VIROPHARMA INC Form 10-Q November 13, 2001

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

or

[_] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 0-21699

VIROPHARMA INCORPORATED (Exact Name of Registrant as Specified in its Charter)

Delaware (State or other jurisdiction of incorporation or organization) 94-2347624 (I.R.S. Employer Identification No.)

405 Eagleview Boulevard
Exton, Pennsylvania 19341
(Address of Principal Executive Offices and Zip Code)

610-458-7300 (Registrant's Telephone Number, Including Area Code)

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 ____

Number of shares outstanding of the issuer's Common Stock, par value 0.002 per share, as of November 5, 2001: 18,719,457 shares.

1

VIROPHARMA INCORPORATED

INDEX

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements:

Balance Sheets at December 31, 2000 and September 30, 2001

Statements of Operations for the three months ended September 30, 2000 and 2001, the nine months ended September 30, 2000 and 2001, and the period from December 5, 1994 (inception) to September 30, 2001

Statements of Cash Flows for the nine months ended September 30, 2000 and 2001 and the period from December 5, 1994 (inception) to September 30, 2001

Notes to Financial Statements

- Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.
- Item 3. Quantitative and Qualitative Disclosures About Market Risk

PART II. OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K Signatures

2

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ViroPharma Incorporated (A Development Stage Company) Balance Sheets (unaudited) December 31, 2000 and September 30, 2001

Assets

Current assets:

Cash and cash equivalents Short-term investments Notes receivable from officers - current Due from partners

2

\$

Other current assets

Total current assets
Equipment and leasehold improvements, net
Restricted investments
Notes receivable from officers - noncurrent
Debt issue costs, net
Other assets

Total assets

Liabilities and Stockholders' Equity (Deficit)

Current liabilities:

Accounts payable

Loans payable - current

Deferred revenue - current

Accrued expenses and other current liabilities

Total current liabilities

Loans payable - noncurrent Deferred revenue - noncurrent Convertible subordinated notes Other liabilities

Commitments

Stockholders' equity:

Preferred stock, par value \$.001 per share. 5,000,000 shares authorized;
Series A convertible participating preferred stock; 2,300,000 issued and outstanding at December 31, 2000 and no shares issued and outstanding at September 30, 2001
Series A junior participating preferred stock; 200,000 shares designated; no shares issued and outstanding
Common stock, par value \$.002 per share. Authorized 100,000,000 shares; issued and outstanding 15,450,349 shares at December 31, 2000 and 18,702,768 shares at September 30, 2001

Additional paid-in capital Deferred compensation Unrealized gains on available for sale securities

Deficit accumulated during the development stage

Total stockholders' equity (deficit)

Total liabilities and stockholders' equity (deficit)

See accompanying notes to financial statements.

3

ViroPharma Incorporated
(A Development Stage Company)

Statements of Operations (unaudited)

Three months ended September 30, 2000 and 2001, the nine months ended September 30, 2000 and 2001, and the period from December 5, 1994 (inception) to September 30, 2001

	Three mon Septem	Nine mo Septe	
	2000		2000
Revenues:			
License fee and milestone revenue Grant revenue	\$ 250,000 -	\$ 346,154 -	\$ 1,750,000 -
Total revenues	250,000	346,154	
Operating expenses incurred in the development stage:			
Research and development Acquisition of technology rights	_	12,340,218	22 , 946 , 047
Sales and marketing	276,163	4,207,810	1,280,197
General and administrative	1,488,544	4,481,589	4,443,333
Total operating expenses	13,937,407	21,029,617	28,669,577
Loss from operations	(13,687,407)	(20,683,463)	(26,919,577
Interest income		2,744,007	
Interest expense	2,925,757 	·	6,865,259
Net loss	(\$12,724,643) =======	(\$20,852,367) =======	
Preferred stock dividends	181,838	-	545 , 514
Net loss allocable to common stockholders	(\$12,906,481) =======	(\$20,852,367) =======	
Basic and diluted net loss per share allocable to common stockholders	(\$0.85)	(\$1.12)	(\$1.68
Shares used in computing basic and diluted net loss per share allocable to common stockholders	15,210,428	18,611,706	15,167,736

See accompanying notes to financial statements.

