

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 SEPTEMBER 30, 2001

Commission File Number 0-9314

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)

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 No

The number of shares outstanding of each of the issuer's classes of common stock, as of November 12, 2001 was 12,863,705 shares of common stock, \$0.01 par value per share.

Total No. of Pages 13

1

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 R, carbohydrate targeting technology and agents for the prevention and treatment of viral disease, including HIV. In addition, our partner, GlaxoSmithKline (formerly Block Drug Company), is marketing in the United States a product, 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 rights for the use of amlexanox in additional indications from GlaxoSmithKline for numerous markets excluding the U. S. and the worldwide rights for mucositis.

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 September 30, 2001, our accumulated deficit was \$36,313,000, of which \$8,894,000 was the result of the write-off of excess purchase price of mergers.

RECENT DEVELOPMENTS

Strakan, Ltd, our United Kingdom and Ireland licensee for amlexanox 5% paste, received marketing authorization in September 2001 for this product in the United Kingdom. Strakan's trade name for the product is Aptheal TM. We licensed the exclusive United Kingdom and Ireland rights for the sale and

R - Registered Mark

TM - Trademark

2

marketing of amlexanox 5% paste for the treatment of aphthous ulcers (canker sores) to Strakan in August 1998. Under the terms of this license Strakan is responsible for the product registration throughout Europe. Additionally, Strakan will make milestone payments on achievement of performance objectives and we will receive royalties on product sales.

Strakan is also the worldwide licensee of our ResiDerm R technology. ResiDerm R A, which will be marketed under the tradename Zindaclin TM, received marketing authorization in September 2001 in the United Kingdom. The product incorporates clindamycin within the ResiDerm R topical delivery system for the treatment of acne. In February 1998, we licensed the exclusive worldwide rights for the manufacturing, sales and marketing of ResiDerm R to Strakan. Under the terms of the license, Strakan is responsible for all product development activities including product registration. Additionally, Strakan will make milestone payments on achievement of commercial objectives and Access will receive royalties on product sales.

LIQUIDITY AND CAPITAL RESOURCES

Working capital as of September 30, 2001 was \$20,655,000 representing a decrease in working capital of \$3,742,000 as compared to the working capital as of December 31, 2000 of \$24,397,000. The decrease in working capital was due to the loss from operations for the first nine months of 2001.

Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit as of September 30, 2001 of \$36,313,000. 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 currently planned operations through June 2004.

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.

3

THIRD QUARTER 2001 COMPARED TO THIRD QUARTER 2000

Revenue in the third quarter of 2001 was \$11,000, as compared to no revenue in the same period of 2000. Revenue in the third quarter of 2001 was recognized over the period of the performance obligation of several licensing agreements, including various amlexanox projects.

Total research spending for the third quarter of 2001 was \$1,295,000, as compared to \$1,051,000 for the same period in 2000, an increase of \$244,000. The increase in expenses was the result of:

- * higher development costs for polymer platinite (\$294,000) due to manufacturing and ongoing clinical trials;
- * higher scientific salary cost (\$111,000) due to additional employees on staff;
- * higher clinical development costs (\$37,000) for amlexanox cream and gel projects due to the start of clinical trials in 2001; and
- * other net increases (\$30,000).

The increase in expenses was partially offset by lower clinical development costs for amlexanox product development projects for OraDisc™ (\$163,000) and OraRinse™ (\$65,000). Higher costs for these projects were incurred in the third quarter 2000 due to ongoing clinical trials during that time period as compared with no trials ongoing for these projects in the third quarter 2001.

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 \$457,000 for the third quarter of 2001, an increase of \$125,000 as compared to the same period in 2000. The increase in spending was due primarily to

- * executive search fees (\$30,000);
- * higher compensation expenses (\$24,000);
- * higher legal expenses (\$68,000); and

* higher patent expenses (\$13,000).

These general and administrative expenses increases were partially offset by lower other net costs (\$10,000).

Depreciation and amortization was \$103,000 for the third quarter of 2001 as compared to \$110,000 for the same period in 2000 reflecting a decrease of \$7,000. The decrease in amortization is due to lower depreciation reflecting that some major assets have been fully depreciated.

Total operating expenses in the third quarter of 2001 were \$1,855,000 as compared to total operating expenses of \$1,493,000 for the same period in 2000.

Loss from operations in the third quarter of 2001 was \$1,844,000 as compared to a loss of \$1,493,000 for the same period in 2000.

