ARQULE INC
Form 10-Q
May 07, 2004

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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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, 2004

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)

(Registrant s Telephone Number, including Area Code)

(781) 994-0300

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 Exchange 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 þ No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes þ No o

Number of shares outstanding of the registrant s Common Stock as of May 4, 2004:

Common Stock, par value $.01	28,825,522 shares outstanding

ARQULE, INC.

QUARTER ENDED MARCH 31, 2004

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ARQULE, INC.

CONSOLIDATED BALANCE SHEET (UNAUDITED)

	March 31, 2004	December 31, 2003
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,965	$ 32,139
Marketable securities	41,833	44,585
Accounts receivable	10,366	741
Prepaid expenses and other current assets	2,801	2,455
Total current assets	70,965	79,920
Property and equipment, net	46,207	47,942
Other assets	427	562
	$ 117,599	$ 128,424
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 10,400	$ 14,468
Current portion of long-term debt	4,494	5,980
Current portion of deferred revenue	5,433	4,774
Total current liabilities	20,327	25,222
Long-term debt, net of current portion	966	1,218
Deferred revenue, net of current portion	14,921	15,507
Total liabilities	36,214	41,947
Stockholders equity:		
Common stock, $0.01 par value; 30,000,000 shares authorized; 28,731,958 and 28,724,771 shares issued and outstanding at March 31, 2004 and December 31, 2003, respectively	287	287
Additional paid-in capital	270,765	270,663
Accumulated other comprehensive income	(80)	(137)
Accumulated deficit	(189,587)	(184,336)
Total stockholders equity	81,385	86,477
	$ 117,599	$ 128,424

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

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ARQULE, INC.

CONSOLIDATED STATEMENT OF OPERATIONS (UNAUDITED)

	Three Months Ended March 31,	
	2004	2003
	(In thousands, except per share data)	
Revenue:		
Compound development revenue	$ 11,493	$ 15,653
Compound development revenue related party	268	
Total revenue	11,761	15,653
Costs and expenses:		
Cost of revenue	8,404	9,333
Cost of revenue related party	134	
Research and development	4,968	4,567
Marketing, general and administrative	2,603	2,647
Restructuring charge	1,072	
Total costs and expenses	17,181	16,547
Loss from operations	(5,420)	(894)
Net investment income	169	144
Net loss	$ (5,251)	$ (750)
Basic and diluted net loss per share	$ (0.18)	$ (0.03)
Weighted average common shares outstanding basic and diluted	28,729	21,691

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

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ARQULE, INC.

CONSOLIDATED STATEMENT OF CASH FLOWS (UNAUDITED)

	Three Months Ended March 31,	
	2004	**2003**
	(In thousands)	
Increase (decrease) in cash and cash equivalents		
Cash flows from operating activities:		
Net loss	$ (5,251)	$ (750)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,839	2,800
Non-cash restructuring charge	76	
Changes in operating assets and liabilities:		
Accounts receivable	(9,625)	(1,896)
Prepaid expenses and other current assets	(346)	(858)
Other assets	135	
Accounts payable and accrued expenses	(4,060)	(4,979)
Deferred revenue	73	188
Net cash used in operating activities	(17,159)	(5,495)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(7,249)	(6,640)
Proceeds from sale or maturity of marketable securities	10,034	10,758
Additions to property and equipment	(103)	(287)
Net cash provided by investing activities	2,682	3,831
Cash flows from financing activities:		
Principal payments of long-term debt	(1,738)	(1,875)
Proceeds from issuance of common stock	29	5,061
Net cash provided by/(used in) financing activities	(1,709)	3,186
Effect of foreign exchange rates on cash and cash equivalents	12	(146)
Net increase/(decrease) in cash and cash equivalents	(16,174)	1,376
Cash and cash equivalents, beginning of period	32,139	40,283
Cash and cash equivalents, end of period	$ 15,965	$41,659

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

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ARQULE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Nature of Operations

We are a biotechnology company engaged in the research and development of small molecule cancer therapeutics based on a novel biological approach to cancer, our Activated Checkpoint Therapy[SM] (ACT[SM]) platform, and our expertise in small molecule chemistry and intelligent drug design. We also provide fee-based services to pharmaceutical companies and biotechnology companies, using our chemistry based technology and expertise to attract collaborators. We have an experienced and highly qualified scientific and management team that can apply our chemistry technology platform to produce compounds that have medicinal attributes.