4

ViroPharma Incorporated (A Development Stage Company)

Statements of Cash Flows (unaudited)

Nine months ended September 30, 2000 and 2001 and the period from December 5, 1994 (inception) to September 30, 2001

	Nine months end	
	September 3 2000	
Cash flows from operating activities:		
Net loss	\$ (24,883,815)	\$ (
Adjustments to reconcile net loss to net cash		
used in operating activities:		
Non-cash acquisition of technology rights	_	
Non-cash compensation expense	44,580	
Non-cash warrant value	=	
Non-cash consulting expense	_	
Non-cash interest expense	473,649	
Depreciation and amortization expense	618,416	
	010,410	
Changes in assets and liabilities:	(2 400 500)	
Other current assets	(2,499,588)	
Notes receivable from officers	(325,570)	
Due from partners	(1,783,130)	
Other assets	36,000	
Accounts payable	1,056,863	
Deferred revenue	(750,000)	
Accrued expenses and other current liabilities	1,745,309	
Other liabilities	-	
Net cash used in operating activities	(26, 267, 286)	
Cash flows from investing activities:		
Purchase of equipment and leasehold improvements	(1,573,340)	
Purchase of short-term and restricted investments	(220,303,882)	(1
Sales of short-term investments	_	,
Maturities of short-term investments	72,370,497	1
Net cash (used in) provided by investing activities	(149,506,725)	
Cash flows from financing activities:		
Net proceeds from issuance of preferred stock	_	
Net proceeds from issuance of common stock	836,805	
Preferred stock cash dividends	(545,514)	
Proceeds from loans payable and milestone advance	(010,011)	
Payment of loans payable	(1,150,000)	
Proceeds received on notes receivable	(1,130,000)	
	180 000 000	
Gross proceeds from notes payable	180,000,000	
Issuance costs on notes payable	(5,725,417)	
Payment of notes payable Obligation under capital lease	(2 , 807)	
Web and the state of the state	172 412 067	
Net cash provided by financing activities	173,413,067	
Net increase (decrease) in cash and cash equivalents	(2,360,944)	
Cash and cash equivalents at beginning of period	6,984,707	
Cash and cash equivalents at end of period	\$ 4,623,763 =========	\$ ====
Supplemental disclosure of penagh transactions.		
Supplemental disclosure of noncash transactions:		
Conversion of milestone advance to loan payable	245 601	
Unrealized gains (losses) on available for sale securities	345,601	ļ

Deferred compensation
Supplemental disclosure of interest paid

1,056,250 5,681,207

See accompanying notes to financial statements.

5

ViroPharma Incorporated (A Development Stage Company) Notes to Financial Statements

September 30, 2000 and 2001 (unaudited)

(1) Organization and Business Activities

ViroPharma Incorporated (a development stage company) (the "Company") commenced operations on December 5, 1994. The Company is a development stage pharmaceutical company engaged in the discovery and development of new antiviral medicines.

The Company is devoting substantial effort towards conducting drug discovery and development, raising capital, conducting clinical trials, pursuing regulatory approval for products under development, recruiting personnel and building the sales and marketing organization and infrastructure to support the anticipated commercial launch of Picovir(TM) in mid-2002, if the drug is approved by the Food and Drug Administration. In the course of such activities, the Company has sustained operating losses and expects such losses to continue for at least the next several years. The Company has not generated any significant revenues or product sales and has not achieved profitable operations or positive cash flow from operations. The Company's deficit accumulated during the development stage aggregated \$181,391,975 through September 30, 2001. There is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis.

The Company plans to continue to finance its operations with a combination of stock issuances, debt issuances, license payments, payments from strategic research and development arrangements and, in the longer term, revenues from product sales or collaborations. There are no assurances, however, that the Company will be successful in obtaining an adequate level of financing needed for the long-term development and commercialization of its planned products.

Reclassification

Certain prior year amounts have been reclassified to conform to current year presentation.

Basis of Presentation

The information at September 30, 2001 and for the three and nine months ended September 30, 2000 and 2001, is unaudited but includes all adjustments (consisting only of normal recurring adjustments) which, in the opinion of management, are necessary to state fairly the financial information set forth therein in accordance with accounting principles generally accepted in the United States of America. The interim results are not necessarily indicative of results to be expected for the full fiscal year. These financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2000 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission.

(2) Comprehensive Loss

In the Company's annual financial statements, comprehensive loss is presented as a separate financial statement. For interim financial statements, the Company is permitted to disclose the information in the footnotes to the financial statements. The disclosures are required for comparative purposes. The only comprehensive income item the Company has is unrealized gains and losses on available for sale securities.

