

VIRAGEN INC  
Form 10-Q  
November 05, 2004

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

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**FORM 10-Q**

*(Mark One)*

FOR THE QUARTER ENDED SEPTEMBER 30, 2004

OR

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

**Commission File Number 001-15823**

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**VIRAGEN, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**59-2101668**

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

**865 SW 78<sup>th</sup> Avenue, Suite 100, Plantation, Florida 33324**

(Address of principal executive offices)

**(954) 233-8746**

(Registrant's telephone number, including area code)

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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 requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of November 4, 2004, there were 36,568,385 shares of the registrant's common stock outstanding, par value \$0.01.

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**VIRAGEN, INC. AND SUBSIDIARIES**

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Table of Contents**VIRAGEN, INC. AND SUBSIDIARIES****CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS****(Unaudited)**

	<b>Three Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
Product sales	\$ 30,417	\$ 51,606
Costs and expenses		
Cost of sales	476,260	369,007
Research and development	1,090,869	814,422
Selling, general and administrative	1,813,519	1,466,263
Amortization of intangible assets	40,380	37,413
Interest expense	1,286,259	1,791,632
Other expense (income), net	37,688	(223,224)
	<hr/>	<hr/>
Loss before income taxes and minority interest	(4,714,558)	(4,203,907)
Income tax benefit	10,957	10,957
Minority interest in net loss of subsidiary	382,711	289,697
	<hr/>	<hr/>
Net loss	(4,320,890)	(3,903,253)
Deduct required dividends on convertible preferred stock, Series A	537	662
	<hr/>	<hr/>
Net loss attributable to common stock	\$ (4,321,427)	\$ (3,903,915)
	<hr/>	<hr/>
Basic and diluted net loss per share of common stock, after deduction for required dividends on convertible preferred stock	\$ (0.12)	\$ (0.14)
	<hr/>	<hr/>
Weighted average common shares basic and diluted	36,568,385	27,336,080
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See notes to consolidated condensed financial statements which are an integral part of these statements.

Table of Contents**VIRAGEN, INC. AND SUBSIDIARIES****CONSOLIDATED CONDENSED BALANCE SHEETS**

	<b>September 30, 2004</b>	<b>June 30, 2004</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 11,976,882	\$ 22,753,271
Short-term investments	5,398,208	
Accounts receivable	22,318	31,788
Inventories	3,544,610	3,477,214
Prepaid expenses	1,304,568	1,353,350
Other current assets	763,290	1,022,356
	<hr/>	<hr/>
Total current assets	23,009,876	28,637,979
Property, plant and equipment		
Land, building and improvements	3,842,605	3,805,834
Equipment and furniture	5,609,413	5,520,677
Construction in progress	1,917,970	1,861,846
	<hr/>	<hr/>
	11,369,988	11,188,357
Less accumulated depreciation	(4,565,680)	(4,362,976)
	<hr/>	<hr/>
	6,804,308	6,825,381
Goodwill	10,574,815	10,295,140
Developed technology, net	1,836,664	1,828,122
Deposits and other assets	455,207	633,374
	<hr/>	<hr/>
	\$ 42,680,870	\$ 48,219,996
	<hr/>	<hr/>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities		
Accounts payable	\$ 742,562	\$ 814,253
Accrued expenses and other liabilities	842,558	1,411,458
Line of credit and short term borrowings	230,355	1,076,645
Current portion of long-term debt	35,391	153,723
	<hr/>	<hr/>
Total current liabilities	1,850,866	3,456,079
Convertible notes and debentures	13,258,163	12,490,919

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Long-term debt, less current portion	663,585	1,072,087
Deferred income tax liability	489,411	500,368
Royalties payable	107,866	107,866
Minority interest in subsidiary	1,200,202	1,403,096
Commitments		
Stockholders' equity		
Convertible 10% Series A cumulative preferred stock, \$1.00 par value. Authorized 375,000 shares; 2,150 and 2,250 issued and outstanding at September 30, 2004 and June 30, 2004, respectively. Liquidation preference value: \$10 per share, aggregating \$21,500 at September 30, 2004 and \$22,500 at June 30, 2004	2,150	2,250
Common stock, \$.01 par value. Authorized 100,000,000 shares; 36,568,385 issued and outstanding at September 30, 2004 and June 30, 2004	365,685	365,685
Capital in excess of par value	146,235,660	146,337,835
Accumulated deficit	(124,791,690)	(120,470,263)
Accumulated other comprehensive income	3,298,972	2,954,074
	<u>                    </u>	<u>                    </u>
Total stockholders' equity	25,110,777	29,189,581
	<u>                    </u>	<u>                    </u>
	\$ 42,680,870	\$ 48,219,996
	<u>                    </u>	<u>                    </u>

See notes to consolidated condensed financial statements which are an integral part of these statements.

Table of Contents**VIRAGEN, INC. AND SUBSIDIARIES****CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS****(Unaudited)**

	<b>Three Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (4,320,890)	\$(3,903,253)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	197,834	215,709
Amortization of intangible assets	40,380	37,413
Amortization of fees paid with common stock	30,000	
Unrealized losses on foreign exchange remeasurement	242,280	
Compensation expense on stock options and warrants		21,415
Minority interest in net loss of subsidiary	(382,711)	(289,697)
Amortization of discount on convertible debentures and promissory notes	767,244	1,524,628
Amortization of deferred financing costs	116,677	223,083
Deferred income tax benefit	(10,957)	(10,957)
Increase (decrease) relating to operating activities from:		
Accounts receivable	9,470	(48,334)
Inventories	(67,396)	(151,070)
Prepaid expenses	268,782	68,755
Other current assets	44,061	12,249
Accounts payable	(84,934)	(959,363)
Accrued expenses and other liabilities	(554,037)	(237,898)
	<hr/>	<hr/>
Net cash used in operating activities	(3,704,197)	(3,497,320)
<b>INVESTING ACTIVITIES</b>		
Purchase of short-term investments	(5,519,700)	
Additions to property, plant and equipment	(98,694)	(44,038)
Proceeds from sale of property, plant and equipment	24,738	
	<hr/>	<hr/>
Net cash used in investing activities	(5,593,656)	(44,038)
<b>FINANCING ACTIVITIES</b>		
Proceeds from private placements of common stock, net		4,764,940
Payments on lines of credit and short term promissory notes, net	(791,570)	(205,792)
Payments on long-term debt	(560,086)	(8,050)
Payments on convertible debentures		(23,649)
Repurchase of preferred stock shares, Series A	(1,000)	
Proceeds from exercise of debt and equity offering warrants		1,312,241
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Net cash (used in) provided by financing activities	(1,352,656)	5,839,690
Effect of exchange rate fluctuations on cash and cash equivalents	(125,880)	140,911
	<u>                    </u>	<u>                    </u>
(Decrease) increase in cash and cash equivalents	(10,776,389)	2,439,243
Cash and cash equivalents at beginning of period	22,753,271	5,942,501
	<u>                    </u>	<u>                    </u>
Cash and cash equivalents at end of period	\$ 11,976,882	\$ 8,381,744
	<u>                    </u>	<u>                    </u>

During the three months ended September 30, 2004 and September 30, 2003, we had the following non-cash financing activities:

	<b>Three Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
	<u>          </u>	<u>          </u>
Purchase of insurance with notes payable	\$	\$ 301,570
Conversion of convertible debentures and accrued interest into common stock		3,341,602

See notes to consolidated condensed financial statements which are an integral part of these statements.



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**VIRAGEN, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS  
(Unaudited)**

**NOTE A OVERVIEW AND BASIS OF PRESENTATION**

We are a biopharmaceutical company engaged in the research, development, manufacture and sale of a natural human alpha interferon product indicated for treatment of a broad range of viral and malignant diseases. We are also developing innovative technologies aimed at improving the manufacturing processes used to manufacture certain medical therapies and we are developing novel therapeutics for the treatment of cancer. Specifically, we are primarily focused on three fields of research and development:

Human leukocyte derived interferon natural alpha interferon derived from human white blood cells for the treatment of a wide range of viral and malignant diseases.

Avian transgenics technologies designed to produce protein-based drugs inside the egg whites of transgenic developed chickens.

Oncological therapies therapeutic proteins and peptides for the treatment of targeted cancers.

We own approximately 81.2% of Viragen International, Inc. We operate primarily through Viragen International, Inc., and its wholly owned subsidiaries, ViraNative AB ( ViraNative ), a company located in Umea, Sweden, and Viragen (Scotland) Limited ( Viragen (Scotland) ), a company located near Edinburgh, Scotland. ViraNative and Viragen (Scotland) house our manufacturing and research laboratory facilities.

On June 15, 2004, we effected a 1-for-10 reverse split of our outstanding common stock. All share and per share information herein have been restated to retroactively reflect this reverse stock split

The accompanying unaudited interim consolidated condensed financial statements include Viragen, Inc., Viragen International, Inc. and all subsidiaries, including those operating outside the United States of America. All significant intercompany balances and transactions have been eliminated. Minority interest in net loss of subsidiary represents the minority stockholders share of the net loss of Viragen International. These statements have been prepared in conformity with accounting principles generally accepted in the United States, consistent in all material respects with those applied in our Annual Report on Form 10-K for the fiscal year ended June 30, 2004, filed with the Securities and Exchange Commission.

