GENTA INC DE/
Form 10-Q
May 10, 2004

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2004

OR

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

For the transition period from _____ to _____

Commission File Number 0-19635

GENTA INCORPORATED

(Exact name of Registrant as specified in its charter)

Delaware	33-0326866
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
Two Connell Drive Berkeley Heights, NJ	07922
(Address of principal executive offices)	**(Zip Code)**

(908) 286-9800

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES þ NO o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934).

YES þ NO o

As of April 30, 2004, the registrant had 77,751,389 shares of common stock outstanding.

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GENTA INCORPORATED
CONSOLIDATED BALANCE SHEETS

(In thousands, except par value data)

ASSETS	March 31, 2004	December 31, 2003
	(Unaudited)	
Current assets:		
Cash and cash equivalents (Note 2)	$ 36,149	$ 25,153
Marketable securities (Note 3)	31,337	57,776
Accounts receivable - net (Note 4)	8,945	16,675
Notes receivable	200	200
Inventory (Note 6)	6,696	518
Prepaid expenses and other current assets	1,184	3,313
Total current assets	84,511	103,635
Property and equipment, net (Note 7)	5,683	4,917
Notes receivable (Note 5)	4,387	3,542
Intangibles, net (Note 8)	718	863
Prepaid royalties (Note 9)	1,268	1,268
Other assets	1,481	450
Total assets	$ 98,048	$ 114,675
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 12,579	$ 15,319
Notes payable	374	748
Deferred revenues, current portion (Note 11)	5,282	5,287
Total current liabilities	18,235	21,354
Deferred revenues (Note 11)	34,763	36,067
Convertible debt (Note 12)	10,000	10,000
Long term debt (Note 13)	35,000	35,000
Total liabilities	97,998	102,421
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Series A convertible preferred stock, $.001 par value; 5,000 shares authorized, 10 shares and 261 shares issued and outstanding, liquidation value of $485 and $13,025 at March 31, 2004 and December 31, 2003 respectively	--	--
Common stock, $.001 par value; 120,000 shares authorized, 77,879 and 75,927 shares issued and outstanding at March 31, 2004 and December 31, 2003, respectively	78	76
Additional paid-in capital	335,987	335,713
Deferred financing costs	(33)	--
Accumulated deficit	(335,832)	(323,299)

Deferred compensation	(191)	(261)
Accumulated other comprehensive income	41	25
	50	12,254
Total liabilities and stockholders' equity	$ 98,048	$ 114,675

See accompanying notes to consolidated financial statements

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)	Three Months Ended March 31, 2004	Three Months Ended March 31, 2003
	(Unaudited)	
Revenues:		
Product sales - net	$ 372	$ --
License fees and royalties	261	266
Development funding (Note 10)	1,049	1,043
	1,682	1,309
Cost of goods sold	93	--
Gross margin	1,589	1,309
Costs and expenses:		
Research and development (including non-cash compensation expense of $52 for the three months ended March 31, 2004 and March 31, 2003)	12,353	15,509
Selling, general and administrative (including non-cash compensation expense of $17 and $92 for the three months ended March 31, 2004 and March 31, 2003, respectively)	9,224	4,872
Total costs and expenses - gross	21,577	20,381
Aventis reimbursement	(7,433)	(9,157)
Total costs and expenses - net	14,144	11,224
Loss before other income	(12,555)	(9,915)
Other income	23	312
Net loss	$ (12,532)	$ (9,603)
Net loss per basic and diluted share	$ (0.16)	$ (0.13)
Shares used in computing net loss per basic and diluted share	76,859	74,233

See accompanying notes to consolidated financial statements

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)	Three Months Ended March 31, 2004	2003
	(Unaudited)	
Operating activities:		
Net loss	$ (12,532)	$ (9,603)
Items reflected in net loss not requiring cash:		
Depreciation and amortization	787	495
Compensation expense related to stock options (Note 16)	70	144
Changes in operating assets and liabilities:		
Accounts, notes and loan receivable (Note 4)	7,730	4,442
Inventory (Note 6)	(6,178)	--
Notes receivable (Note 5)	(845)	(832)
Accounts payable, accrued expenses and other current liabilities	(3,114)	(20,494)
Deferred revenue (Note 11)	(1,309)	(1,309)
Other assets	1,099	(185)
Net cash used in operating activities	(14,292)	(27,342)
Investing activities:		
Purchase of marketable securities	(7,281)	(24,178)
Maturities and sales of marketable securities	33,735	53,824
Purchase of property and equipment	(1,409)	(345)
Net cash provided by investing activities	25,045	29,301
Financing activities:		
Borrowings under the line of credit (Note 12)	--	17,500
Purchase of treasury stock	--	(303)
Deferred financing costs	(33)	--
Issuance of common stock upon exercise of warrants and options	276	97
Net cash provided by financing activities	243	17,294
Increase in cash and cash equivalents	10,996	19,253
Cash and cash equivalents at beginning of period	25,153	32,700
Cash and cash equivalents at end of period	$ 36,149	$ 51,953

See accompanying notes to consolidated financial statements

GENTA INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2004
(Unaudited)

1. Organization and Business

Genta Incorporated (Genta or the Company) is a biopharmaceutical company engaged in pharmaceutical (drug) research and development, its sole reportable segment. The Company is dedicated to developing innovative drugs to treat cancer. In the past, the Company s research efforts have focused primarily on the development of antisense drugs, which are designed to selectively prevent the production of specific proteins that contribute to the cause or progression of disease. More recently, the Company has broadened its research portfolio into other DNA medicines , which, in addition to antisense drugs, consist of decoy aptamers and small molecules, which include the Company s gallium products.