The following reconciles net loss to comprehensive loss for the quarter and nine-month periods ended September 30, 2000 and 2001:

6

	Quarter ended September 30,		Nine-month period e September 30,	
	2000	2001	2000	2
Net loss	(\$12,724,643)	(\$20,852,367)	(\$24,883,815)	(\$61,6
Other comprehensive income (loss):				
Unrealized gains (losses) on available for sale securities	154,260	(285,549)	345,601	(4
Comprehensive loss	(\$12,570,383)	(\$21,137,916)	(\$24,538,214)	(\$62 , 0

(3) Conversion of Preferred Stock

Effective May 7, 2001, pursuant to the terms of our Series A Convertible Participating Preferred Stock, 2,300,000 shares of preferred stock were converted into 2,346,295 shares of common stock.

(4) Employee Stock Plan

In June 2001, the stockholders of the Company approved an amendment to the Company's Stock Option and Restricted Share Plan (the "plan") to increase the number of shares eligible to grant under the plan by 1,000,000 shares and allow for the issuance of restricted shares.

(5) Acquisition of Technology Rights

In February 2001, the Company revised its agreement with Sanofi-Synthelabo for Picovir(TM), the Company's most advanced drug candidate. The original agreement signed in 1995 provided the Company with exclusive rights to develop and commercialize the product in the United States and Canada. Under the revised agreement, the Company expanded its intellectual property position, eliminated obligations for future milestone payments, reduced royalty rate obligations to Sanofi-Synthelabo on future sales of products, if any, under certain conditions, in exchange for a reduction of royalty rate obligations by Sanofi-Synthelabo to the Company on future sales of products, if any, under certain conditions, outside of the United States and Canada and the issuance of 750,000 shares of the Company's common stock. Included in operating expenses in the nine months ended September 30, 2001 is a non-cash charge of \$16.5 million resulting from the issuance of 750,000 shares of common stock to Sanofi-Synthelabo in exchange for the expansion of the Company's intellectual property rights related to

Picovir(TM), the Company's most advanced product candidate, as these additional intellectual property rights licensed from Sanofi-Synthelabo have not reached technological feasibility and have no alternative uses.

(6) Co-Promotion and Co-Development Agreement

In September 2001, the Company entered into a collaboration to co-develop and co-promote Picovir(TM) (pleconaril) in the United States with Aventis Pharmaceuticals Inc. (Aventis), the U.S. pharmaceutical company of Aventis Pharma AG. As part of the agreement, the Company received an initial payment of \$25 million from Aventis, and may receive additional cash payments, each of which is dependent upon reaching certain regulatory and other milestones. \$5 million of the initial payment received by the Company is reflected in Deferred revenue, and will be recognized as revenue over the estimated performance period. The balance of the initial payment is reflected in Other liabilities, as part or all of this balance will have to be repaid by the Company if certain milestones are not met. The Company and Aventis will share the cost of preparing for the commercial launch of Picovir(TM) and the continued marketing and commercialization efforts: 55 percent by Aventis and 45 percent by ViroPharma. Additionally, Aventis will fund 50% of the company's research and development efforts for the use of Picovir(TM) in the treatment of adult and pediatric viral respiratory infection. If Picovir(TM) is approved by the U.S. Food and Drug Administration (FDA), Aventis will distribute Picovir(TM) and both companies will share profits: 55 percent to Aventis and 45 percent to ViroPharma. If ViroPharma hires its initial sales force by early 2002, ViroPharma will copromote certain Aventis Pharmaceuticals prescription products to primary care physicians in the United States, and will receive detailing fees from Aventis for such calls. The term of the agreement is through the market exclusivity period for Picovir (TM), currently 2012, unless such period is extended or the agreement is terminated earlier due to the failure to attain certain milestones.

7

Upon FDA marketing clearance of Picovir(TM) for adult viral respiratory infection, an Aventis affiliate will purchase \$20 million in ViroPharma common stock priced at a trailing average of the last sale prices of ViroPharma's common stock.

(7) Registration Statement

In July 2001, ViroPharma filed a Form S-3 universal shelf registration statement with the Securities and Exchange Commission (the "SEC") for the registration and potential issuance of up to \$300 million of ViroPharma securities, along with the common stock held by, and common stock issuable upon exercise of warrants owned by, PSV, LP and Perseus Capital, LLC. The registration statement will provide ViroPharma the flexibility to determine the type of security it chooses to sell, including common stock, preferred stock, warrants and debt securities, as well as the ability to time such sales when market conditions are favorable.

The securities covered by the universal shelf registration statement are being registered on a delayed basis because ViroPharma does not intend to sell securities immediately upon the effectiveness of the registration statement. The actual amount of any securities to be issued, and the terms of those securities, will be determined at the time of sale, if such sales occur. On October 19, 2001 the SEC declared the registration statement effective.

