3 fair value measurements on a gross basis, rather than as one net amount. As this accounting standard only requires enhanced disclosure, the adoption of this standard did not impact our financial position or results of operations and will not affect them in the future.

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:

	March 31, 2011	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 48,020	$ 48,020	$	$
Marketable securities	46,593		46,593	
Marketable securities long term	27,685		25,613	2,072
Total	$ 122,298	$ 48,020	$ 72,206	$ 2,072

	December 31, 2010	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 16,871	$ 16,871	$	$
Marketable securities	60,238		60,238	
Marketable securities long term	2,154			2,154
Total	$ 79,263	$ 16,871	$ 60,238	$ 2,154

Due to the lack of market quotes relating to our auction rate securities, the fair value measurements for our auction rate securities have been estimated using an income approach model (discounted cash flow analysis), which is exclusively

Table of Contents

based on Level 3 inputs. The model considers factors that reflect assumptions market participants would use in pricing including, among others, the collateralization underlying the investments, the creditworthiness of the counterparty, the expected future cash flows, liquidity premiums, the probability of successful auctions in the future, and interest rates. The assumptions used are subject to volatility and may change as the underlying sources of these assumptions and markets conditions change.

Due to the lack of market quotes relating to our auction rate put option, the fair value measurements for our put option at March 31, 2010 were estimated using a valuation approach commonly used for forward contracts in which one party agrees to sell a financial instrument (generating cash flows) to another party at a particular time for a predetermined price, which is based on Level 3 inputs. In this approach the present value of all expected future cash flows is subtracted from the current fair value of the security, and the resulting value is calculated as a future value at an interest rate reflective of counterparty risk. On June 30, 2010, the company exercised the auction rate put option and in July 2010, UBS AG redeemed at par value all of the Company s auction rate securities held by UBS AG that were outstanding at June 30, 2010.

The following tables roll forward the fair value of our auction rate securities and put option, whose fair values are determined by Level 3 inputs for the periods presented:

		Amount
Balance at December 31, 2010	$	2,154
Gain on auction rate securities		16
Settlements		(98)
Balance at March 31, 2011	$	2,072

		Amount
Balance at December 31, 2009	$	59,791
Loss on auction rate securities and put option		(492)
Settlements		(6,225)
Balance at March 31, 2010	$	53,074

4. COMPREHENSIVE LOSS

Comprehensive loss is comprised of net loss and other comprehensive loss. Other comprehensive loss includes unrealized losses on our available-for-sale securities that are excluded from net loss. Total comprehensive loss for the three months ended March 31, 2011 and 2010 was as follows:

	Three Months Ended March 31,	
	2011	2010
Net loss	$ (1,466)	$ (9,752)
Unrealized loss on marketable securities	(37)	(29)
Comprehensive loss	$ (1,503)	$ (9,781)

5. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses include the following at March 31, 2011 and December 31, 2010:

	2011	2010
Accounts payable	$ 1,955	$ 1,260
Accrued payroll	1,296	3,450
Accrued outsourced pre-clinical and clinical fees	13,388	10,375
Accrued professional fees	763	785
Other accrued expenses	793	966
	$ 18,195	$ 16,836

Accrued outsourced pre-clinical and clinical fees includes amounts payable for our share of tivantinib collaboration costs that are netted against revenue as contra-revenue.

Table of Contents

6. 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 7,536,247 and 6,207,330 for the three months ended March 31, 2011 and 2010, respectively.

7. 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 three months ended March 31, 2011 and 2010.

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

	Three Months Ended March 31,	
	2011	2010
Research and development	$ 437	$ 356
General and administrative	655	510
Total stock-based compensation expense	$ 1,092	$ 866

In the three months ended March 31, 2011 and March 31, 2010, 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 three months ended March 31, 2011 was as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2010	6,355,827	$ 5.29
Granted	1,522,950	6.70
Exercised	(194,580)	5.22
Cancelled	(147,950)	12.04
Outstanding as of March 31, 2011	7,536,247	$ 5.45

Exercisable as of March 31, 2011	4,355,475	$	5.63

The aggregate intrinsic value of options outstanding at March 31, 2011 was $13,980, of which $7,777 related to exercisable options. The weighted average fair value of options granted in the three months ended March 31, 2011 and 2010 was $4.00 and $2.05 per share, respectively. The intrinsic value of options exercised in the three months ended March 31, 2011 and 2010 was $277 and $32, respectively.