We are subject to risks common to companies in the biotechnology, medical services and diagnostics industries, including but not limited to, development by the company or our competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with governmental regulation.

2. Basis of Presentation

We have prepared the accompanying consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission. 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 consolidated financial statements should be read in conjunction with our audited financial statements and footnotes related thereto for the year ended December 31, 2003 included in our annual report on Form 10-K filed with the Securities and Exchange Commission on March 12, 2004. The unaudited 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, 2004, and the results of our operations and cash flows for the three months ended March 31, 2004 and March 31, 2003. The results of operations for such interim periods are not necessarily indicative of the results to be achieved for the full year.

3. Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income. Other comprehensive income includes certain changes in stockholders equity that are excluded from net loss. Other comprehensive income includes unrealized gains and losses on our available-for-sale securities and interest rate swaps and foreign currency translation amounts. Total comprehensive loss for the three months end March 31, 2004 and March 31, 2003 were as follows (in thousands):

	2004	2003
Net loss	$(5,251)	$(750)
Unrealized gain on marketable securities and interest rate swaps	42	66
Foreign currency translation adjustments	15	(172)
Comprehensive loss	$(5,194)	$(856)

4. Restructuring Actions

In the first quarter of 2004, we implemented a restructuring to shift resources from our chemical technologies business to our internal cancer therapy research. The restructuring included the termination of 53 staff and managerial employees, or approximately 18% of the workforce, in the following areas: 30 in chemistry production positions, 7 in chemistry-based research and development positions and 16 in administrative positions. In connection with these actions we recorded a restructuring charge of $1.1 million in the first quarter of 2004 for termination benefits.

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Current quarter activity against the restructuring accrual (which is included in accrued liabilities in the Consolidated Balance Sheet) was as follows (in thousands):

	Balance as of December 31, 2003	1st Quarter Provisions	1st Quarter Payments	Balance as of March 31, 2004
Termination benefits	$ 10	$1,072	$(587)	$ 495
Facility related	6,160		(318)	5,842
Other charges	69		(32)	37
Total restructuring accrual	$6,239	$1,072	$(937)	$6,374

As of March 31, 2004, substantially all employee terminations are complete and all remaining termination benefits will be paid by August 31, 2004. Facility costs will be paid out through the remaining lease term of the California facility, which extends through 2010, unless we are able to offset such costs by subleasing the facility or settling our leasehold position by paying to the landlord a lump-sum payment on favorable terms.

5. Loss Per Share

The computations of basic and diluted loss per common share are based upon the weighted average number of common shares outstanding and potentially dilutive securities. Potentially dilutive securities include stock options. Options to purchase 4,447,996 and 3,959,952 shares of common stock were not included in the March 31, 2004 and March 31, 2003 computations of diluted net loss per share, respectively, because inclusion of such shares would have an anti-dilutive effect on net loss per share.

We apply APB No. 25 and related interpretations in accounting for option grants under the Company s stock option plans. Had compensation cost been determined based on the estimated fair value of options at the grant date consistent with the provisions of SFAS No. 123, our pro forma net loss and pro forma basic and diluted net loss per share would have been as follows for the three months ended March 31, 2004 and 2003:

	2004	2003
Net loss ($000s):		
Net loss as reported	$(5,251)	$ (750)
Add: Stock based employee compensation expense included in reported net loss		
Less: Total stock-based employee compensation under the fair value method of SFAS 123	(2,955)	(3,668)
Pro forma net loss	$(8,206)	$(4,418)
Basic and diluted net loss per share:		
As reported	$ (0.18)	$ (0.03)
Pro forma	$ (0.29)	$ (0.20)

For the purposes of pro forma disclosure, the estimated value of each employee and non-employee option grant was calculated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option-pricing models require the use of highly subjective assumptions, including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective assumptions can materially affect the fair value estimates, in management s opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock-based compensation. The model was calculated using the following weighted-average assumptions: no dividend yield for all years; volatility of 95% for 2003 and 2004; risk-free interest rates of 3.85% in 2003 and 1.5% in 2004; and expected lives of five years for 2003 and 2004 for options granted.

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6. Contingencies Medford Lease

ArQule leases approximately 56,000 square feet of laboratory and office space in Medford, Massachusetts. The Company leases this facility from Cummings Properties, LLC (Cummings) under two lease agreements, one of which expires on July 30, 2005 and one of which expires on July 30, 2006. The Company subleases portions of these facilities pursuant to two sublease agreements.

