CORTEX PHARMACEUTICALS INC/DE/
Form 10-Q/A
February 12, 2004
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U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A

(Mark One)

x **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE**

ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED September 30, 2003

.. **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE**

ACT OF 1934
FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission file number 0-17951

Cortex Pharmaceuticals, Inc.

(Exact name of small business issuer as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**33-0303583** **(I.R.S. Employer Identification No.)**

15241 Barranca Parkway, Irvine, California 92618

(Address of principal executive offices, including zip code)

(949) 727-3157

(Registrant s telephone number, including area code)

NOT APPLICABLE

(Former name, former address and former fiscal year, if changed since last year)

Indicate by mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days.

YES x NO ¨

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2).

YES ¨ NO x

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

28,034,614 shares of Common Stock as of February 9, 2004

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EXPLANATORY NOTE

This Amendment No. 1 on Form 10-Q/A amends Items 1 and 2 of Part I of the Quarterly Report on Form 10-Q previously filed for the quarter ended September 30, 2003 by Cortex Pharmaceuticals, Inc. (the Company). This Form 10-Q/A is filed in connection with the Company s restatement of its financial statements for the three months ended September 30, 2003. Financial statement information and related disclosures included in this Form 10-Q/A reflect, where appropriate, changes as a result of the restatement. All other information contained in this Form 10-Q/A is as of the date of the original filing.

This restatement results from recording additional non-cash charges related to warrants issued in connection with the Company s August 2003 private placement of equity securities. These additional non-cash charges are required by EITF 00-19, Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company s Own Stock. The Company has restated its financial statements for the three months ended September 30, 2003 to record the increase in Black-Scholes value for these warrants from the transaction date of the financing through September 30, 2003, and to adjust certain other items, which, considered in relation to the financial statements taken as a whole, are not material.

The adjustments for applying EITF 00-19 were triggered by the terms of the Company s August 2003 private placement, specifically the potential penalties if the Company did not timely register the common stock underlying the warrants issued in the transaction. The related registration statement was declared effective by the Securities and Exchange Commission within the contractual deadline and the Company incurred no penalties. The adjustments for EITF 00-19 had no impact on the Company s financial position, or the Company s past or future business operations, given that such adjustments represent only non-cash charges.

As required by EITF 00-19, the Company re-classified the estimated fair value of the warrants as of September 30, 2003 to a liability, rather than equity. After the registration statement became effective, as reflected during the quarter ended December 31, 2003, the Company re-classified the estimated fair value of the warrants back to equity, evidencing the non-impact of these adjustments to the Company s financial position or its business operations.

The significant effects of the restatement on the consolidated balance sheet as of September 30, 2003 and the related Statement of Operations for the three months then ended are as follows:

	As Previously Reported	As Restated
At September 30, 2003:		
Other assets capitalized financing costs	$	$ 634,100
Total assets	5,210,692	5,844,792
Common stock warrant liability		8,833,335
Stockholders equity (deficit)	3,048,354	(5,150,881)
For the three months ended September 30, 2003:		
Other expenses increase in fair value of common stock warrants		(3,844,082)
Net loss	(474,580)	(4,318,662)
Net loss per share	$ (0.03)	$ (0.24)

For more information regarding EITF 00-19 and the above restatement, see Note 3 to the Financial Statements.

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CORTEX PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Cortex Pharmaceuticals, Inc.

Balance Sheets

	(Unaudited) September 30, 2003 As restated, See Note 3	*(Note)* June 30, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 4,468,970	$ 1,125,054
Marketable securities	199,885	
Restricted cash	40,070	83,411
Accounts receivable	93,740	428,451
Other current assets	98,279	210,539
Total current assets	4,900,944	1,847,455
Furniture, equipment and leasehold improvements, net	276,341	298,268
Capitalized financing costs	634,100	
Other	33,407	33,407
	$ 5,844,792	$ 2,179,130
Liabilities and Stockholders Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 695,521	$ 852,016
Accrued wages, salaries and related expenses	207,014	213,037
Unearned licensing revenue	988,426	988,426
Unearned research revenue		1,028,752
Advance for Alzheimer s project	271,377	270,140
Total current liabilities	2,162,338	3,352,371
Unearned revenue, net of current portion		247,107
Common stock warrants	8,833,335	
Stockholders deficit:		
Series B convertible preferred stock, $0.001 par value; $0.6667 per share liquidation preference; shares authorized: 3,200,000; shares issued and outstanding: 37,500; common shares issuable upon conversion: 3,679	21,703	21,703
Common stock, $0.001 par value; shares authorized: 30,000,000; shares issued and outstanding: 20,639,526 (September 30) and 17,153,659 (June 30)	20,639	17,153
Additional paid-in capital	43,214,542	42,629,899
Accumulated deficit	(48,407,765)	(44,089,103)

Total stockholders deficit	(5,150,881)	(1,420,348)
	$ 5,844,792	$ 2,179,130

See accompanying notes.

Note: The balance sheet as of June 30, 2003 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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Cortex Pharmaceuticals, Inc.

Statements of Operations

(Unaudited)

	Three months ended September 30,	
	2003	2002
	As restated, see Note 3	
Revenues:		
Research and license revenue	$ 1,275,859	$ 945,801
Grant revenue	61,388	176,642
Total revenues	1,337,247	1,122,443
Operating expenses:		
Research and development expenses	1,140,827	1,115,829
General and administrative expenses	675,064	688,655
Total operating expenses	1,815,891	1,804,484
Loss from operations	(478,644)	(682,041)
Interest, net	4,064	7,636
Increase in fair value of common stock warrants	(3,844,082)	
Net loss applicable to common shares	$ (4,318,662)	$ (674,405)
Basic and diluted net loss per share:	$ (0.24)	$ (0.04)
Shares used in calculating per share amounts		
Basic and diluted	18,320,510	16,849,383

See accompanying notes.

