# 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 JUNE 30, 1997

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 X No

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

Common stock outstanding as of August 14, 1997 31,991,324 shares, \$0.04 par value

Total No. of Pages 12

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** 

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 Access Pharmaceuticals Inc.'s ("Access" or the "Company") research and development focus, uncertainties associated with research and development activities, future capital requirements, anticipated option and licensing revenues, dependence on others, and other risks detailed in the Company's reports filed under the Securities Exchange Act, including but not limited to the Company's Annual Report on Form 10-K for the year ended December 31, 1996.

Since its inception in February 1988, Access has devoted its resources primarily to fund its research and development programs. The Company has been unprofitable since inception and to date has not received any revenues from the sale of products. No assurance can be given that the Company will be able to generate sufficient product revenues to attain profitability on a sustained basis or at all. The Company expects to incur losses for the next several years as it continues to invest in product research and development, preclinical studies, clinical trials and regulatory compliance. At June 30, 1997, the Company's accumulated deficit was approximately \$17.0 million.

#### RECENT DEVELOPMENTS

On August 1, 1997, the Company announced that it had signed an agreement to enter into collaboration with The Dow Chemical Company ("Dow") for the development of products incorporating Dow's chelation technology and Access' bioresponsive polymer systems. The collaboration will focus on the development of MRI contrast agents and radiopharmaceutical diagnostics and therapeutics. The advancement of the Access developments in these areas are dependent on securing chelation technology, which encapsulates metals to avoid adverse effects on the body.

On May 29, 1997, the Company's Shareholders gave their approval to amend Access' Certificate of Incorporation, as amended, to effect a recapitalization (the "Recapitalization") of the Company through a one-for-four reverse stock split of Access common stock (the "Common Stock") and decrease the number of authorized shares of Common Stock from 60.0 million shares, par value \$.04 per share to 25.0 million shares, par value \$.01 per share. The reduction in authorized shares of Common Stock would in fact proportionately increase the number of authorized but unissued shares when compared with the number of issued and outstanding shares before and after the Recapitalization. This proposal, when effective, would decrease the number of outstanding shares of Common Stock from approximately 31.4 million to 7.9 million. As of August 14, 1997 the

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Recapitalization is not effective.

The Company intends to submit an application for listing on the NASDAQ SmallCap Market or an exchange when it meets all qualifications for such listing and the reverse stock split becomes effective. The Company believes that securing a NASDAQ or an exchange listing together with the Recapitalization would improve Access' ability to finance the Company's research activities under more favorable terms since institutional investors and investment community members generally have restrictions on investing in unlisted companies. There can be no assurances that the market price immediately after the implementation of the proposed Recapitalization will increase, and if it does increase, there can be no assurance that such increase can be maintained for any period of time, or that such market price will approximate four times the market price before the proposed reverse stock split. There can be no assurances that the Company will be listed on the NASDAQ SmallCap Market or any exchange.

On April 26, 1996, Access executed a letter of intent to acquire Tacora Corp., a privately-held pharmaceutical Company based in Seattle. The transaction is expected to close shortly. Under the terms of the letter of intent, the purchase price is contingent upon the achievement of certain milestones. In addition to cash of \$250,000 and \$100,000 in Common Stock paid at closing, stock up to a maximum value of \$14,000,000 could be payable to Tacora's shareholders over a 30 month period on an escalating value over the milestone period. The consummation of the transaction is subject to customary conditions to closing and approval of the stockholders of Tacora Corp.

Liquidity and Capital Resources

Since its inception, the Company has financed its operations primarily through private sales of its equity securities, contract research payments from corporate alliances and the merger with Chemex Pharmaceuticals, Inc. At June 30, 1997, the Company had working capital of \$2.2 million and cash, cash equivalents and short-term investments of \$2.5 million.

The Company expects its cash requirements to increase in future periods. The Company will require substantial funds to conduct research and development programs, preclinical studies and clinical trials of its potential products. The Company's future capital requirements will depend on many factors, including the ability to establish and maintain collaborative arrangements for research, development and commercialization of products with corporate partners, continued scientific progress in the Company's research and development programs, the 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 and the ability to establish and maintain effective commercialization activities and arrangements. Based on its current plans, the Company believes that its available cash, including proceeds from projected interest income, will be sufficient to meet the Company's operating expenses and capital requirements into the second half of 1998. There can be no assurance, however, that changes in the Company's operating expenses will not result in the expenditure of such resources before such time.