On August 1, 2001, Cummings significantly raised ArQule s rent on the lease that expires July 30, 2006. We believe this increase to be in excess of that which is permissible under the lease agreement. Accordingly, on January 16, 2002, we brought a complaint for declaratory relief and damages against Cummings arising, in part, out of Cummings attempts to increase the lease rates. Nevertheless, during the pendency of this dispute, we are paying the rental rates proposed by Cummings. The Company seeks recovery of the excess funds that it has already paid, and is paying, under protest. Management has made an estimate of the most likely outcome of this contingency and has concluded that no provision is required at March 31, 2004. However, if we are unsuccessful in our claim against Cummings, and must pay all or a portion of the rental expense increase currently proposed by Cummings, we may be required to record an additional expense of up to approximately $700,000 to record the difference between our contractual rental payments and contractual sublease rental income over the remaining period of the lease. Conversely, if the contingency is resolved in ArQule s favor and the Company is entitled to a refund of amounts previously paid, the Company may record a gain in a future period.

7. Pfizer Inc.

Since the inception of our relationship with Pfizer Inc. in 1999, we have produced collections of chemical compounds exclusively for Pfizer using our automated high-speed compound production system. Pfizer also received a non-exclusive license to use this system in its internal production program. We expanded this contract in December 2001 to a seven-year agreement. We renegotiated this contract again in early February 2004. Under the amended terms of the contract ArQule will continue to work with Pfizer s scientists to more closely match its compound deliveries to those libraries which Pfizer believes have the greatest developmental opportunity. Under this new agreement, ArQule will maintain compound deliveries at approximately the same level to be supplied in 2004 instead of increasing compound deliveries as specified in the previous agreement. If our amended relationship with Pfizer is successful, we could earn up to $291 million over the term of the contract (2001 2008). This will result in a decrease in the total potential contract value of $55 million compared to the terms agreed to in 2001.

In May 2003, the Financial Accounting Standards Board issued Emerging Issues Task Force 00-21, Accounting for Revenue Arrangements with Multiple Deliverables, (EITF 00-21). EITF 00-21, which became effective for contracts entered into after July 1, 2003, addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting for purposes of revenue recognition. In applying the guidance, revenue arrangements with multiple deliverables can only be considered as separate units of accounting if: a) the delivered item has value to the customer on a standalone basis, b) there is objective and reliable evidence of the fair value of the undelivered items and c) if the right of return exists, delivery of the undelivered items is considered probable and substantially in the control of the vendor. If these criteria are not met, the revenue elements must be considered a single unit of accounting for purposes of revenue recognition. We concluded that the modification was substantial enough to require evaluation of the contract to determine if EITF 00-21 applied. We concluded that because the contract does contain multiple deliverables (license to technology, research services and compound deliveries) EITF 00-21 did apply. We determined that there was not sufficient evidence of fair value of the undelivered elements (compound delivery), and therefore the amended contract represented a single unit of accounting for revenue recognition purposes. As a result, in the first quarter of 2004 ArQule began treating the amended Pfizer agreement as a single unit of accounting and recognizing revenue based on the delivery and acceptance of compounds against the contractual compound delivery schedule.

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8. Subsequent Event

On April 2, 2004, ArQule announced an alliance with Hoffmann-La Roche (Roche) to discover and develop drug candidates targeting the E2F biological pathway. The alliance includes a compound which is currently in phase 1 clinical development. Under the terms of the agreement, Roche obtained an option to license ArQule s E2F program in the field of cancer therapy. Roche will provide immediate research funding of $15 million, and financial support for ongoing research and development. ArQule will be 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 payments, plus royalties based on net sales. Additionally, ArQule has the option to co-promote products in the U.S.

ArQule considers the arrangement to be a single unit of accounting under EITF 00-21 for purposes of revenue recognition, and will recognize the initial payment and the ongoing payments for research and development over the estimated development period. The Company estimates the development period will extend until December 2009, although this period may ultimately be shorter pending the outcome of the development work. Milestone and royalty payments will be recognized as revenue when earned.

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

Overview

We are a biotechnology company engaged in the research and development of small molecule cancer therapeutics. We also provide fee-based chemistry services to pharmaceutical and biotechnology companies to produce novel chemical compounds with drug-like characteristics.