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Cortex Pharmaceuticals, Inc.

Statements of Cash Flows

(Unaudited)

	Three months ended September 30,	
	2003	
	As restated, See Note 3	**2002**
Cash flows from operating activities:		
Net loss	$ (4,318,662)	$ (674,405)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	29,622	38,475
Stock option compensation expense	323,066	60,971
Amortization of capitalized financing costs	10,747	
Increase in fair value of common stock warrants	3,833,335	
Changes in operating assets/liabilities:		
Restricted cash	43,341	
Accounts receivable	334,826	(368,374)
Other current assets	112,260	175,907
Accounts payable and accrued expenses	(162,518)	525,684
Unearned revenue	(1,275,859)	(416,667)
Other current liabilities	1,237	1,468
Net cash used in operating activities	(1,068,605)	(656,941)
Cash flows from investing activities:		
Purchase of marketable securities	(200,000)	
Purchase of fixed assets	(7,695)	(964)
Net cash used in investing activities	(207,695)	(964)
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of stock options	114,992	2,171
Proceeds from issuance of common stock in August 2003 private placement	4,505,224	
Net cash provided by financing activities	4,620,216	2,171
Increase (decrease) in cash and cash equivalents	3,343,916	(655,734)
Cash and cash equivalents, beginning of period	1,125,054	1,849,009
Cash and cash equivalents, end of period	$ 4,468,970	$ 1,193,275

See accompanying notes.

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Cortex Pharmaceuticals, Inc.

Notes to Financial Statements

(Unaudited)

Note 1 Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three-month period ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ending June 30, 2004. For further information, refer to the financial statements and notes thereto included in the Company s 2003 Annual Report on Form 10-K.

In January 1999, Cortex Pharmaceuticals, Inc. (Cortex or the Company) entered into a research collaboration and exclusive worldwide license agreement with NV Organon (Organon). The agreement will enable Organon to develop and commercialize the Company s AMPAKINE® technology for the treatment of schizophrenia and depression. In October 2000, the Company entered into a research collaboration and exclusive license agreement with Les Laboratoires Servier (Servier), in defined territories. The agreement, as amended in October 2002, will enable Servier to develop and commercialize the Company s AMPAKINE technology for the treatment of anxiety disorders and memory impairment associated with aging and neurodegenerative diseases such as Alzheimer s disease (Note 2).

The Company is seeking collaborative arrangements with other pharmaceutical companies for other applications of the AMPAKINE compounds, under which such companies would provide additional capital to the Company in exchange for exclusive or non-exclusive license or other rights to the technologies and products that the Company is developing. Competition for corporate partnering with major pharmaceutical companies is intense, with a large number of biopharmaceutical companies attempting to arrive at such arrangements. Accordingly, although the Company is in discussions with candidate companies, there is no assurance that an agreement will arise from these discussions in a timely manner, or at all, or that an agreement that may arise from these discussions will successfully reduce the Company s short or longer-term funding requirements.

To supplement its existing resources, in addition to seeking licensing arrangements with other pharmaceutical companies, the Company is seeking to raise additional capital through the sale of debt or equity. There can be no assurance that such capital will be available on favorable terms, or at all. If additional funds are raised by issuing equity securities, dilution to existing stockholders is likely to result.

Revenue Recognition

The Company recognizes research revenue from its collaboration with Servier (Note 2) as services are performed under the agreement. The Company records grant revenues as the expenses related to the grant projects are incurred. All amounts received under collaborative research agreements or research grants are nonrefundable, regardless of the success of the underlying research.

Revenues from milestone payments are recognized when earned, as evidenced by written acknowledgement from the collaborator, provided that (i) the milestone event is substantive and its achievement was not reasonably assured at the inception of the agreement, and (ii) the Company s performance obligations after the milestone achievement will continue to be funded by the collaborator at a comparable level to that before the milestone achievement. If both of these criteria are not met, the milestone payment is recognized over the remaining period of the Company s performance obligations under the arrangement. Royalties, if any, will be recognized as earned.

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In November 2002, the Emerging Issues Task Force (EITF) of the Financial Accounting Standards Board reached consensus on Issue 00-21. EITF Issue 00-21 addresses the accounting for arrangements that may involve the delivery or performance of multiple products, services and/or rights to use assets. Specifically, Issue 00-21 requires the recognition of revenue from milestone payments over the remaining minimum period of performance obligations under such multiple element arrangements. As required, the Company will apply the principles of Issue 00-21 to multiple element research and licensing agreements that it may enter into after July 1, 2003.

In accordance with the Securities and Exchange Commission s Staff Accounting Bulletin No. 101 (SAB 101), amounts received for upfront technology license fees under multiple-element arrangements are deferred and recognized over the period of committed services or performance, if such arrangements require the Company s on-going services or performance.

Employee Stock Options and Stock-based Compensation

In December 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure (SFAS 148), which is effective for fiscal years ending after December 15, 2002. SFAS 148 provides alternative methods of transition to the fair value method of accounting for stock-based employee compensation under Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123). SFAS 148 also requires disclosure of the effects of stock-based employee compensation on reported net income or loss and earnings or loss per share in annual and interim financial statements.