The Company intends to seek additional funding through research and development arrangements with potential corporate partners, public or private financing, or from other sources. There can be no assurance that additional financing will be available on favorable terms, if at all. In the event that adequate funding is not available, the Company may be required to delay, reduce or eliminate one or more of its research or development programs or obtain funds through arrangements with corporate collaborators or others that may require the Company to relinquish greater or all rights to

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product candidates at an earlier stage of development or on less favorable terms than the Company would otherwise seek. Insufficient financing may also require the Company to relinquish rights to certain of its technologies that the Company would otherwise develop or commercialize itself.

The Company's business is subject to significant risks, including, without limitation, uncertainties associated with the length and expense of the regulatory approval process, uncertainty associated with obtaining and enforcing patents and risks associated with dependence on corporate partners. Although certain of the Company's products may appear promising at an early stage of development, they may not be successfully commercialized for a number of reasons, such as the possibility that the potential products will be determined to be ineffective during clinical trials, fail to receive necessary approvals, or be precluded from commercialization by proprietary rights of third parties. Further, there can be no assurance that any collaborations will be initiated, continued or result in successfully commercialized products.

Second Quarter 1997 Compared to Second Quarter 1996

The Company had \$50,000 in licensing revenue in the second quarter 1997 as compared to no revenues in 1996. Second quarter 1997 revenues were comprised of licensing income from an ongoing agreement.

Total research spending for the second quarter of 1997 was \$538,000 as compared to \$268,000 for the same period in 1996, an increase of \$270,000. The increase in expenses was the result of the increase in external contract research costs- \$136,000; additional staffing for projects- \$92,000; increased equipment lease costs- \$21,000; and other costs- \$21,000. Research spending is expected to increase in future quarters as the Company has hired additional scientific management and staff and is accelerating activities to develop the Company's product candidates.

Total general and administrative expenses were \$424,000 for the second quarter of 1997, an increase of \$61,000 as compared to the same period in 1996. The increase in spending was due primarily to the following:

increased general business consulting fees- \$78,000; salaries and salary related expenses of recently hired employees- \$35,000; and other costs-\$2,000; offset by decreases in patent costs- \$54,000.

Interest and miscellaneous income was \$37,000 for the second quarter of 1997 as compared to \$50,000 for the same period in 1996, a decrease of \$13,000. The decrease was due to interest income from higher cash balances in 1996 due to \$6 million in gross proceeds from a private placement of 8.57 million shares of common stock in March 1996.

Accordingly, total expenses exceeded revenues, resulting in a loss for the second quarter of \$912,000, or \$.03 per share.

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Six Months ended June 30, 1997 Compared to Six Months ended June 30, 1996

Net revenues for the six months ended June 30, 1997 were \$188,000 as compared to \$165,000 in the same period in 1996, an increase of \$23,000. 1997 revenues were comprised of licensing income from an ongoing agreement where 1996 revenues were from an option agreement for rights to certain of the Company's technology that terminated in April 1996.

Research spending for the six months ended June 30, 1997 was \$1,042,000 as compared to \$476,000 for the same period in 1996, an increase of \$566,000. The increase in expenses was due to: increased external research spending-\$247,000; additional scientific staff- \$233,000; increased equipment lease costs- \$45,000; additional travel expenses- \$38,000; and other increases of \$3,000. Research spending will increase in future quarters as the Company has hired additional scientific management and staff and is accelerating activities to develop the Company's product candidates.

General and administrative expenses were \$829,000 for the six months ended June 30, 1997, an increase of \$157,000 as compared to the same period in 1996. The increase was due to the following: general business consulting fees and expenses-\$117,000; salaries and moving expenses of newly hired employees \$90,000, director fees and director and officer insurance-\$33,000; offset by lower patent expenses-\$67,000; and other decreases-\$16,000.