4

Interest and miscellaneous income was \$386,000 for the third quarter of 2001 as compared to \$236,000 for the same period in 2000, an increase of \$150,000. The increase in interest income (\$80,000) was due to higher cash balances in 2001 resulting from our private placements of common stock and convertible note offering in 2000. The increase in miscellaneous income (\$70,000) in the third quarter of 2001 was due to a dispute settlement with a vendor.

Interest expense was \$286,000 for the third quarter of 2001 as compared to \$53,000 for the same period in 2000, an increase of \$233,000. The increase in interest expense was due to interest accrued in 2001 on the \$13.5 million convertible notes that were issued in 2000 and amortization of debt issuance costs.

Net loss in the third quarter of 2001 was \$1,744,000, or a \$0.13 basic and diluted loss per common share, compared with a loss of \$1,310,000, or a \$0.11 basic and diluted loss per common share for the same period in 2000.

NINE MONTHS ENDED SEPTEMBER 30, 2001 COMPARED TO NINE MONTHS ENDED SEPTEMBER 30, 2000

Revenue in the first nine months of 2001 was \$232,000, as compared to no revenue in the same period of 2000. Revenue in the first nine months of 2001 was recognized over the period of the performance obligation of several licensing agreements, including various amlexanox projects and ResiDerm R.

Total research spending for the first nine months of 2001 was \$3,330,000, as compared to \$2,723,000 for the same period in 2000, an increase of \$607,000. The increase in expenses was the result of:

- * higher development costs for polymer platinate (\$325,000) due to manufacturing and ongoing clinical trials;
- * higher clinical development costs (\$285,000) for amlexanox product development projects for cream and gel projects. During the first nine months of 2001 we commenced amlexanox gel and cream clinical studies; and
- * higher scientific salary cost (\$277,000) due to additional employees on staff.

The increase in expenses was partially offset by:

- * lower clinical development costs for amlexanox product development projects for OraDisc TM (\$128,000) and OraRinse TM (\$72,000). Higher costs for these projects were incurred in the third quarter 2000 due to ongoing clinical trials during that time period as compared with no trials ongoing for these projects in the third quarter 2001;
- * lower moving and recruiting expenses for scientific personal (\$74,000); and
- * other net decreases (\$6,000).

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 \$1,356,000 for the first nine months of 2001, an increase of \$108,000 as compared to the same period in 2000. The increase in spending was due primarily to the following:

5

- * higher shareholder expenses (\$59,000);
- * higher patent costs (\$55,000);
- * executive search fee (\$31,000);
- * legal fees (\$18,000); and
- * other net increases (\$4,000).

These general and administrative expense increases were partially offset by lower compensation expenses (\$59,000).

Depreciation and amortization was \$304,000 for the first nine months of 2001 as compared to \$333,000 for the same period in 2000 reflecting a decrease of \$29,000. The decrease in amortization was due to lower depreciation reflecting that some major assets have been fully depreciated.

Total operating expenses in the first nine months of 2001 were \$4,990,000 as compared to total operating expenses of \$4,304,000 for the same period in 2000.

Loss from operations in the first nine months of 2001 was \$4,758,000 as compared to a loss of \$4,304,000 for the same period in 2000.

Interest and miscellaneous income was \$1,178,000 for the first nine months of 2001 as compared to \$524,000 for the same period in 2000, an increase of \$654,000. The increase in interest income (\$584,000) was due to higher cash balances in 2001 resulting from our private placements of common stock and convertible note offering in 2000. The increase in miscellaneous income (\$70,000) in the third quarter of 2001 was due to a dispute settlement with a vendor.

Interest expense was \$852,000 for the first nine months of 2001 as compared to \$56,000 for the same period in 2000, an increase of \$796,000. The increase in interest expense is due to interest accrued on the \$13.5 million convertible notes issued in 2000 and amortization of debt issuance costs.

Net loss in the first nine months of 2001 was \$4,432,000, or a \$0.34 basic and diluted loss per common share, compared with a loss of \$3,836,000, or a \$0.37 basic and diluted loss per common share for the same period in 2000.

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.

6

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:

None

Reports on Form 8-K:

On November 6, 2001, we filed a Current Report on Form 8-K pursuant to Item 5 thereof that the Board of Directors of the Company has adopted a stockholder rights plan.