The accompanying unaudited interim consolidated condensed financial statements for Viragen, Inc. have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, certain information and footnote disclosures normally included in financial statements included in our Annual Report on Form 10-K have been condensed or omitted. The accompanying unaudited interim consolidated condensed financial statements should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations contained in this report and the audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the fiscal year ended June 30, 2004.

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. The accounting estimates that require management s most difficult and subjective judgments include: the assessment of recoverability of goodwill and long-lived assets; and the valuation of inventories. Actual results could

differ materially from those estimates.

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**VIRAGEN, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**NOTE A OVERVIEW AND BASIS OF PRESENTATION (Continued)**

The interim financial information is unaudited, but, in the opinion of management, reflects all adjustments, including normal recurring adjustments, considered necessary for a fair presentation of results of the interim periods presented. Operating results for the three months ended September 30, 2004 are not necessarily indicative of the results that may be expected for the fiscal year ending June 30, 2005.

During the three months ended September 30, 2004 we incurred a loss of approximately \$4,321,000. During the fiscal years ended June 30, 2004, 2003 and 2002, we incurred significant losses of approximately \$18,177,000, \$17,349,000 and \$11,089,000, respectively, and had an accumulated deficit of approximately \$124,792,000 as of September 30, 2004. We have cash and short-term investments totaling approximately \$17,375,000 and working capital of approximately \$21,159,000 at September 30, 2004. We anticipate additional future losses as we commercialize our natural human alpha interferon product and conduct additional research and development activities and clinical trials to obtain additional regulatory approvals. We believe we have sufficient cash to support operations, including those of our subsidiaries, through at least December 31, 2005. However, we will require substantial additional funding to support our operations subsequent to December 31, 2005. If we are unable to generate sufficient cash flows from operations, our plans include seeking additional capital through equity and debt financings. No assurance can be given that additional capital will be available when required or upon terms acceptable to us.

**NOTE B STOCK-BASED COMPENSATION**

As currently permitted under Statement of Financial Accounting Standards (SFAS) No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, which amended SFAS No. 123, *Accounting for Stock-Based Compensation*, our employee stock option plans are accounted for under Accounting Principles Board Opinion No. 25 (APB No. 25), *Accounting for Stock Issued to Employees*, and related interpretations. Compensation expense for stock option grants is recognized if the exercise price is less than the fair value of our common stock on the grant date. See Note L for proposed pronouncement.

The following table illustrates the effect on net loss and net loss per common share if we had applied the fair value method to measure stock-based compensation as required under the disclosure provisions of SFAS No. 123:

	<b>Three Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
Net loss as reported	\$(4,320,890)	\$(3,903,253)
Stock based compensation determined under the fair value method	(29,148)	(13,160)
Pro forma net loss	(4,350,038)	(3,916,413)
Deduct preferred stock dividends, Series A	537	662

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Pro forma net loss attributable to common stock	<u>\$ (4,350,575)</u>	<u>\$ (3,917,075)</u>
Loss per common share after deduction of required dividends on convertible preferred stock:		
Basic and diluted as reported	\$ (0.12)	\$ (0.14)
Basic and diluted pro forma	\$ (0.12)	\$ (0.14)

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**VIRAGEN, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**NOTE B STOCK BASED COMPENSATION (Continued)**

The effects of applying SFAS No. 123 and SFAS No. 148 on pro forma disclosures of net loss and net loss per common share for the three months ended September 30, 2004 and 2003, are not likely to be representative of the pro forma results of net loss and net loss per common share in future periods since the number of options to be issued under our stock option plans is not known and the assumptions used to determine the fair value of stock options can vary significantly.

**NOTE C SHORT-TERM INVESTMENTS**

We invest excess cash in highly liquid instruments with maturities of less than twelve months as of the date of purchase. At September 30, 2004, our short-term investments totaling approximately \$5,398,000 consisted of UK Pound Sterling denominated certificates of deposit with maturities of six and nine months. During the three months ended September 30, 2004, we recognized a net remeasurement loss totaling approximately \$121,000 related to these short-term investments.

**NOTE D INVENTORIES**

Inventories consist of raw materials and supplies, work in process, and finished product. Finished product consists of purified natural human alpha interferon. Costs of raw materials and supplies are determined on a first-in, first-out basis. Costs of work in process and finished product, consisting of raw materials, labor and overhead, are recorded at a standard cost (which approximates actual cost). Excess/idle capacity costs represent fixed production costs incurred at our Swedish manufacturing facility, which were not absorbed as a result of the suspension of routine manufacturing. Excess/idle capacity costs are expensed in the period in which they are incurred and are included in cost of sales.

Our inventories are stated at the lower of cost or market (estimated net realizable value). If the cost of the inventories exceeds their expected market value, provisions are recorded currently for the difference between the cost and the market value. These provisions are determined based on estimates. The valuation of our inventories also requires us to estimate excess inventories and inventories that are not saleable. The determination of excess or non-saleable inventories requires us to estimate the future demand for our product and consider the shelf life of the inventory. If actual demand is less than our estimated demand, we could be required to record inventory reserves, which would have an adverse impact on our results of operations.

Inventories consisted of the following at September 30, 2004 and June 30, 2004:

	<b>September 30, 2004</b>	<b>June 30, 2004</b>
	<hr/>	<hr/>
Finished product	\$1,030,741	\$1,038,944
Work in process	2,235,231	2,176,116
Raw materials and supplies	278,638	262,154
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Total inventories	\$3,544,610	\$3,477,214
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**VIRAGEN, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**NOTE E GOODWILL AND OTHER INTANGIBLE ASSETS**

On September 28, 2001, Viragen International, Inc., our majority owned subsidiary, acquired all of the outstanding shares of BioNative AB ( BioNative ), a privately held biotechnology company located in Umeå, Sweden. Subsequent to the acquisition, BioNative was renamed ViraNative. The initial purchase consideration consisted of 2,933,190 shares of Viragen International common stock. In January 2002, ViraNative achieved two milestones defined in the acquisition agreement. As a result, the former shareholders of ViraNative were issued an additional 8,799,570 shares of Viragen International common stock.

The goodwill reported in our balance sheets as of September 30, 2004 and June 30, 2004 arose from Viragen International's acquisition of ViraNative and the subsequent achievement of the milestones. Subsequent to the initial recording of goodwill, the gross carrying amount has increased by approximately \$2,987,000 as a result of foreign currency fluctuations between the U.S. dollar and the Swedish Krona. The following table reflects the changes in the carrying amount of goodwill for the three months ended September 30, 2004:

Balance as of June 30, 2004	\$ 10,295,140
Foreign exchange adjustment	279,675
	<hr/>
Balance as of September 30, 2004	\$ 10,574,815
	<hr/>

In accordance with Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets*, goodwill is not amortized but is reviewed for impairment on an annual basis or sooner if indicators of impairment arise. We periodically evaluate that acquired business for potential impairment indicators. Our judgments regarding the existence of impairment indicators are based on legal factors, market conditions, and the operational performance of the acquired business. As of April 1, 2004, we evaluated our goodwill for impairment with the assistance of an independent valuation firm. The impairment review indicated that our goodwill was not impaired. Future changes in the estimates used to conduct the impairment review, including revenue projections or market values, could cause our analysis to indicate that our goodwill is impaired in subsequent periods and result in a write-off of a portion or all of our goodwill.

The developed technology intangible asset reported in our balance sheets as of September 30, 2004 and June 30, 2004 arose from Viragen International's acquisition of ViraNative. A detail of our developed technology intangible asset as of September 30, 2004 and June 30, 2004 is as follows:

	<b>September 30, 2004</b>	<b>June 30, 2004</b>
	<hr/>	<hr/>
Developed technology	\$2,330,096	\$2,268,472
Accumulated amortization	(493,432)	(440,350)

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Developed technology, net	\$1,836,664	\$1,828,122
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**VIRAGEN, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**NOTE E GOODWILL AND OTHER INTANGIBLE ASSETS (Continued)**

Our developed technology consists of the production and purification methods developed by ViraNative prior to the acquisition by Viragen International. This technology was complete and ViraNative had been selling the resultant natural interferon product prior to the acquisition by Viragen International. Developed technology was recorded at its estimated fair value at the date of acquisition. Subsequent to the initial recording of this intangible asset, the gross carrying amount has increased by approximately \$680,000 as a result of foreign currency fluctuations between the U.S. dollar and the Swedish Krona.

Developed technology is being amortized over its estimated useful life of approximately 14 years. The 14-year life assigned to this asset was determined using a weighted average of the remaining lives of the patents on the various components of the production and purification processes.

**NOTE F CONVERTIBLE NOTES AND DEBENTURES**

Details of our convertible notes and debentures outstanding at September 30, 2004 and June 30, 2004 are as follows:

	<b>September 30, 2004</b>	<b>June 30, 2004</b>
	<hr/>	<hr/>
Outstanding principal	\$20,000,000	\$20,000,000
Less discounts	(6,741,837)	(7,509,081)
	<hr/>	<hr/>
	\$13,258,163	\$12,490,919
	<hr/>	<hr/>

At September 30, 2004 and June 30, 2004, the convertible notes and debentures balance consists of the 7% convertible notes issued on June 18, 2004 totaling \$20 million.