The Company has had recurring operating losses since inception and management expects that such losses will continue until Genasense receives approval from the FDA for commercial sales and we receive a full year of royalties from Aventis Pharmaceuticals Inc. (Aventis) on worldwide sales. Although no assurances can be expressed, management believes that at the current rate of spending, coupled with the amounts to be reimbursed by and the available line of credit from Aventis, the Company should have sufficient cash funds to maintain its present operations to the end of 2004. Additional Aventis milestone payments and other funding available to the Company upon the anticipated NDA approval of Genasense should provide sufficient capital resources for beyond 2004.

The Company may also seek collaborative agreements, equity financing and other financing arrangements with potential corporate partners and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available on favorable terms, if at all. The Company will need substantial additional funds before it can expect to realize significant product revenue.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements are presented on the basis of accounting principles generally accepted in the United States. All professional accounting standards that are effective as of March 31, 2004 have been considered in preparing the consolidated financial statements. Such financial statements include the accounts of the Company and all majority-owned subsidiaries. All material intercompany transactions and balances have been eliminated in consolidation. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make certain estimates and assumptions that affect reported earnings, financial position and various disclosures. Actual results could differ from those estimates. Certain reclassifications have been made to prior-year amounts to conform with current-year presentation. The unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the interim financial information have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2003. Results for the interim periods are not necessarily indicative of results for the full years.

The Company has experienced significant quarterly fluctuations in operating results and it expects that these fluctuations will continue.

Revenue Recognition

In April 2002, the Company entered into a development and commercialization agreement (Collaborative Agreement) with Aventis. Under the terms of the Collaborative Agreement, the Company and Aventis will jointly develop and commercialize Genasense in the U.S. (the Alliance), and Aventis will have exclusive development and marketing rights to the compound in all countries outside of the U.S. Under the Collaborative Agreement, Aventis will pay 75% of U.S. NDA-directed development costs incurred by either Genta or Aventis, subsequent to the execution of the Collaborative Agreement, and 100% of all other development, marketing, and sales costs incurred within the U.S. and elsewhere as subject to the Collaborative Agreement (Note 10). Reimbursements are to be made pursuant to a single net payment from one party to the other. Such payments are due and payable 60 days following the end of the quarter in which such expenses are incurred.

We follow the provisions of the Securities and Exchange Commission s Staff Accounting Bulletin No. 104 (SAB No. 104), *Revenue Recognition*, and Emerging Issues Task Force No. 00-21 (EITF No. 00-21), *Accounting for Revenue Arrangements with Multiple Deliverables*.

In accordance with EITF No. 00-21 we analyze our multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. We recognize license payments as revenue if the license has stand-alone value and the fair value of the undelivered items can be determined. If the license is considered to have stand-alone value but the fair value on any of the undelivered items cannot be determined, the license payments are recognized as revenue over the period of performance for such undelivered items or services. Our estimate of the period of performance involves management judgment. Amounts received for milestones are recognized upon achievement of the milestone, as long as the milestone is deemed to be substantive and we have no other performance obligations.

We have determined that, due to the nature of the on-going development work related to our Collaborative Agreement with Aventis, the end of the development phase and the fair-value of the undelivered elements is not determinable. Accordingly, we have deferred recognition of the initial licensing fee and up-front development funding received from Aventis and are recognizing these payments on a straight-line basis over the original estimated useful life of the related first-to-expire patent of 115 months. Any subsequent milestone payments that may be received from Aventis will also be recognized over the then remaining estimated useful life of the first-to-expire patent.

Genta recognizes revenue from product sales when title to product and associated risk of loss has passed to the customer and we are reasonably assured of collecting payment for the sale. All revenue from product sales are recorded net of applicable allowances for returns rebates and other applicable discounts and allowances. We allow return of our product for up to twelve months after product expiration.

Research and Development

Research and development costs are expensed as incurred, including raw material costs required to manufacture products for clinical trials. Reimbursements for applicable Genasense -related costs, under the Collaborative Agreement (Note 10), have been recorded as a reduction to expenses in the consolidated statement of operations.

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents consisted entirely of money market funds. The carrying amounts of cash, cash equivalents and marketable securities approximate fair value due to the short-term nature of these instruments. Marketable securities consisted primarily of corporate notes and government securities, all of which are classified as available-for-sale marketable securities. Management determines the appropriate classification of debt and equity securities at the time of purchase and reassesses the classification at each reporting date. The Company invests its excess cash primarily in debt instruments of domestic corporations and government-backed securities. The Company has established guidelines relative to diversification and maturities that attempt to maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

Property and Equipment

Property and equipment is stated at cost and depreciated on the straight-line method over the estimated useful lives of the assets, ranging from three to five years. Leasehold improvements incurred in the renovation of the Company s current offices are being amortized over the remaining life of the leases. The Company s policy is to evaluate the appropriateness of the carrying value of the undepreciated value of long-lived assets on the basis of estimated future cash flows (undiscounted) and other factors. If such evaluation were to indicate an impairment of these intangible assets, such impairment would be recognized by a write-down of the applicable assets. Based on the valuation, no impairment was indicated in accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets.*

Intangible Assets

Intangible assets, consisting primarily of licensed technology and capitalized patent costs, are amortized using the straight-line method over their estimated useful lives of five years. The Company s policy is to evaluate the appropriateness of the carrying values of the unamortized balances of intangible assets on the basis of estimated future cash flows (undiscounted) and other factors. If such evaluation were to indicate an impairment of these assets, such impairment would be recognized by a write-down of the applicable assets. The Company evaluates, each financial reporting period, the continuing value of patents and patent applications. Through this evaluation, the Company may elect to continue to maintain these patents, seek to out-license them, or abandon them. Based on the valuation, no impairment was indicated in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets.*

Inventories

Inventories are stated at the lower of cost or market with cost being determined using the first-in, first-out (FIFO) method.