Shares vested, expected to vest and exercisable at March 31, 2011 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 March 31, 2011	7,394,922	$	5.45	6.8	$	13,708
Exercisable at March 31, 2011	4,355,475	$	5.63	5.2	$	7,777

The total compensation cost not yet recognized as of March 31, 2011 related to non-vested option awards was $8.9 million, which will be recognized over a weighted-average period of 3.1 years. During the three months ended March

Table of Contents

31, 2011, there were 8,000 shares forfeited with a weighted average grant date fair value of $3.12 per share. The weighted average remaining contractual life for options exercisable at March 31, 2011 was 5.2 years.

No restricted stock was granted in 2010. In 2009, we granted 412,200 shares of restricted stock to employees, vesting annually over a four year period. In 2008 we granted 103,316 shares of restricted stock to employees, vesting annually over a four year period and 125,000 shares vesting annually over a two year period. The shares of restricted stock were issued at no cost to the recipients. The weighted average fair value of the restricted stock at the time of grant in 2009 and 2008 was $3.54 and $4.31 respectively, per share, and is being expensed ratably over the vesting period. Through March 31, 2011, 42,571 shares have been forfeited, and 383,592 shares have vested. We recognized share-based compensation expense related to restricted stock of $98 and $85 for the three months ended March 31, 2011 and 2010, respectively.

Restricted stock activity under the Plan for the three months ended March 31, 2011 was as follows:

Restricted Stock	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2010	333,314	$ 3.68
Granted		
Vested	(117,648)	3.74
Cancelled	(1,313)	4.06
Unvested as of March 31, 2011	214,353	$ 3.65

The fair value of restricted stock vested in the three months ended March 31, 2011 and 2010 was $440 and $449, 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% vest annually over the following three years, and a maximum of 390,000 performance-based stock units that vest upon the achievement of certain performance and market based targets. Through March 31, 2011, no expense has been recorded for these performance-based stock units.

8. STOCK OFFERING

On January 25, 2011, we sold 8,050,000 shares of common stock at $6.15 per share for aggregate net proceeds of approximately $46.8 million after commissions and other offering expenses.

9. 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.

Recently Issued Accounting Standards

In October 2009, the FASB issued an accounting standards update (ASU) on Multiple-Deliverable Revenue Arrangements. This standards update amends existing revenue recognition accounting pronouncements and provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. Among other provisions, this guidance eliminates the requirement to have objective evidence for undelivered products and services and instead provides for separate revenue recognition based upon management s best estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Previous accounting principles required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately. Revenue from our existing multiple-deliverable arrangements is recognized over the estimated development period using the contingency adjusted performance model. Under the new approach, revenue for new agreements or material modifications of existing agreements will be recognized based upon the relative selling price of each element in the arrangement. The Company adopted this guidance prospectively on January 1, 2011 and the adoption of this standard did not have a material impact on our financial position and results of operations; however, the new guidance will impact any new collaboration agreements or material modifications to any existing agreements.

Table of Contents

In April 2010, the FASB issued ASU No. 2010-17, *Revenue Recognition Milestone Method*. This ASU provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. Under the milestone method of revenue recognition, consideration that is contingent upon achievement of a milestone in its entirety can be recognized as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. This standard provides the criteria to be met for a milestone to be considered substantive which includes that: a) performance consideration earned by achieving the milestone be commensurate with either performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from performance to achieve the milestone; and b) relate to past performance and be reasonable relative to all deliverables and payment terms in the arrangement. The Company adopted this guidance on a prospective basis for milestones on or after January 1, 2011 and the adoption of this standard did not have a material impact on our financial position and results of operations; however, the new guidance will impact any new collaboration agreements or material modifications to any existing agreements.

In January 2011, we adopted ASU No. 2010-06, *Improving Disclosures About Fair Value Measurements* which requires additional disclosure about the amounts of and reasons for significant transfers in and out of Level 1 and Level 2 fair value measurements. In addition, effective for interim and annual periods beginning after December 15, 2010, which for us is January 1, 2011, this standard further requires an entity to present disaggregated information about activity in Level 3 fair value measurements on a gross basis, rather than as one net amount. As this accounting standard only requires enhanced disclosure, the adoption of this newly issued accounting standard did not impact our financial position or results of operations.