Excess purchase price over the fair value of Chemex Pharmaceuticals, Inc.'s ("Chemex") net assets of \$8,314,000 was recorded and written off in the first quarter of 1996, due to an immediate impairment of the excess purchase price.

Accordingly, total expenses exceeded revenues which resulted in a loss for the six months ended June 30, 1997 of \$1,676,000, or \$.05 per share.

### PART II -- OTHER INFORMATION

ITEM 1 LEGAL PROCEEDINGS

None

ITEM 2 CHANGES IN SECURITIES

None

ITEM 3 DEFAULTS UPON SENIOR SECURITIES

None

### ITEM 4 SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

The annual meeting of stockholders was held on May 28, 1997 in New York, NY. At that meeting the following matters were submitted to a vote of the stockholders of record. All such proposals were approved by the stockholders, as follows:

\* Elizabeth M. Greetham and Stephen B. Howell were elected Directors for three year

terms. The votes were Greetham 18,932,986 - For and 5,534,068 - Withheld Authority; and, Howell, 18,951,297 - For and 5,515,756 - Withheld Authority.

- \* A proposal to amend the Company's Certificate Incorporation to effect the recapitalization was approved with 18,107,276 For, 5,598,034 Against, 6,233 Abstain and 0 Non-votes.
- \* A proposal to ratify the appointment of KPMG Peat Marwick LLP as independent certified public accountants for the Company for fiscal year December 31, 1997 was approved with 24,425,863 For, 18,689 Against and 22,501 Abstain.

## ITEM 5 OTHER INFORMATION

None

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

Exhibits: None

Reports on Form 8-K: None

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# **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: August 14, 1997 By: /s/ Kerry P. Gray

Kerry P. Gray

President and Chief Executive Officer

(Principal Executive Officer)

Date: August 14, 1997 By: /s/ Stephen B. Thompson

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

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ACCESS PHARMACEUTICALS, INC. a development stage company

**Balance Sheets** 

<TABLE> <CAPTION> Assets

June 30, 1997 December 31, 1996

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<S><C>

Current Assets

\$ 2,462,000 \$ 4,428,000 Cash and cash equivalents Accounts receivable 10,000 1,000

Prepaid expenses and other current assets 144,000 190,000

Total current assets 2,616,000 4,619,000

585,000 Property and Equipment, at cost 681,000 Less accumulated depreciation (285,000)(347,000)

> 334,000 300,000

Other Assets 9,000 9,000

Total Assets \$ 2,959,000 \$ 4,928,000

Liabilities and Stockholders' Equity

**Current Liabilities** 

Accounts payable and accrued expenses \$ 209,000 \$ 449,000 Accrued insurance premium 26,000 74,000

Current portion of obligations under

capital leases 176,000 152,000

Total current liabilities 411,000 675,000

Obligations under capital leases,

net of current portion 54,000 83,000 Note payable 110,000 110,000

Total liabilities 575,000 868,000

Stockholders' Equity

Preferred stock, at June 30, 1997 and December 31, 1996 \$.01 par value, authorized 10,000,000 shares, none issued or outstanding

Common stock, at June 30, 1997 and December 31, 1996 \$.04 par value, authorized 60,000,000 shares, issued

and outstanding 31,391,324 shares 1,256,000 1,256,000 Additional paid-in capital 18,111,000 18,111,000 Deficit accumulated during the

(16,983,000)development stage (15,307,000)

Total Stockholders' Equity 4,060,000 2,384,000

Total Liabilities and Stockholder's

Equity \$ 2,959,000 \$ 4,928,000

</TABLE>

See accompanying notes to financial statements and Management's Discussion and Analysis of Financial Conditions and Results of Operations.

