

ARQULE INC
Form 10-Q
May 10, 2007

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, 2007

Commission File No. 000-21429

ArQule, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State of Incorporation)

04-3221586

(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 ☒ No ☐

Indicate by check mark whether the registrant is large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check One)

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

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 May 4, 2007:

Common Stock, par value \$.01

35,922,771 shares outstanding

ARQULE, INC.

QUARTER ENDED MARCH 31, 2007

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ARQULE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

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	March 31, 2007	December 31, 2006
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)		
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,136	\$ 6,242
Marketable securities	77,591	89,590
Prepaid expenses and other current assets	3,263	2,162
Total current assets	86,990	97,994
Property and equipment, net	4,140	4,549
Other assets	2,076	2,277
Total assets	\$ 93,206	\$ 104,820
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,364	\$ 10,276
Current portion of deferred revenue	9,609	6,609
Current portion of deferred gain on sale leaseback	552	552
Total current liabilities	19,525	17,437
Restructuring accrual, net of current portion	1,212	1,366
Deferred revenue, net of current portion	1,565	1,967
Deferred gain on sale leaseback, net of current portion	3,958	4,096
Total liabilities	26,260	24,866
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; 35,831,456 and 35,811,709 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively	358	358
Additional paid-in capital	309,382	307,965
Accumulated other comprehensive loss	(73)	(152)
Accumulated deficit	(242,721)	(228,217)
Total stockholders' equity	66,946	79,954
Total liabilities and stockholders' equity	\$ 93,206	\$ 104,820

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

ARQULE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

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	THREE MONTHS ENDED MARCH 31, 2007 2006 (IN THOUSANDS, EXCEPT PER SHARE DATA)	
Revenue:		
Research and development revenue	\$ 1,652	\$ 1,652
Costs and expenses:		
Research and development	13,704	10,511
General and administrative	3,510	2,200
	17,214	12,711
Loss from continuing operations	(15,562)	(11,059)
Investment income	1,058	1,340
Net loss from continuing operations	(14,504)	(9,719)
Income from discontinued operations		14,005
Net income (loss)	\$ (14,504)	\$ 4,286
Basic and diluted net income (loss) per share:		
Net loss from continuing operations	\$ (0.40)	\$ (0.28)
Income from discontinued operations		0.40
Net income (loss) per share	\$ (0.40)	\$ 0.12
Weighted average basic and diluted common shares outstanding	35,823	35,330

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

ARQULE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

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	THREE MONTHS ENDED MARCH 31, 2007 2006 (IN THOUSANDS)	
Cash flows from operating activities:		
Net income (loss)	\$ (14,504)	\$ 4,286
Income from discontinued operations		(14,005)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	476	430
Amortization of premium/discount on marketable securities	(40)	26
Amortization of deferred gain on sale leaseback	(138)	(138)
Non-cash stock compensation	1,362	955
Loss on disposal of fixed assets	121	
Changes in operating assets and liabilities:		
Accounts receivable		6
Prepaid expenses and other current assets	(1,101)	(386)
Other assets	201	(139)
Accounts payable and accrued expenses	(912)	2,437
Restructuring accrual, net of current portion	(154)	(191)
Deferred revenue	2,598	(404)
Net cash used in operating activities from discontinued operations		(2,115)
Net cash used in operating activities	(12,091)	(9,238)
Cash flows from investing activities:		
Purchases of marketable securities	(20,165)	(28,914)
Proceeds from sale or maturity of marketable securities	32,283	39,947
Additions to property and equipment	(188)	(79)
Net cash provided by investing activities	11,930	10,954
Cash flows from financing activities:		
Proceeds from issuance of common stock	55	198
Net cash provided by financing activities	55	198
Net increase (decrease) in cash and cash equivalents	(106)	1,914
Cash and cash equivalents, beginning of period	6,242	4,805
Cash and cash equivalents, end of period	\$ 6,136	\$ 6,719