*June 2004 Convertible Notes*

On April 1, 2004, we entered into purchase agreements for the issuance and sale of 7% convertible notes and common stock purchase warrants in the aggregate amount of \$20 million. The notes were placed with a group of new and returning institutional investors. The \$20 million purchase price for the notes and warrants was placed in escrow pending satisfaction of all conditions precedent to closing, including receipt of stockholder approval for the sale of the notes and warrants, as well as a one for ten reverse split of our common stock. On June 11, 2004 our stockholders voted to approve the sale of the notes and a one for ten reverse split of our common stock. On June 18, 2004, we completed the sale of the notes and warrants. Under the terms of these agreements, we received approximately \$18.96 million, net of finder's fees and legal expenses. These agreements also provided for the issuance to the purchasers of an aggregate of 5,357,051 three-year common stock purchase warrants exercisable at \$1.819 per share. In connection with the April 1, 2004 purchase agreements, we paid a finder's fee of 5% or \$1 million and issued the

finder 80,000 three-year common stock purchase warrants exercisable at a price of \$1.516 per share.

These convertible notes mature on March 31, 2006. Interest is payable quarterly commencing July 1, 2004. Quarterly interest payments are payable in cash or, at our option, in shares of our common stock based upon the average market price of our common stock during the 20 consecutive trading days prior to and including the interest payment date, subject to certain conditions.

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**VIRAGEN, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**NOTE F CONVERTIBLE NOTES AND DEBENTURES (Continued)**

The notes are convertible immediately by the investors, in whole or in part, into shares of our common stock at a conversion price equal to \$1.516. This conversion price is subject to reductions if we enter into additional financing transactions for the sale of our stock below the market price or below the conversion price.

These notes may be prepaid at 110% of their face amount, plus the issuance to note holders of additional warrants to purchase the number of shares of our common stock into which the notes would otherwise have been convertible, at an exercise price equal to the prevailing conversion price of the notes. If issued on prepayment, the warrants may be exercised for the period that would have been the remaining life of the notes had they not been prepaid. Commencing one year after issuance, we also have the right to require note holders to convert their notes, subject to certain limitations; provided that our common stock has traded at 200% or more of the conversion price of the notes on each of the 30 trading days ending five days prior to the date fixed for conversion.

The warrants issued in connection with the notes are exercisable during the three year period ending June 18, 2007 and can be exercised on a cashless basis whereby the holder may surrender a number of warrants equal to the exercise price of the warrants being exercised. The relative fair value of these warrants was calculated to be approximately \$3,264,000 using a Black-Scholes valuation model. The relative fair value of these warrants was recorded as a discount on the principal amount of the notes and is amortized to interest expense using the effective interest rate method over the life of the notes. For the three months ended September 30, 2004, we recognized approximately \$328,000 as non-cash interest expense from the amortization of the discount that arose from the issuance of the warrants.

As a result of the common stock purchase warrants issued in connection with the notes and the calculated effective conversion price of the notes, a beneficial conversion amount of approximately \$4,372,000 was calculated and recorded as a discount on the principal amount of the notes at the date of issuance. For the three months ended September 30, 2004, we recognized approximately \$439,000 as non-cash interest expense from the amortization of the discount that arose from the beneficial conversion feature.

We incurred costs of approximately \$1,161,000 in connection with the notes and warrants, which primarily consisted of the finder's fees, the fair value of warrants issued to the finder, and legal and accounting expenses. These costs will be amortized to interest expense over the life of the notes using the effective interest rate method. For the three months ended September 30, 2004, we recognized approximately \$117,000 as interest expense from the amortization of these debt issuance costs.

As of September 30, 2004, the entire principal amount of these convertible notes of \$20 million remained outstanding. The amount of interest paid on these notes for the three months ended September 30, 2004 totaled \$350,000. All common stock purchase warrants issued in connection with this transaction remain unexercised as of September 30, 2004.

Resale of the shares issuable upon conversion or payment of the notes and upon exercise of warrants are registered under our Form S-3 registration statement (File No. 333-117338) filed with the Securities and Exchange Commission, which was declared effective on July 28, 2004.



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**VIRAGEN, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**NOTE F CONVERTIBLE NOTES AND DEBENTURES (Continued)**

*June 2003 Convertible Debentures*

On June 27, 2003, we entered into a securities purchase agreement with five unrelated institutional investors. The securities purchase agreement provided for the purchase and sale of our convertible debentures in the aggregate amount of approximately \$5.55 million. Under the terms of the agreement, Viragen received approximately \$4.55 million, net of original issue discounts of \$661,333, and a 6.5% finder's fee and legal expenses. This agreement also provided for the issuance to the purchasers of an aggregate of 1,354,664 five-year common stock purchase warrants exercisable at a price of \$1.722 per share. In connection with the June 2003 securities purchase agreement, we also issued the finder 19,571 five-year common stock purchase warrants exercisable at a price of \$1.722 per share.

These convertible debentures were to mature on September 1, 2005, and were payable, without interest, in 24 equal payments of principal commencing September 1, 2003. In lieu of interest, the debentures provided for an original issue discount equal to \$661,333, the equivalent of 10% interest over the two year life of the debenture. For the three months ended September 30, 2003, we recognized approximately \$243,000 as interest expense from the amortization of the original issue discount. The debentures were convertible immediately by the investors, in whole or in part, into shares of our common stock at a conversion price equal to \$3.17, which was subsequently reduced to \$2.24 as a result of our September 2003 financing transaction.

The warrants issued in connection with these debentures are exercisable during the five year period ending June 1, 2008 and can be exercised on a cashless basis whereby the holder may surrender a number of warrants equal to the exercise price of the warrants being exercised. The relative fair value of these warrants was calculated to be approximately \$1,381,000 using a Black-Scholes valuation model. The relative fair value of these warrants was recorded as a discount on the principal amount of the debentures and was amortized to interest expense using the effective interest rate method over the life of the debentures. For the three months ended September 30, 2003, we recognized approximately \$507,000 as non-cash interest expense from the amortization of the discount that arose from the issuance of the warrants.

As a result of the common stock purchase warrants issued in connection with these debentures and the calculated effective conversion price of the debentures, a beneficial conversion amount of approximately \$689,000 was calculated and recorded as a discount on the principal amount of the debentures at the date of issuance. As a result of a subsequent financing transaction entered into in September 2003, the conversion price of these debentures was reduced from \$3.17 to \$2.24. Due to this reduction in the conversion price of these debentures, additional beneficial conversion of approximately \$1,382,000 was calculated and recorded as a discount on the principal amount of the debentures. These discounts were amortized to interest expense using the effective interest rate method over the life of the debentures. For the three months ended September 30, 2003, we recognized approximately \$253,000 as non-cash interest expense from the amortization of the discount that arose from the beneficial conversion feature.

We incurred costs of approximately \$369,000 in connection with the debentures issued in the June 27, 2003 agreement, which primarily consisted of the finder's fees, the fair value of warrants issued to the finder, and legal and accounting expenses. These costs were amortized to interest expense over the life of the debentures using the effective interest rate method. For the three months ended September 30, 2003, we recognized approximately \$135,000 as interest expense from the amortization of these debt issuance costs.



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**VIRAGEN, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**NOTE F CONVERTIBLE NOTES AND DEBENTURES (Continued)**

As of December 31, 2003, these convertible debentures had been satisfied and no further amounts were due as the purchasers had converted approximately \$5.5 million of principal resulting in the issuance of approximately 2.34 million shares of our common stock and we repaid approximately \$65,000 of principal in cash. Warrants to purchase 315,305 shares of our common stock issued in connection with this transaction remain unexercised as of September 30, 2004.

Resale of the shares issuable upon conversion or payment of the debentures and upon exercise of warrants are registered under our Form S-3 registration statement (File No. 333-107176) filed with the Securities and Exchange Commission, which was declared effective on August 1, 2003.

*April 2003 Convertible Debentures, as Amended*

On April 16, 2003, we entered into a securities purchase agreement with three unrelated institutional investors. This agreement was amended on May 8, 2003 and May 16, 2003, to among other things, include an additional unrelated institutional investor. The securities purchase agreement, as amended, provided for the purchase and sale of our convertible debentures in the aggregate amount of approximately \$3.8 million. Under the terms of the agreement, we received approximately \$3.1 million, net of original issue discounts of \$453,395, a 6.5% finder's fee, and legal expenses. This agreement also provided for the issuance to the purchasers of an aggregate of 3,171,200 three-year common stock purchase warrants exercisable at a price of \$0.625 per share.

In connection with the April 2003 debentures, we also issued the finder 13,408 three-year common stock purchase warrants exercisable at a price of \$0.625 per share.

These convertible debentures were to mature on July 1, 2005, and were payable, without interest, in 24 equal payments of principal commencing August 1, 2003. The debentures were convertible immediately, in whole or in part, by the purchasers into shares of our common stock at a conversion price equal to \$2.00 per share.

The warrants issued in connection with the April 16, 2003 securities purchase agreement and the amendments dated May 8, 2003 and May 16, 2003, were exercisable during the three year period ending April 2006. The relative fair value of these warrants was calculated to be approximately \$800,000 using a Black-Scholes valuation model. The relative fair value of the warrants was recorded as a discount on the principal amount of the debentures and was amortized to interest expense using the effective interest rate method over the life of the debentures. For the three months ended September 30, 2003, we recognized approximately \$268,000 as non-cash interest expense from the amortization of the discount that arose from the issuance of these warrants. As of September 30, 2003, the entire initial discount resulting from the issuance of the warrants had been fully amortized to interest expense.