Stock Options

The Company accounts for stock-based compensation arrangements in accordance with the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* and complies with the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*. Under APB Opinion No. 25, compensation expense is based on the difference, if any, on the date of grant, between the fair value of the Company s stock and the exercise price. The Company accounts for stock options issued to non-employees in accordance with the provisions of SFAS No. 123 and 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*. The Company is amortizing deferred stock compensation using the graded vesting method, in accordance with Financial Accounting Standards Board Interpretation No. 28, over the vesting period of each respective option, which is generally four years.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* Amendment of FASB Statement No. 123, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation and amends the disclosure requirements of Statement No. 123. The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

($ thousands, except per share data)	Three Months Ended March 31, 2004	2003
Net loss applicable to common shares, as reported	$ (12,532)	$ (9,603)
Add: Equity related employee compensation expense included in reported net income, net of related tax effects	70	144
Deduct: Total stock-based employee compensation expense determined under fair values based method for all awards, net of related tax effects	(2,345)	(1,548)
Pro forma net loss	$ (14,807)	$ (11,007)
Net loss per share attributable to common shareholders:		
As reported: Basic and diluted	$ (0.16)	$ (0.13)
Pro forma: Basic and diluted	$ (0.19)	$ (0.15)

The pro-forma disclosure shown above were calculated for all options using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended March 31, 2004	2003
Risk-free interest rate	2.9%	2.8%
Dividend yield	--	--
Expected life (years)	4.0	4.0
Volatility	61%	65%

Net Loss Per Common Share

Basic earnings per share are based upon the weighted-average number of shares outstanding during the period. Diluted earnings per share includes the weighted average number of all potentially dilutive common shares such as shares outstanding, options, warrants and convertible preferred stock outstanding.

Net loss per common share for the three months ended March 31, 2004 and 2003 is based on the weighted average number of shares of common stock outstanding during the periods. Basic and diluted loss per share are identical for all periods presented as potentially dilutive securities, including options, warrants and convertible preferred stock have been excluded from the calculation of the diluted net loss per common share because the inclusion of such securities would be antidilutive.

3. Marketable Securities

The carrying amounts of the company s marketable securities, which are solely corporate debt securities, approximate fair value due to the short-term nature of these instruments. The fair value of available-for-sale marketable securities is as follows ($ thousands):

	March 31, 2004	December 31, 2003
Amortized cost	$ 31,296	$ 57,751
Gross unrealized gains	43	29
Gross unrealized losses	(2)	(4)
Estimated fair value	$ 31,337	$ 57,776

The estimated fair value of each marketable security has been compared to its cost, and therefore, a net unrealized gain of approximately $41 thousand has been recognized in accumulated other comprehensive income at March 31, 2004.

4. Accounts Receivable-Net

Included in accounts receivable and netted against operating expenses in the consolidated statement of operations at March 31, 2004, is $8.7 million in net expense reimbursements due from Aventis for various third-party costs, internal costs of scientific and technical personnel (Full-time Equivalents or FTE s) and Genasense drug supply costs for the three month period ended March 31, 2004. Net expense reimbursement consists of the appropriate reimbursement rate (75% or 100%) for costs incurred by Genta and internal costs of Genta scientific and technical personnel net of our 25% share of expenses incurred by Aventis and internal costs of Aventis scientific and technical personnel. Also included in accounts receivable-net are receivables of $0.2 million related to the sale of Ganite®, which are net of allowances of $0.1 million. At March 31, 2003, $9.2 million in net expense reimbursements due from Aventis for various third-party costs, internal costs of scientific and technical personnel and Genasense drug supply costs for the three month period ended March 31, 2003 was included in accounts receivable and netted against operating expenses in the consolidated statement of operations.

5. Notes Receivable

At March 31, 2004, the Company had recorded $4.4 million as a note receivable relating to advance financing provided to Avecia Biotechnology, Inc. (Avecia) for facility expansion, which will be repaid with interest through future payments determined as a function of drug substance purchases to be made by the Company in the future.

	March 31, 2004	December 31, 2003
Advance funding for facility expansion	$ 4,504	$ 3,552
Interest recorded	154	95
Payments received	(271)	(105)
	$ 4,387	$ 3,542

6. Inventories

Inventories, comprised of Ganite® and Genasense™ , are stated at the lower of cost or market with cost being determined using the first-in, first-out (FIFO) method. Inventories consisted of the following (in thousands):

	March 31, 2004	December 31, 2003
Raw materials	$ 2,029	$ 189
Work in process	4,302	318
Finished goods	365	11
	$ 6,696	$ 518

7. Property and Equipment

Property and equipment is comprised of the following ($ thousands):

	Estimated Useful Lives	March 31, 2004	December 31, 2003
Computer equipment	3	$ 3,457	$ 3,337
Software	3	3,289	2,632
Furniture and fixtures	5	1,125	1,009
Leasehold improvements	Life of lease	1,001	767
Equipment	5	579	299
		9,451	8,044
Less accumulated depreciation and amortization		(3,768)	(3,127)
		$ 5,683	$ 4,917