> ACCESS PHARMACEUTICALS, INC. a development stage company

Statements of Operations

<TABLE> <CAPTION>

Three Months ended		Six Months ended		ended
June 30		June 3	30, February 24, 19	
 1997	 1996	 1997	1996	(inception) to June 30, 1997
1997	1990	1997	1990	Julie 30, 1997

<s></s>					
Sponsored Research and development       \$ - \$ - \$ - \$ 2,711,000         Licensing revenue       50,000       - 188,000       - 188,000         Option income       165,000       2,039,000					
Licensing revenue 50,000 - 188,000 - 188,000					
Total Revenues 50,000 - 188,000 165,000 4,938,000					
Expenses					
Research and development 538,000 268,000 1,042,000 476,000 7,218,000 General and administrative 424,000 363,000 829,000 672,000 5,908,000					
General and administrative 424,000 363,000 829,000 672,000 5,908,000 Depreciation and amortization 30,000 36,000 62,000 72,000 956,000					
Write off of excess purchase price 8,314,000 8.314,000					
Total Expenses 992,000 667,000 1,933,000 9,534,000 22,396,000					
Loss from operations (942,000) (667,000) (1,745,000) (9,369,000) (17,458,000)					
Other Income (Expense)					
Interest and miscellaneous income 37,000 50,000 84,000 80,000 739,000  Interest expense (7,000) (14,000) (15,000) (27,000) (137,000)					
30,000 36,000 69,000 53,000 602,000					
Loss before income taxes (912,000) (631,000) (1,676,000) (9,316,000) (16,856,000)					
Provision for income taxes 127,000					
Net loss \$ (912,000) \$(631,000)\$ (1,676,000)\$(9,316,000) \$(16,983,000)					
Loss per share \$(0.03) \$(0.02) \$(0.05) \$(0.33)					
Average number of common and equivalent common shares outstanding 31,391,324 31,346,866 31,391,324 28,285,296					

| See accompanying notes to financial statements and Management's Discussion and | | | | | |
| Analysis of Financial Conditions and Results of Operations |
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| ACCESS PHARMACEUTICALS, INC. a development stage company |
| Statements of Cash Flows |
|  |
|  |
| Six Months ended June 30, February 24, 1988 |
| (inception) to 1997 1996 June 30, 1997 |
| <\$> |
| Cash Flows form Operating Activities  Net loss \$(1,676,000) \$ (9,316,000) \$(16,983,000) |
| Adjustments to reconcile |
net loss to cash used in						
operating activities: Write off of excess						
purchase price - 8,314,000 8,314,000						
Consulting expense related						
to warrants granted 344,000 Depreciation and amortization 62,000 72,000 956,000						
Change in assets and liabilities:						
Accounts receivable (9,000) 3,000 (10,000) Prepaid expenses and other						
current assets 46,000 (142,000) (145,000)						

Other assets	-	- (7,000)		
Accounts payable and expenses Unearned revenue		15,000		
Net Cash Used in Operating Activities		(1,204,000)	(7,343,000)	
Cash Flows From Invest Capitalized expenditure	es (96,000)	(1,000)	(1,244,000)	
Net Cash Used in Investing Activities		(1,000)	(1,244,000)	
Cash Flows From Finance Payments of principal of under capital leases Proceeds from notes pa and capital leases	eing Activities on obligations (77,000) yable	(56,000)		
Proceeds from merger v Chemex Pharmaceutic Proceeds from stock iss	with cals - suances, - 5,514,0	1,587,000 00 9,022,0	1,587,000	
	Jsed in) (5,000)			
Net Increase (Decrease) and Cash Equivalents Cash and Cash Equivalent Beginning of Period	in Cash (1,966,000 nts at	) 5,950,000	2,462,000	
Cash and Cash Equivaler End of Period	nts at		\$2,462,000	
Supplemental disclosure non cash transactions: eliminations of note pa to Chemex Pharmaceu due to merger 				

 ayable itical | 100,000 \$ | 100,000 |See accompanying notes to financial statements and Management's Discussion and Analysis of Financial Conditions and Results

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ACCESS PHARMACEUTICALS, INC. a development stage company Notes to Financial Statements Six Months Ended June 30, 1997 and 1996

# (1) Interim Financial Statements

The balance sheet as of June 30, 1997 and the statements of operations and cash flows for the six months ended June 30, 1997 and 1996 were prepared by management without audit. In the opinion of management, all adjustments, including only normal recurring adjustments necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made. Certain reclassifications have been made to prior year financial statements to conform with the June 30, 1997 presentation.

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 the Company's Annual Report to the SEC on Form 10-K for the year ended December 31, 1996. The results of operations for the period ended June 30, 1997 are not necessarily indicative of the operating results, which may be expected for a full year. The balance sheet as of December 31, 1996 contains financial information taken from the audited financial statements as of that date.