As a result of the common stock purchase warrants issued along with the April 2003 debentures and the calculated effective conversion price of the debentures, a beneficial conversion amount of approximately \$335,000 was calculated and recorded as a discount on the principal amount of the debentures at the date of issuance. This discount was amortized to interest expense using the effective interest rate method over the life of the debentures. For the three months ended September 30, 2003, we recognized approximately \$120,000 as non-cash interest expense from the amortization of the discount that arose from the beneficial conversion. As of September 30, 2003, the entire initial discount resulting from the beneficial conversion feature had been fully amortized to interest expense.





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**VIRAGEN, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**NOTE F CONVERTIBLE NOTES AND DEBENTURES (Continued)**

We incurred costs of approximately \$301,000 in connection with the April 2003 convertible debentures, which primarily consisted of the finder's fees, the fair value of warrants issued to the finder, and legal and accounting expenses. These costs were amortized to interest expense over the life of the debentures using the effective interest rate method. For the three months ended September 30, 2003, we amortized approximately \$88,000 to interest expense. As of September 30, 2003, these debt issuance costs had been fully amortized to interest expense.

As of September 30, 2003, the purchasers had converted the entire principal balance on the April 2003 debentures resulting in the issuance of approximately 1.9 million shares of our common stock. In addition, all common stock purchase warrants issued in connection with this transaction have been exercised.

Resale of the shares issued upon conversion or payment of the debentures and upon exercise of warrants are registered under our Form S-3 registration statement (File No. 333-105668) filed with the Securities and Exchange Commission, which was declared effective on June 9, 2003.

*August 2002 Note, as Amended*

During August 2002, we executed a \$500,000, 90 day Note with Isosceles Fund Limited. The Note bore interest at 8% and was secured by 250,000 shares of our common stock. In connection with this transaction, we issued 5,387 common stock purchase warrants exercisable at \$5.30 per share for a period of three years. In November 2002, the Note was amended to eliminate the fixed maturity date and make the Note payable within three business days following demand. The Note was also amended to provide for conversion of outstanding principal and interest into shares of our common stock at a price of \$1.75 per share in lieu of cash at Isosceles' option. As a result of our subsequent financing transactions, this conversion price was reduced to \$0.56. Since Isosceles did not elect to convert the Note within 90 days of the amendment, we issued Isosceles 11,650 warrants at \$2.50 per share, 11,650 warrants at \$3.00 per share, 11,650 warrants at \$3.50 per share, 40,625 warrants at \$5.00 per share and 37,500 warrants at \$6.00 per share. The warrants were exercisable for a three-year period. The fair value of the warrants, which was calculated to be \$67,845, was charged to interest expense at the time of issuance. As a result of subsequent financing transactions, the exercise price of these warrants was reduced to \$0.56. As a result of the stock purchase warrants issued and the calculated effective conversion price of the Note, a beneficial conversion amount of approximately \$485,000 was calculated and charged to interest expense. All of these items charged to interest expense were non-cash items.

During the three months ended September 30, 2003, we issued 960,000 shares upon conversion of the principal of the August 2002 Note and accrued interest totaling approximately \$536,000. No further amounts are due on this Note. In addition, Isosceles converted all 118,462 warrants issued in connection with this Note resulting in net proceeds to us of approximately \$66,300. Resale of the shares issued upon conversion of the Isosceles Note and exercise of warrants issued in connection with this Note as amended are registered under our Form S-3 registration statement (File No. 333-106536) filed with the Securities and Exchange Commission, which was declared effective on July 11, 2003.

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**VIRAGEN, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**NOTE G DEBT**

*Line of Credit and Short Term Borrowings*

Our Swedish subsidiary maintains an overdraft facility, denominated in Swedish Krona, with a bank in Sweden. In July 2004, the terms of this overdraft facility were renegotiated to provide for a reduced interest rate and a reduction in the maximum borrowing capacity. Maximum borrowing capacity on this overdraft facility was approximately \$817,000 as of September 30, 2004 compared to \$1.1 million at June 30, 2004. Borrowings outstanding under this facility are at a floating rate of interest, which was approximately 5.25% at September 30, 2004 compared to 7.4% at June 30, 2004. The facility renews annually and was renewed in December 2003. Outstanding borrowings under this agreement were approximately \$49,000 and \$807,000 as of September 30, 2004 and June 30, 2004, respectively. The overdraft facility is secured by certain assets of ViraNative including inventories and accounts receivable.

During June 2004, we obtained short term financing of approximately \$270,000 for the purchase of certain corporate insurance policies. Outstanding borrowings under this arrangement bear interest at an effective rate of 5.19%. Principal and interest payments of approximately \$31,000 are payable in nine equal monthly installments. The outstanding balance on this short term borrowing was approximately \$181,000 and \$270,000 as of September 30, 2004 and June 30, 2004, respectively.

*Long-Term Debt*

Our Swedish subsidiary has a 25-year mortgage with a Swedish bank obtained to purchase one of our facilities in Sweden. The outstanding principal balance on this loan, which is payable in Swedish Krona, was approximately \$699,000 and \$689,000 at September 30, 2004 and June 30, 2004, respectively. This loan carries a floating rate of interest which was approximately 5.25% at September 30, 2004 and June 30, 2004. We are required to make quarterly payments of principal and interest of approximately \$12,000 under this agreement. This loan matures in September 2024 and is secured by the related land and building, including improvements, with a carrying value of approximately \$2.8 million as of September 30, 2004.

Under the terms of a loan with a Swedish governmental agency that was obtained for the purposes of conducting clinical trials, we were required to make quarterly payments of principal and interest of approximately \$34,000. The loan carried a floating rate of interest at the Stockholm interbank offered rate (STIBOR) 90 plus 7%, which was approximately 10.60% as of June 30, 2004. This loan had an outstanding balance, which was payable in Swedish Krona, of approximately \$537,000 at June 30, 2004. On September 30, 2004, we paid the entire outstanding principal including accrued interest on this loan. No amounts are due on this loan as of September 30, 2004.

**NOTE H CAPITAL STOCK**

On June 11, 2004, our stockholders approved an amendment to our Articles of Incorporation to effect a 1-for-10 reverse split of our outstanding common stock and change the number of shares of common stock that Viragen is authorized to issue to 100 million. All share and per share information herein have been restated to retroactively reflect this reverse stock split.



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**VIRAGEN, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**NOTE H CAPITAL STOCK (Continued)**

As of November 4, 2004, there were 22,040,445 shares of our common stock issuable upon exercise or conversion of the following securities:

Convertible preferred stock, Series A	916
Officers, employees, and directors options (exercisable at an average price of \$6.40 through March 2014)	409,800
Consultant warrants (exercisable at an average price of \$23.26 through February 2009)	181,100
Debt and equity offering warrants (exercisable at an average price of \$1.98 through June 2008)	8,256,012
Convertible notes (convertible at \$1.516 through March 2006)	13,192,617
	<hr/>
	22,040,445
	<hr/>

**NOTE I COMPREHENSIVE LOSS**

Comprehensive loss is comprised of our net loss and other comprehensive income. Other comprehensive income refers to revenue, expenses, gains and losses that under accounting principles generally accepted in the United States are included in comprehensive loss but are excluded from net loss as these amounts are recorded directly as an adjustment to stockholders' equity. Our other comprehensive income consists of foreign currency translation adjustments. The following table sets forth the computation of comprehensive loss for the periods indicated:

	<b>Three Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
	<hr/>	<hr/>
Net loss	\$(4,320,890)	\$(3,903,253)
Other comprehensive income:		
Currency translation adjustment	344,898	685,927
	<hr/>	<hr/>
Comprehensive loss	\$(3,975,992)	\$(3,217,326)
	<hr/>	<hr/>

**NOTE J ROYALTY AGREEMENT**

In November 1986, we entered into a royalty agreement with Medcore, Inc. with respect to interferon, transfer factor and products using interferon and transfer factor. The agreement was subsequently amended in November 1989 and May 1993. The amended agreement provides for a maximum cap on royalties to be paid to Medcore of \$2,400,000. It includes a schedule of royalty payments of:

5% of the first \$7,000,000 of sales,

4% of the next \$10,000,000, and

3% of the next \$55,000,000

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**VIRAGEN, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**NOTE J ROYALTY AGREEMENT (Continued)**

These royalties are to be paid until the total of \$2,400,000 is achieved. The amended agreement also states that royalties of approximately \$108,000 previously accrued prior to May 1993 under the agreement are payable to Medicore as the final payment. From May 1993 through September 2001, we paid royalties under the amended agreement totaling approximately \$70,000.

Royalties owed to Medicore of approximately \$90,000, based on our natural human alpha interferon sales from October 1, 2001 through June 30, 2003, are payable in three installments: \$30,000 was payable by August 1, 2003; \$30,000 was payable by August 1, 2004; and \$30,000 is payable by August 1, 2005. The first two installments totaling \$60,000, plus \$3,000 in interest, have been made. Subsequent to June 30, 2003, in accordance with the terms of the amended agreement, royalties are paid to Medicore based on sales of natural human alpha interferon on a quarterly basis. For the three months ended September 30, 2004 and 2003, royalties due under the agreement totaled approximately \$2,000 and \$2,600, respectively.