We have incurred a cumulative net loss of $190 million from inception through March 31, 2004. Our losses prior to the acquisition of Cyclis Pharmaceuticals, Inc. in September 2003 related to development activities associated with our chemistry services, the associated administrative costs required to support those efforts, and the cost of acquisitions. We expect research and development costs to increase in 2004 as we pursue development of our cancer programs. We do not expect to make additional investments to expand chemistry services capacity during 2004. Although we have generated positive cash flow from operations for the last five years, we have recorded a net loss in all but one of those years, and expect to record a loss for 2004. Based on our cash position at the end of 2003 we will be able to dedicate approximately $25 million per year over the next three years to our oncology research and development program. This estimate is based upon the assumption that we will continue to operate our chemistry services on a cash flow positive basis, and to invest in cancer related research and development.

Our revenue is primarily derived from compound development chemistry services performed for our customers. Revenue, expenses and gross margin fluctuate from quarter to quarter based upon contractual deliverables and the timing of the recognition of revenue under our revenue recognition policy (see the discussion of this under Critical Accounting Policies below). As we increase our activities in cancer related research and development, the timing and extent of these efforts, together with the length and outcome of our clinical trials, will further impact the fluctuation of results from operations. While our focus will be on cancer related research and development, we will continue to pursue revenue opportunities from our chemistry services.

In February 2004, we amended our contract with Pfizer. Under the amended terms of the contract ArQule will continue to work with Pfizer s scientists to more closely match its compound deliveries to those libraries which Pfizer believes have the greatest developmental opportunity. Under this new agreement, ArQule will maintain compound deliveries at approximately the same level to be supplied in 2004 instead of increasing compound deliveries as specified in the previous agreement. If our amended relationship with Pfizer is successful, we could earn up to $291 million over the term of the contract (2001 2008). This will result in a decrease in the total potential contract value of $55 million compared to the terms agreed to in 2001.

On April 2, 2004 we announced an alliance with Roche to discover and develop drug candidates targeting the E2F biological pathway. The alliance includes a compound that is currently in phase 1 clinical development. Under the terms of the agreement, Roche obtained an option to license our E2F program in the field of cancer therapy. Roche will provide immediate research funding of $15 million, and significant financial support for ongoing research and development. We will be 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, 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.

This report, including the Management s Discussion and Analysis of Financial Condition and Results of Operation (MD&A), contains statements reflecting management s current expectations regarding our future performance. These statements are forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements also may be included in other statements that we make. All statements that are not descriptions of historical fact are forward-looking statements, based on estimates, assumptions and projections that are subject to risks and uncertainties. These statements can generally be identified by use of forward looking terminology such as believes , expects , intends , may , will , should , anticipates

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or similar terminology. Although we believe that the expectations reflected in such forward looking statements are reasonable as of the date thereof, such expectations are based on certain assumptions regarding the progress of product development efforts under collaborative agreements, the execution of new collaborative agreements and other factors relating to our growth. Such expectations may not materialize if product development efforts, including any necessary trials of our potential drug candidates, are delayed or suspended, if positive early results are not repeated in later studies or in humans, if planned acquisitions or negotiations with potential collaborators are delayed or unsuccessful, if we are unsuccessful at integrating acquired assets or technologies, if our planned transition to a drug discovery and development company takes longer or is more expensive than we anticipated or if other assumptions prove incorrect. As a result, actual results could differ materially from those currently anticipated. See also the risks and uncertainties discussed in our Annual Report on Form 10-K for the year ended December 31, 2003 filed on March 12, 2004.

Liquidity and Capital Resources

	March 31, 2004	December 31, 2003	Increase/(Decrease) $	Increase/(Decrease) %
		(In millions)		
Cash, cash equivalents and marketable securities	$57.8	$76.7	$(18.9)	(25)%
Working capital	50.6	54.7	(4.1)	(7)%

	Q1 2004	Q1 2003		
Cash flow from:				
Operating activities	$(17.2)	$(5.5)	$(11.7)	(212)%
Investing activities	2.7	3.8	(1.1)	(30)%
Financing activities	(1.7)	3.2	(4.9)	(154)%

Cash flow from operating activities. For Q1 2004, the total use of $17.2 million was comprised of an operating loss (excluding non-cash charges) of $3.3 million, an increase in accounts receivable of $9.6 million related to amounts due from Pfizer under the amended collaborative agreement, and a decrease in accounts payable and accruals of $4.1 million resulting from the pay down in Q1 2004 of annual bonuses and other accruals at December 31, 2003. At December 31, 2003, Pfizer had prepaid for a portion of their contractual obligations due in Q1 2004; similar payment obligations for Q2 2004 were received in April 2004. Although cash flow from operations was adversely impacted by the increase in unpaid accounts receivable in Q1 2004, we do not anticipate outstanding accounts receivable will significantly increase in subsequent periods.