As permitted under SFAS 123, the Company has elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25), in accounting for its employee stock options, given that the alternative fair value accounting provided for under SFAS 123 requires use of option valuation models that were not developed for use in valuing employee stock options. According to APB 25, no compensation expense is recognized since the exercise price of the Company s stock options generally equals the market price of the underlying stock on the date of grant. Adoption of SFAS 123 for options issued to employees would require recognition of employee compensation expense based on the computed fair value of the options on the date of grant. In accordance with SFAS 123 and EITF Issue 96-18, Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods and Services, stock options and warrants issued to consultants and other non-employees as compensation for services to be provided to the Company are accounted for based upon the fair value of the services provided or the estimated fair market value of the option or warrant, whichever can be more clearly determined. The Company recognizes this expense over the period in which the services are provided.

Pro forma information regarding net loss and net loss per share has been determined as if the Company had accounted for its employee stock plans under the fair value method. The fair value was estimated at the date of grant using the Black-Scholes option pricing model and the following assumptions for the three-month periods ended September 30, 2003 and 2002, respectively: weighted average risk-free interest rates of 2.1% and 2.7%; dividend yields of 0%; volatility factors of the expected market price of the Company s common stock of 106% and 101%; and a weighted average life of 2.8 years and 4.0 years.

The Black-Scholes option valuation 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 valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Because the Company s 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 estimate, in management s opinion the existing models do not provide a reliable single measure of the fair value of its employee stock options.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized as expense over the vesting period of the options, resulting in the following pro forma information for the three-month

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period ended September 30, 2003:

	Three months ended September 30,	
	2003	2002
Net loss, as reported	$ (4,318,662)	$ (674,405)
Stock-based employee compensation included in net loss	82,844	
Fair value of stock-based employee compensation	(142,813)	(149,647)
Pro forma net loss	$ (4,378,631)	$ (824,052)
Net loss per share:		
Basic and diluted as reported	$ (0.24)	$ (0.04)
Basic and diluted pro forma	$ (0.24)	$ (0.05)

Stock-based employee compensation included in net loss, as detailed above, represents recorded charges for previously re-priced stock options held by employees. The accounting for these re-priced stock options is described more fully immediately below.

In March 2000, the Financial Accounting Standards Board issued FASB Interpretation No. 44 (FIN 44 or the Interpretation), Accounting for Certain Transactions Involving Stock Compensation, an interpretation of APB 25. As required, the Company adopted FIN 44 on July 1, 2000. The Interpretation requires that stock options that have been modified to reduce the exercise price be accounted for as variable. Prior to release of FIN 44, in December 1998 the Company re-priced previously issued stock options to purchase approximately 970,000 shares of common stock to a price of $0.375 per share, which represented the fair market value of the common stock on the date of the re-pricing. By adopting the Interpretation, the Company now applies variable accounting for these options until such options are exercised or forfeited. Of the options re-priced in December 1998, as of September 30, 2003 options to purchase approximately 264,000 shares of the Company s common stock remained outstanding. Consequently, if the market price of the Company s stock increases above $2.50 per share, the fair market value of the Company s common stock on the date that it adopted FIN 44, the Company will recognize additional compensation expense that it otherwise would not have incurred.

For the three months ended September 30, 2003, the effect of applying FIN 44 was an increase in the net loss of $235,000, or $0.01 per share. This amount includes $83,000 for options held by employees, $115,000 for options held by non-employee directors and $37,000 for options held by scientific consultants. Due to fluctuations in the market price of the Company s common stock, for the three months ended September 30, 2002, applying FIN 44 had no impact on the Company s net loss or the net loss per share.

Note 2 Research and License Agreement with Les Laboratoires Servier

In October 2000, the Company entered into a research collaboration and exclusive license agreement with Servier. The agreement will enable Servier to develop and commercialize Cortex s proprietary AMPAKINE technology for the treatment of declines in cognitive performance associated with aging and neurodegenerative diseases. The indications covered include, but are not limited to, Alzheimer s disease, mild cognitive impairment (MCI), sexual dysfunction, and the dementia associated with multiple sclerosis and amyotrophic lateral sclerosis. The territory covered by the exclusive license excludes North America, allowing Cortex to retain commercialization rights in its domestic market. The territory covered by the agreement also excludes South America (except Argentina, Brazil and Venezuela), Australia and New Zealand. The agreement includes an up-front payment by Servier of $5,000,000 and research support payments of approximately $2,000,000 per year for three years ending in early December 2003 (subject to Cortex providing agreed-upon levels of research personnel and subject to annual adjustment based upon the increase in the U.S. Department of Labor s Consumer Price Index). Cortex is eligible to receive milestone payments, based upon

successful clinical development, plus royalty payments on sales in licensed territories.

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In October 2002, Servier and the Company agreed to amend the October 2000 agreement. Under the amendment, Servier will provide Cortex with $4,000,000 of additional research support, in exchange for rights to the Company s AMPAKINE compounds as a potential treatment for anxiety disorders in Servier s licensed territories. The $4,000,000 will be paid in quarterly installments of $500,000 over a two-year period, beginning in October 2002.

Cortex had been recording revenue from Servier s earlier $5,000,000 up-front payment over the three-year collaborative research phase that began in December 2000. With the amendment to the agreement signed in October 2002, Cortex adjusted the period that the Company records the Servier licensing revenue to include the extended research term.