**NOTE K TRANSACTIONS WITH RELATED PARTIES**

We provide certain administrative services including management and general corporate assistance to Viragen International, our majority owned subsidiary. We also incur certain costs attributable to Viragen International including insurance and rent. These expenses are charged on the basis of direct usage, when identifiable, or on the basis of estimated time spent. We believe that the expenses allocated to Viragen International are representative of the operating expenses incurred on their behalf. For the three months ended September 30, 2004 and 2003, expenses allocated to Viragen International totaled approximately \$277,000 and \$224,000, respectively.

Viragen (Scotland), a wholly owned subsidiary of Viragen International, conducts research and development and performs administrative functions on our behalf. These costs incurred by Viragen (Scotland) relate to oncology and avian transgenic projects and are allocated to us as incurred. For the three months ended September 30, 2004 and 2003, research and development costs allocated by Viragen (Scotland) totaled approximately \$347,000 and \$234,000, respectively. The amount of administrative expenses allocated by Viragen (Scotland) totaled approximately \$45,000 and \$26,000, for the three months ended September 30, 2004 and 2003, respectively.

In connection with the acquisition of ViraNative discussed in Note D, the former shareholders of ViraNative are entitled to additional shares of Viragen International common stock contingent upon the attainment of certain milestones related to regulatory approvals:

8,799,570 additional shares when and if a Mutual Recognition Procedures application is filed and receives approval from the requisite national and EU regulatory authorities for the use, sale and marketing of *Multiferon* in certain countries, which must include Germany; and

2,933,190 additional shares when and if *Multiferon* has been approved by the requisite regulatory bodies in the EU for the treatment of Melanoma or when *Multiferon* has been approved by the requisite regulatory bodies for sale in the USA.

If and as each of these milestones is met, additional shares of Viragen International will be issued.

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**VIRAGEN, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**NOTE L RECENT ACCOUNTING PRONOUNCEMENTS**

In October 2004, FASB announced that SFAS No. 123R, *Share-Based Payment*, which would require all companies to measure compensation cost for all share-based payments (including employee stock options) at fair value, would be effective for public companies for interim or annual periods beginning after June 15, 2005. The proposed standard would require companies to expense the fair value of all stock options that have future vesting provisions, are modified, or are newly granted beginning on the grant date of such options. We will evaluate the requirements of the final standard, which is expected to be issued on or around December 15, 2004, to determine the impact on our consolidated financial position and results of its operations.

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

**Introduction**

We are a biopharmaceutical company engaged in the research, development, manufacture and sale of a natural human alpha interferon product indicated for treatment of a broad range of viral and malignant diseases. We are also developing innovative technologies aimed at improving the manufacturing processes used to manufacture certain medical therapies and we are developing novel therapeutics for the treatment of cancer. Specifically, we are primarily focused on three fields of research and development:

Human leukocyte derived interferon – natural alpha interferon derived from human white blood cells for the treatment of a wide range of viral and malignant diseases.

Avian transgenics technologies designed to produce protein-based drugs inside the egg whites of transgenic developed chickens.

Oncological therapies – therapeutic proteins and peptides for the treatment of targeted cancers.

We own approximately 81.2% of Viragen International, Inc. We operate primarily through Viragen International Inc., and its wholly owned subsidiaries, ViraNative AB ( ViraNative ), a company located in Umea, Sweden, and Viragen (Scotland) Limited ( Viragen (Scotland) ), a company located near Edinburgh, Scotland. ViraNative and Viragen (Scotland) house our manufacturing and research laboratory facilities.

**Cautionary Factors That May Affect Future Results**

This document and other documents we may file with the Securities and Exchange Commission contain forward-looking statements. Also, our management may make forward-looking statements orally to investors, analysts the media and others. Forward-looking statements express our expectations or predictions of future events or results. They are not guarantees and are subject to many risks and uncertainties. There are a number of factors – many beyond our control – that could cause actual events or results to be significantly different from those described in the forward-looking statement. Any or all of our forward-looking statements in this report or in any other public statements we make may turn out to be wrong.

Forward-looking statements might include one or more of the following:

projections of future revenue;

anticipated debt or equity fundings;

anticipated clinical trial commencement dates, completion timelines or results;

anticipated receipt of regulatory approvals;

descriptions of plans or objectives of management for future operations, products or services;

forecasts of future economic performance; and

descriptions or assumptions underlying or relating to any of the above items.

Forward-looking statements can be identified 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 or words of similar



They may also use words such as would, should, could or may .

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Factors that may cause actual results to differ materially include the risks and uncertainties discussed below, as well as in the Risk Factors section included in our Prospectus (File No. 333-117338) filed July 28, 2004 with the Securities and Exchange Commission. You should read them. You should also read the risk factors identified from time to time in our reports on Form 10-Q or 10-K, and registration statements on Form S-1 or S-3 and amendments, if any, to these documents. Viragen will provide you with a copy of any or all of these reports at no charge. Copies of these documents may also be obtained free of charge from our website at [www.viragen.com](http://www.viragen.com) or the Securities and Exchange Commission website at [www.sec.gov](http://www.sec.gov). The information on our website is neither incorporated into, nor a part of, this report.

Our business, results of operations and financial condition could be adversely affected by a number of risks and uncertainties, including the following:

whether we are able to secure sufficient funding to maintain our operations, complete clinical trials and successfully market our product;

whether our stock price will enable us to conduct future financings;

whether the efficacy, price and timing of approvals of our natural human alpha interferon will enable us to compete with other well established, highly capitalized, biopharmaceutical companies;

whether clinical testing confirms the efficacy of our product, and results in the receipt of regulatory approvals. We have not sought the approval of our natural human alpha interferon product from the U.S. Food and Drug Administration or its European Union counterparts, except Sweden;

whether our patent applications result in the issuance of patents, or whether patents and other intellectual property rights provide adequate protections in the event of misappropriation or infringement by third parties;

whether our avian transgenics program will succeed in being able to produce targeted drugs in egg whites of transgenic chickens in commercially viable quantities;

whether, despite receipt of regulatory approvals, our products are accepted as a treatment superior to that of our competitors; and

whether we can generate revenue sufficient to offset our historical losses and achieve profitability.

Our natural human alpha interferon product was developed and is manufactured overseas in our Swedish facility. Our avian transgenic and oncology programs are also being researched and developed in Europe. Our dependence on foreign manufacturing and expected international sales exposes us to a number of risks, including:

unexpected changes in regulatory requirements;

tariffs and other trade barriers, including import and export restrictions;

political or economic instability;

compliance with foreign laws;

transportation delays and interruptions;

difficulties in protecting intellectual property rights in foreign countries; and

currency exchange risks.

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### **Recent Developments**

In October 2004, we announced the results from a 7-year follow-up to a Phase II/III clinical study that evaluated the use of *Multiferon*®, our natural human alpha interferon, for the treatment of malignant melanoma after surgical removal of all tumor masses compared to surgery alone. The analysis confirmed a statistically significant increase in overall survival for patients treated with adjuvant dacarbazine (DTIC) followed by *Multiferon*, compared to patients with no adjuvant treatment. The study data will serve as the basis for an application that we intend to file in Sweden to seek expanded approval for *Multiferon* to include the first-line adjuvant treatment of high-risk malignant melanoma.

After a 7-year follow-up, the results showed an actual 51.3% overall survival in high-risk patients treated with short-term DTIC, followed by *Multiferon* as adjuvant low-dose treatment for 6 months versus 30.3% overall survival among patients who underwent surgery only (p=0.0077).

A follow-up beyond 7 years was obtained in most patients and 9-year follow-up results showed an estimated 50.9% overall survival in the treated population versus 23.5% in the control group. This suggests that a significant survival benefit is sustained beyond 7 years.

### **Critical Accounting Policies**

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses. On an on-going basis, we evaluate our estimates, including those related to inventories, depreciation, amortization, asset valuation allowances, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

*Inventories.* Inventories consist of raw materials and supplies, work in process and finished product. Finished product consists of purified natural human alpha interferon. Costs of raw materials and supplies are determined on a first-in, first-out basis. Costs of work in process and finished product, consisting of raw materials, labor and overhead, are recorded at a standard cost (which approximates actual cost). Excess/idle capacity costs are expensed in the period in which they are incurred and are recorded in cost of sales. Our inventories are stated at the lower of cost or market (estimated net realizable value). If the cost of our inventories exceeds their expected market value, provisions are recorded currently for the difference between the cost and the market value. These provisions are determined based on estimates. The valuation of our inventories also requires us to estimate excess inventories and inventories that are not saleable. The determination of excess or non-saleable inventories requires us to estimate the future demand for our product and consider the shelf life of the inventory. If actual demand is less than our estimated demand, we could be required to record inventory writedowns, which would have an adverse impact on our results of operations.

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*Long-lived assets.* In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, we review our long-lived assets, including intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of these assets may not be fully recoverable. The assessment of possible impairment is based on our ability to recover the carrying value of our asset based on our estimate of its undiscounted future cash flows. If these estimated future cash flows are less than the carrying value of the asset, an impairment charge is recognized for the difference between the asset's estimated fair value and its carrying value. As of the date of these financial statements, we are not aware of any items or events that would cause us to adjust the recorded value of our long-lived assets, including intangible assets, for impairment.