8. Intangibles, net

Intangible assets consist of the following ($ thousands):

	March 31, 2004	December 31, 2003
Patent and patent applications	$ 3,992	$ 3,992
Less accumulated amortization	(3,274)	(3,129)
	$ 718	$ 863

Future amortization expense related to intangibles at March 31, 2004 are as follows ($ thousands):

	Amortization Expense
2004	$ 433
2005	285
Total	$ 718

9. Prepaid Royalties

In December 2000, the Company recorded $1.3 million as the fair value for its commitment to issue 162,338 shares of common stock to a major university as consideration for an amendment to a license agreement initially executed on August 1, 1991 related to antisense technology licensed from the university. The amendment provided for a reduction in the royalty percentage rate to be paid to the university based on the volume of sales of the Company s products containing the antisense technology licensed from such university. These shares were issued in the first quarter of 2001. The Company will amortize the prepaid royalties upon the commercialization of Genasense , the Company s leading antisense drug, through the term of the arrangement which expires twelve years from the date of first commercial sale.

10. Collaborative Agreement

In April 2002, the Company entered into a development and commercialization agreement (Collaborative Agreement) with Aventis Pharmaceuticals Inc. (Aventis). Under the terms of the Collaborative Agreement, the Company and Aventis will jointly develop and commercialize Genasense in the U.S. (the Alliance), and Aventis will have exclusive development and marketing rights to the

compound in all countries outside of the U.S. The Company will retain responsibility for global manufacturing and for regulatory filings within the U.S., while Aventis will assume all regulatory responsibilities outside the U.S. Joint management teams, including representatives from both Genta and Aventis, will oversee the Alliance. Collectively, this Collaborative Agreement could provide up to $476.9 million in cash, equity and convertible debt proceeds to the Company. In addition, under the Collaborative Agreement, Genta is entitled to royalties on any worldwide sales of Genasense , from which Genta is required to pay third-party pass-through royalties to the University of Pennsylvania (UPenn) and The National Institutes of Health (NIH) based on net worldwide sales. Furthermore, under the Collaborative Agreement, Aventis will pay 75% of U.S. NDA-directed development costs incurred by either Genta or Aventis subsequent to the execution of the Collaborative Agreement, and 100% of all other development, marketing, and sales costs incurred within the U.S. and elsewhere as subject to the Collaborative Agreement.

As of March 31, 2004, the Company has received a total of $249.9 million in initial and near-term funding, which included a $10.0 million licensing fee and $40.0 million in development funding, $10.0 million in convertible debt proceeds (Note 10), $71.9 million pursuant to an at-market equity investment in the Company s common stock, $83.0 million in paid expense reimbursements and $35.0 million in line of credit proceeds. A further $8.8 million in accrued expense reimbursement is due for receipt during the second quarter of 2004. The remaining amounts that could be received under the Collaborative Agreement, $280.0 million in cash and $65.0 million in convertible note proceeds, are contingent upon the achievement of certain research and development milestones.

11. Deferred Revenues

As of March 31, 2004, the Company had recorded $40.0 million, net of amortization in deferred revenues relating to the initial $10.0 million licensing fee and $40.0 million development funding received from Aventis under the Collaborative Agreement (Note 10), of which $5.3 million is included in current liabilities and $34.7 million is classified as long-term deferred revenues, which will be recognized on a straight-line basis over the estimated original useful life of the related first-to-expire patent of 115 months, in accordance with SAB No. 104. Any subsequent milestone payments that may be received from Aventis will also be recognized over the then remaining estimated useful life of the related first-to-expire patent.

12. Convertible Debt

At March 31, 2004, the Company had $10.0 million in convertible debt that was issued in connection with the Collaborative Agreement (Note 10). The Company received $10.0 million in debt proceeds from Aventis, and issued a $10.0 million convertible promissory note to Aventis (Aventis Note). Interest accrues at the rate of 5.63% per annum until April 26, 2009 (the Maturity Date) and compounds annually on each anniversary date of the Aventis Note through the Maturity Date. The Company may redeem the Aventis Note for cash in whole or in part (together with any accrued and unpaid interest with respect to such principal amount) in amounts of not less than $0.5 million. In addition, the Company may convert the Aventis Note on or prior to the Maturity Date in whole or in part into fully paid and non-assessable shares of common stock. As of any date, the number of shares of common stock into which the Aventis Note may be converted shall be determined by a formula based on the then market value of the common stock (the Conversion Price), subject to a minimum Conversion Price of $8.00 per share.

As of March 31, 2004, the Company has accrued interest of $1.1 million on the Aventis Note.

13. Long Term Debt

At March 31, 2004, the Company had $35.0 million outstanding on a line of credit that was issued in connection with an amendment, dated March 14, 2003, to the Collaborative Agreement (Note 10) that established a line of credit of up to $40.0 million related to the development, manufacturing and commercialization of Genasense (Aventis Line of Credit). This revolving debt is considered an advance against both past and future costs. At the

time of Genasense NDA approval in the U.S., any outstanding balance will be offset against the first milestone payment that is due to Genta from Aventis. The terms of the Aventis Line of Credit provide for a favorable interest rate, which is set two days prior to the first day of each calendar quarter. The Aventis Line of Credit terminates upon the earlier of (i) the receipt of Genasense NDA approval in the U.S. or (ii) December 31, 2004, all amounts payable under the agreement are due six months after termination. As security for the repayment of the Aventis Line of Credit, Genta has granted Aventis a security interest in all of its accounts and/or other rights to payments under the Collaborative Agreement as well as all inventory related to Genasense .