8

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

Our disclosure and analysis in this report contains some forward-looking statements. Forward-looking statements give our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. They use words such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. In particular, these include statements relating to present or anticipated scientific or regulatory progress, development of potential pharmaceutical products, future revenues, capital expenditures, research and development expenditures, future financings and collaborations, personnel, manufacturing requirements and capabilities, and other statements regarding matters that are not historical facts or statements of current condition.

Any or all of our forward-looking statements in this report may turn out to be wrong. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Many factors, including those mentioned in the discussion below and those described in the "Risk Factors" discussion of our most recent registration statement on form S-3 filed with the Securities and Exchange Commission, will be important in determining future results. Consequently, no forward-looking statement can be guaranteed. Actual future results may vary materially. We do not intend to update our forward-looking statements to reflect future events or developments.

Since inception, we have devoted substantially all of our resources to our research and product development programs. We have generated no revenues from product sales and have been dependent upon funding primarily from equity and debt financing. We do not expect any revenues derived from Picovir(TM) sales until Picovir(TM) is approved by the U.S. Food and Drug Administration (FDA) which we do not expect to occur before mid-2002, at the earliest. There can be no assurance that we will receive such approval from the FDA. We have not been profitable since inception and have incurred a cumulative net loss of \$181,391,975 through September 30, 2001. Losses have resulted principally from costs incurred in research and development activities and general and administrative expenses. We expect to incur additional operating losses over at least the next several years. We expect our expenses to increase significantly over historical levels and our losses during the next several years to be higher than we have experienced in the past. Our level of losses during this period, however, depends upon if we are successful in commercializing Picovir(TM) and whether or not we receive certain milestone payments from Aventis. Our anticipated significant increase in expenses will be due to the near-term costs of developing our marketing and sales staff and building the requisite infrastructure, significant investments in Picovir(TM) marketing and market research activities, research and development activities related to additional clinical trials and supporting studies for the potential expansion of the use of Picovir(TM) and to discovery and development activities with our hepatitis C and RSV disease programs. Our ability to achieve profitability is dependent on developing and obtaining regulatory approvals for our product candidates, successfully commercializing such product candidates (which may include entering into collaborative agreements for product development and commercialization), and securing contract manufacturing services and distribution and logistics services.

Liquidity and Capital Resources

We commenced operations in December 1994. We are a development stage company and to date have not generated revenues from product sales. The cash flows used in operations historically have been applied to research and development activities and the supporting marketing and general and

administrative expenses. We expect to incur significant additional expenses related to the anticipated commercialization of Picovir(TM). Through September 30, 2001, we have used approximately \$124.0 million in operating activities. We invest our cash in short-term investments. Through September 30, 2001, we have used approximately \$163.2 million in investing activities, including \$153.7 million in short-term investments and \$9.5 million in equipment purchases and new construction. Through September 30, 2001, we have financed our operations primarily through public offerings of common stock, a convertible subordinated notes offering, private placements of redeemable preferred stock, two bank loans and equipment lease lines totaling approximately \$316.8 million. At September 30, 2001, we had cash and cash equivalents and short-term investments aggregating approximately \$183.6 million.

9

We lease our corporate and research and development facilities under an operating lease expiring in 2008. We also have the right, under certain circumstances, to purchase the facility. We have exercised our right to expand our current facility by 16,500 square feet. This expansion began in the third quarter of 2001 and we expect to incur approximately \$3.0 million of capital expenditures in connection with this expansion through the second quarter of 2002. We expect that rent expense in future years will increase approximately \$200,000 per year, commencing in mid-2002. In September 2001, we entered into a lease for 30,000 square feet of additional office space which will result in an annual increase in rent expense of approximately \$600,000 starting in mid-to late 2002 and capital expenditures of approximately \$500,000 through mid-2002. Additionally, we will be renovating and expanding our existing research and development and warehousing facilities over the next six to nine months which will result in capital outlays of approximately \$1.5 million. We expect to secure bank financing of approximately \$5 million to fund these expansions and renovations.

We have financed substantially all of our equipment under two bank loans and two master lease agreements. The first bank loan, which we entered into in February 1997, is for \$600,000, is payable in equal monthly installments over 72 months and has a 9.06% interest rate. The second bank loan, which we entered into in December 1998, is for \$500,000, is payable in equal monthly installments over 60 months and has a 7.25% interest rate. As of September 30, 2001, aggregate outstanding borrowings under these bank loans were approximately \$375,000. We have paid off both of the lease agreements.