10. INCOME TAXES

As of December 31, 2010, we had federal net operating loss (NOL), state NOL, and research and development credit carryforwards of approximately $219,187, $159,727 and $22,816 respectively, which can be used to offset future federal and state income tax liabilities and expire at various dates through 2030. Federal net capital loss carryforwards of approximately $571 can be used to offset future federal capital gains and expire in 2015. Approximately $15,004 of our federal NOL and $1,568 of our state NOL were generated from excess tax deductions from share- based awards, the tax benefit of which will be credited to additional paid-in-capital when the deductions reduce current taxes payable.

At March 31, 2011, and December 31, 2010 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. We recognize interest and penalties related to uncertain tax positions in income tax expense. As of March 31, 2011 and December 31, 2010, we had no accrued interest or penalties related to uncertain tax positions. The tax years 2007 through 2010 remain open to examination by the major taxing jurisdictions to which we are subject, which is primarily the U.S. 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 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 tax, 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 shareholders 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 in the fourth quarter of 2009 to determine whether such amounts are likely to be limited by Section 382. As a result of this analysis, and a detailed review of ownership changes in 2010, we currently do not believe Sections 382 s 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.

11. NOTES PAYABLE

On July 8, 2008, we entered into a collateralized, revolving credit line agreement for up to $47.5 million with UBS Bank USA, secured by a first priority lien and security interest in the auction rate securities held by us in an account with UBS Financial Services Inc. On June 30, 2010, the company exercised its UBS auction rate put option and in July 2010, UBS AG redeemed at par value all of the Company s auction rate securities held by them that were outstanding at June 30, 2010. The Company used a portion of the 2010 redemptions to retire the notes payable to UBS AG and the credit line at UBS AG was cancelled in July 2010.

Table of Contents

In October 2008, we entered into a margin loan agreement with another financial institution collateralized by $2.9 million of our auction rate securities and borrowed $1.7 million which is the maximum amount allowed under this facility. The amount outstanding under this facility of $1.7 million at March 31, 2011 is due on demand and is collateralized by $2.5 million of auction rate securities. Interest expense was $6 and $122 for the three months ended March 31, 2011 and 2010, respectively.

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

OVERVIEW

We are a clinical-stage biotechnology company engaged in the research and development of innovative cancer therapeutics. Our mission is to produce novel medicines with differentiated mechanisms of action that target specific biological pathways implicated in a wide range of cancers. We employ novel technologies such as our ArQule Kinase Inhibitor Platform (AKIP) to design and develop drugs that have the potential to fulfill this mission.

Our products and programs span a continuum of research and development ranging from drug discovery to advanced clinical testing. They 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 lead product candidate is tivantinib (ARQ 197), an orally administered, small molecule inhibitor of the c-Met receptor tyrosine kinase (c-Met) which recently was assigned the non-proprietary generic name, tivantinib. 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 clinical development program designed to realize the broad potential of tivantinib as a well tolerated single agent and in combination with other anti-cancer therapies in a number of disease indications. These include non-small cell lung cancer (NSCLC) (our most advanced indication), liver cancer, colorectal cancer and gastric cancer. We are also completing earlier-stage combination therapy trials with tivantinib and other anti-cancer agents that may provide data to support later-stage trials in additional indications.

In January 2011, we enrolled the first patient in the Phase 3 trial of tivantinib in NSCLC in combination with erlotinib, an approved anti-cancer agent, and in February 2011, we received a $25 million payment from Daiichi Sankyo resulting from the achievement of this clinical milestone. The Phase 3 trial is a randomized, double-blinded, controlled study of previously treated patients with locally advanced or metastatic, non-squamous, NSCLC who will receive tivantinib plus erlotinib or placebo plus erlotinib. This trial is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA).

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.

Our proprietary pipeline is directed toward molecular targets and biological processes with demonstrated roles in the development of human cancers. The most advanced candidates in this pipeline are ARQ 621, an inhibitor of the Eg5 kinesin motor protein, and ARQ 736, an inhibitor of the RAF kinases, both of which are in Phase 1 clinical testing. A third pipeline program, focused on small molecule inhibitors of fibroblast growth factor receptor, is in pre-clinical development.