As of March 31, 2004, the Company has accrued interest of $0.4 million on the Aventis Line of Credit.

14. Comprehensive Loss

An analysis of comprehensive loss is presented below:

	Three Months Ended March 31,	
($ in thousands)	**2004**	**2003**
Net loss	$ (12,532)	$ (9,603)
Change in market value on available-for-sale short-term investments	16	(15)
Total comprehensive loss	$ (12,516)	$ (9,618)

15. Supplemental Disclosure of Cash Flows Information and Non-cash Investing and Financing Activities

No interest or income taxes were paid for the three months ended March 31, 2004 and 2003.

16. Commitments and Contingencies

Litigation and Potential Claims

JBL Scientifics, Inc.

During May 2000, Promega notified Genta of two claims against Genta and Genta s subsidiary, Genko Scientific, Inc. (formerly known as JBL Scientifics, Inc.), for indemnifiable damages in the aggregate amount of $2.8 million under the purchase agreement pursuant to which Promega acquired the assets of JBL. Promega s letter stated that it intended to reduce to zero the principal amount of the $1.2 million promissory note it issued as partial payment for the assets of Genko Scientific, Inc. and that therefore Genta owed Promega approximately $1.6 million. On October 16, 2000 Genta filed suit in a U.S. District Court in California against Promega for the non-payment of the $1.2 million note plus accrued interest. On November 6, 2000, Promega filed a counterclaim alleging indemnifiable damages in the aggregate amount of $2.8 million. During the first quarter of 2001, we agreed to resolve the matter with Promega, and, in connection therewith, agreed to restructure its $1.2 million promissory note receivable to provide for a $0.2 million non-interest bearing note due to be repaid by Promega upon final resolution of certain environmental issues related to JBL and forgave all accrued interest. While we have resolved one of these environmental issues, we are awaiting final acceptance by the EPA of our settlement offer on the other environmental issue before the restructured note will be repaid by Promega. We are uncertain as to whether and when the EPA will issue such final acceptance.

Genta Pharmaceutical Europe S.A.

During 1995, Genta Pharmaceutical Europe S.A., or Genta Europe, a wholly-owned subsidiary of Genta, received funding in the form of a loan from ANVAR, a French government agency, of which the proceeds were intended to fund research and development activities. In October 1996, in connection with a restructuring of Genta s operations, Genta terminated all scientific personnel of Genta Europe. In 1998,

ANVAR asserted that Genta Europe was not in compliance with the ANVAR Agreement, notified Genta Europe of its demand for accelerated repayment of the loan and notified Genta that it was liable as a guarantor on the note. Based on the advice of French counsel, Genta does not believe that ANVAR is entitled to payment under the terms of the ANVAR Agreement and that Genta will likely not incur any liability in this matter, although there can be no assurances thereof. During the quarter ended September 30, 2003, we reversed the accrued net liability of $0.2 million related to this matter, as management believes that a loss is not probable.

University of Pennsylvania

In October 2002, a licensing officer from the University of Pennsylvania asserted a claim to a portion of the initial $40.0 million development funding we received from Aventis pursuant to the collaborative agreement between Genta and Aventis. In October 2003, we reached a settlement with the University of Pennsylvania with respect to this claim. Under the terms of the settlement, in exchange for an agreement by the University of Pennsylvania to forego any and all claims in the future to any portion of any milestone and other payments (other than royalty payments on sales) made to Genta pursuant to the collaborative agreement, Genta has agreed to make the following payments to the University of Pennsylvania: (i) $750,000 on November 5, 2003, (ii) $250,000 on February 2, 2004, (iii) $1.5 million upon the first new drug application or foreign equivalent approval of Genasense and (iv) provided that the first new drug application or foreign equivalent approval of Genasense has been received by Genta, $750,000 on the earlier of (a) the second new drug application or foreign equivalent approval of Genasense or (b) December 30, 2004.

17. Subsequent Event

On May 3, 2004 we presented results of our Phase 3 trial of Genasense in combination with dacarbazine versus dacarbazine alone to the Oncology Drugs Advisory Committee of the FDA. In the absence of increased survival, the committee voted that the evidence presented did not provide substantial evidence of effectiveness, as measured by response rate and progression-free survival, to outweigh the increased toxicity of administering Genasense for the treatment of patients with metastatic melanoma who have not received prior chemotherapy. While the advisory committee s recommendation is not binding, the FDA will consider it as the agency completes its Priority Review of the NDA for Genasense .

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

Certain Factors Affecting Forward-Looking Statements Safe Harbor Statement

The statements contained in this Quarterly Report on Form 10-Q that are not historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the expectations, beliefs, intentions or strategies regarding the future. The Company intends that all forward-looking statements be subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect the Company s views as of the date they are made with respect to future events and financial performance, but are subject to many risks and uncertainties, which could cause actual results to differ materially from any future results expressed or implied by such forward-looking statements. Forward-looking statements include, without limitation, statements about:

- U.S. Federal Drug Administration (FDA) approval or failure to approve Genasense™;
- the Company s ability to develop, manufacture and sell its products;
- the safety and efficacy of the Company s products;
- the commencement and completion of pre-clinical and clinical trials;
- the Company s ability to obtain necessary regulatory approvals;
- the Company s contractual collaborative arrangements;
- the adequacy of the Company s capital resources;
- the ability to obtain sufficient financing to maintain the Company s planned operations;
- the possibility and effect of patent infringement claims;
- the impact of competitive products and market conditions;
- the other risks described under Certain Risks and Uncertainties Related to the Company s Business.