We amended and restated our agreement with Sanofi-Synthelabo in February 2001. Under this agreement, we are required to make royalty payments on any sales in the United States and Canada of products developed under the agreement, which royalty payments will be reduced upon the expiration of the last patent on Picovir(TM) or any related drug.

In May 2001, we entered into a manufacturing agreement with Produits Chimiques Auxilliaires et de Synthese for Picovir(TM) drug substance. We currently are negotiating commercial supply agreements for Picovir(TM) with additional drug substance and final product manufacturers and with drug micronizers. These agreements will commit these suppliers to manufacture and supply Picovir(TM) to us at prices based on the quantity of product we require from them. We expect that prior to the anticipated commercial launch of Picovir (TM) we may pay up to approximately \$12.0 million during the next nine months under these arrangements.

In September 2001, the we entered into a collaboration to co-develop and co-promote Picovir(TM) (pleconaril) in the United States with Aventis Pharmaceuticals Inc. (Aventis), the U.S. pharmaceutical company of Aventis Pharma AG. As part of the agreement, we received an initial payment of \$25

million from Aventis, and may receive additional cash payments, each of which is dependent upon reaching certain regulatory and other milestones. \$5 million of the initial payment received is reflected in Deferred revenue, and will be recognized as revenue over the estimated performance period. The balance of the initial payment is reflected in Other liabilities, as part or all of this balance will have to be repaid if certain milestones are not met. We will share the cost of preparing for the commercial launch of Picovir(TM) and the continued marketing and commercialization efforts: 55 percent by Aventis and 45 percent by us. Additionally, Aventis will fund 50% of our research and development efforts for the use of Picovir(TM) in the treatment of adult and pediatric viral respiratory infection. If Picovir (TM) is approved by the U.S. Food and Drug Administration (FDA), Aventis will distribute Picovir(TM) and both companies will share profits: 55 percent to Aventis and 45 percent to us. If we hire our initial sales force by early 2002, we will co-promote certain Aventis Pharmaceuticals prescription products to primary care physicians in the United States, and will receive detailing fees from Aventis for such calls. The term of the agreement is through the market exclusivity period for Picovir(TM), currently 2012, unless such period is extended or the agreement is terminated earlier due to the failure to attain certain milestones. We expect to incur significant expenses under this agreement over the next several years related to marketing and market research activities for Picovir(TM), the development of a marketing and sales staff, building the requisite infrastructure and further clinical trials for Picovir(TM).

We have incurred losses from operations since inception because we have generated minimal revenue to date. We expect to incur additional operating losses over at least the next several years. We expect our expenses to increase significantly over historical levels and our losses during the next several years to be higher than we have experienced in the past. Our level of losses during this period, however, depends upon if we are successful in commercializing Picovir(TM) and whether or not we receive certain milestone payments from Aventis. Our anticipated significant increase in expenses will be due to the near-term cost of developing our marketing and sales staff and building the requisite infrastructure, significant investments in Picovir(TM) marketing and market research activities, research and development activities related to additional clinical trials and supporting studies for the potential expansion of the use of Picovir(TM) and to discovery and development activities with our hepatitis C and RSV disease programs. We expect that our spending in the general and administrative areas to increase modestly over the next nine to twelve months when compared to such spending to date in 2001.

10

In November 2001, we and American Home Products (AHP), through its subsidiary Wyeth-Ayerst laboratories, announced that we have halted further development of VP50406, our first product candidate for the treatment of hepatitis C. We will continue to fund the development of additional compounds under our collaboration agreement with AHP, one of which we expect to enter clinical trials in the second half of 2002.

We expect that we will need to raise additional funds to continue our business activities, fund debt service and to further expand our facilities. We have convertible notes payable in the amount of \$180.0 million. These notes bear interest at 6% per annum and become due in March 2007. We may need additional financing to complete all Picovir(TM) clinical studies, to develop our marketing and sales staffs for Picovir(TM) and to build the requisite infrastructure. We expect that we will need additional financing for the development and required testing of our hepatitis C and RSV disease compounds, and for any other product candidates. To obtain this financing, we intend to access the public or private equity or debt markets or enter into additional arrangements with corporate