Our drug discovery efforts are focused primarily on AKIP , which we are using to generate compounds designed to inhibit kinases without competing with adenosine triphosphate (ATP) for binding to the target kinase, as well as other types of kinase inhibitors. ATP is a chemical found in all living cells and is the energy source involved in a variety of physiological processes. We have assessed the potential of AKIP to target multiple kinases in oncology and other therapeutic areas, and we are generating and validating compounds that inhibit these kinases. We have incurred a cumulative deficit of $400.2 million from inception through March 31, 2011. We expect research and development costs to increase

Table of Contents

during the course of 2011, due to clinical testing of our lead product candidates. We recorded a net loss for 2008, 2009, 2010 and expect a net loss for 2011.

Our revenue consists almost exclusively 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.

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. 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 that we incur are compared with those of Daiichi Sankyo. If our costs for the quarter exceed Daiichi Sankyo s we recognize revenue on the amounts due to us under the contingency adjusted performance model. Revenue is calculated on a pro-rata basis using the time elapsed from inception of the agreement over the estimated duration of the development period under the agreement. If our costs for the quarter are less than those of Daiichi Sankyo s, we report the amount due to Daiichi Sankyo as contra-revenue in that quarter. In the quarter ended March 31, 2011, our tivantinib collaboration costs incurred were less than those of Daiichi Sankyo s by $5.0 million and accordingly that amount was recognized as contra-revenue and was netted against our tivantinib Daiichi Sankyo research and development revenue.

The dosing of the first patient in a Phase 3 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 with an estimated development period through December 2013.

On November 7, 2008, we entered into a research collaboration, exclusive license and co-commercialization agreement with Daiichi Sankyo under which we will apply our proprietary technology and know-how from our AKIP platform for the discovery of therapeutic compounds that selectively inhibit certain kinases. The agreement defines two such kinase targets, and Daiichi Sankyo will have an option to license compounds directed to these targets following the completion of certain pre-clinical studies. The agreement provides for a $15 million upfront payment, which we received in November 2008, research support payments for the first two years of the collaboration, 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. We retain the option to co-commercialize licensed products developed under this agreement in the U.S. In May 2009, we entered into an agreement with Daiichi Sankyo related to potential future milestones and royalties for our AKIP collaboration, under which we could receive up to $265 million in potential development and sales milestone payments for each product selected for clinical development. Upon commercialization of a licensed product, we would also receive tiered, double-digit royalties on its net sales. On October 12, 2010, we and Daiichi Sankyo announced the expansion of this agreement, establishing a third target, with an option for a fourth, in oncology, and including a two-year extension through November 2012. Revenue for this agreement is recognized using the contingency-adjusted performance model with an estimated performance period through 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 regulatory milestone payments totaling $123 million, the Company will be eligible for future milestone payments based on the achievement of certain levels of net sales. The Company will recognize the payments, if any, as revenue in accordance with its revenue recognition policies. As of March 31, 2011, the Company has not recognized any revenue from these sales milestone payments, and there can be

Table of Contents

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

	March 31, 2011	December 31, 2010	Increase (decrease) $	Increase (decrease) %
		(in millions)		
Cash, cash equivalents and marketable securities-short term	$ 110.1	$ 80.7	$ 29.4	36%
Marketable securities-long term	27.7	2.2	25.5	1185%
Notes payable	1.7	1.7		
Working capital	58.0	34.9	23.1	66%

	Q1 2011	Q1 2010	Increase (decrease)
		(in millions)	
Cash flow from:			
Operating activities	$ 7.8	$ (9.6)	$ 17.4
Investing activities	(12.4)	2.8	(15.2)
Financing activities	47.6	(6.3)	53.9

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 quarter ended March 31, 2011, our net source of cash was primarily driven by the difference between cash receipts from our collaborators, including the $25 million milestone payment from Daiichi Sankyo triggered by the dosing of the first patient in the Phase 3 NSCLC clinical trial, and payments for operating expenses which resulted in a net cash inflow of $7.8 million.

Cash flow from investing activities. Our net cash used in investing activities of $12.4 million for the quarter ended March 31, 2011, 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.

Our cash equivalents and marketable securities include U.S. Treasury bill funds, money market funds, commercial paper fully guaranteed by the FDIC under the Temporary Liquidity Guarantee Program, commercial paper, and U.S. federal and state agency backed certificates, including auction rate securities 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. ArQule s marketable securities portfolio includes $2.5 million (at cost) at March 31, 2011 and $2.6 million (at cost) at December 31, 2010, invested in auction rate securities.

Cash flow from financing activities. Our net cash provided by financing activities for the quarter ended March 31, 2011 consisted of $46.8 million from the net proceeds of our January 2011 stock offering and $0.8 million from the issuance of common stock from the exercise of stock options.