*Goodwill.* In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, goodwill is not amortized. Goodwill is reviewed for impairment on an annual basis or sooner if indicators of impairment arise. All of our goodwill arose from the acquisition of ViraNative in September 2001 and the subsequent achievement of certain milestones defined in the acquisition agreement. We periodically evaluate that acquired business for potential impairment indicators. Our judgments regarding the existence of impairment indicators are based on legal factors, market conditions, and the operational performance of the acquired business. During the fourth quarter of fiscal 2004, we completed our annual impairment review of our goodwill with the assistance of an independent valuation firm. The impairment review indicated that our goodwill was not impaired. Future changes in the estimates used to conduct the impairment review, including revenue projections or the fair market value of Viragen International's common stock, could cause our analysis to indicate that our goodwill is impaired in subsequent periods and result in a write-off of a portion or all of our goodwill.

*Stock-based compensation.* Our employee stock option plans are currently accounted for under Accounting Principles Board Opinion No. 25 ( APB 25 ), *Accounting for Stock Issued to Employees*, and related interpretations. We grant stock options for a fixed number of shares to employees with an exercise price equal to the fair market value of the shares at the date of grant. In accordance with APB 25, we recognize no compensation expense for these stock option grants. We account for our stock-based compensation arrangements with non-employees in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 123, *Accounting for Stock-Based Compensation* and related guidance, including Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Accordingly, we recognize as expense the estimated fair value of such instruments as calculated using the Black-Scholes valuation model. The estimated fair value is re-determined each quarter using the methodologies allowable by SFAS No. 123 and EITF No. 96-18 and the expense is amortized over the vesting period of each option or the recipient's contractual arrangement, if shorter.

*Convertible Debt Issued with Stock Purchase Warrants:* Viragen accounts for convertible debt issued with stock purchase warrants in accordance with APB No. 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants*, EITF No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*, and EITF No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*. The determination of the relative fair value of the components of our convertible debentures issued with common stock purchase warrants requires the use of estimates. Changes in those estimates would result in different relative values being attributed to the components, which could result in more or less discount on the principal amount of the debentures.

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*Revenue recognition.* We recognize revenue from sales of our natural human alpha interferon product when title and risk of loss has been transferred, which is generally upon shipment. Moreover, recognition requires persuasive evidence that an arrangement exists, the price is fixed and determinable, and collectibility is reasonably assured.

*Litigation and other contingencies.* We monitor the status of our litigation and other contingencies for purposes of loss accrual. If we believed a loss to be probable and reasonably estimated, as required by SFAS No. 5, *Accounting for Contingencies*, we would establish an appropriate accrual. We would base our accruals on information available at the time of such determination. Information may become available to us after that time, for which additional accruals may be required.

## **Liquidity and Capital Resources**

As of September 30, 2004, we had approximately \$17,375,000 in cash and short-term investments. As of September 30, 2004, we had working capital of approximately \$21,159,000, compared to working capital of approximately \$25,182,000 as of June 30, 2004. Cash used to fund operations during the three months ended September 30, 2004 totaled approximately \$3,704,000, including the reduction in our accounts payable and other accrued expenses balance by approximately \$639,000. For the three months ended September 30, 2004, capital expenditures totaled approximately \$99,000 and financing expenditures included the repayment of our line of credit and short-term borrowings and long-term debt of approximately \$1,352,000.

We have experienced losses and a negative cash flow from operations since inception. During the three months ended September 30, 2004 we incurred a loss of approximately \$4,321,000. During the years ended June 30, 2004, 2003 and 2002, we incurred significant losses of approximately \$18,177,000, \$17,349,000, and \$11,089,000, respectively, and had an accumulated deficit of approximately \$124,792,000 as of September 30, 2004. We anticipate additional future losses as we commercialize our natural human alpha interferon product and conduct additional research activities and clinical trials to obtain additional regulatory approvals. We believe we have sufficient cash to support operations through at least December 31, 2005. However, we will require substantial additional funding to support our operations subsequent to December 31, 2005. If we are unable to generate sufficient cash flows from operations, our plans include seeking additional capital through equity and debt financings. No assurance can be given that additional capital will be available when required or upon terms acceptable to us.

Manufacturing of *Multiferon* at our leased facility in Umea, Sweden, had been suspended since March 31, 2003. This planned break in routine manufacturing was necessary to allow for certain steps of our production process to be segregated and transferred to our owned facility also located in Umea, Sweden. Renovation of this facility commenced in 2003 and was in line with our plan to expand our productive capacity of our natural human alpha interferon. The cost of this initial phase totaled approximately \$1.5 million and was completed during September 2004. Following final validation of this facility, production of *Multiferon* will resume as demand dictates. We believe that our current inventory levels are sufficient to meet our current sales forecasts for the remainder of at least fiscal 2005. We plan to expand the use of our owned facility in phases based on product demand and available financing. Maximum expansion, if warranted, could cost up to an additional estimated \$10 million.

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Our future cash requirements are dependent upon many factors, including:

revenue generated from the sale of our natural human alpha interferon product;

progress with future clinical trials;

the costs associated with obtaining regulatory approvals;

the costs involved in patent applications;

competing technologies and market developments; and

our ability to establish collaborative arrangements and effective commercialization activities.

For the remainder of fiscal 2005, we anticipate the need of approximately \$9.0 million for operating activities, \$1.1 million for investing activities and \$1.3 million to service our financing obligations.

*Line of Credit*

Our Swedish subsidiary maintains an overdraft facility, denominated in Swedish Krona, with a bank in Sweden. In July 2004, the terms of this overdraft facility were renegotiated to provide for a reduced interest rate and a reduction in the maximum borrowing capacity. Maximum borrowing capacity on this overdraft facility was approximately \$817,000 as of September 30, 2004 compared to \$1.1 million at June 30, 2004. Borrowings outstanding under this facility are at a floating rate of interest, which was approximately 5.25% at September 30, 2004 compared to 7.4% at June 30, 2004. The facility renews annually and was renewed in December 2003. Outstanding borrowings under this agreement totaled approximately \$49,000 and \$807,000 as of September 30, 2004 and June 30, 2004, respectively. The overdraft facility is secured by certain assets of ViraNative including inventories and accounts receivable.

*Convertible Notes and Debentures*

On June 18, 2004, we completed the sale of convertible notes and common stock purchase warrants in the aggregate amount of \$20 million. We received approximately \$18.96 million, net of finder's fees and legal expenses. These convertible notes mature on March 31, 2006 and are convertible immediately by the investors, in whole or in part, into shares of our common stock at a conversion price equal to \$1.516. This conversion price is subject to reductions if we enter into additional financing transactions for the sale of our stock below the public trading price and below the conversion price.

Interest is payable quarterly commencing July 1, 2004. Quarterly interest payments are payable in cash or, at our option, in shares of our common stock based upon the average market price of our common stock during the 20 consecutive trading days prior to and including the interest payment date, subject to certain conditions.

These notes may be prepaid at 110% of their face amount, plus the issuance to note holders of additional warrants to purchase the number of shares of our common stock into which the notes would otherwise have been convertible, at an exercise price equal to the prevailing conversion price of the notes. If issued on prepayment, the warrants may be exercised for the period that would have been the remaining life of the notes had they not been prepaid. Commencing one year after issuance, we also have the right to require note holders to convert their notes, subject to certain limitations; provided that our common stock has traded at 200% or more of the conversion price of the notes on each of the 30 trading days ending five days prior to the date fixed for conversion.





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As of September 30, 2004, the entire principal amount of these convertible notes of \$20 million remained outstanding. The amount of interest paid on these notes for the three months ended September 30, 2004 totaled \$350,000.

### *Off Balance Sheet Arrangements*

Under SEC regulations, we are required to disclose our off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors. An off-balance sheet arrangement means a transaction, agreement or contractual arrangement to which any entity that is not consolidated with us is a party, under which we have:

Any obligation under certain guarantee contracts;

Any retained or contingent interest in assets transferred to an unconsolidated entity or similar arrangement that serves as credit, liquidity or market risk support to that entity for such assets;

Any obligation under a contract that would be accounted for as a derivative instrument, except that it is both indexed to our stock and classified in stockholders' equity in our statement of financial position; and

Any obligation arising out of a material variable interest held by us in an unconsolidated entity that provides financing, liquidity, market risk or credit risk support to us, or engages in leasing, hedging or research and development services with us.

As of the date of this report, we do not have any off-balance sheet arrangements that we are required to disclose pursuant to these regulations. In the ordinary course of business, we enter into operating lease commitments, purchase commitments and other contractual obligations. These transactions are recognized in our financial statements in accordance with generally accepted accounting principles in the United States.

## **Results of Operations**

### *Product sales*

For the three months ended September 30, 2004, product sales totaled approximately \$30,000 compared to product sales of approximately \$52,000 for the three months ended September 30, 2003. This decrease in product sales of approximately \$22,000 is primarily attributed to sales of our natural human alpha interferon product in Indonesia during the three months ended September 30, 2003 totaling approximately \$15,000 with no corresponding sales during the quarter ended September 30, 2004.