Note 3 Private Placement of Common Stock and Warrants

On August 21, 2003, the Company issued 3,333,334 shares of common stock to accredited investors in a private placement transaction for $1.50 per share, raising gross proceeds of $5,000,000. Net proceeds from the transaction, after issuance costs and placement fees, were approximately $4.5 million. In connection with the transaction, the Company also issued five-year warrants to the investors to purchase up to an additional 3,333,334 shares of the Company s common stock at an exercise price of $2.55 per share. The Company also issued warrants to two placement agents to purchase 30,000 and 83,061 shares of the Company s common stock, respectively. The warrant to purchase 30,000 shares of the Company s common stock has an exercise price of $1.50 per share and a five-year term. The warrant to purchase 83,061 shares of the Company s common stock has an exercise price of $2.71 per share and a three-year term. All of the warrants issued in the transaction provide a call right in favor of the Company to the extent that the price per share of the Company s common stock exceeds $6.00 per share for 13 consecutive trading days, subject to certain circumstances. The Company cannot exercise this call right until the second anniversary of the effective date of the registration statement.

Pursuant to the terms of the registration rights agreement entered into in connection with the transaction, within five calendar days following the date that the Company files its Annual Report on Form 10-K, the Company is required to file, and did file, with the Securities and Exchange Commission (the SEC) a registration statement under the Securities Act of 1933, as amended, covering the resale of all of the common stock purchased and the common stock underlying the warrants, including the common stock underlying the placement agents warrants.

The registration rights agreement further provides that if a registration statement is not filed, or does not become effective, within the defined time period, then in addition to any other rights the holders may have, the Company would be required to pay each holder an amount in cash, as liquidated damages, equal to 2% per month of the aggregate purchase price paid by such holder in the private placement for the common stock and warrants then held, prorated daily. The registration statement was filed within the allowed time, and was declared effective by the SEC on December 8, 2003. As a result, the Company was not required to pay any liquidated damages in connection with the initial registration.

In accordance with EITF 00-19, Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company s Own Stock, and the terms of the warrants and the transaction documents, at the closing date, August 21, 2003, the fair value of the warrants was accounted for as a liability, with an offsetting reduction to additional paid-in capital received in the private placement. The warrant liability will be reclassified to equity as of December 8, 2003, the effective date of the registration statement, evidencing the non-impact of these adjustments on the Company s financial position and business operations.

The fair value of the warrants was estimated using the Black-Scholes option pricing model with the following assumptions: no dividends; risk-free interest rate of 3.37%; the contractual life of 5 years and volatility of 100%. The fair value of the warrants was estimated to be $5,000,000 on the closing date of the transaction. The fair value of the warrants was then re-measured at September 30, 2003 and estimated to be

$8,833,000 with the increase in fair value due to the increase in the market value of the Company s common stock. The increase in fair value of $3,833,000 from the transaction date to September 30, 2003 was recorded as a charge to other expense in the Company s Statement of Operations. The fair value of the warrants decreased by approximately $367,000 from September 30, 2003 to December 8, 2003, and such decrease will be reflected as a decrease to other expense in the Statement of Operations for the quarter ended December 31, 2003.

The adjustments required by EITF 00-19 were triggered by the terms of the Company s agreements for the private placement it completed in August 2003, specifically the potential penalties if the Company did not timely register the common stock underlying the warrants issued in the transaction. The related registration statement was declared effective by the SEC within the contractual deadline and the Company incurred no penalties. The adjustments for EITF 00-19 had no impact on the Company s working capital, liquidity, or business operations.

Note 4 Advance from the Institute for the Study of Aging

In June 2000, the Company received $247,300 from the Institute for the Study of Aging (the Institute) to fund testing of the Company s AMPAKINE CX516 in patients with MCI. Patients with MCI represent the earliest clinically-defined group with memory impairment beyond that expected for normal individuals of the same age and education, but such patients do not meet the clinical criteria for Alzheimer s disease. The Institute is a non-profit foundation based in New York City and dedicated to the improvement in quality of life for the elderly.

The funding from the Institute must be used solely for the Company s clinical trials in MCI patients, which completed testing in mid-August 2003. Although the patients have completed testing in this study, the Company anticipates that additional costs have yet to be billed. Cortex has recorded the unused balance from amounts received from the Institute as restricted cash in the Company s balance sheet. Provided that Cortex complies with the conditions of the funding agreement, including the restricted use of the amounts received, repayment of the advance shall be forgiven unless Cortex enters an AMPAKINE compound into Phase III clinical trials for Alzheimer s disease. Upon such potential clinical trials, repayment would include interest computed at a rate equal to one-half of the prime lending rate. In lieu of cash, in the event of repayment the Institute may elect to receive the balance of outstanding principal and accrued interest as shares of Cortex common stock. The conversion price for such form of repayment shall initially equal $4.50 per share, subject to adjustment under certain circumstances.

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

The following discussion and analysis should be read in conjunction with the Financial Statements and Notes relating thereto appearing elsewhere in this report and with Management s Discussion and Analysis of Financial Condition and Results of Operations presented in the Company s 2003 Annual Report on Form 10-K.

Introductory Note

This Quarterly Report on Form 10-Q contains certain 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, and the Company intends that such forward looking statements be subject to the safe harbors created thereby. These forward-looking statements relate to, among other things, (i) future research plans, expenditures and results, (ii) potential collaborative arrangements, (iii) the potential utility of the Company s proposed products and (iv) the need for, and availability of, additional financing.