Cash flow from investing activities. For Q1 2004, the total source of $2.7 million was primarily comprised of net proceeds from the purchase, sale or maturity of marketable securities. The composition and mix of cash, cash equities and marketable securities may change frequently as a result of the Company s constant evaluation of conditions in financial markets, the timing of specific investments and the Company s near term need for liquidity.

Cash flow from financial activities. For Q1 2004, the total use of $1.7 million was primarily comprised of principal repayments on long-term debt.

We have been cash flow positive from operations for five consecutive years. We expect that our available cash and marketable securities of $58 million at March 31, 2004, together with operating revenues and investment income, will be sufficient to finance our working capital and capital requirements for the next three years. In April 2004, we entered into a strategic alliance agreement with Roche, under which we will receive $15 million in immediate research funding and could receive up to $276 million in payments, plus royalties. In addition, we are currently considering raising additional capital through a follow-on public offering of our securities. We have filed a shelf registration statement on Form S-3 with the Security and Exchange Commission covering securities having an aggregate maximum amount of $50 million.

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 any additional corporate collaborations in the future and the terms of such collaborations, results of research and development, the need for currently

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unanticipated capital expenditures, competitive and technological advances, acquisitions and other factors. We cannot guarantee that we will be able to obtain additional customers for our chemistry services, or that such services will produce revenues adequate to fund our operating expenses. We cannot guarantee that we will be able to develop any of our drug candidates into a commercial product. If we experience increased losses, we may have to seek additional financing from public and private sale of our securities, including equity securities. There can be no assurance that additional funding will be available when needed or on acceptable terms.

Our principle contractual obligations were comprised of the following as of March 31, 2004 (in thousands):

	Total	Within 1 Year	Within 1-4 Years	Within 4-7 Years	After 7 Years
Long-term debt obligations	$ 5,208	$4,354	$ 854	$	$
Capital lease obligations	252	140	112		
Operating lease obligations	10,408	2,958	5,197	2,253	
Purchase obligations	5,931	2,201	2,884	495	351
Total	$21,799	$9,653	$9,047	$2,748	$351

Included in the total minimum payments for operating leases is approximately $6.4 million related to unoccupied real estate in California which was accrued as a liability, net of assumed sublease income, as a part of the Company s restructuring actions in 2002, and as adjusted in 2003 (see Restructuring Charges below). 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.

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. See the discussion in our significant accounting policies in Note 2 to the Consolidated Financial Statements included in our Annual Report on Form 10-K for additional information.

Revenue Recognition

Historically, ArQule has entered into various chemistry-based collaborative agreements with pharmaceutical and biotechnology companies under which ArQule produces and delivers compound arrays and other research and development services. In each instance, the Company analyzes each distinct revenue element of the contract to determine the basis for revenue recognition. Revenue for each element is generally recognized over the period compounds are delivered and/or services performed, provided there is a contractual obligation on behalf of the customer to pay ArQule and payment is reasonably assured. The nature of each distinct revenue element, the facts surrounding the services provided and ArQule s ongoing obligations to provide those services dictate how revenue is recognized for each revenue element. This accounting conforms to Generally Accepted Accounting Principles in the United States, in particular Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, and is disclosed more fully in Note 2 to the Consolidated Financial Statements included in our Annual Report on Form 10-K.

In May 2003, the Financial Accounting Standards Board reached a consensus on Emerging Issues Task Force No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21). EITF 00-21 addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting. In applying the guidance, revenue arrangements with multiple deliverables can only be considered as separate units of accounting if: a) the delivered item has value to the customer on a standalone basis, b) there is objective and reliable evidence of the fair value of the undelivered items and c) if the right of return exists, delivery of the undelivered items is considered probable and substantially in the control of the vendor. If these criteria are not met, the revenue elements must be considered a single unit of

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accounting for purposes of revenue recognition. EITF 00-21 became effective for new revenue arrangements entered into after July 30, 2003.