The Company does not undertake to update any forward-looking statements.

We make available free of charge on our Internet website (http://www.genta.com) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. The content on the Company s website is available for informational purposes only. It should not be relied upon for investment purposes, nor is it incorporated by reference into this Form 10-K.

Overview

Since its inception in February 1988, Genta has devoted its principal efforts toward drug discovery and research and development. Genta s strategy is to build a product and technology portfolio primarily focused on its cancer-related products. Genta has been unprofitable to date and expects to incur substantial operating losses due to continued requirements for ongoing and planned research and development activities, pre-clinical and clinical testing, manufacturing activities, regulatory activities and establishment of a sales and marketing organization. From our inception to March 31, 2004, we have incurred a cumulative net loss of $335.8 million. We have experienced significant quarterly fluctuations in operating results and we expect that these fluctuations in revenues, expenses and losses will continue.

Our financial results in 2004 may be significantly affected by FDA action with respect to Genasense™. We have filed a New Drug Application (NDA) for Genasense™ to be used in combination with dacarbazine for the treatment of patients with advanced melanoma who have not previously received chemotherapy. The FDA accepted our NDA filing on February 5, 2004 and granted Priority Review status to the application, which targets an agency action on or before June 8, 2004. On February 10, 2004, we were invited by the FDA to meet on May 3, 2004 with the FDA Oncology Drugs Advisory Committee (ODAC). On May 3, 2004 we presented results of our Phase 3 trial of Genasense in combination with dacarbazine versus

dacarbazine alone to ODAC. In the absence of increased survival, the committee voted that the evidence presented did not provide substantial evidence of effectiveness, as measured by response rate and progression-free survival, to outweigh the increased toxicity of administering Genasense for the treatment of patients with metastatic melanoma who have not received prior chemotherapy. While the advisory committee s recommendation is not binding, the FDA will consider it as the agency completes its Priority Review of the NDA for Genasense .

If the FDA approves the NDA and qualifies Avecia, our contract manufacturer, then Aventis, Genta s collaborative partner, will begin to market the product in the United States, Avecia will begin to manufacture the product and Genta will sell the product to Aventis. Genta will also earn a royalty from Aventis on all sales of Genasense™.

Results of Operations for the Three Months Ended March 31, 2004 and 2003

	Summary Operating Results For the three months ended March 31,			
($ thousands)		Increase (Decrease)		
	2004	**$**	**%**	**2003**
Revenues:				
Product sales net	$ 372	$ 372	100%	$ --
License fees and royalties	261	(5)	(2)%	266
Development funding	1,049	6	6%	1,043
Net revenues	1,682	373	28%	1,309
Cost of goods sold	93	93	100%	--
Gross margin	1,589	280	21%	1,309
Costs and expenses:				
Research and development (including non-cash compensation expense of $52 for the three months ended March 31, 2004 and March 31, 2003)	12,353	(3,156)	(20)%	15,509
Selling, general and administrative (including non-cash compensation expense of $17 and $92 for the three months ended March 31, 2004 and March 31, 2003, respectively)	9,224	4,352	89%	4,872
Total costs and expenses gross	21,577	1,196	6%	20,381
Less: Aventis reimbursement	7,433	(1,724)	(19)%	9,157
Total costs and expenses net	14,144	2,920	26%	11,224
Loss before other income	(12,555)	(2,640)	(27)%	(9,915)
Other income, principally net interest income	23	(289)	(93)%	312
Net loss	$ (12,532)	$ (2,929)	(31)%	$ (9,603)

Net Revenues

Net revenues, consisting of license fees and royalties, development funding and product sales were $1.7 million for the three months ended March 31, 2004 compared to $1.3 million in for the three months ended March 31, 2003. License fees and development funding revenues are generated by the initial $10.0 million licensing fee and $40.0 million development funding received from Aventis in 2002 under the Collaborative Agreement (see Note 10 to our financial statements), along with non-exclusive sub-license agreements involving antisense technology. The initial payments received from Aventis are being recognized over the original estimated useful life of the related first-to-expire patent of 115 months.

Research and Development Expenses

Research and development expenses before reimbursement were $12.4 million for the three months ended March 31, 2004 compared to $15.5 million for the three months ended March 31, 2003. Approximately $10.7 million or 87% of research and development expenses before reimbursement were incurred on the Genasense™ project for the three months ended March 31, 2004. For the three months ended March 31, 2003, research and development expenses were higher due to the Phase 3 clinical trials related to Genasense™. Of the $12.4 million in research and development expenses for the three months ended March 31, 2004, $7.4 million is reimbursable pursuant to our collaborative agreement with Aventis and is expected to be reimbursed by Aventis in the second quarter of 2004.

For the twelve months ended December 31, 2003, research and development expenses before reimbursement were $82.9 million, including a $13.5 million write-off of acquired in-process research and development expenses related to the acquisition of Salus Therapeutics, Inc. in August 2003. Research and development expenses incurred on the Genasense™ project for the twelve months ended December 31, 2003 were $63.5 million, representing 91% of research and development expenses net of the write-off of acquired in-process research and development expenses.