7
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: November 13, 2001 By: /s/ Kerry P. Gray

Kerry P. Gray
President and Chief Executive Officer

Date: November 13, 2001 By: /s/ Stephen B. Thompson

Stephen B. Thompson
Vice President and
Chief Financial Officer

8

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

Condensed Consolidated Balance Sheets

<TABLE>
<CAPTION>

	September 30, 2001	December 31, 2000

ASSETS	(unaudited)	
<S>	<C>	<C>
Current assets		
Cash and cash equivalents	\$ 8,723,000	\$ 8,415,000
Short term investments, at cost, (restricted \$600,000)	13,300,000	17,394,000
Accounts receivable	196,000	251,000
Accrued interest receivable	131,000	196,000
Prepaid expenses and other current assets	89,000	133,000

Total current assets	22,439,000	26,389,000
Property and equipment, net	398,000	116,000
Debt issuance costs, net	724,000	861,000
Licenses, net	803,000	887,000
Goodwill, net	1,930,000	2,115,000
Other assets	159,000	158,000

Total assets	\$ 26,453,000	\$ 30,526,000
	=====	

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities

Accounts payable and accrued expenses	\$ 1,111,000	\$ 1,158,000
Accrued interest payable	49,000	283,000
Deferred revenues	519,000	551,000
Current portion of note payable	105,000	-
	-----	-----
Total current liabilities	1,784,000	1,992,000
Note payable, net of current portion	495,000	-
Convertible notes	13,530,000	13,530,000
	-----	-----
Total liabilities	15,809,000	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, 12,863,705 at September 30, 2001 and 12,844,669 at December 31, 2000	133,000	132,000
Additional paid-in capital	47,873,000	47,802,000
Notes receivable from stockholders	(1,045,000)	(1,045,000)
Treasury stock, at cost - 819 shares	(4,000)	(4,000)
Deficit accumulated during the development stage	(36,313,000)	(31,881,000)
	-----	-----
Total stockholders' equity	10,644,000	15,004,000
	-----	-----
Total liabilities and stockholders' equity	\$ 26,453,000	\$ 30,526,000

</TABLE>

The accompanying notes are an integral part of these statements.

9

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

Condensed Consolidated Statements of Operations
(unaudited)

<TABLE>

<CAPTION>

	Three months ended		Nine months ended		February 24,	
	September 30,		September 30,		1988	
	2001	2000	2001	2000	September 30, 2001	(inception) to
	-----	-----	-----	-----	-----	-----
	<C>	<C>	<C>	<C>	<C>	<C>
Revenues						
Research and development	\$ -	\$ -	\$ -	\$ -	\$ 2,711,000	
Option income	-	-	-	-	2,164,000	
Licensing revenues	11,000	-	232,000	-	664,000	
	-----	-----	-----	-----	-----	
Total revenues	11,000	-	232,000	-	5,539,000	
Expenses						
Research and development	1,295,000	1,051,000	3,330,000	2,723,000	19,310,000	
General and administrative	457,000	332,000	1,356,000	1,248,000	13,017,000	
Depreciation and amortization	103,000	110,000	304,000	333,000	2,280,000	
Write-off of excess purchase price	-	-	-	-	8,894,000	
	-----	-----	-----	-----	-----	
Total expenses	1,855,000	1,493,000	4,990,000	4,304,000	43,501,000	
	-----	-----	-----	-----	-----	
Loss from operations	(1,844,000)	(1,493,000)	(4,758,000)	(4,304,000)	(37,962,000)	
Other income (expense)						
Interest and miscellaneous income	386,000	236,000	1,178,000	524,000	3,035,000	
Interest and debt expense	(286,000)	(53,000)	(852,000)	(56,000)	(1,386,000)	

	100,000	183,000	326,000	468,000	1,649,000
Net loss	\$(1,744,000)	\$(1,310,000)	\$(4,432,000)	\$(3,836,000)	\$(36,313,000)
Basic and diluted loss per common share	\$(0.13)	\$(0.11)	\$(0.34)	\$(0.37)	
Weighted average basic and diluted common shares outstanding	12,860,114	12,133,463	12,854,170	10,436,095	

</TABLE>

The accompanying notes are an integral part of these statements.