The forward-looking statements included herein are based on current expectations, which involve a number of risks and uncertainties and assumptions regarding the Company s business and technology. These assumptions involve judgments with respect to, among other things, future scientific, economic and competitive conditions, and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the control of the Company. Although the Company believes that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate and, therefore, there can be no assurance that the results contemplated in forward-looking statements will be realized and actual results may differ materially. In light of the significant uncertainties inherent in the forward-looking information included herein, the inclusion of such information should not be regarded as a representation by the Company or any other person that the objectives or plans of the Company will be achieved. The Company undertakes no obligation to publicly release the result of any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events. Readers should carefully review the risk factors described in this and other documents that the Company files from time to time with the Securities and Exchange Commission, including Quarterly Reports on Form 10-Q, Annual Reports on Form 10-K and subsequent Current Reports on Form 8-K.

Critical Accounting Policies and Management Estimates

The Securities and Exchange Commission defines critical accounting policies as those that are, in management s view, most important to the portrayal of the Company s financial condition and results of operations and most demanding of its judgment. The Company s discussion and analysis of its financial condition and results of operations are based upon its financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures of contingent assets and liabilities.

The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. This process forms the basis for making judgments

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about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition

The Company s revenue recognition policies are in accordance with the Securities and Exchange Commission s Staff Accounting Bulletin No. 101, Revenue Recognition (SAB 101). SAB 101 provides guidance in applying accounting principles generally accepted in the United States to revenue recognition issues, and specifically addresses revenue recognition for up-front, nonrefundable fees received in connection with research collaboration arrangements.

In accordance with SAB 101, revenues from up-front fees from the Company s collaborators are deferred and recorded over the term that it provides ongoing services. Similarly, research support payments are recorded as revenue as it performs the research under the related agreements. The Company records grant revenues as it incurs expenses related to the grant projects. All amounts received under collaborative research agreements or research grants are nonrefundable, regardless of the success of the underlying research.

Revenues from milestone payments are recognized when earned, as evidenced by written acknowledgment from the Company s collaborator, provided that (i) the milestone event is substantive and its achievement was not reasonably assured at the inception of the agreement, and (ii) the Company s performance obligations after the milestone achievement will continue to be funded by its collaborator at a comparable level to that before the milestone achievement. If both of these criteria are not met, the milestone payment is recognized over the remaining minimum period of the Company s performance obligations under the agreement.

In November 2002, the Emerging Issues Task Force (EITF) of the Financial Accounting Standards Board reached consensus on Issue 00-21. EITF Issue 00-21 addresses the accounting for arrangements that may involve the delivery or performance of multiple products, services and/or rights to use assets. Specifically, Issue 00-21 requires the recognition of revenue from milestone payments over the remaining minimum period of performance obligations. As required, the Company will apply the principles of Issue 00-21 to multiple element agreements that it may enter into after July 1, 2003.

The Company s revenue recognition policies, although critical in management s view, are not the sole accounting policies that it has adopted. In many cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the United States, with no need for management s judgment in their application. There are also areas in which management s judgment in selecting any available alternative would not produce a materially different result.

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Results of Operations

General

In January 1999, the Company entered into a research collaboration and exclusive worldwide license agreement with NV Organon (Organon). The agreement will allow Organon to develop and commercialize the Company s proprietary AMPAKINE® technology for the treatment of schizophrenia and depression. In connection with the agreement, the Company received a $2,000,000 up-front licensing payment and research support payments of approximately $3,000,000 per year for the two years ended in mid-January 2001.

The agreement with Organon also includes milestone payments based upon clinical development, plus royalty payments on worldwide sales. Cortex achieved its first milestone under the agreement in May 2000, when Organon selected a candidate compound to pursue in Phase I clinical testing as a treatment for schizophrenia. Achieving this milestone triggered a $2,000,000 payment to Cortex from Organon, which was recorded as revenue upon achievement.

Cortex achieved its second milestone under the agreement in September 2001, when Organon elected to continue development of the selected compound in Phase II clinical testing. Achieving the second milestone triggered another $2,000,000 payment to Cortex from Organon, with the related revenue recorded upon achievement of the milestone.

In order to retain its rights to the AMPAKINE technology in the field of depression, the agreement with Organon requires a $2,000,000 milestone payment to Cortex on or before January 13, 2004. Organon has notified the Company in writing of its intent to pay this milestone, which Cortex will record as revenue upon achievement.

In October 2000, the Company entered into a research collaboration and exclusive license agreement with Les Laboratoires Servier (Servier). The agreement will allow Servier to develop and commercialize the Company s AMPAKINE technology for the treatment of declines in cognitive performance associated with aging and neurodegenerative diseases. The indications covered include, but are not limited to, Alzheimer s disease, mild cognitive impairment (MCI), sexual dysfunction, and the dementia associated with multiple sclerosis and amyotrophic lateral sclerosis. The agreement includes an up-front payment by Servier of $5,000,000 and research support payments of approximately $2,000,000 per year for three years ending in early December 2003 (subject to Cortex providing agreed-upon levels of research personnel). The agreement also includes milestone payments, plus royalty payments on sales in licensed territories.

In October 2002, in exchange for an additional $4,000,000 of research support, Servier expanded its rights to the AMPAKINE compounds to include the field of anxiety disorders, in its licensed territories. The $4,000,000 will be paid in quarterly installments of $500,000 over a two-year period, beginning in October 2002.