In February 2004, the Company entered into an amended contract with Pfizer. The amendment modified the quantity and composition of compounds to be produced and delivered by ArQule, with a corresponding adjustment to the remaining contractual billings for undelivered elements under the contract. We concluded that the modification was substantial enough to require evaluation of the contract to determine if EITF 00-21 applied. We concluded that because the contract does contain multiple deliverables (license to technology, research services and compound deliveries) EITF 00-21 did apply. We determined that there was not sufficient evidence of fair value of the undelivered elements (compounds), and therefore the amended contract represented a single unit of accounting for revenue recognition purposes. As a result, in Q1 2004 ArQule began treating the amended Pfizer agreement as a single unit of accounting and recognizing revenue based on the delivery and acceptance of compounds against the contractual compound delivery schedule.

Results of Operations

Three months (Q1) ended March 31, 2004 and 2003:

Revenue

	Q1 2004	Q1 2003	Increase/(Decrease) $	Increase/(Decrease) %
			(In millions)	
Revenue	$11.8	$15.7	$(3.9)	(25)%

The decrease primarily reflects a reduction in revenue from Pfizer of $2.2 million, resulting from the February 2004 amendment to the collaborative agreement, and a decrease in revenue of $2.2 million from Bayer whose contract ended in the third quarter of 2003, partially offset by the receipt of a milestone payment from Wyeth resulting from the filing of an Investigative New Drug application with the Food and Drug Administration for a compound, the discovery of which was facilitated by a collaborative program with ArQule. We expect revenue to decrease in 2004 as a result of the amended Pfizer agreement, but to be partially offset for the remainder of 2004 by the inclusion of revenue from the Roche alliance signed in April 2004 for the discovery and development of drug candidates targeting the E2F pathway.

Cost of Revenue and Gross Margin Percentage

	Q1 2004	Q1 2003	Increase/(Decrease) $	Increase/(Decrease) %
			(In millions)	
Cost of revenue	$ 8.5	$ 9.3	$(0.8)	(9)%
Gross margin % of revenue	27.4%	40.4%		(13)% points

Cost of revenue in absolute dollars decreased due to reduced activity in Q1 2004 compared to Q1 2003, plus a reduction in personnel dedicated to the Pfizer program as a result of the amended collaborative agreement. In February 2004, the Company eliminated 30 production positions that were no longer required to service Pfizer, resulting in a savings of approximately $265,000 during the first quarter of 2003. Gross margin percentage decreased due to the overall lower level of revenue available to offset fixed overhead and facility-related expenses. We anticipate cost of revenue in 2004 will continue to be lower than 2003 based on the lower revenue levels.

Research and Development

	Increase/(Decrease)

	Q1 2004	Q1 2003	$	%
			(In millions)	
Research and development	$5.0	$4.6	$0.4	9%

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The increase in research and development expenses reflects the hiring of additional scientists, increased laboratory and facility expenses and the cost of preclinical and clinical studies to develop further the ACTSM platform and ARQ 501. We expect research and development expenses to increase throughout 2004 as we expand our oncology discovery pipeline and begin preclinical and clinical trials as part of the development process.

Marketing General and Administrative

	Q1 2004	Q1 2003	Increase/(Decrease) $	Increase/(Decrease) %
			(In millions)	
Marketing, general and administrative	$2.6	$2.6		

Marketing, general and administrative expenses were essentially flat period over period. In February 2004, the Company eliminated 16 administrative positions as part of its restructuring actions to reallocate resources to its oncology drug discovery efforts, resulting in savings in salaries and benefits of approximately $176,000 during the first quarter of 2004. These savings were offset by higher legal expenses related to the negotiation of the alliance agreement with Roche and increased costs associated with the protection of intellectual property. We anticipate marketing, general and administrative expenses in 2004 will remain approximately the same as 2003.

Restructuring Charges

In the first quarter of 2004, we implemented a restructuring to shift resources from our chemical technologies business to our internal cancer therapy research. The restructuring included the termination of 53 staff and managerial employees, or approximately 18% of the workforce, in the following areas: 30 in chemistry production positions, 7 in chemistry-based research and development positions and 16 in administrative positions. The Company anticipates annualized savings associated with the terminations of approximately $4.4 million. In connection with these actions we recorded a restructuring charge of $1.1 million in the first quarter of 2004 for termination benefits.