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

Table of Contents

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.

In January 2011, we received net proceeds of $46.8 million from our 8,050,000 share stock offering. In February 2011, we received a $25 million milestone payment from Daiichi Sankyo triggered by the dosing of the first patient in the Phase 3 NSCLC clinical trial. In light of these two cash inflows, cash, cash equivalents and marketable securities on hand at March 31, 2011 and our collaboration agreements, we expect that our available cash and cash equivalents will be sufficient to finance our working capital and capital requirements into 2013.

Our contractual obligations were comprised of the following as of March 31, 2011 (in thousands):

	Payment due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**
Note payable	$ 1,700	$ 1,700	$	$	$
Operating lease obligations	13,543	3,536	6,549	3,458	
Purchase obligations	13,598	13,598			
Total	$ 28,841	$ 18,834	$ 6,549	$ 3,458	$

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. Interest on notes payable is variable and is excluded from the table above. Notes payable currently bears interest at LIBOR plus 125 basis points.

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 Consolidated Financial Statements included in our Annual Report for the fiscal year ended December 31, 2010 on Form 10-K filed with the SEC on March 2, 2011.

RESULTS OF OPERATIONS

The following are the results of operations for the three months ended March 31, 2011 and 2010:

Revenue

	2011	2010	Increase (decrease) $	Increase (decrease) %
	(in millions)			
For the three months ended March 31:				
Research and development revenue	$ 13.4	$ 6.3	$ 7.1	112%

Research and development revenue in the three months ended March 31, 2011 is comprised of revenue from the Daiichi Sankyo development and research collaborations agreements entered into in 2008 and the Kyowa Hakko Kirin exclusive license agreement. The increase in the three month period is primarily due to revenue from Daiichi Sankyo.

Under the terms of our tivantinib collaboration agreement with Daiichi Sankyo we share development costs equally with our share of Phase 3 costs funded from milestones and royalties. In each quarter the tivantinib collaboration costs that we incur are compared with those of Daiichi Sankyo. If our costs for the quarter exceed Daiichi Sankyo s we recognize revenue on the amounts due to us under the contingency adjusted performance model. Revenue is calculated on a pro-rata basis using the time elapsed from inception of the agreement over the estimated duration of the development period under the agreement. If our costs for the quarter are less than those of Daiichi Sankyo s, we report the amount due to Daiichi Sankyo as contra-revenue in that quarter. In the quarter ended March 31, 2011 our tivantinib collaboration costs incurred were less than those of Daiichi Sankyo s by $5.0 million and accordingly that amount was recognized as contra-revenue and was netted against our tivantinib Daiichi Sankyo research and development revenue.

Table of Contents

The $7.1 million revenue increase in the quarter ended March 31, 2011 is primarily due to $11.4 million of revenue recognized on the $25 million milestone payment from Daiichi Sankyo triggered by the dosing of the first patient in the Phase 3 NSCLC clinical trial. This revenue increase was partially offset by $5.0 million of contra revenue.

Research and development

	2011	2010	Increase (decrease) $	Increase (decrease) %
	(in millions)			
For the three months ended March 31:				
Research and development	$ 11.4	$ 12.4	$ (1.0)	(8)%

Research and development expense in the quarter ended March 31, 2011 decreased by $1.0 million. The decrease is primarily due to the completion of our Phase 2 NSCLC clinical trial. At March 31, 2011 we had 84 employees dedicated to our research and development program compared to 83 at March 31, 2010.

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 our research and development expense to increase 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	Three Months Ended March 31, 2011	Program-to-date
c-Met program tivantinib	Phase 3	$ 2.3	$ 67.3

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, but 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 these types of products to each 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

Table of Contents

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 are not substantially dependent 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 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

	2011	2010	Increase (decrease) $	Increase (decrease) %
	(in millions)			
For the three months ended March 31:				
General and administrative	$ 3.5	$ 3.3	$ 0.2	6%

General and administrative expense increased in the first quarter of 2011 principally due to an increase in non-cash stock-based compensation expense. General and administrative headcount was 29 at March 31, 2011, compared to 28 at March 31, 2010.