From inception (February 10, 1987) through September 30, 2003, the Company has sustained losses aggregating $46,376,000. Continuing losses are anticipated over the next several years. During that time, the Company s ongoing operating expenses will only be offset, if at all, by proceeds from Small Business Innovative Research (SBIR) grants, research support payments from the collaboration with Servier and by possible milestone payments from Organon and Servier. Ongoing operating expenses may also be funded by payments under planned strategic alliances that the Company is

seeking with other pharmaceutical companies for the clinical development, manufacturing and marketing of its products. The nature and timing of payments to Cortex under the Organon and Servier agreements or other planned strategic alliances, if and when entered into, are likely to significantly affect the Company s operations and financing activities and to produce substantial period-to-period fluctuations in reported financial results. Over the longer term, the Company will be dependent upon the successful introduction of a new product into the North American market from its internal development, as well as the successful commercial development of its products by Organon, Servier or its other prospective partners to attain profitable operations from royalties or other product-based revenues.

Comparison of the Three Months ended September 30, 2003 and 2002

For the three months ended September 30, 2003, the net loss of $4,319,000 compares with a net loss of $674,000 for the corresponding prior year period.

Revenues for the three months ended September 30, 2003 increased from $1,122,000 to $1,337,000, or by 19% compared to the three months ended September 30, 2002, primarily due to increased research revenues from the agreement with Servier.

Research revenues for the current year period include $500,000 related to the amendment to the agreement signed with Servier in October 2002. That amendment granted Servier rights to the Company s AMPAKINE technology in the field of anxiety disorders, in Servier s licensed territories. In exchange for those rights, Cortex will receive $4,000,000 of research support from Servier, paid as $500,000 per quarter over a two-year period.

With the amendment to the agreement, Cortex extended the period that it amortizes licensing revenues from Servier s earlier up-front fee. Under the original October 2000 agreement, Cortex received a $5,000,000 licensing fee from Servier, which Cortex was recording as revenue over that agreement s three-year collaborative research phase. After amending the agreement in October 2002, Cortex began amortizing the remaining unearned licensing revenues over the two-year period of the extended research support. Compared to the corresponding prior year period, licensing revenues for the three months ended September 30, 2003 decreased by $170,000 as a result of this change.

Grant revenues for the three months ended September 30, 2003 decreased by $115,000 relative to the corresponding prior year period due to decreased expenses for the schizophrenia and stroke projects.

Research and development expenses for the three-month period ended September 30, 2003 increased to $1,141,000 from $1,116,000 for the corresponding prior year period. The slight increase primarily represented non-cash stock compensation charges, partially offset by decreased personnel costs due to comparatively lower staffing levels. The stock compensation charges related to earlier re-priced stock options as well as stock options issued to consultants during the period.

General and administrative expenses of $675,000 for the three-month period ended September 30, 2003 were materially consistent with expenses for the corresponding prior year period, with severance costs in the prior year period to the Company s former President and Chief Executive Officer partially offset by non-cash stock compensation charges in the current year period, primarily related to earlier re-priced stock options.

Other expenses include non-cash charges of $3,800,000 recorded for the increase in the estimated fair value of warrants issued in connection with the private equity financing from the transaction date of August 21, 2003 through September 30, 2003. This transaction is described more fully in Note 3 to the Financial Statements.

The Company believes that inflation and changing prices have not had a material impact on its ongoing operations to date.

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Liquidity and Capital Resources

Sources

From inception (February 10, 1987) through September 30, 2003, Cortex has funded its organizational and research and development activities primarily through the issuance of equity securities, funding related to collaborative agreements and net interest income.

Research and licensing payments received in connection with the January 1999 agreement with Organon totaled $11,880,000 as of September 30, 2003. This amount includes a $2,000,000 milestone payment from the agreement, triggered in September 2001 when Organon elected to continue development of an AMPAKINE compound by entering Phase II clinical testing as a potential treatment for schizophrenia.

In order to retain its rights to the Ampakine technology in the field of depression, the agreement with Organon requires a $2,000,000 milestone payment to Cortex on or before January 13, 2004. Organon has notified the Company in writing of its intent to pay this milestone. Under the terms of the agreement, the Company may receive additional milestone payments based on further clinical development of the licensed technology and, ultimately, royalties on worldwide sales.

Under the agreement with Servier signed in October 2000 and amended in October 2002, Cortex received research and licensing payments of $12,814,000 through September 30, 2003. The October 2000 agreement currently provides research support of approximately $2,000,000 per year through early December 2003. The agreement also includes milestone payments based upon successful clinical development and royalties on sales in licensed territories. Beginning in October 2002, Servier agreed to provide the Company an additional $4,000,000 of research support, to be paid in quarterly installments of $500,000 over a two-year period ending in early October 2004.

In October 2000, the Company received notice of a Phase II SBIR award from the National Institutes of Health. The award, as extended, will provide up to $1,074,000 over a four-year period and will support the Company s research of its Ampakine compounds as a potential new therapy for stroke. As of September 30, 2003, Cortex has received approximately $700,000 related to this grant award.

In October 2001, the Company received notice of a second Phase II SBIR award from the National Institutes of Health. This award, as extended, will provide up to $770,000 over a three-year period. The award will allow Cortex to follow-up on previously reported clinical tests of the Ampakine CX516 as a combination therapy for schizophrenia. Earlier tests were encouraging, with Ampakine-treated patients showing improvement in a number of clinical and neurocognitive scores. As of September 30, 2003, Cortex has received approximately $500,000 in connection with this grant award.