collaborators to whom we may issue shares of our stock. In July 2001, we filed a Form S-3 universal shelf registration statement with the Securities and Exchange Commission for the registration and potential issuance of up to \$300.0 million of our securities. On October 19, 2001 the SEC declared the registration statement effective. The registration statement will provide us with the flexibility to determine the type of security we choose to sell, including common stock, preferred stock, warrants and debt securities, as well as the ability to time such sales when market conditions are favorable. Also, in connection with certain of our collaboration agreements, American Home Products Corporation and Aventis will purchase our common stock at the time of completion of certain product development and regulatory approval events, respectively. If we raise additional capital by issuing equity securities, the terms and prices for these financings may be much more favorable to the new investors than the terms obtained by our existing stockholders. These financings also may dilute the ownership of existing stockholders. Collaborative arrangements may require us to grant product development programs or licenses to third parties for products that we might otherwise seek to develop or commercialize ourselves. Additional financing, however, may not be available on acceptable terms from any source. If sufficient additional financing is not available, we may need to delay, reduce or eliminate current research and development programs, delay or reduce our commercialization efforts for Picovir(TM) or reduce or eliminate other aspects of our business.

Results of Operations

Quarters ended September 30, 2001 and 2000

We earned license fee revenue from our collaboration with Wyeth-Ayerst in the hepatitis C area of \$250,000 in each of the quarters ended September 30, 2001 and 2000. Additionally, in the quarter ended September 30, 2001, we earned license fee revenue of approximately \$96,000 in connection with our Picovir(TM) collaboration with Aventis, which was entered into in September 2001. Research and development expenses of approximately \$12.3 million in the quarter ended September 30, 2001 were essentially flat when compared to the same period in the prior year. Higher employee costs of approximately \$1.7 million (associated with increased development and discovery staffing levels), higher spending of approximately \$0.8 million related to increased efforts in discovery research and the cost associated with the manufacturing of validation batches of Picovir(TM) were offset by lower spending in Picovir(TM) development efforts of approximately \$3.4 million. A portion of the reduction in Picovir(TM) costs in the third quarter of 2001 versus the third quarter of 2000 is due to the cost sharing provisions of our agreement with Aventis. In the third quarter of 2001 we continued manufacturing validation batches of Picovir(TM), completed and submitted our new drug application (NDA) for Picovir(TM) to the FDA, commenced additional clinical trials for Picovir(TM) for the treatment of pediatric VRI and for the prophylaxis of VRI in healthy adults, and were conducting two-phase 2a studies for the treatment of hepatitis C. During the same period in 2000, we initiated two large phase 3 trials with Picovir(TM) for the treatment of VRI and additional pre-clinical studies for the treatment of RSV disease, and we were preparing for, but had not yet initiated, patient studies for the treatment of hepatitis C.

Sales and marketing expense for the third quarter of 2001 was \$4.2 million compared to approximately \$0.3 million for the same period in 2000. This increase reflects our significant investments, net of the Aventis cost sharing, in pre-launch activities, including medical education, brand development and market research for Picovir(TM), as well as initial investments in the development of a sales force that is expected to commence selling two Aventis products in the first quarter of 2002, and Picovir(TM) in the second half of 2002 if the NDA for Picovir(TM) is approved by the FDA.

General and administrative expenses for the third quarter of 2001 were

approximately \$4.5 million compared to approximately \$1.5 million for the same period in 2000. The increase in general and administrative expenses is primarily due to costs associated with the completion of the collaboration agreement with Aventis, higher employee related expenses due to increased staffing levels and facilities cost of approximately \$0.8 million.

11

Interest expense for the quarter ended September 30, 2001 was essentially flat when compared to the same period in the prior year due to relatively consistent levels of debt in both periods. Interest income fell approximately \$1.2 million during the third quarter 2001 when compared to the same quarter in 2000 primarily due to lower levels of cash and short term investments. The net loss increased to \$20.9 million for the quarter ended September 30, 2001 from \$12.7 million for the quarter ended September 30, 2000. As of September 30, 2001 we had approximately \$183.6 million in cash, cash equivalents and short-term investments. Also, at September 30, 2001, the weighted average interest rate that we are earning on our short-term investments was approximately 6.3%.