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

ARQULE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

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We are a clinical-stage biotechnology company organized as a Delaware Corporation in 1993 and are engaged in the research and development of cancer therapeutics. Our mission is to research, develop, and commercialize broadly effective, targeted cancer drugs with reduced toxicities compared to conventional cancer chemotherapeutics. Our expertise in molecular biology enables us to understand certain biological processes that are responsible for numerous types of human cancers and to discover novel drug candidates for these diseases. Our chemistry capabilities derived from our history of providing chemistry services for the pharmaceutical and biotechnology industries enable us to generate product candidates possessing certain pre-selected drug-like properties and a high degree of specificity for cancer cells. 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 products are in clinical-stage development. We are conducting human clinical trials with three product candidates, designated as: ARQ 197, ARQ 501 and ARQ 171. We retain proprietary rights with the exception of certain Asian development and commercial rights licensed to Kyowa Hakko Kogyo, Ltd. (Kyowa) on April 27, 2007 to ARQ 197 and are developing ARQ 501 and ARQ 171 pursuant to a collaboration with Hoffmann-La Roche (Roche).

As part of our business since inception until 2006, we provided chemistry services to collaborators and customers for their discovery programs. In September 2005, we announced a strategic decision to exit our chemistry services operations in order to focus operationally on developing our oncology portfolio. On December 2, 2005, we received notice that our major collaborator and customer, Pfizer Inc (Pfizer), pursuant to the terms of the Collaborative Agreement (Agreement) with ArQule, was terminating the Agreement effective on May 22, 2006. We continued to provide chemistry services to Pfizer through the effective date of termination.

We have prepared the accompanying condensed consolidated financial statements pursuant to the rules and regulations of the 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, 2006 included in our annual report on Form 10-K filed with the SEC on March 12, 2007.

The unaudited condensed consolidated financial statements include, in our opinion, all adjustments (consisting only of normal recurring adjustments) necessary to present fairly our financial position as of March 31, 2007, and the results of our operations and cash flows for the three months ended March 31, 2007 and March 31, 2006. The results of operations for such interim periods are not necessarily indicative of the results to be achieved for the full year.

2. DISCONTINUED OPERATIONS

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On September 27, 2005, we announced our intention to exit our chemistry services operations. We received notice on December 2, 2005 that Pfizer had elected to terminate the Agreement, pursuant to the Agreement terms, effective on May 22, 2006. The Agreement provided for six months prior written notice by either party to the other for termination without cause and, in the event of termination by Pfizer, certain payments to us. In accordance with these provisions, we received approximately \$19.8 million in December 2005 in connection with the termination. This amount was recorded as deferred revenue and was recognized as revenue when compounds were delivered through the termination date. We have fulfilled our compound production obligations under the Agreement, recognized the remaining deferred revenue, and ceased chemistry services operations in 2006.

The net book value of the assets associated with the chemistry services operations, which totaled \$1.4 million, approximated the fair market value of the underlying assets. In December 2006, management

completed the sale of the chemistry services assets, which consisted of commercially available laboratory instrumentation, for approximately \$1.3 million, net of direct costs to sell such assets.

We considered the chemistry services asset group to be a component of an entity, as defined in Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144), since it comprised operations and cash flows that were clearly distinguished, both operationally and for financial reporting purposes, from the remainder of our operations. Pursuant to SFAS 144, we reported the results of the chemistry services component as discontinued operations, since the related cash flows had been eliminated from our ongoing operations and we did not have any significant continuing involvement in the operations of the component or the assets that were disposed.

The following table presents operating results for the discontinued chemical services operations:

	Three Months Ended March 31,	
	2007	2006
Revenue	\$	\$ 21,800
Costs and expenses:		
Cost of revenue		5,818
Restructuring charge		1,977
Total costs and expenses		7,795
Income from discontinued operations	\$	\$ 14,005

3. COMPREHENSIVE INCOME (LOSS)

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Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes unrealized gains (losses) on our available-for-sale securities that are excluded from net income (loss). Total comprehensive income (loss) for the three months ended March 31, 2007 and March 31, 2006 was as follows:

	Three Months Ended March 31,	
	2007	2006
Net income (loss)	\$ (14,504)	\$ 4,286
Unrealized gain on marketable securities	79	12
Comprehensive income (loss)	\$ (14,425)	\$ 4,298

4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

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Accounts payable and accrued expenses include the following at March 31, 2007 and December 31, 2006:

	Three Months Ended March, 31, 2007	December 31, 2006
Accounts payable	\$ 363	\$ 208
Accrued payroll	1,364	1,726
Accrued outsourced pre-clinical and clinical fees	5,790	6,197
Accrued professional fees	396	434
Accrued restructuring-current portion	664	678
Other accrued expenses	787	1,033
	\$ 9,364	\$ 10,276

