## UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

# FORM 10-Q

## /x/ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

# FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2001

Commission File Number 0-9314

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# ACCESS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

83-0221517

(State of Incorporation)

(I.R.S. Employer I.D. No.)

2600 Stemmons Frwy, Suite 176, Dallas, TX 75207

(Address of principal executive offices)

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Telephone Number (214) 905-5100

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 requirement for the past 90 days.

Yes X No

The number of shares outstanding of each of the issuer's classes of common stock, as of May 11, 2001 was 12,850,478 shares of common stock, \$0.01 par value per share.

Total No. of Pages 9

PART I -- FINANCIAL INFORMATION

ITEM 1 FINANCIAL STATEMENTS

The response to this Item is submitted as a separate section of this report.

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

## **OVERVIEW**

Access Pharmaceuticals, Inc. is a Delaware corporation in the development stage. We are an emerging pharmaceutical company

focused on developing both novel low development risk product candidates and technologies with longer-term major product opportunities. Together with our subsidiaries, we have proprietary patents or rights to five technology platforms: synthetic polymers, bioerodible hydrogels, Residerm TM, carbohydrate targeting technology and agents for the prevention and treatment of viral disease, including HIV. In addition, our partner, GlaxoSmithKline, formally Block Drug Company, is marketing in the United States, a product named Aphthasol R, a drug jointly developed, the first U.S. Food and Drug Administration, or FDA, approved product for the treatment of canker sores. We are developing new formulations and delivery forms to evaluate this product in additional clinical indications. We have licensed certain of the rights for amlexanox from GlaxoSmithKline for certain countries excluding the U. S. and the worldwide rights for certain additional indications including mucositis and oral diseases in other territories.

Except for the historical information contained herein, the following discussions and certain statements in this Form 10-Q are forward-looking statements that involve risks and uncertainties. In addition to the risks and uncertainties set forth in this Form 10-Q, other factors could cause actual results to differ materially, including but not limited to our research and development focus, uncertainties associated with research and development activities, clinical trials, uncertainty associated with preclinical and clinical testing, the timing of regulatory approvals, future cash flow, timing and receipt of licensing revenues, collaborations, dependence on others, and other risks detailed in our reports filed under the Securities Exchange Act of 1934, as amended, including but not limited to our Annual Report on Form 10-K for the year ended December 31, 2000.

Since our inception, we have devoted our resources primarily to fund our research and development programs. We have been unprofitable since inception and to date have received limited revenues from the sale of products. We cannot assure you that we will be able to generate sufficient product revenues to attain profitability on a sustained basis or at all. We expect to incur losses for the next several years as we continue to invest in product research and development, preclinical studies, clinical trials and regulatory compliance. As of March 31, 2001, our accumulated deficit was \$33,052,000 of which \$8,894,000 was the result of the write-off of excess purchase price of mergers.

## LIQUIDITY AND CAPITAL RESOURCES

Working capital as of March 31, 2001 was \$23,424,000 representing a decrease in working capital of \$973,000 as compared to the working capital as of December 31, 2000 of \$24,397,000.

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The decrease in working capital was due to the loss from operations for the first quarter of 2001.

Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit as of March 31, 2001 of \$33,052,000. We have funded our operations primarily through private sales of common stock and convertible notes. Contract research payments from corporate alliances and mergers have also provided funding for operations.

We have incurred negative cash flows from operations since inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. We expect that our existing capital resources will be adequate to fund our current level of operations through the year 2002. We will require substantial funds to conduct research and development programs, preclinical studies and clinical trials of potential products. Our future capital requirements and adequacy of available funds will depend on many factors, including:

- \* the successful commercialization of amlexanox;
- \* the ability to establish and maintain collaborative arrangements with corporate partners for the research, development and commercialization of products;
- continued scientific progress in our research and development programs;
- \* the magnitude, scope and results of preclinical testing and clinical trials;
- \* the costs involved in filing, prosecuting and enforcing patent claims;
- \* competing technological developments;
- \* the cost of manufacturing and scale-up;
- \* the ability to establish and maintain effective commercialization arrangements and activities; and
- \* successful regulatory filings.

# FIRST QUARTER 2001 COMPARED TO FIRST QUARTER 2000

Revenue in the first quarter of 2001 was \$211,000, as compared to no revenue in the same period of 2000. Revenue recognized in the first quarter is from several licensing agreements, including various amlexanox projects and ResiDerm TM.