Nine-months ended September 30, 2001 and 2000

We earned license fee and milestone revenue from our collaboration with Wyeth-Ayerst in the hepatitis C area of \$2.75 million for the nine-month period ended September 30, 2001 compared to \$1.75 million during the same period in 2000. In the nine-month period ended September 30, 2001, we achieved one milestone and earned \$2.0 million compared to achieving one milestone and earning \$1.0 million for the nine-month period ended September 30, 2000. Research and development expenses increased to \$31.2 million for the nine-month period ended September 30, 2001 from \$22.9 million for the nine-month period ended September 30, 2000. The increase in the nine-month period ended September 30, 2001 over the same period in 2000 was primarily due to higher clinical, preclincal and manufacturing costs of approximately \$3.5 million, partly offset by increased costs to be repaid by our development partners. Employee related expenses for nine months in 2001 were approximately \$4.0 million higher when compared to the same period in 2000, primarily as a result of higher staffing levels necessary to support development and discovery programs. The increased efforts in discovery research resulted in increased spending of approximately \$2.2 million during the nine months ended 2001 when compared to the same period in 2000. The increase in development expenses for the nine-months ended September 30, 2001 over the same period for 2000 was due primarily to the completion of two phase 3 clinical trials for Picovir(TM) for the treatment of VRI in adults, the preparation and submission of our NDA for Picovir(TM), manufacturing of validation batches of Picovir(TM) and the completion of all clinical and pre-clinical studies included in the NDA. Also, in the nine-month period ended September 30, 2001, the company initiated additional clinical trials with Picovir(TM) for the treatment of pediatric VRI and for the prophylaxis of VRI in healthy adults. The company also was conducting two phase 2a studies for the treatment of hepatitis C and completed one phase 1 study for the treatment of RSV disease. In comparison, during the nine months in 2000 we completed three phase 3 clinical trials of pleconaril, and were conducting a phase 1 clinical trials for the treatment of hepatitis C and the advancement of our drug candidate for the treatment of RSV disease.

Sales and marketing expenses in the nine-months ended September 30, 2001 were \$8.1 million compared to \$1.3 million for the same period of 2000. This increase reflects our significant investments, net of the Aventis cost sharing, in pre-launch activities for Picovir(TM), including medical education, brand development and market research, as well as initial investments in the development of a sales force that is expected to commence selling two Aventis

products in the first quarter of 2002, and Picovir(TM) in the second half of 2002 if our NDA for Picovir(TM) is approved by the FDA.

General and administrative expenses increased to \$9.3 million in the ninemonths ended September 30, 2001 from \$4.4 million for the same period of 2000. The increase in general and administrative expenses primarily is due to costs associated with the completion of the collaboration agreement with Aventis, and higher employee related expenses due to increased staffing levels and facilities cost of approximately \$2.4 million. Included in operating expenses in the ninemonth period ended September 30, 2001 is a non-cash charge of \$16.5 million resulting from the issuance of 750,000 shares of common stock to Sanofi-Synthelabo in exchange for the expansion of our intellectual property rights related to Picovir(TM), as these additional intellectual property rights licensed from Sanofi-Synthelabo have not reached technological feasibility and have no alternative uses. Interest expense and interest income increased in the nine-month period ended September 30, 2001 compared to the same period in 2000. The increase in interest income is due to the investing of \$180.0 million convertible subordinated debentures issued in March of 2000 which pay 6% interest per annum. The increase in interest expense is due to the debt service costs associated with such convertible subordinated debentures. The net loss increased to \$61.7 million for the nine-month period ended September 30, 2001 from \$24.9 million for the nine-month period ended September 30, 2000.

12

Recently Issued Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, Business Combinations. SFAS No. 141 requires the use of the purchase method of accounting for all business combinations initiated after June 30, 2001 and eliminates the pooling-of-interest method. We do not believe that the adoption of SFAS No. 141 will have an impact on our financial statements.

In July 2001, the FASB issued SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 142 requires goodwill and other intangible assets with indefinite lives to no longer be amortized, but instead tested for impairment at least annually. In addition, the standard includes provisions for the reclassification of certain existing intangibles as goodwill and reassessment of the useful lives of existing recognized intangibles. The standard is effective for fiscal years beginning after December 15, 2001. We do not believe that the adoption of SFAS No. 142 will have an impact on our financial statements.

In July 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations. SFAS No. 143 requires the recognition of a liability for an asset retirement in the period in which it is incurred. A retirement obligation is defined as one in which a legal obligation exists in the future resulting from existing laws, statues or contracts. The standard is effective for fiscal years beginning after June 15, 2002. We do not believe the adoption of SFAS No. 143 will have a material impact on our financial statements.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, which supersedes both SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of and the accounting and reporting provisions of APB Opinion No. 30, Reporting the Results of Operations—Reporting the Effects of Diposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business (as previously defined in that Opinion). SFAS No. 144 retains the fundamental provisions in SFAS No. 121 for recognizing and measuring impairment losses on long-lived assets held for use and long-lived assets to be disposed of by sale, while also resolving significant implementation issues associated with SFAS No. 121. For example,

SFAS No. 144 provides guidance on how a long-lived asset that is used as part of a group should be evaluated for impairment, establishes criteria for when a long-lived asset is held for sale, and prescribes the accounting for a long-lived asset that will be disposed of other than by sale. SFAS No. 144 retains the basic provisions of APB No. 30 on how to present discontinued operations in the income statement but broadens that presentation to include a component of an entity (rather than a segment of a business). Unlike SFAS No. 121, an impairment assessment under SFAS No. 144 will never result in a write-down of goodwill. Rather, goodwill is evaluated for impairment under SFAS No. 142, Goodwill and Other Intangible Assets.