5. RESTRUCTURING CHARGES

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In 2002, we recorded a restructuring charge associated with abandoning our facility in Redwood City, California, which was comprised of the difference between the remaining lease obligation, which runs through 2010, and our estimate of potential future sublease income. The accrual balance was adjusted in 2003 to reflect a change in estimate due to continued deterioration in the local real estate market. The accrual balance was adjusted again in 2004 as a result of us entering into a sublease for the facility. The remaining facility-related restructuring accrual is primarily comprised of the difference between our lease obligation for this facility, which will be paid out through 2010, and the amount of sublease payments we will receive under our sublease agreement.

Activities against the restructuring accrual in the three months ended March 31, 2006 and March 31, 2007 was as follows:

	Balance as of December 31, 2005	2006 Provisions	2006 Payments	Balance as of March 31, 2006
Termination benefits-discontinued operations	\$	\$ 1,847	\$	\$ 1,847
Other charges-discontinued operations		130	(78)	52
Facility-related	2,706		(191)	2,515
Total restructuring accrual	\$ 2,706	\$ 1,977	\$ (269)	\$ 4,414

	Balance as of December 31, 2006	2007 Provisions	2007 Payments	Balance as of March 31, 2007
Facility-related	\$ 2,044	\$	\$ (168)	\$ 1,876

6. NET INCOME (LOSS) PER SHARE

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Net loss per share is computed using the weighted average number of common shares outstanding. Basic and diluted net income (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 from continuing operations. In accordance with Statement of Financial Accounting Standards (SFAS) No. 128, *Earnings Per Share*, no potential common shares are included in the computation of any diluted per share amounts, including income (loss) per share from discontinued operations, as the Company reported a net loss from continuing operations for all periods presented. Potential common shares, the shares that would be issued upon the exercise of outstanding stock options, were 4,610,118 and 4,618,717 for the three months ended March 31, 2007 and 2006, respectively.

7. STOCK-BASED COMPENSATION AND STOCK PLANS

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Effective January 1, 2006, we adopted the provisions of SFAS No.123(R), Share-Based Payment (SFAS 123 (R)), which establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123(R), 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 employee's 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, 2007 and March 31, 2006.

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

	Three Months Ended March 31,	
	2007	2006
Research and development	\$ 1,020	\$ 423
General and administrative	342	241
Discontinued operations		291
Total stock-based compensation expense	\$ 1,362	\$ 955

In the three months ended March 31, 2007 and March 31, 2006, no stock-based compensation expense was capitalized and there were no recognized tax benefits associated with the stock-based compensation charge. Stock-based compensation expense of \$637, included in research and development was related to Boston Biomedical, Inc. transition costs (see Note 9 Boston Biomedical, Inc. Collaboration in this Form 10-Q).

Option activity under our stock plans for the quarter ended March 31, 2007 was as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2006	3,872,946	\$ 6.66
Granted	1,028,809	6.18
Exercised	(32,516)	4.77
Cancelled	(259,121)	5.78
Outstanding as of March 31, 2007	4,610,118	\$ 6.62
Exercisable as of March 31, 2007	2,375,202	\$ 7.19

The aggregate intrinsic value of options outstanding at March 31, 2007 was \$7.5 million, of which \$4.2 million related to exercisable options. The weighted average fair value of options granted in the three months ended March 31, 2007 and 2006 was \$3.23 and \$4.03 per share, respectively. The intrinsic value of options exercised in the three months ended March 31, 2007 and 2006 was \$70,000 and \$53,000.

The total compensation cost not yet recognized as of March 31, 2007 related to non-vested option awards was \$7.6 million, which will be recognized over a weighted-average period of 4.2 years. During the three months ended March 31, 2007, there were 237,079 shares forfeited with a weighted average grant date fair value of \$4.08 per share. The weighted average remaining contractual life for options exercisable at March 31, 2007 was 5.8 years.

8. RECENT ACCOUNTING PRONOUNCEMENTS

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In September 2006, the FASB issued SFAS No. 157 (SFAS 157), *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This accounting standard is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS 157 is not anticipated to have a material effect on our financial position or results of operations.