We have entered into several agreements for the distribution of our natural human alpha interferon, *Multiferon*, in various countries. To date, we have not recognized revenue from many of these agreements. The majority of these agreements require that the distributor obtain the necessary regulatory approvals, which may not yet be obtained. Regulatory approval is a mandatory step in the marketing of a drug, but it is by no means the final challenge in marketing a biopharmaceutical product. In addition, *Multiferon* is a critical care product that is typically administered in a hospital setting. Therefore, in certain instances, it must be part of a hospital's approved formulary to enable physicians to be able to prescribe the product. This may include becoming approved within a nationalized network of hospitals. Also, the physicians must be educated as to the potential merits and advantages of the product.

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There are other challenges associated with international marketing activities including: language and cultural barriers, in some cases poorly organized regulatory infrastructure and/or compliance procedures in certain countries where *Multiferon* may be marketed, performance of our distribution partners, government's willingness to promote cheaper generic products and the general population's inability to afford private care drug products. It will take significant time to overcome these challenges with no assurance that a particular market will ever be effectively penetrated.

*Cost of Sales*

Cost of sales, which includes excess/idle production costs, totaled approximately \$476,000 for the three months ended September 30, 2004. The increase in cost of sales of approximately \$107,000 for the three months ended September 30, 2004, and the resulting negative margins, are attributed to excess/idle capacity costs. Excess/idle capacity costs represent fixed production costs incurred at our Swedish manufacturing facility, which were not absorbed as a result of the suspension of routine manufacturing as of March 31, 2003. This planned break in routine manufacturing was necessary to allow for certain steps of our production process to be segregated and transferred to our owned facility located in Umea, Sweden. We will continue to incur excess/idle production costs until we resume production at normal operating levels that absorb our fixed production costs.

*Research and Development Costs*

Research and development costs include scientific salaries and support fees, laboratory supplies, consulting fees, contracted research and development, equipment rentals, repairs and maintenance, utilities and research related travel. For the three months ended September 30, 2004, research and development costs totaled approximately \$1,091,000 compared to approximately \$814,000 for the three months ended September 30, 2003. This increase of approximately \$277,000 is mainly attributed to increases in costs incurred related to our avian transgenics and oncology projects totaling approximately \$75,000 and \$83,000, respectively. Also contributing to the increase in research and development was an increase in consulting fees at our Florida headquarters totaling approximately \$67,000.

We will continue incurring research and development costs, including projects associated with *Multiferon* as well as other projects to more fully develop potential commercial applications of our natural human alpha interferon product, as well as broaden our potential product lines in the areas of avian transgenics and oncology. Our ability to successfully conclude additional clinical trials, a prerequisite for expanded commercialization of any product, is dependent upon our ability to raise significant additional funding necessary to conduct and complete these trials.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses include administrative personnel salaries and related expenses, office and equipment leases, utilities, repairs and maintenance, insurance, legal, accounting, consulting, depreciation and amortization expenses. Selling, general and administrative expenses totaled approximately \$1,814,000 for the three months ended September 30, 2004 compared to approximately \$1,466,000 for the three months ended September 30, 2003. This increase of approximately \$348,000 is mainly attributed to increases in personnel-related costs, consulting fees, legal fees and travel related costs at our Florida headquarters totaling approximately \$101,000, \$70,000, \$24,000 and \$11,000, respectively. Also contributing to the increase in selling, general and administrative expenses were increases in patent related legal fees at our Scottish and Swedish subsidiaries totaling approximately \$31,000 and \$19,000, respectively.

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We anticipate that selling related expenses will increase significantly in fiscal 2005. This increase is expected due to the planned expansion of our *Multiferon* sales efforts. These increases will be incurred in sales personnel related expenses, consulting fees, travel related expenses, promotional materials and other marketing related costs. We also expect to incur significant costs associated with efforts necessary to comply with the requirements of Section 404 of the Sarbanes Oxley Act of 2002.

*Amortization of Intangible Assets*

Amortization of intangible assets represents the amortization of our acquired developed technology. This developed technology is being amortized over its estimated useful life of approximately 14 years. For the three months ended September 30, 2004, amortization of intangible assets totaled approximately \$40,000, compared to approximately \$37,000 during the three months ended September 30, 2003.

*Interest Expense*

Interest expense for the three months ended September 30, 2004 totaling approximately \$1,286,000 primarily represents interest expense on the June 2004 convertible notes consisting of interest payments totaling \$350,000 and non-cash interest expense related to the amortization of the discounts on these notes totaling approximately \$883,000. For the three months ended September 30, 2003, interest expense totaling approximately \$1,792,000 primarily consisted of interest expense on the April 2003 and June 2003 convertible debentures totaling approximately \$1,750,000. Approximately \$1,148,000 of this amount represented non-cash interest expense comprised of the amortization of the discounts on those debentures.

Also included in interest expense for the three months ended September 30, 2004 and September 30, 2003, is interest incurred on the debt facilities maintained by our Swedish subsidiary totaling approximately \$49,000 and \$39,000, respectively. These credit facilities have interest rates of approximately 5.25%. We expect interest expense to decrease at our Swedish subsidiary in fiscal 2005 compared to fiscal 2004 due to the repayment in July 2004 of one of our loans that carried a high interest rate and a reduction in the interest rate on our line of credit in Sweden.

*Other Expense (Income), net*

The primary components of other expense (income), net are interest earned on cash and cash equivalents and short-term investments, grant income from government agencies in Scotland, sublease income on certain office space in our facility in Scotland, transaction gains or losses on foreign exchange, remeasurement gains or losses on assets and liabilities denominated in currencies other than the functional currency, gains or losses on the disposal of property, plant and equipment, and income generated from research and development support services provided by our Swedish subsidiary. Other expense for the three months ended September 30, 2004, totaled approximately \$38,000 compared to other income totaling approximately \$223,000 for the three months ended September 30, 2003. This decrease in other income totaling approximately \$261,000 is mainly attributed to remeasurement losses on foreign exchange totaling approximately \$242,000. These foreign exchange losses arose from the remeasurement of British Pound denominated bank accounts and short-term investments to U.S. dollars. Also contributing to the decrease in other income for the three months ended September 30, 2004, was a decrease in income generated from research and development support services provided by our Swedish subsidiary totaling approximately \$95,000. These decreases in other income were offset in part by an increase in interest earned on cash and cash equivalents and short-term investments totaling approximately \$102,000.

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### *Income Tax Benefit*

We are subject to tax in the United States, Sweden, and the United Kingdom. These jurisdictions have different marginal tax rates. For the three months ended September 30, 2004 and 2003, income tax benefit totaled approximately \$11,000. Income tax benefit for these periods arose from of the amortization expense on certain intangible assets. Due to the treatment of the identifiable intangible assets under Statement of Financial Accounting Standards (SFAS) No. 109, *Accounting for Income Taxes*, our balance sheet reflects a deferred income tax liability of approximately \$489,000 as of September 30, 2004, all of which is related to our developed technology intangible asset acquired on September 28, 2001.

Based on our accumulated losses, a full valuation allowance is provided to reduce deferred income tax assets to the amount that will more likely than not be realized. As of June 30, 2004, we had a net operating loss carry-forward of approximately \$61 million for U.S. federal income tax purposes. The expiration dates on these net operating loss carry-forwards range from 2005 through 2024. At June 30, 2004, Viragen (Scotland) and ViraNative had net operating loss carry-forwards totaling approximately \$24.8 million and \$8.2 million, respectively.

### **Research and Development Projects**

We have four ongoing research and development projects in the fields of avian transgenics and oncological therapies.

#### *Avian Transgenics*

Our avian transgenic project is designed to enable us to produce protein-based drugs, including monoclonal antibodies, inside the egg whites of transgenic developed chickens. Our goal is to develop a technology which will enable us to meet the large-scale production requirements for our own therapeutic protein products. We also believe that this technology will allow us to offer to others in the biopharmaceutical industry an alternate faster method of production of their protein-based products with a higher capacity and at a lower cost.

Avian transgenics offers a potential solution to the projected production bottleneck, which could limit the growth and contribute to the high cost of protein drugs. Existing protein production technologies are often inefficient and costly. In addition, the anticipated explosion in protein drug approvals together with protein-based drugs in pre-clinical and Phase I or Phase II clinical trials is forecast to create a worldwide shortage of production capacity for these protein-based products.

We believe our avian transgenics project could offer a rapid and cost effective way to produce large volumes of therapeutic proteins. In addition to meeting the current and future alternative production demands of the biopharmaceutical industry and generating significant revenue for us, this project could also accelerate the progress of several life-saving drugs to the market at an affordable cost.

For the three months ended September 30, 2004, costs incurred in the field of avian transgenics totaled approximately \$390,000. For the fiscal years ended 2004, 2003, and 2002, we incurred costs related to the avian transgenics project totaling approximately \$1,865,000, \$949,000 and \$778,000, respectively. Since the date of inception of this project, we have incurred approximately \$4,459,000 in research and development costs.

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***Oncological Therapies***

Our research and development projects in the field of oncology are focused on the development of therapeutic proteins for the treatment of targeted cancers. Our oncological projects are defined as follow:

*CD55 Therapy*

In collaboration with Cancer Research UK, we are developing a monoclonal antibody designed to block the protective effect of the protein CD55 on the surface of tumor cells. The protein CD55 is one of a number of proteins which protect normal healthy cells from being destroyed by the complement system. The problem arises when cancer cells also express this control protein to camouflage themselves from the immune system at levels up to 100 fold greater than normal. Under a worldwide exclusive commercial license granted to us, we are developing an antibody to remove this protection from tumor cells. A successful therapy could also offer protection against cancer spreading. We believe this technology may prove useful in the treatment of colorectal, breast, ovarian and certain bone cancers.