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are not reasonably estimable. Results from clinical trials may not be favorable. Data from clinical trials are subject to varying interpretation and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

Selling, general and administrative expenses

Selling, general and administrative expenses were $9.2 million for the three months ended March 31, 2004 compared to $4.9 million for the three months ended March 31, 2003. Expenses have substantially increased due to the creation of a sales force, Ganite® launch activities, a larger administrative staff and higher general corporate expenses driven by business growth. There were no sales and marketing related expenses reimbursable at 100% pursuant to our collaborative agreement with Aventis for the three months ended March 31, 2004, as sales and marketing related expenses related to Genasense ™ are incurred by, billed to and paid by Aventis.

Aventis Reimbursement

Under the Collaborative Agreement with Aventis, (see Note 10 to our financial statements), Aventis will pay 75% of U.S. NDA-directed development costs incurred by either Genta or Aventis and 100% of all other development, marketing and sales costs incurred within the U.S. and elsewhere as subject to the Collaborative Agreement. A breakdown of the various third-party, drug supply costs and internal costs of scientific and technical personnel, (Full-Time Equivalents or FTE s) that Aventis is required to reimburse under our collaborative agreement with Aventis, follows:

($ thousands)	**March 31,**	
Reimbursement to Genta	**2004**	**2003**
Third-party costs	$ 6,363	$ 6,048
Drug supply costs	(244)	2,048
FTE s	1,731	1,540
Amount due to Genta	7,850	9,636
Reimbursement to Aventis	(417)	(479)
Net reimbursement to Genta	$ 7,433	$ 9,157

Reimbursement to Aventis is comprised of our 25% share of third party costs incurred by Aventis and internal costs of Aventis s scientific and technical personnel.

Other Income

Net other income for the three months ended March 31, 2004 declined $0.3 million, or 93% from the comparable period in 2003, principally as a result of lower investment balances and higher borrowings from Aventis (see Note 13 to our financial statements).

Net Loss

Genta incurred a net loss of $12.5 million, or $0.16 per share, for the three months ended March 31, 2004, compared to a net loss of $9.6 million, or $0.13 per share, for the three months ended March 31, 2003. The increase in net loss and per share net loss to common shareholders was primarily due to increased selling, general and administrative expenses described above.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through private placements and public offerings of our equity securities. Cash provided from these offerings totaled approximately $278.8 million through March 31, 2004, including net proceeds of $71.0 million received in 2002 and $32.2 million received in 2001. At March 31, 2004, the Company had cash, cash equivalents and marketable securities totaling $67.5 million compared to $103.3 million at March 31, 2003.

During the first quarter of 2004, cash flow used in operating activities was $14.3 million, primarily resulting from a net loss of $12.5 million. The company had proceeds of $33.7 million from sale of marketable securities. At March 31, 2004, we had cash and cash equivalents totaling $36.1 million compared to $52.0 million at March 31, 2003. The decrease in our cash and cash equivalents was primarily due to cash used to fund our operations.

During the first quarter of 2004, the Company used approximately $6.2 million related to increases in inventory, attributable to the capitalization of Genasense™ inventory in anticipation of the launch of this product and an increase in Ganite® raw material inventory to support increased sales activity of the product. We evaluate our ending inventories on a quarterly basis for excess quantities, impairment of value and obsolescence.

In March 2003, Genta and Aventis negotiated a line of credit for an amount up to $40.0 million which terminates with respect to additional borrowings on the earlier to occur of FDA approval of Genasense™ or December 31, 2004. Loans under this line of credit are subject to repayment six months after termination. As of March 31, 2004, approximately $4.6 million remained available under this line of credit. FDA approval of Genasense™ would trigger a milestone payment from Aventis of $75.0 million and an obligation by Aventis to purchase, at our option, $20.0 million of convertible notes from Genta. Management believes that at the current rate of spending, primarily in support of ongoing and anticipated clinical trials, and after considering expense reimbursement and the line of credit provided by Aventis, we should have sufficient cash funds to maintain our present operations through 2004.

Our principal expenditures relate to our research and development activities, which include our ongoing and future clinical trials. We expect these expenditures to continue. We expect increased total expenditures, prior to expense reimbursement, for clinical trials and drug supply related to Genasense™ as a result of our collaboration agreement with Aventis. In addition, expenditures associated with other products under development by us may increase as research and development activities become more focused and as other clinical trials are initiated.

If we successfully secure sufficient levels of collaborative revenues and other sources of financing, we expect to use such financing to continue to expand our ongoing research and development activities, pre-clinical testing and clinical trials, costs associated with the market introduction of potential products and expansion of our administrative activities.

We anticipate that significant additional sources of financing, primarily expense reimbursement from Aventis, will be required in order for us to continue our planned operations. We also anticipate seeking additional product development opportunities through potential acquisitions or investments. Such acquisitions or investments may consume cash reserves or require additional cash or equity. Our working capital and additional funding requirements will depend upon numerous factors, including: (i) the progress of our research and development programs; (ii) the timing and results of pre-clinical testing and clinical trials; (iii) the level of resources that we devote to sales and marketing capabilities; (iv) technological advances; (v) the activities of competitors; and (vi) our ability to establish and maintain collaborative arrangements with others to fund certain research and development efforts, to conduct clinical trials, to obtain regulatory approvals and, if such approvals are obtained, to manufacture and market products.