9. BOSTON BIOMEDICAL, INC. COLLABORATION

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In January 2007, we entered into a \$5.0 million, eight-month sponsored research agreement with the newly established Boston Biomedical, Inc. (BBI), an independent corporation led by our former chief scientific officer. Approximately 26 former employees of ArQule joined BBI.

BBI is conducting scientific research under the agreement that will include a number of *in vivo* and *in vitro* studies, reports and publications related to mechanisms of action and biomarkers for our lead products, which are in human clinical trials. These products include ARQ 197, ARQ 501 and ARQ 171. We will retain all intellectual property and technology rights related to research conducted by BBI employees under the contract. ArQule has no equity position in BBI.

In connection with the foregoing events, on January 26, 2007, our former chief scientific officer entered into a separation agreement and general release with us and was paid a lump sum severance payment comprised of (i) one year's salary in the amount of \$321 (ii) the average of his cash bonuses over the last two years in the amount of \$110 and (iii) the amount of \$113 to which he was entitled under our Annual Incentive Program for fiscal year 2006.

In addition, he was granted an option to purchase 64,375 shares of our common stock, which is fully vested and exercisable on the date of grant and expires on December 31, 2008. His previously vested option grants covering 216,250 shares were amended to extend the exercise period through December 31, 2007. In connection with his appointment as Chairman of our Scientific Advisory Board, he was granted an additional option to purchase 12,500 shares, which are fully vested and exercisable on the date of grant and will expire ten years after the date of grant. As a result of his separation of service, all his unvested options have lapsed.

Approximately 26 of our former employees joined BBI in January 2007 and each employee who transitioned to BBI executed and delivered a Separation Agreement and General Release. In consideration for entering into such agreement, each employee received a fully-vested option to purchase shares of our common stock with an exercise period terminating December 31, 2008, as well as an amendment to their previously vested stock options to extend the exercise period through December 31, 2007. The total number of fully vested stock options issued to these employees was 87,500, and the total number of stock options that were amended to extend the exercise was 92,504. As a result of separation of service all unvested options of such employees have lapsed.

In the first quarter of 2007, we expensed approximately: \$431 related to lump sum cash payments under the separation and general release agreement with our former chief scientific officer, as well as certain non-cash charges for stock based compensation including \$201 for stock options granted to him, and \$168 arising from the extension of the exercise period of his vested options. Additionally, in the first quarter of 2007 we expensed approximately \$197 for stock options granted to other employees related to their separation agreements and releases, and \$71 arising from the extension of the exercise period of their vested options.

In the first quarter of 2007, in conjunction with the sponsored research agreement we made payments of \$2,287 to BBI, \$1,241 of which is included in research and development expense, and the remaining \$1,046 is reported in prepaid expenses and other current assets.

10. INCOME TAXES

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We adopted the provisions of Financial Standards Accounting Board Interpretation No. 48 (FIN 48) Accounting *for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109* (SFAS 109) on January 1, 2007. As a result of the implementation of FIN 48, we recorded no adjustment for unrecognized income tax benefits. At the adoption date of January 1, 2007 and also at March 31, 2007, we had no unrecognized tax benefits.

We recognize interest and penalties related to uncertain tax positions in income tax expense. As of March 31, 2007, we had no accrued interest or penalties related to uncertain tax positions.

The tax years 2003 through 2006 remain open to examination by the major taxing jurisdictions to which we are subject, which is primarily the U.S.

As of December 31, 2006, we had federal net operating loss (NOL), state NOL, and research and development (R&D) credit carryforwards of approximately \$126,104, \$75,723 and \$13,724 respectively, which can be used to offset future federal and state income tax liabilities and expire at various dates through 2026. Federal net capital loss carryforwards of approximately \$5,000 can be used to offset future federal capital gains and expire at various dates through 2008.

Utilization of NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future provided by Section 382 of the Internal Revenue Code of 1986, as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by section 382, results from transactions increasing 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. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions which, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382, or could result in a change of control in the future upon subsequent disposition. The Company has not currently completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since the Company's formation due to the significant complexity and cost associated with such study and that there could be additional changes in control in the future. If we have experienced a change of control at any time since Company formation, utilization of our NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being presented as an uncertain tax position under FIN 48.