Interest income, interest expense and other income (expense)

	2011	2010	Increase (decrease) $	Increase (decrease) %
	(in thousands)			
For the three months ended March 31:				
Interest income	$ 55	$ 310	$ (255)	(82)%
Interest expense	(6)	(122)	(116)	(95)%
Other income (expense)	16	(492)	508	103%

Interest income is comprised primarily of interest income derived from our portfolio of cash, cash equivalents and investments and decreased in the first quarter of 2011 due to a decrease in interest rates. Interest expense was incurred on our notes payable and decreased in the first quarter of 2011 due to a lower outstanding loan balance. Other income (expense) in

Table of Contents

the first quarter of 2011 includes a gain of $16 from the increase in fair value of our auction rate securities. Other income (expense) in the first quarter of 2010 includes a net loss of $492 from the decrease in fair value of our auction rate securities and auction rate securities put option.

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.

Recently Issued Accounting Standards

In October 2009, the FASB issued an accounting standards update (ASU) on Multiple-Deliverable Revenue Arrangements. This standards update amends existing revenue recognition accounting pronouncements and provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. Among other provisions, this guidance eliminates the requirement to have objective evidence for undelivered products and services and instead provides for separate revenue recognition based upon management s best estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Previous accounting principles required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately. Revenue from our existing multiple-deliverable arrangements is recognized over the estimated development period using the contingency adjusted performance model. Under the new approach, revenue for new agreements or material modifications of existing agreements will be recognized based upon the relative selling price of each element in the arrangement. The Company adopted this guidance prospectively on January 1, 2011 and the adoption of this standard did not have a material impact on our financial position and results of operations; however, the new guidance will impact any new collaboration agreements or material modifications to any existing agreements.

In April 2010, the FASB issued ASU No. 2010-17, *Revenue Recognition Milestone Method*. This ASU provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. Under the milestone method of revenue recognition, consideration that is contingent upon achievement of a milestone in its entirety can be recognized as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. This standard provides the criteria to be met for a milestone to be considered substantive which includes that: a) performance consideration earned by achieving the milestone be commensurate with either performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from performance to achieve the milestone; and b) relate to past performance and be reasonable relative to all deliverables and payment terms in the arrangement. The Company adopted this guidance on a prospective basis for milestones on or after January 1, 2011 and the adoption of this standard did not have a material impact on our financial position and results of operations; however, the new guidance will impact any new collaboration agreements or material modifications to any existing agreements.

In January 2011, we adopted ASU No. 2010-06, *Improving Disclosures About Fair Value Measurements* which requires additional disclosure about the amounts of and reasons for significant transfers in and out of Level 1 and Level 2 fair value measurements. In addition, effective for interim and annual periods beginning after December 15, 2010, which for us is January 1, 2011, this standard further requires an entity to present disaggregated information about activity in Level 3 fair value measurements on a gross basis, rather than as one net amount. As this accounting standard only requires enhanced disclosure, the adoption of this newly issued accounting standard did not impact our financial position or 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 o similar meaning. You also can identify them by 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.

Table of Contents

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, our ability to liquidate our investments in auction rate securities 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. Finally, we can not assure that UBS will have adequate financial resources to fulfill its repurchase obligations to us.

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, 2010 filed with the SEC on March 2, 2011, 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 and marketable securities include US Treasury bill funds, money market funds, and U.S. federal and state agency backed certificates, including auction rate securities that have strong credit 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

Table of Contents

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.

Auction rate securities are securities that are structured with short-term interest reset dates of generally less than 90 days, but with contractual maturities that can be well in excess of ten years. At the end of each reset period, which occurs every seven to twenty-eight days, investors can sell or continue to hold the securities at par value. If any of our auction rate securities were to fail an auction, due to sell orders exceeding buy orders, the funds associated with a failed auction would not be accessible until a successful auction occurred, a buyer was found outside the auction process, the underlying securities matured or a settlement with the underwriter is reached. ArQule s marketable securities portfolio at March 31, 2011 included $2.5 million (at cost) and $2.6 million (at cost) at December 31, 2010 invested in auction rate securities that have not successfully auctioned since February 12, 2008.

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 March 31, 2011. 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 March 31, 2011, 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, 2010 filed with the SEC on March 2, 2011, 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. (REMOVED AND RESERVED) None.

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 Chief Financial Officer, filed herewith.

Table of Contents

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: May 5, 2011

/s/ PETER S. LAWRENCE
Peter S. Lawrence
President and Chief Operating Officer
(Principal Financial Officer)

/s/ ROBERT J. WEISKOPF
Robert J. Weiskopf
Vice President of Finance,
Corporate Controller and Treasurer
(Principal Accounting Officer)