10

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

Condensed Consolidated Statements of Cash Flows
(unaudited)

<TABLE>

<CAPTION>

February 24,
Nine months ended September 30, 1988
----- (inception) to
2001 2000 September 30, 2001

<S>

<C> <C> <C>

Cash flows from operating activities:			
Net loss	\$(4,432,000)	\$(3,836,000)	\$(36,313,000)
Adjustments to reconcile net loss to cash used in operating activities:			
Write-off of excess purchase price	-	-	8,894,000
Warrants issued in payment of consulting expenses	41,000	-	970,000
Research expenses related to common stock granted	-	-	100,000
Depreciation and amortization	304,000	333,000	2,280,000
Amortization of debt costs	137,000	-	191,000
Deferred revenue	(32,000)	503,000	409,000
Change in operating assets and liabilities:			
Accounts receivable	55,000	(198,000)	(196,000)
Accrued interest receivable	65,000	(154,000)	(131,000)
Prepaid expenses and other current assets	44,000	34,000	(89,000)
Licenses	-	(100,000)	(525,000)
Other assets	(1,000)	-	(9,000)
Accounts payable and accrued expenses	(47,000)	187,000	349,000
Accrued interest payable	(234,000)	-	49,000
Net cash used in operating activities	(4,100,000)	(3,231,000)	(24,021,000)

Cash flows from investing activities:

Capital expenditures	(317,000)	(68,000)	(1,562,000)
Sales of capital equipment	-	-	15,000
Purchases and redemptions of short term investments and certificates of deposit, net	4,094,000	(19,676,000)	(13,300,000)
Purchase of businesses, net of cash acquired	-	-	(226,000)
Other investing activities	-	-	(150,000)

Net cash provided by (used in) investing activities	3,777,000	(19,744,000)	(15,223,000)
---	-----------	--------------	--------------

Cash flows from financing activities:			
Proceeds from notes payable	600,000	-	1,321,000
Payments of principal on obligations under capital leases	-	(26,000)	(750,000)
Purchase of treasury stock	-	(752,000)	(754,000)
Cash acquired in merger with Chemex	-	-	1,587,000
Notes receivable from shareholders	-	-	(1,045,000)
Proceeds from convertible note, net	-	12,622,000	12,615,000
Proceeds from stock issuances, net	31,000	17,428,000	34,993,000

Net cash provided by financing activities	631,000	29,272,000	47,967,000

Net increase in cash and cash equivalents	308,000	6,297,000	8,723,000
Cash and cash equivalents at beginning of period	8,415,000	869,000	-

Cash and cash equivalents at end of period	\$ 8,723,000	\$ 7,166,000	\$ 8,723,000
	=====		

</TABLE>

The accompanying notes are an integral part of these statements.

11

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

Notes to Condensed Consolidated Financial Statements
Nine Months Ended September 30, 2001 and 2000
(unaudited)

(1) Interim Financial Statements

The consolidated balance sheet as of September 30, 2001 and the consolidated statements of operations and cash flows for the three and nine months ended September 30, 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 classifications.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America 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 September 30, 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.

(2) Recent Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standard No. 141, "Business Combination" (FAS 141) and Statement of Financial Accounting Standard No. 142, "Goodwill and Other Intangible Assets" (FAS 142). FAS 141 eliminates the pooling-of-interests method of accounting for business combinations except for qualifying business combinations that were initiated prior to July 1, 2001. FAS 141 further clarifies the criteria to recognize intangible assets separately from goodwill. The requirements of FAS 141 are effective for any business combination accounted for by the purchase method that is completed after June 30, 2001 (i.e., the acquisition date is July 1, 2001 or thereafter). Under FAS 142, goodwill and indefinite-lived intangible assets are no longer amortized but are reviewed annually (or more frequently if impairment indicators arise) for impairment. Separable intangible assets that are not deemed to have an indefinite life will continue to be amortized over their

useful lives. We will continue to amortize goodwill recognized prior to July 1, 2001, under the current method until we adopt FAS 141 and FAS 142 which must be adopted in 2002.

We do not believe that the adoption of FAS 141 will have any material impact on our financial position or results of operations. When we adopt FAS 142, annual and quarterly goodwill amortization of \$246,000 and \$61,500 will no longer be recognized. Prior to adopting

12

FAS 142 we will complete a transitional fair value based impairment test of goodwill. Impairment losses, if any, resulting from transitional testing will be recognized.

(3) Stockholders' Rights Offering

On October 19, 2001, the Board of Directors of the Company declared a special dividend distribution of a preferred share purchase right (a "Right") for each outstanding share of common stock of the Company. This dividend was distributed on November 9, 2001 to stockholders of record as of the close of business on that date. Each Right, when exercisable, generally entitles the registered holder to purchase from the Company one one-hundredth of a share of Series A Junior Participating Preferred Stock of the Company, par value \$0.01 per share (the "Preferred Shares"), at a price of \$30 per one one-hundredth of a Preferred Share, subject to adjustment or substitution of other securities of the Company in place of Preferred Shares. The description and terms of the Rights are set forth in a Rights Agreement, dated as of October 31, 2001, between the Company and American Stock Transfer & Trust Company, a New York corporation.

13