11. SUBSEQUENT EVENT

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On April 27, 2007, we entered into an exclusive license agreement with Kyowa to develop and commercialize ARQ 197, a small molecule, selective inhibitor of the c-Met receptor tyrosine kinase, 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 recorded as deferred revenue at March 31, 2007. An additional \$27 million in upfront licensing fees was received on May 7, 2007 under this agreement. The agreement includes \$123 million in upfront and potential development milestone payments from Kyowa to ArQule, including the \$30 million cash upfront licensing payments. In addition, the agreement includes sales milestone payments. Upon commercialization, ArQule will receive double-digit royalties from Kyowa on net sales of ARQ 197. Kyowa will be responsible for clinical development costs and commercialization of the compound in certain Asian countries, consisting of Japan, China (including Hong Kong), South Korea and Taiwan.

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

OVERVIEW

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We are a clinical-stage biotechnology company organized as a Delaware Corporation in 1993 and are engaged in the research and development of cancer therapeutics. Our mission is to research, develop, and commercialize broadly effective, targeted cancer drugs with reduced toxicities compared to conventional cancer chemotherapeutics. Our expertise in molecular biology enables us to understand certain biological processes that are responsible for numerous types of human cancers and to discover novel drug candidates for these diseases. Our chemistry capabilities derived from our history of providing chemistry services for the pharmaceutical and biotechnology industries enable us to generate product candidates possessing certain pre-selected drug-like properties and a high degree of specificity for cancer cells. 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 products are in clinical-stage development. We are conducting human clinical trials with three product candidates, designated as: ARQ 197, ARQ 501 and ARQ 171. We retain proprietary rights with the exception of certain Asian development and commercial rights licensed to Kyowa on April 27, 2007 to ARQ 197 and we are developing ARQ 501 and ARQ 171 pursuant to collaboration with Roche.

ARQ 197 is the lead product from our Cancer Survival Pathways Program. In pre-clinical studies, ARQ 197 blocks the activity of c-Met, an enzyme believed to play key roles in human cancer, including cancer cell growth, survival, angiogenesis, invasion and metastasis. We believe the inappropriate expression of c-Met in many cancers and its role in multiple signal transduction pathways promoting tumor growth and metastasis render it a highly compelling target for cancer therapy.

ARQ 501 and ARQ 171, the lead product candidates from our Activated Checkpoint Therapy® (ACT) program, are designed to kill cancer cells selectively while sparing normal cells through direct activation of DNA damage response/checkpoint pathways. Based on pre-clinical studies, we believe these compounds activate checkpoint pathways regulated by the E2F-1 regulatory protein, thereby restoring the cell's natural defense mechanism against DNA damage and initiating the process of apoptosis, or programmed cell death, in these cells.

In addition, we maintain a number of pre-clinical programs directed toward molecular targets that we believe play critical roles in the development of human cancers. The targets, mechanisms of action and chemistry related to compounds generated from these programs differ, offering the potential for multiple therapeutic opportunities. We are applying a broad spectrum of chemistry capabilities developed and validated in the course of multiple collaborations with large pharmaceutical companies to our internal oncology drug discovery and development efforts. These capabilities are designed to facilitate the progression of our programs from initial discovery through pre-clinical development.

In September 2005, we announced a strategic decision to exit our chemistry services operations in order to focus operationally on developing our oncology portfolio. We continued to provide chemistry services to Pfizer Inc (Pfizer) under a previous agreement until May 2006, at which time the collaboration with Pfizer was terminated, and we ceased chemistry services operations. We are retaining and continuing to use a broad spectrum of well-established chemistry capabilities in the discovery and development of our oncology portfolio.

We have incurred a cumulative net loss of \$243 million from inception through March 31, 2007. We expect research and development costs to increase throughout 2007, due to clinical testing of our lead product candidates. Although we have generated positive cash flow from operations for the six consecutive years from 2000-2005, these cash flows were attributable to our discontinued chemistry services operations. We recorded a net loss for all but one of those years. We recorded a net loss for 2006 and expect a net loss for 2007.

Our revenue consists of development funding from our alliance with Roche. Under this alliance, we are responsible for advancing drug candidates from early stage development to Phase 2 trials. Roche may opt to license worldwide rights for the development and commercialization of products resulting from this collaboration by paying an option fee. Assuming the successful development and commercialization of a compound under the program, we could receive up to \$276 million in pre-determined payments, plus royalties based on net sales. Additionally, we have the option to co-promote products in the U.S.