In August 2003, the Company completed a private placement of an aggregate of 3,333,334 shares of its common stock at $1.50 per share and five-year warrants to purchase up to an additional aggregate of 3,333,334 shares at an exercise price of $2.55 per share. See Note 3 to the Financial Statements. The Company received approximately $4,500,000 in net proceeds from the private placement. The warrants are subject to a call right in favor of the Company to the extent that the closing price of the Company s common stock exceeds $6.00 per share for any thirteen consecutive trading day period following the second anniversary of the date that the registration statement filed pursuant to the terms of the private placement is first declared effective by the Securities and Exchange Commission, subject to certain conditions. If the warrants are fully exercised, of

which there can be no assurance, these warrants would provide approximately $8,500,000 of additional capital.

Cash Proceeds

As of September 30, 2003, the Company had cash, cash equivalents and marketable securities totaling $4,669,000, accounts receivable of $94,000 and working capital of $2,739,000. In comparison, as of June 30, 2003, the Company had cash and cash equivalents of $1,125,000, accounts receivable of $428,000 and a working capital deficit of $1,505,000. The increases in cash and working capital reflect approximately $4,500,000 of net proceeds from the private placement of the Company s common stock in August 2003, partially offset by amounts required to fund the Company s operations.

As of September 30, 2003 and June 30, 2003, current liabilities included approximately $988,000 of deferred revenue relating to the Company s $5,000,000 non-refundable, up-front payment from Servier in October 2000. In accordance with SAB No. 101, the revenue related to the up-front fee is being amortized over the collaborative research phase that ends, as extended, in early October 2004.

Current liabilities as of September 30, 2003 and June 30, 2003 also included the advance from the Institute for the Study of Aging (the Institute). This advance is being utilized to offset the Company s limited expenses related to the cross national Phase II study in MCI conducted with Servier. According to the agreed-upon terms, repayment of the advance shall be forgiven unless the Company enters Phase III clinical testing for Alzheimer s disease. In the event that the Company enters such clinical trials with one of its AMPAKINE compounds, the Company believes that sufficient resources would become available under its partnering agreements to permit repayment of the advance.

Commitments

The Company leases approximately 32,000 square feet of research laboratory, office and expansion space under an operating lease that expires May 31, 2004. The remaining commitments under the lease agreement for the year ending June 30, 2004 total $201,000. The Company is evaluating whether to renew its current lease or to pursue other leasing opportunities.

Additionally, the Company is committed to $539,000 for sponsored research and other remuneration to academic institutions, all of which is payable over the next twelve months.

Together with its corporate partner, Servier, the Company conducted a cross-national clinical study with the AMPAKINE CX516 in patients with MCI. Preliminary results are expected in either late calendar year 2003 or early calendar year 2004. Servier has agreed to incur the bulk of the related costs for the study. Remaining Cortex commitments for Phase I/IIa clinical studies on the AMPAKINE compounds are not significant.

In June 2000, the Company received $247,000 from the Institute, which will partially offset the Company s limited costs for its testing in patients with MCI. Given that Cortex must use the funding from the Institute solely for the clinical trials, the Company has recorded the unused balance from the amounts received as restricted cash in its balance sheet. Provided that Cortex complies with the conditions of the funding agreement, including the restricted use of the amounts received, repayment

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of the advance shall not be required unless Cortex enters an AMPAKINE compound into Phase III clinical trials for Alzheimer s disease. Upon such potential clinical trials, repayment would include interest computed at a rate equal to one-half of the prime lending rate. In lieu of cash, in the event of repayment the Institute may elect to receive the balance of outstanding principal and accrued interest as shares of Cortex common stock. The conversion price for such form of repayment shall initially equal $4.50 per share, subject to adjustment under certain circumstances.

Staffing

As of September 30, 2003, Cortex had a total of 20 full-time research and administrative employees. Neither significant increases to staffing or substantial investments in plant or equipment are planned through fiscal year 2004.

Outlook

Cortex anticipates that its cash, cash equivalents and marketable securities, the scheduled research support payments from its agreements with Servier and the expected milestone payment from the agreement from Organon will be sufficient to satisfy its capital requirements into fiscal year 2005. Additional funds will be required to continue operations beyond that time. Cortex may receive additional milestone payments from the Organon and Servier agreements. However, there is no assurance that the Company will receive such milestone payments from Organon or Servier within the desired timeframe, or at all.

In order to provide for both its immediate and longer-term capital requirements, the Company is presently seeking additional collaborative or other arrangements with larger pharmaceutical companies. Under these agreements, it is intended that such companies would provide capital to the Company in exchange for an exclusive or non-exclusive license or other rights to certain of the technologies and products that the Company is developing. Competition for such arrangements is intense, however, with a large number of biopharmaceutical companies attempting to secure alliances with more established pharmaceutical companies. Although the Company has been engaged in discussions with candidate companies, there is no assurance that an agreement or agreements will arise from these discussions in a timely manner, or at all, or that revenues that may be generated thereby will offset operating expenses sufficiently to reduce the Company s short and longer-term funding requirements.

Because there is no assurance that the Company will secure additional corporate partnerships, the Company is seeking to raise additional capital through the sale of debt or equity securities. There is no assurance that funds will be available on favorable terms, or at all. If equity securities are issued to raise additional funds, dilution to existing stockholders is likely to result. Such additional capital would, more importantly, enhance the ability of Cortex to achieve significant milestones in its efforts to develop the AMPAKINE technology.