Total research spending for the first quarter of 2001 was \$1,003,000, as compared to \$603,000 for the same period in 2000, an increase of \$400,000. The increase in expenses was the result of:

- \* higher clinical development costs (\$225,000) for amlexanox product development projects for OraRinse TM and OraDisc TM and the polymer platinate clinical development project. The OraRinse TM Phase II trial is ongoing and we anticipate that this study will be completed and the results published in the second quarter. The first Phase III study evaluating OraDisc TM was completed and another Phase III study has started. The Phase I polymer platinate study is ongoing;
- \* higher scientific consulting costs (\$112,000);
- \* higher scientific salary costs (\$63,000) due to additional employees; and,

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\* higher scientific consulting costs (\$41,000) as the results of warrants granted to consultants in 2001.

The increase in expenses was partially offset by:

- \* lower moving expenses for scientific personal (\$34,000); and
- \* other net decreases (\$7,000).

We expect research spending to increase in future quarters and remain higher than in prior quarters as we intend to hire additional scientific and clinical staff, commence additional clinical trials and accelerate preclinical development activities as we continue to develop our product candidates. Total general and administrative expenses were \$436,000 for the first quarter of 2001, an increase of \$7,000 as compared to the same period in 2000. The increase in spending was due primarily to the following:

- \* higher shareholder expenses (\$35,000);
- \* higher patent costs (\$20,000); and
- \* higher salary expenses (\$17,000).

These general and administrative expenses increases were partially offset by:

- \* lower professional fees (\$28,000);
- \* lower license fees (\$16,000);
- \* lower travel and entertainments costs (\$12,000); and
- \* other net decreases (\$9,000).

Depreciation and amortization was \$102,000 for the first quarter of 2001 as compared to \$111,000 for the same period in 2000 reflecting a decrease of \$9,000. The decrease in amortization is due to lower depreciation reflecting that some major assets have been fully depreciated.

Total operating expenses in the first quarter of 2001 was \$1,541,000 as compared to total operating expenses of \$1,143,000 for the same period in 2000.

Loss from operations in the first quarter of 2001 was \$1,330,000 as compared to a loss of \$1,143,000 for the same period in 2000.

Interest and miscellaneous income was \$442,000 for the first quarter of 2001 as compared to \$65,000 for the same period in 2000, an increase \$377,000. The increase in interest income was due to higher cash balances in 2001 resulting from our private placements of common stock and convertible note offering in 2000.

Interest expense was \$283,000 for the first quarter of 2001 as compared to \$2,000 for the same period in 2000, an increase of \$281,000. The increase is interest expense is due to interest accrued on the \$13.5 million convertible notes interest in September 2000 and amortization of debt issuance costs.

Net loss in the first quarter of 2001 was \$1,171,000, or a \$0.09 basic and diluted loss per common share, compared with a loss of \$1,080,000, or a \$0.14 basic and diluted loss per common share for the same period in 2000.

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## PART II -- OTHER INFORMATION

## ITEM 1 LEGAL PROCEEDINGS

The Company is not a party to any material legal proceedings.

## ITEM 2 CHANGES IN SECURITIES

None

ITEM 3 DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4 SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None

## ITEM 5 OTHER INFORMATION

#### None

## ITEM 6 EXHIBITS AND REPORTS ON FORM 8-K

Exhibits:

3.8 Certificate of Amendment of Certificate of Incorporation filed July 31, 2000.

Reports on Form 8-K:

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None

## 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.

## ACCESS PHARMACEUTICALS, INC.

Date: May 14, 2001 By:/s/ Kerry P. Gray

Kerry P. Gray President and Chief Executive Officer (Principal Executive Officer)

Date: May 14, 2001 By:/s/ Stephen B. Thompson

Stephen B. Thompson Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

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Access Pharmaceuticals, Inc. and Subsidiaries (a development stage company)

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Condensed Consolidated Balance Sheets <TABLE> <CAPTION>

CAI HON>	March 31, 2001 December 31, 2000			
Assets	(unaudited)			
<s> Current assets</s>	<c> <c></c></c>			
Cash and cash equivalents	s \$ 4,869,000 \$ 8,415,000			
Short term investments, at				
Accounts receivable	7,000 251,000			
Accrued interest receivable				
Prepaid expenses and othe	er current assets 114,000 133,000			
Total current assets	25,280,000 26,389,000			
Property and equipment, ne	et 109,000 116,000			
Debt issuance costs	816,000 861,000			
Licenses, net	859,000 887,000			
Goodwill, net	2,053,000 2,115,000			
Other assets	158,000 158,000			
Total assets	\$ 29,275,000 \$ 30,526,000			

## LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities

Accounts payable and accrued expenses \$ 796,000 1,158 Accrued interest payable 520,000 283,000 Deferred revenues 540,000 551,000	8,000
Total current liabilities 1,856,000 1,992,000	
Convertible notes 13,530,000 13,530,000	
Total liabilities 15,386,000 15,522,000	
Commitments and contingencies	
Stockholders' equity Preferred stock - \$.01 par value; authorized 2,000,000 shares; none issued or outstanding Common stock - \$.01 par value; authorized 50,000,000 shares; issued, 12,850,478 at March 31, 2001 and 12,844,699 at December 31, 2000 133,000 132,000 Additional paid-in capital 47,857,000 47,802,000 Notes receivable from stockholders (1,045,000) (1,045,0 Treasury stock, at cost - 819 shares (4,000) (4,000) Deficit accumulated during the	
development stage (33,052,000) (31,881,000)	
Total stockholders' equity 13,889,000 15,004,000	

Total liabilities and stockholders' equity \$29,275,000 \$30,526,000

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# </TABLE>

The accompanying notes are an integral part of these statements.

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Access Pharmaceuticals, Inc. and Subsidiaries (a development stage company)

# Condensed Consolidated Statements of Operations (unaudited)

# <TABLE> <CAPTION>

		onths ended	l Marc		
	2001	2000	M	arch 31, 20	
<s></s>		<c></c>			
Revenues					
Research and develo	pment	\$-	\$	- \$2	,711,000
Option income		-	-	2,164,00	00
Option income Licensing revenues		211,000		- 64	3,000
Total revenues Expenses Research and develo General and adminis Depreciation and am Write-off of excess p	pment strative portization	436,00 102,0	000 00 000	- 5,518 603,000 429,000 111,000	) 16,983,000 12,097,000 ) 2,078,000
Total expenses		,541,000			0,052,000
Loss from operation	S 	(1,330,000	)) (1 	,143,000)	(34,534,000)

Other income (expense)			
Interest and miscellaneous income	442,000	65,000	2,299,000

Interest expense	(283,000) (52,000) (817,000)
	159,000 63,000 1,482,000
Net loss	\$(1,171,000) \$(1,080,000) \$(33,052,000)
Basic and diluted loss common share	\$ per \$(0.09) \$(0.14)
Weighted average bas common shares outs	

	The accompanying	g notes are an integral part of these statements.
	7 naceuticals, Inc. and Subsidiaries elopment stage company)	
	onsolidated Statements of Cash Flows naudited)	
	Educion: 24	
	February 24, Three Months ended March 31, 1988	
	(inception) to 2001 2000 March 31, 2001	
~~Cash flows form open Net loss Adjustments to recor to cash used in opera Write-off of excess Warrants issued in p~~	\$(1,171,000) \$(1,080,000) \$(33,052,000) ncile net loss ting activities: purchase price 8,894,000	
consulting expense Research expenses r	related to	
common stock grau Depreciation and an Amortization of deb Deferred revenue Change in operating liabilities:	nortization 102,000 111,000 2,078,000 tt costs 45,000 - 99,000 (11,000) 428,000 430,000	
Accounts receivable Accrued interest re		
Prepaid expenses a current assets	19,000 32,000 (115,000)	
Licenses Other assets	- (100,000) (525,000)  (6,000)	
Accounts payable a	and	
accrued expenses Accrued interest pa	(362,000) 48,000 34,000 ayable 237,000 - 520,000	
Net cash used in oper	rating activities (795,000) (685,000) (20,716,000)	
Purchase of short ter and certificates of de Purchase of business	(5,000) (38,000) (1,250,000) pment 15,000 m investments eposit (2,761,000) (10,960,000) (20,155,000) s, net of	
cash acquired Other investing activ	(226,000) rities (150,000)	
Net cash used in inve	sting activities (2,766,000) (10,998,000) (21,766,000)	
Cash flows from fina		

Proceeds from notes payable Payments of principal on obligations under capital leases721,000Purchase of treasury stock-(20,000)(750,000)Purchase of treasury stock-(750,000)(754,000)Cash acquired in merger with Chemex Notes receivable from shareholders1,587,000Deposits received for private placement-2,967,000-Proceeds from convertible note, net Proceeds from stock issuances, net-12,015,000
Net cash provided by financing activities 15,000 14,233,000 47,351,000
Net increase (decrease) in cash and cash equivalents(3,546,000)2,550,0004,869,000
Cash and cash equivalents at beginning of period 8,415,000 869,000 -
Cash and cash equivalents at end of period \$4,869,000 \$3,419,000 \$4,869,000 ==================================
Cash paid for interest\$-\$2,000\$239,000Cash paid for income taxes
Supplemental disclosure of noncash transactionsPayable accrued for fixed asset purchasepurchase\$ - \$ - \$ 47,000Elimination of note payable to Chemex Pharmaceuticals due to mergerPharmaceuticals due to merger100,000Stock issued for license on patentscapital leases82,000Net liabilities assumed in acquisition of Tacora CorporationAssets acquired including goodwill Liability assumed

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The accompanying notes are an integral part of these statements.