We are required to adopt SFAS No. 144 no later than the year beginning after December 15, 2001, and plans to adopt its provisions for the quarter ending March 31, 2002. We do not expect the adoption of SFAS No. 144 for long-lived assets held for use to have a material impact on our financial statements because the impairment assessment under SFAS No. 144 is largely unchanged from SFAS No. 121. The provisions of the new standard for assets held for sale or other disposal generally are required to be applied prospectively after the adoption date to newly initiated disposal activities. Therefore, we cannot determine the potential effects that the adoption of the provisions of SFAS No. 144 will have on our financial statements.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Our holdings of financial instruments are comprised of a mix of U.S. corporate debt, government securities and commercial paper. All such instruments are classified as securities available for sale. Our debt security portfolio represents funds held temporarily pending use in our business and operations. We manage these funds accordingly. We seek reasonable assuredness of the safety of principal and market liquidity by investing in rated fixed income securities while at the same time seeking to achieve a favorable rate of return. Our market risk exposure consists principally of exposure to changes in interest rates. Our holdings are also exposed to the risks of changes in the credit quality of issuers. We typically invest in the shorter-end of the maturity spectrum. The principal amount and weighted average interest rate of our short-term investment portfolio at September 30, 2001 was \$153,975,485 and approximately 6.3%, respectively.

13

The Company has \$180.0 million of convertible subordinated notes due 2007. The notes are convertible into shares of the Company's common stock at a price of \$109.15 per share, subject to certain adjustments. The notes bear interest at a rate of 6 % per annum, payable semi-annually in arrears, and can be redeemed by the Company, at certain premiums over the principal amount, at any time on or after March 6, 2003.

14

PART II - OTHER INFORMATION

ITEM 6. Exhibits and Reports on Form 8-K

(a) List of Exhibits:

10.35 + Copromotion and Codevelopment Agreement dated as of September 9, 2001 between ViroPharma Incorporated and

Aventis Pharmaceuticals Inc.

- 10.36 Stock Purchase Agreement dated as of September 9, 2001 between ViroPharma Incorporated and Aventis Pharma Inc.
- 10.37 Agreement of Lease dated as of September 24, 2001 between LV Associates, L.P. and ViroPharma Incorporated.
 - + Portions of this exhibit were omitted and filed separately with the Securities and Exchange Commission pursuant to an application for confidential treatment.
- (b) Reports on Form 8-K:

We filed the following Current Reports on Form 8-K during the quarter ended September 30, 2001:

- (i) We filed a Current Report on Form 8-K dated July 26, 2001 to report, pursuant to item 5, our financial results for the second quarter ended June 30, 2001.
- (ii) We filed a Current Report on Form 8-K dated July 31, 2001 to report, pursuant to item 5, that we submitted a New Drug Application to the U.S. Food and Drug Administration for clearance to market Picovir(TM) (pleconaril) for the treatment of viral respiratory infection (VRI, otherwise known as the common cold) in adults.
- (iii) We filed a Current Report on Form 8-K dated September 10, 2001 to report, pursuant to item 5, that we entered into a Copromotion and Codevelopment Agreement for Picovir(TM), our lead product candidate, with Aventis Pharmaceuticals, Inc. and a Stock Purchase Agreement with Aventis Pharma Inc.

15

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.

VIROPHARMA INCORPORATED

Date: November 12, 2001 By: /s/ Michel de Rosen

Michel de Rosen
President and Chief Executive Officer

By: /s/ Vincent J. Milano

(Principal Executive Officer)

Vincent J. Milano

16

Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)

16

Exhibit Index

Exhibit	Description
10.35 +	Copromotion and Codevelopment Agreement dated as of September 9, 2001 between ViroPharma Incorporated and Aventis Pharmaceuticals Inc.
10.36	Stock Purchase Agreement dated as of September 9, 2001 between ViroPharma Incorporated and Aventis Pharma Inc.
10.37	Agreement of Lease dated as of September 24, 2001 between LV Associates, L.P. and ViroPharma Incorporated.

+ Portions of this exhibit were omitted and filed separately with the Securities and Exchange Commission pursuant to an application for confidential treatment.