- (2) With the Company's current budget and it's anticipated option and licensing revenues, management believes working capital will cover planned operations into the second half of 1998. If the anticipated revenues are delayed or do not occur or the Company is unsuccessful in raising additional capital on acceptable terms, research and development and general and administrative expenditures would be curtailed so that working capital would cover operations through approximately the end of 1998.
- (3) SFAS No. 125. "Accounting For Transfers and Servicing of Financial Assets and Extinguishments of Liabilities", effective for transfers and servicing of financial assets and extinguishments of liabilities occurring after December 31, 1996 was adopted by the Company and does not have a material impact on the Company's financial position, results of operations, or liquidity. This Statement provides accounting and reporting standards for transfers and servicing of financial assets and extinguishments of liabilities based on consistent application of financial-components approach that focuses on control. It distinguishes transfers of financial assets that are sales from transfers that are secured borrowings.
- (4) SFAS No. 128. "Earnings Per Share", which is required to be adopted for financial statements issued for periods ending after December 15, 1997. This statement establishes new, simplified standards for computing and presenting earnings per share. It replaces the traditional presentations of primary earnings per share and fully diluted earnings per share with presentations of basic earnings per share and diluted earnings per share, respectively. When adopted by the Company, during the quarter ending December 31, 1997, basic earnings per share is expected to increase slightly from primary earnings per share and diluted earnings per share is expected to approximate fully diluted earnings per share.

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(5) On May 29, 1997, the Company's Shareholders gave their approval to amend Access' Certificate of Incorporation, as amended, to effect a recapitalization (the "Recapitalization") of the Company through a one-for-four reverse stock split of Access common stock (the "Common Stock") and decrease the number of authorized shares of Common Stock from 60.0 million shares, par value \$.04 per share to 25.0 million shares, par value \$.01 per share. The reduction in authorized shares of Common Stock would in fact proportionately increase the number of authorized but unissued shares when compared with the number of issued and outstanding shares before and after the Recapitalization. This proposal, when effective, would decrease the number of outstanding shares of Common Stock from approximately 31.4 million to 7.9 million. As of August 14, 1997 the Recapitalization is not effective.

The Company intends to submit an application for listing on the NASDAQ SmallCap Market or an exchange when it meets all qualifications for such listing and the reverse stock split becomes effective. The Company believes that securing a NASDAQ or an exchange listing together with the Recapitalization would improve Access' ability to finance the Company's research activities under more favorable terms since institutional investors and investment community members generally have restrictions on investing in unlisted companies. There can be no assurances that the market price immediately after the implementation of the proposed Recapitalization will increase, and if it does increase, there can be no assurance that such increase can be maintained for any period of time, or that such market price will approximate four times the market price before the proposed reverse stock split. There can be no assurances that the Company will be listed on the NASDAQ SmallCap Market or any exchange.

(6) On August 1, 1997, the Company announced that it had signed an agreement to enter into collaboration with The Dow Chemical Company ("Dow") for the development of products incorporating Dow's chelation technology and Access' bioresponsive polymer systems. The collaboration will focus on

the development of MRI contrast agents and radiopharmaceutical diagnostics and therapeutics. The advancement of the Access developments in these areas are dependent on securing chelation technology, which encapsulates metals to avoid adverse effects on the body.

(7) On April 26, 1996, Access executed a letter of intent to acquire Tacora Corp., a privately held pharmaceutical company based in Seattle. The transaction is expected to close shortly. Under the terms of the letter of intent, the purchase price is contingent upon the achievement of certain milestones. In addition to cash of \$250,000 and \$100,000 in common stock paid at closing, stock up to a maximum value of \$14,000,000 could be payable to Tacora's shareholders over a 30 month period on an escalating value over milestone period. The consummation of the transaction is subject to customary conditions to closing and approval of the stockholders of Tacora Corp.

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THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION FROM THE
CONSOLIDATED BALANCE SHEET AND THE CONSOLIDATED STATEMENT OF INCOME
FILED AS PART OF THE QUARTERLY REPORT ON FORM-10Q AND IS
QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH QUARTERLY REPORT ON
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