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 duration and outcomes of our clinical trials.

Revenue from our chemistry services operations ceased in the second quarter of 2006 as a result of our strategic decision to exit this business and the subsequent decision by Pfizer to terminate its Agreement with us effective on May 22, 2006. From December 2001 until that date, we produced for Pfizer annually an average of approximately 160,000 synthetic chemical compounds and received average annual cash payments of approximately \$50 million for those compounds and related services. The Agreement provided for six months prior written notice by either party to the other for termination without cause and, in the event of termination by Pfizer, certain payments to us. In accordance with these provisions, we received approximately \$19.8 million in December 2005 in connection with the termination.

LIQUIDITY AND CAPITAL RESOURCES

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	March 31, 2007 (in millions)	December 31, 2006	Increase (decrease) \$	%
Cash, cash equivalents and marketable securities	\$ 83.7	\$ 95.8	\$ (12.1)	(13)%
Working capital	67.5	80.6	(13.1)	(16)%

	Q1 2007 (in millions)	Q1 2006	Increase (decrease) \$
Cash flow from:			
Operating activities	\$ (12.1)	\$ (9.2)	(2.9)
Investing activities	11.9	11.0	0.9
Financing activities	0.1	0.2	(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 pre-clinical and clinical studies, laboratory supplies and materials, and professional fees. The sources of our cash flow from operating activities have consisted primarily of payments from our collaborators for services performed or upfront payments for future services. For the three months ending March 31, 2007, our net use of cash was primarily driven by the difference between cash receipts from collaborators, and payments for operating expenses which resulted in a net cash outflow of \$12.1 million.

Cash flow from investing activities. Our net cash provided by investing activities of \$11.9 million in 2007 was comprised of net sales of marketable securities of \$12.1 million. This source of cash was partially offset by acquisitions of fixed assets of \$0.2 million. The composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of the Company's constant evaluation of conditions in financial markets, the maturity of specific investments, and our near term liquidity needs.

Cash flow from financing activities. Our net cash provided by financing activities of \$0.1 million in 2007 was from the issuance of common stock associated with the exercise of outstanding stock options.

Although we were cash flow positive from operations from 1999 through 2005, we were not cash flow positive from operations in 2006 or the first three months of 2007, nor do we expect to be cash flow positive in the remainder of 2007, as a result of our decision to exit our chemistry services operations and the increased cost of developing our clinical candidates. We expect that our available cash and marketable securities, together with cash from operations and investment income, will be sufficient to finance our working capital and capital requirements until early 2009, depending on decisions we may make regarding our clinical trials.

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

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ability to raise additional funds will depend on financial, economic and market conditions and other factors, many of which are beyond our control. There can be no assurance that sufficient funds will be available to us when required, on satisfactory terms, or at all. 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.

Our contractual obligations were comprised of the following as of March 31, 2007 (in thousands):

Contractual Obligations	Payment due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	\$ 29,191	\$ 3,456	\$ 7,836	\$ 6,999	\$ 10,900
Purchase obligations	7,082	7,072	10		
Total	\$ 36,273	\$ 10,528	\$ 7,846	\$ 6,999	\$ 10,900

Included in the total minimum payments for operating leases is approximately \$1.9 million related to abandoned real estate in California, net of contractual sublease income. This net amount has been accrued as a liability as a part of the Company's restructuring charge in 2002 and subsequently adjusted in 2003 and 2004 (see Note 5 Restructuring Charges to the Condensed Consolidated Financial Statements in this Form 10-Q). Purchase obligations are comprised primarily of outsourced pre-clinical and clinical trial expenses and payments to license certain intellectual property to support the Company's research efforts.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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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 3 to the Consolidated Financial Statements included in our Annual Report on Form 10-K.

Research and Development Revenue Recognition

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Under the terms of the Roche agreement, Roche obtained an option to license ArQule's E2F program in the field of cancer therapy. Roche provided immediate research funding of \$15 million, and financial support for ongoing research and development. ArQule is responsible for advancing drug candidates from early stage development into Phase 2 trials. Roche may opt to license worldwide rights for the development and commercialization of products resulting from this collaboration by paying an option fee. Assuming the successful development and commercialization of a compound under the program, ArQule could receive up to \$276 million in pre-determined milestone payments, plus royalties based on net sales. ArQule considers the development portion of the arrangement to be a single unit of accounting under Emerging Issues Task Force No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* for purposes of revenue recognition, and will recognize the initial and ongoing development payments as research and development revenue over the maximum estimated development period. We estimate the maximum development period could extend until December 2009. This period may ultimately be shorter depending upon the outcome of the development work, resulting in accelerated recognition of the development revenue. Milestone and royalty payments will be recognized as revenue when earned. The cost associated with satisfying the Roche contract is included in research and development expense in the Condensed Consolidated Statement of Operations.