Recent Accounting Pronouncements

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Liabilities, Equity, or Both*. This limited scope statement prescribes changes to the classification of mandatorily redeemable preferred stock, preferred securities of subsidiary trusts and the accounting for forward purchase contracts issued by a company in its own stock among other issues. SFAS No. 150 does not apply to features that are embedded in a financial instrument that is not a derivative in its entirety and requires all preferred securities of subsidiary trusts to be classified as debt on the consolidated balance sheet and the related dividends as interest expense. The Company adopted the provisions of SFAS No. 150, including the deferral of certain effective dates as a result of the provisions of FASB Staff Position 150-3, *Effective Date, Disclosures, and Transition for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests Under FASB Statement No. 150 Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. The adoption of this statement did not have any impact on the Company s results of operations, financial position or cash flows.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. In particular, SFAS No. 149 (1) clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative discussed in paragraph 6(b) of SFAS No. 133, (2) clarifies when a derivative contains a financing component, (3) amends the definition of an underlying to conform it to language used in FIN 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, and (4) amends certain other existing pronouncements. SFAS No. 149 is to be applied prospectively to contracts entered into or modified after June 30, 2003, with certain exceptions, and for hedging relationships designated after June 30, 2003. The adoption of this statement did not have any impact on the Company s results of operations, financial position or cash flows.

In January 2003, the FASB issued Interpretation No. 46 *Consolidation of Variable Interest Entities*. This interpretation defines when a business must consolidate a variable interest entity. This interpretation applies immediately to variable interest entities created after January 31, 2003 and became effective for all other transactions as of July 1, 2003. However, in October 2003 the FASB permitted companies to defer the July 1, 2003 effective date to December 31, 2003. Again in December 2003, the FASB permitted companies to defer the December 31, 2003 effective date, in certain circumstances, to the first interim or annual period ending after March 15, 2004. The Company has determined that it is not reasonably probable that it will be required to consolidate or disclose information about a variable interest entity.

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

Our carrying values of cash, marketable securities, accounts payable, accrued expenses and debt are a reasonable approximation of their fair value. The estimated fair values of financial instruments have been determined by us using available market information and appropriate valuation methodologies (see Note 2 to our financial statements).

However, considerable judgment is required in interpreting market data to develop the estimates of fair value. Accordingly, the estimates utilized in the consolidated financial statements are not necessarily indicative of the amounts that we could realize in a current market exchange. We have not entered into, and do not expect to enter into, financial instruments for trading or hedging purposes. We do not currently anticipate entering into interest rate swaps and/or similar instruments.

Genta s primary market risk exposure with regard to financial instruments is to changes in interest rates, which would impact interest income earned on such instruments. We have no material currency exchange or interest rate risk exposure as of March 31, 2004. Therefore there will be no ongoing exposure to material adverse effect on our business, financial condition or results of operation for sensitivity to changes in interest rates or to changes in currency exchange rates.

Item 4. ***Controls and Procedures***

Evaluation of disclosure controls and procedures. Genta s Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of the Company s disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report (the Evaluation Date), have concluded that as of the Evaluation Date, our disclosure controls and procedures were adequate and designed to ensure that material information relating to the Company would be made known to them by others within the Company.

Changes in internal controls. There were no significant changes in our internal controls or, to our knowledge, in other factors that could significantly affect the Company s disclosure controls and procedures during the period covered by this report.

PART II OTHER INFORMATION

Item 1. ***Legal Proceedings***

In the first week of May, several complaints were filed in the United States District Court for the District of New Jersey against us and certain of our principal officers and directors on behalf of purported classes of our shareholders who purchased our securities during several class periods. The complaints generally allege that we and certain of our principal officers and directors violated the federal securities laws by issuing materially false and misleading statements regarding Genasense™ for the treatment of advanced melanoma that had the effect of artificially inflating the market price of our securities. The complaints in the various actions seek monetary damages in an unspecified amount and seek recovery of plaintiffs costs and attorneys fees. All of these actions are in their earliest stages and we intend to defend them vigorously.

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

(a) Exhibits

Exhibit Number	Description of Document
3.1.a	Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).1 to the Company s Annual Report on Form 10-K for the year ended December 31, 1995, Commission File No. 0-19635)
3.1.b	Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i) to the Company s Current Report on Form 8-K filed on February 28, 1997, Commission File No. 0-19635)
3.1.c	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.d	Amended Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).4 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.e	Certificate of Increase of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).5 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.f	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).4 to the Company s Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)
3.1.g	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company s Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)
3.1.h	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).8 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.i	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.i to the Company s Registration Statement on Form S-1, Commission File No. 333-110238)
3.1.j	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.j to the Company s Registration Statement on Form S-1, Commission File No. 333-110238)
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3(ii).1 to the Company s Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

Exhibit Number	Description of Document
31.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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

Genta Incorporated

Date: May 10, 2004

By: /s/ RAYMOND P. WARRELL, R., M.D.

Raymond P. Warrell, Jr., M.D.
Chairman, President and Chief Executive Officer

Date: May 10, 2004

By: /s/ WILLIAM P. KEANE

William P. Keane
Vice President, Chief Financial Officer and Corporate Secretary

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(b) Reports on Form 8-K.

On February 11, 2004 the Company furnished a current report on Form 8-K disclosing a press release regarding the Company s forth quarter and year-end 2003 financial results and developments.

On April 30, 2004 the Company filed a current report on form 8-K announcing that the United States Food and Drug Administration (FDA) had posted on its website briefing documents for the Oncologic Drugs Advisory Committee (ODAC) meeting on Monday, May 3, 2004