For the three months ended September 30, 2004, costs incurred related to the CD55 project totaled approximately \$83,000. For the fiscal years ended 2004, 2003, and 2002, we incurred costs related to the CD55 project totaling approximately \$206,000, \$144,000 and \$298,000, respectively. Since the date of inception of this project, we have incurred approximately \$989,000 in research and development costs.

In April 2004, our Scottish subsidiary, Viragen (Scotland), was awarded a grant from the Scottish government for approximately \$833,000 for the purpose of supporting the CD55 project, to be funded over a three-year period.

The CD55 project has not reached clinical trials and we do not expect to enter into clinical trials earlier than calendar 2005, if at all.

*IEP 11*

We entered into an agreement with the University of Miami's Sylvester Comprehensive Cancer Center to develop an anti-cancer technology. The joint project is designed to develop a novel form of an immune enhancing drug that has shown promise by inhibiting tumor growth in rats for a broad range of cancers. This drug is a novel 11 amino acid peptide called IEP 11, which was derived from a tumor transmembrane glycoprotein.

For the three months ended September 30, 2004, costs incurred related to the IEP11 project totaled approximately \$38,000. For the fiscal years ended 2004 and 2003 we incurred costs related to the IEP 11 project totaling approximately \$95,000 and \$85,000, respectively. Since the date of inception of this project, we have incurred approximately \$218,000 in research and development costs.

As of September 30, 2004, we are in the process of performing confirmation studies in animal models at the University of Miami. Final results of these studies are expected around the middle of calendar 2005.

It is too early to determine if and when this project will be considered for clinical trials.

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*R24 Monoclonal Antibody*

In collaboration with Memorial Sloan-Kettering Cancer Center (MSKCC), we have initiated research on monoclonal antibodies targeting ganglioside GD3 for the treatment of melanoma and possibly certain other cancers. Monoclonal antibodies are laboratory-produced, highly specialized therapeutic proteins designed to locate and bind to targeted cancer cells.

During the fiscal years 2005 and 2004, we have incurred minimal costs associated with our R24 project. For the fiscal years 2003 and 2002, we incurred costs in connection with this project totaling approximately \$598,000 and \$629,000, respectively. Since the date of inception of this project, we have incurred approximately \$1,538,000 in research and development costs.

We are evaluating alternative approaches toward development of this antibody, including the use of traditional manufacturing of the antibody through a third-party experienced in such processes. By the summer of 2005, we expect to have characterized the traditional antibody and we may then decide to move forward with MSKCC on this project.

Estimated completion dates, completion costs, and future material net cash inflows, if any, for the above oncological projects are not reasonably certain and are not determinable at this time. The timelines and associated costs for the completion of biopharmaceutical research and product development programs are difficult to accurately predict for various reasons, including the inherent exploratory nature of the work. The achievement of project milestones is dependent on issues which may impact development timelines and can be unpredictable and beyond Viragen's control. These issues include; availability of capital funding, presence of competing technologies, unexpected experimental results which may cause the direction of research to change, accumulated knowledge about the intrinsic properties of the candidate product, the availability of contract cell banking and manufacturing slots for the preparation of Good Manufacturing Practices grade material, results from preclinical and clinical studies, potential changes in prescribing practice and patient profiles and regulatory requirements.

The completion of all of the above research and development projects is dependent upon our ability to raise significant additional funding or our ability to identify potential collaborative partners that would share in project costs. Our future capital requirements are dependent upon many factors, including: revenue generated from the sale of our natural human alpha interferon product, progress with future clinical trials; the costs associated with obtaining regulatory approvals; the costs involved in patent applications; competing technologies and market developments; and our ability to establish collaborative arrangements and effective commercialization activities.

**Recent Accounting Pronouncements**

In October 2004, FASB announced that SFAS No. 123R, *Share-Based Payment*, which would require all companies to measure compensation cost for all share-based payments (including employee stock options) at fair value, would be effective for public companies for interim or annual periods beginning after June 15, 2005. The proposed standard would require companies to expense the fair value of all stock options that have future vesting provisions, are modified, or are newly granted beginning on the grant date of such options. We will evaluate the requirements of the final standard, which is expected to be issued on or around December 15, 2004, to determine the impact on our consolidated financial position and results of its operations.

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**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Market risk generally represents the risk of loss that may result from the potential change in value of a financial instrument as a result of fluctuations in interest rates and market prices. Our market risk exposure relates to cash and cash equivalents and short-term investments. We invest excess cash in highly liquid instruments with maturities of less than twelve months as of the date of purchase. These investments are not held for trading or other speculative purposes. Changes in interest rates affect the investment income we earn on our investments and, therefore, impact our cash flows and results of operations.

We have not traded or otherwise transacted in derivatives nor do we expect to do so in the future. We have established policies and internal processes related to the management of market risks which we use in the normal course of our business operations.

*Interest Rate Risk*

The fair value of long-term debt is subject to interest rate risk. While changes in market interest rates may affect the fair value of our fixed-rate long-term debt, we believe a change in interest rates would not have a material impact on our financial condition, future results of operations or cash flows.

*Foreign Currency Exchange Risk*

We conduct operations in several different countries. The balance sheet accounts of our operations in Scotland and Sweden are translated to U.S. dollars for financial reporting purposes and resulting adjustments are made to stockholders' equity. The value of the respective local currency may strengthen or weaken against the U.S. dollar, which would impact the value of stockholders' investment in our common stock. Fluctuations in the value of the British Pound and Swedish Krona against the U.S. dollar have occurred during our history, which have resulted in unrealized foreign currency translation gains and losses, which are included in accumulated other comprehensive income and shown in the equity section of our balance sheet.

While most of the transactions of our U.S. and foreign operations are denominated in the respective local currency, some transactions are denominated in other currencies. Since the accounting records of our foreign operations are kept in the respective local currency, any transactions denominated in other currencies are accounted for in the respective local currency at the time of the transaction. Upon settlement of this type of transaction, any foreign currency gain or loss results in an adjustment to income.

Our results of operations may be impacted by the fluctuating exchange rates of foreign currencies, especially the British Pound and Swedish Krona, in relation to the U.S. dollar. Most of the revenue and expense items of our foreign subsidiaries are denominated in the respective local currency. An unfavorable change in the exchange rate of the foreign currency against the U.S. dollar will result in lower revenue when translated into U.S. dollars. Operating expenses would also be lower in these circumstances.

During the three months ended September 30, 2004, the U.S. dollar experienced adverse fluctuations against the Swedish Krona. Based on foreign currency exchange rates as of September 30, 2004, the U.S. dollar has lost approximately 2.72% of its value against the Swedish Krona since June 30, 2004. The weakening of the U.S. dollar has resulted in greater revenues, operating expenses, assets and liabilities of our foreign subsidiaries when translated to U.S. dollars.

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We do not currently engage in hedging activities with respect to our foreign currency exposure. However, we continually monitor our exposure to currency fluctuations. We have not incurred significant realized losses on exchange transactions. If realized losses on foreign transactions were to become significant, we would evaluate appropriate strategies, including the possible use of foreign exchange contracts, to reduce such losses.

We were not adversely impacted by the European Union's adoption of the Euro currency. Our foreign operations to date have been located in Scotland and Sweden, which have not participated in the adoption of the Euro as of September 30, 2004.



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**Item 4. Controls and Procedures**

*Quarterly Controls Evaluation and Related CEO and CFO Certifications*

We conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (Disclosure Controls) as of the end of the period covered by this Quarterly Report. The controls evaluation was done under the supervision and with the participation of management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO).

Attached as exhibits to this Quarterly Report are certifications of the CEO and the CFO, which are required in accord with Rule 13a-14 of the Exchange Act. This Controls and Procedures section includes the information concerning the controls evaluation referred to in the certifications and it should be read in conjunction with the certifications for a more complete understanding of the topics presented.

*Definition of Disclosure Controls*

Disclosure Controls are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Exchange Act, such as this Quarterly Report, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure Controls are also designed to reasonably assure that such information is accumulated and communicated to our management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure. Our Disclosure Controls include components of our internal control over financial reporting, which consists of control processes designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements in accordance with accounting principles generally accepted in the United States.

*Limitations on the Effectiveness of Controls*

Our management, including the CEO and CFO, does not expect that our Disclosure Controls or our internal control over financial reporting will prevent all potential for error or fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

*Conclusions*

Based upon the controls evaluation, our CEO and CFO have concluded that, subject to the limitations noted above, as of the end of the period covered by this Quarterly Report, our Disclosure Controls were effective to provide reasonable assurance that material information relating to Viragen and its consolidated subsidiaries is made known to management, including the CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

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*Changes in Internal Control over Financial Reporting*

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) of the Exchange Act) that occurred during the quarter ended September 30, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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**PART II OTHER INFORMATION**

**Item 6. Exhibits**

- 31.1 Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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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.

Viragen, Inc.

Date: November 5, 2004

By: /s/ Dennis W. Healey

Dennis W. Healey  
Executive Vice President and  
Principal Financial Officer

Date: November 5, 2004

By: /s/ Nicholas M. Burke

Nicholas M. Burke  
Vice President, Controller and  
Principal Accounting Officer