Current quarter activity against the restructuring accrual (which is included in accrued liabilities in the Consolidated Balance Sheet) was as follows (in thousands):

	Balance as of December 31, 2003	1st Quarter Provisions	1st Quarter Payments	Balance as of March 31, 2004
Termination benefits	$ 10	$1,072	$(587)	$ 495
Facility related	6,160		(318)	5,842
Other charges	69		(32)	37
Total restructuring accrual	$6,239	$1,072	$(937)	$6,374

As of March 31, 2004, substantially all employee terminations are complete and all remaining termination benefits will be paid by August 31, 2004. Facility costs will be paid out through the remaining lease term of the California facility, which extends through 2010, unless we are able to mitigate such costs by subleasing the facility or settling our leasehold position by paying to the landlord a lump-sum payment on favorable terms.

Net Investment Income

	Q1 2004	Q1 2003	Increase/(Decrease) $	Increase/(Decrease) %

			(In millions)	
Net investment income	$0.2	$0.1	$0.1	17%

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The marginal increase in net investment income reflects reduced interest expense due to lower outstanding debt principal, which more than offset lower interest income on a lower average balance of cash and marketable securities.

Net loss

	Q1 2004	Q1 2003	Increase/(Decrease) $	Increase/(Decrease) %
			(In millions)	
Net loss	$5.3	$0.8	$4.5	600%

The increase in net loss is primarily a result of lower revenue during Q1 2004, as well as lower gross margins, increased research and development spending, and the Q1 2004 restructuring charge.

Item 3. ***Quantitative and Qualitative Disclosures About Market Risk***

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 is held for trading purposes. We invest our cash primarily in money market mutual funds and U.S. Government 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.

Our use of derivative financial instruments is limited to the utilization of two interest rate swap agreements. Any differences paid or received on interest rate swap agreements are recognized as adjustments to interest expense over the life of each swap, thereby adjusting the effective interest rate of the underlying obligations. At March 31, 2004, the Company held one interest rate swap agreement which has a notional amount of $1,950,000 and expires on September 30, 2004. The fair market value of this swap at March 31, 2004 was an unrecognized loss of $13,000 which is included in accrued liabilities.

See Notes 2 and 12 to the consolidated financial statements in ArQule s 2003 Annual Report on Form 10-K filed March 12, 2004 for a description of our use of derivatives and other financial instruments. The carrying amounts reflected in the consolidated balance sheet of cash and cash equivalents, trade receivables, and trade payables approximate fair value at March 31, 2004 due to the short-term maturities of these instruments.

Item 4. ***Disclosure Controls and Procedures***

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 it s disclosure controls and procedures. 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, 2004 are effective in controlling 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, 2004 that have materially affected, or are reasonably likely to materially affect, the internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. ***Legal Proceeding***

This information as set forth in Note 6 of Notes to Consolidated Financial Statements, appearing in Item 1 of Part 1 of this report is incorporated herein by reference.

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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.***

In February 2004, ArQule s Audit Committee pre-approved the use of ArQule s external auditors to prepare the Company s 2003 federal and state income tax returns and to provide miscellaneous tax compliance services.

Item 6(a). ***Exhibits.***

10.49	Strategic Alliance Agreement by and between F. Hoffmann-La Roche Ltd., Hoffmann-La Roche Inc. and ArQule, Inc. dated April 1, 2004.
31.1	Rule 13a-14(a) Certificate of Chief Executive Officer
31.2	Rule 13a-14(a) Certificate of Chief Financial Officer
32	Rule 13a-14(b) Certificate of Chief Executive Officer and Chief Financial Officer

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 Exchange Act of 1934, as amended.

Item 6(b). ***Reports on Form 8-K.***

The Company filed a current report on Form 8-K on February 12, 2004 to file its press release announcing its financial results for the quarter and year ended December 31, 2003.

Through its website at www.arqule.com, the Company makes available, free of charge, its annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and all amendments thereto, as soon as reasonably practicable after such reports are filed with or furnished to the Securities and Exchange Commission.

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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.

/s/ LOUISE A. MAWHINNEY

Louise A. Mawhinney
Vice President, Chief Financial Officer and Treasurer

Date: May 7, 2004

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