RESULTS OF OPERATIONS

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The following are the results of operations for the three months ended March 31, 2007 and 2006:

Revenue

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	2007 (in millions)	2006	Increase (decrease)	
			\$	%
<i>For the three months ended March 31:</i>				
Research and development revenue	\$ 1.7	\$ 1.7		%

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The first quarter of 2007 as compared to the first quarter of 2006: Research and development revenue which remained the same in both years is comprised of revenue from Roche in connection with the alliance agreement.

Research and development

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	2007 (in millions)	2006	Increase (decrease)		
			\$		%
<i>For the three months ended March 31:</i>					
Research and development	\$ 13.7	\$ 10.5	\$ 3.2	30	%

Overview

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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, or the cost to support our alliance agreement with Roche. The expenses incurred by us to third-parties for pre-clinical and clinical trials in the first quarter 2007 and since inception of each program were as follows (in thousands):

Oncology program	Current status	Three Months Ended March 31, 2007	Program-to-date
E2F modulation ARQ 501	Phase 2	\$ 2,419	\$ 22,140
E2F modulation ARQ 171	Phase 1	853	4,461
c-Met program ARQ 197	Phase 1	1,639	7,156

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

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 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 agreement with Roche and the recently announced agreement with Kyowa. In the event that third parties have control over the clinical trial process for a product, the estimated completion date would largely 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 are unable to determine 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.

The first quarter of 2007 as compared to the first quarter of 2006: The increase in research and development expense in the first quarter of 2007 is primarily due to \$1.2 million of costs incurred in conjunction with our sponsored research agreement with BBI and a \$0.8 million increase in outsourced pre-clinical, clinical and manufacturing required to advance our oncology programs, principally ARQ 197, ARQ 501 and ARQ 171. In the first quarter of 2007 for those employees who transitioned to BBI, we incurred stock-based compensation charges of \$0.3 million, and we also incurred stock-based compensation charges of \$0.4 million and separation agreement costs of \$0.4 million related to the transition of our former chief scientific officer to BBI. At March 31, 2007, we had 65 employees dedicated to our research and development program, down from 95 employees at March 31, 2006.

General and administrative

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	2007 (in millions)	2006	Increase (decrease)	
			\$	%
<i>For the three months ended March 31:</i>				
General and administrative	\$ 3.5	\$ 2.2	\$ 1.3	60 %

The first quarter of 2007 as compared to the first quarter of 2006: General and administrative expense increased in 2007 primarily due a \$0.5 million increase in personnel related expenses, a \$0.2 increase in consulting fees and a \$0.5 million increase in facility costs which are no longer absorbed by the chemical services operations. General and administrative headcount was 34 at March 31, 2007, compared to 40 at March 31, 2006.

Investment income

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	2007 (in millions)	2006	Increase (decrease)	
			\$	%
<i>For the three months ended March 31:</i>				
Investment income	\$ 1.1	\$ 1.3	\$ (0.2)	(21)%

The first quarter of 2007 as compared to the first quarter of 2006: Investment income is derived from our portfolio of cash and short-term investments. Investment income decreased year-to-year due to the decreased average portfolio balance.

Net income from discontinued operations

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	2007 (in millions)	2006	Increase (decrease)	
			\$	%
<i>For the three months ended March 31:</i>				
Net income	\$	\$ 14.0	\$ (14.0)	(100)%

The first quarter of 2007 as compared to the first quarter of 2006: The decrease in income from the chemical services operations, discontinued operations, in the first quarter of 2007 reflects the termination of the Pfizer collaboration during the second quarter of 2006.

RECENT ACCOUNTING PRONOUNCEMENTS

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In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157 (SFAS 157), *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This accounting standard is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS 157 is not anticipated to have a material effect on our financial position or results of operations.

FORWARD LOOKING STATEMENTS

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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 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.