8 Access Pharmaceuticals, Inc. and Subsidiaries (a development stage company)

Notes to Condensed Consolidated Financial Statements Three Months Ended March 31, 2001 and 2000 (unaudited)

## (1) Interim Financial Statements

The consolidated balance sheet as of March 31, 2001 and the consolidated statements of operations and cash flows for the three months ended March 31, 2001 and 2000 were prepared by management without audit. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, except as otherwise disclosed, necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made.

Certain amounts have been reclassified to conform with current period classification.

Certain information and footnote disclosures normally included in financial

statements prepared in accordance with generally accepted accounting principles have been condensed or omitted. It is suggested that these financial statements be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2000. The results of operations for the period ended March 31, 2001 are not necessarily indicative of the operating results which may be expected for a full year. The consolidated balance sheet as of December 31, 2000 contains financial information taken from the audited financial statements as of that date.

## CERTIFICATE OF AMENDMENT OF CERTIFICATE OF INCORPORATION OF ACCESS PHARMACEUTICALS, INC.

Access Pharmaceuticals, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, DOES HEREBY CERTIFY:

FIRST: That at a meeting of the directors of the Corporation, a resolution was duly adopted setting forth a proposed amendment of the Certificate of Incorporation of the Corporation, as previously amended, and declaring such amendment to be advisable and calling a meeting of the stockholders of the Corporation for consideration thereof. The resolution setting forth the proposed amendment is as follows:

RESOLVED: That it is advisable that Article V of the Corporation's Certificate of Incorporation, as amended, relating to the authorized shares of stock of the Corporation be amended to read as follows:

- A. The aggregate number of shares of Common Stock which the Corporation shall have authority to issue is Fifty Million (50,000,000) shares with a par value of one cent (\$0.01) per share.
- B. The aggregate number of shares of preferred stock which the Corporation shall have authority to issue is Two Million (2,000,000) shares with a par value of one cent (\$0.01) per share in one or more series. Each series of preferred stock shall be designated by the board of directors so as to distinguish the shares thereof and the shares of all other series and classes. The board of directors may, by resolution, from time to time divide shares of the preferred stock into series and fix and determine the number of shares and the relative rights and preferences of any series so established, which relative rights and preferences of any series so established may be greater or lesser than those granted to the common stock as provided herein. Notwithstanding the foregoing, all shares of preferred stock shall be identical, except as to the following relative rights and preferences, in respect of any or all of which there may be variations between different series, namely the rate of dividends (including the date from which dividends shall be cumulative), the price at, and the terms and conditions on which, shares may be redeemed, the amounts payable on shares in the event of voluntary or involuntary

liquidation or dissolution, sinking fund provisions for the redemption or purchase of shares in the event shares of any series or issue with sinking fund provisions, and the terms and conditions on which shares of any series may be converted in the event shares of any series are issued a privilege of conversion. Each share of any series of preferred stock shall be identical with all the shares of such series. The consideration for the issuance of shares may be paid in whole or in part in money and other property, tangible or intangible, or in labor or in services actually performed for the Corporation. When payment of the consideration for which shares are to be issued has been received or, when payment of the capital consideration has been received and the Corporation has received a binding obligation from the purchaser to pay the balance of the purchase price; such shares shall be deemed to be fully paid and not liable for any further call or assessment thereon.

- C. Each stockholder of record of the common stock shall have one vote for each share of stock standing in his name on the books of the Corporation and entitled to vote. In the election of directors, cumulative voting shall be allowed. The voting rights, if any, of the shareholders of any series, if any, of preferred stock, shall be designated, by resolution, of the board of directors.
- D. Stockholders of the common or preferred stock, regardless of the series of the preferred stock shall not have the preemptive right to acquire unissued or treasury shares or securities convertible into such shares or carrying a right to subscribe to or acquire shares. Such provision shall apply to both shares outstanding and to newly issued shares.

SECOND: That thereafter, pursuant to resolution of the board of directors

of the Corporation, a meeting of the stockholders of the Corporation was duly called and held, upon notice in accordance with Section 222 of the General Corporation Law of the State of Delaware at which meeting the necessary number of shares as required by the General Corporation Law of the State of Delaware voted in favor of the amendment.

THIRD: That such amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

FOURTH: That the effective date of this amendment shall be July 31, 2000.

IN WITNESS WHEREOF, Access Pharmaceuticals, Inc. has caused this certificate to be signed by John J. Concannon III, its Secretary, this 31st day of July, 2000.

ACCESS PHARMACEUTICALS, INC.

BY: /s/ John J. Concannon III

John J. Concannon III Secretary