Additional Risks and Uncertainties

The Company s proposed products are in the preclinical or early clinical stage of development and will require significant further research, development, clinical testing and regulatory clearances. They are subject to the risks of failure inherent in the development of products based on innovative technologies. These risks include, but are not limited to, the possibilities that any or all of the proposed products will be found to be ineffective or unsafe, or otherwise fail to receive necessary

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regulatory clearances; that the proposed products, although effective, will be uneconomical to market; that third parties may now or in the future hold proprietary rights that preclude the Company from marketing them; or that third parties will market superior or equivalent products. Accordingly, the Company is unable to predict whether its research and development activities will result in any commercially viable products or applications. Further, due to the extended testing and regulatory review process required before marketing clearance can be obtained, the Company does not expect to be able to commercialize any therapeutic drug for at least five years, either directly or through its current or prospective corporate partners or licensees. There can be no assurance that the Company s proposed products will prove to be safe or effective or receive regulatory approvals that are required for commercial sale.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The Company is exposed to certain market risks associated with interest rate fluctuations on its marketable securities and borrowing arrangement. All investments in marketable securities are entered into for purposes other than trading. The Company is not subject to risks from currency rate fluctuations as it does not typically conduct transactions in foreign currencies. In addition, the Company does not utilize hedging contracts or similar instruments.

The Company s exposure to interest rate risk arises from financial instruments entered into in the normal course of business. Certain of the Company s financial instruments are fixed rate, short-term investments in government and corporate notes and bonds. Changes in interest rates generally affect the fair value of the investments, however, because these financial instruments are considered available for sale, all such changes are reflected in the financial statements in the period affected. The Company manages interest rate risk on its investment portfolio by matching scheduled investment maturities with its cash requirements. As of September 30, 2003, the Company s investment portfolio had a fair value and carrying amount of approximately $200,000. If market interest rates were to increase immediately and uniformly by 10% from levels as of September 30, 2003, the resulting decline in the fair value of fixed rate bonds held within the portfolio would not be material to the Company s financial position, results of operations and cash flows.

The Company s borrowing consists of its advance from the Institute for the Study of Aging, which is subject to potential repayment in the event that Cortex enters an AMPAKINE compound into Phase III clinical testing as a potential treatment for Alzheimer s disease. Potential repayment would include interest accruing at a rate equal to one-half of the prime lending rate. Changes in interest rates generally affect the fair value of such debt, but, based upon historical activity, such changes are not expected to have a material impact on earnings or cash flows. As of September 30, 2003, the principal and accrued interest of the advance amounted to $271,000.

Item 4. Controls and Procedures

The Company performed an evaluation, under the supervision and with the participation of the Company s management, including the Chief Executive Officer (the CEO) and Chief Financial Officer (the CFO), of the effectiveness of the design and operation of the Company s disclosure controls and procedures as of the end of the period covered by this report, pursuant to Rules 13a-15(b) and 15d-15(b) under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based upon that evaluation, the CEO and CFO have concluded that the Company s disclosure controls and procedures, as of the period covered by this report, were effective in timely alerting them

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to material information required to be included in the Company s periodic filings under the Exchange Act. There has been no change in the Company s internal control over financial reporting during the period covered by this report that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

PART II. OTHER INFORMATION

Item 2. Changes in Securities and Use of Proceeds

On August 21, 2003, the Company completed a private placement with a select group of 22 accredited investors and raised an aggregate of $4,500,000 in net proceeds, after deduction of the issuance costs and placement fees related to the sale. Pursuant to the terms of the private placement, the Company issued an aggregate of 3,333,334 shares of the Company s common stock and warrants to purchase up to an additional aggregate of 3,333,334 shares. The warrants have an exercise price of $2.55 per share and a five-year term. In connection with the private placement, the Company also issued two additional warrants to purchase 30,000 and 83,061 shares of the Company s common stock, respectively, to two placement agents. The warrant to purchase 30,000 shares of the Company s common stock has an exercise price of $1.50 per share and a five-year term. The warrant to purchase 83,061 shares of the Company s common stock has an exercise price of $2.71 per share and a three-year term.

The sales and issuances of the foregoing securities were made in reliance upon the exemption from the registration provisions of the Securities Act of 1933, as amended, set forth in Section 4(2) thereof as transactions by an issuer not involving any public offering. The agreements executed in connection with the issuance of the securities contain representations to support the Company s reasonable belief that the purchasers are familiar with or have access to information concerning the operations and financial condition of the Company, and the purchasers are acquiring the securities for investment and not with a view to the distribution thereof. At the time of their issuance, the securities were deemed to be restricted securities for purposes of the Securities Act of 1933, as amended, and the certificates representing the securities bear legends to that effect.

Item 6. Exhibits and Reports on Form 8-K

(a) *Exhibits*

31.1	Certification by Chief Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a), As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by Chief Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a), As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K

On August 22, 2003, the Company filed a Current Report on Form 8-K announcing that it had completed a private placement with a select group of institutional investors with gross proceeds of $5 million.

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On September 22, 2003, the Company filed a Current Report on Form 8-K in connection with the announcement of its earnings for the fiscal year ended June 30, 2003.

SIGNATURES

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

CORTEX PHARMACEUTICALS, INC.

February 12, 2004 By: /s/ MARIA S. MESSINGER

Maria S. Messinger

Vice President and Chief Financial Officer;

Corporate Secretary

(Chief Accounting Officer)

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