In this report we make forward-looking statements regarding our drug development pipeline and our Phase 1 and 2 monotherapy and combination therapy clinical trials involving ARQ 501 and ARQ 197, and the second generation ACT compound, ARQ 171. Additional forward-looking statements relate to our agreement with Kyowa, including potential future milestones and royalty payments that could result from the future development of ARQ 197.

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 unpredictable 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 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, 2006 filed with the SEC on March 12, 2007, 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

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As part of our investment portfolio we own financial instruments that are sensitive to market risk. Our investment portfolio is used to preserve our capital until it is used to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes. We invest our cash primarily in money market mutual funds and U.S. federal and state agency backed obligations and other investment grade debt securities. These investments are evaluated quarterly to determine the fair value of the portfolio. Our investment portfolio includes only marketable securities with active secondary or resale markets to help ensure liquidity. We have implemented policies regarding the amount and credit ratings of investments. Due to the conservative nature of these policies, we do not believe we have material exposure from market risk.

The carrying amounts reflected in the Condensed Consolidated Balance Sheet of cash and cash equivalents, trade receivables, and trade payables approximate fair value at March 31, 2007 due to the short-term maturities of these instruments.

ITEM 4. CONTROLS AND PROCEDURES

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Under the supervision and with the participation of the Company's President and Chief Executive Officer and Chief Financial Officer (its principal executive officer and principal accounting and financial officer), the Company has evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended). Based on that evaluation, the President and Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures as of March 31, 2007 are effective in recording, processing, summarizing and reporting the financial results of the Company's operations. There were no changes in the Company's internal controls and procedures over financial reporting during the quarter ended March 31, 2007 that have materially affected, or are reasonably likely to materially affect, the 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, 2006 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. CHANGES IN SECURITIES AND USE OF PROCEEDS. None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES. None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS. None.

ITEM 5. OTHER INFORMATION. As previously reported in a Form 8-K filed on April 27, 2007, the Company entered into an exclusive license agreement with Kyowa to develop and commercialize in Japan and certain other Asian countries, ARQ 197. At this time, the Company intends to file a copy of the license agreement as an exhibit to the Company's Form 10-Q for the quarter ended June 30, 2007 on or about August 9, 2007.

ITEM 6. EXHIBITS

EXHIBIT

NO.	DESCRIPTION
3.1	Amended and Restated By-laws of ArQule, Inc. (1)
10.1	Scientific Advisory Board Chairman Agreement, by and between the Company and Chiang J. Li, M.D., dated January 26, 2007. (2)
10.2*	Separation Agreement and General Release, by and between the Company and Chiang J. Li, M.D., dated January 26, 2007. (3)
10.3+	Research Agreement, by and between the Company and BBI, dated January 26, 2007. (4)
10.4*	Amended and Restated 1996 Director Stock Option Plan. (5)
10.5*	Amended and Restated 1996 Employee Stock Purchase Plan. (6)
31.1	Rule 13a-14(a) Certificate of Chief Executive Officer (7)
31.2	Rule 13a-14(a) Certificate of Chief Financial Officer (7)
32	Rule 13a-14(b) Certificate of Chief Executive Officer and Chief Financial Officer (7)

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- (1) Previously filed as Exhibit 3.1 to the Company's Current Report on Form 8-K dated March 27, 2007 and incorporated herein by reference.
- (2) Previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated February 1, 2007 and incorporated herein by reference.
- (3) Previously filed as Exhibit 10.2 to the Company's Current Report on Form 8-K dated February 1, 2007 and incorporated herein by reference.
- (4) Previously Filed as Exhibit 10.1 to the Company's Current Report on Form 8-K/A dated March 7, 2007 and incorporated herein by reference.
- (5) Previously filed as Appendix A to the Company's Definitive Proxy Statement filed on April 16, 2007 and incorporated herein by reference.
- (6) Previously filed as Appendix B to the Company's Definitive Proxy Statement filed on April 16, 2007 and incorporated herein by reference.
- (7) Filed herewith.

* Indicates a management contract or compensatory plan.

+ Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended or Rule 24b-2 of the Securities and Exchange Act of 1934, as amended.

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 10, 2007

/s/ RICHARD H. WOODRICH
Richard H. Woodrich

Acting Chief Financial Officer
(Principal Accounting and Financial Officer)
