

Edgar Filing: GENTA INC DE/ - Form 10-Q

GENTA INC DE/  
Form 10-Q  
May 15, 2003

=====

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT UNDER SECTION 13 OR 15 (d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2003

OR

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

Commission File Number 0-19635

GENTA INCORPORATED  
(Exact name of Registrant as specified in its certificate of incorporation)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

33-0326866  
(I.R.S. Employer  
Identification Number)

Two Connell Drive  
Berkeley Heights, NJ  
(Address of principal executive offices)

07922  
(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

No

As of May 13, 2003, the registrant had 73,933,964 shares of common stock outstanding.

=====

Genta Incorporated  
INDEX TO FORM 10-Q

Page

PART I. FINANCIAL INFORMATION

## Edgar Filing: GENTA INC DE/ - Form 10-Q

Item 1.	Financial Statements:	
	Consolidated Balance Sheets at March 31, 2003 and December 31, 2002	3
	Consolidated Statements of Operations for the Three Months Ended March 31, 2003 and 2002	4
	Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2003 and 2002	5
	Notes to Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	16
Item 4.	Controls and Procedures	16
PART II. OTHER INFORMATION		
Item 1.	Legal Proceedings	17
Item 4.	Submission of Matters to a Vote of Security Holders	17
Item 6.	Exhibits and Reports on Form 8-K	18
	SIGNATURES	19
	CERTIFICATIONS	20

### Genta Incorporated CONSOLIDATED BALANCE SHEETS

	March 31, 2003	December 2002
(In thousands, except par value data)	-----	-----
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents .....	\$ 51,953	\$ 32,700
Short-term investments (Note 2) .....	51,354	81,010
Accounts receivable (Note 3) .....	9,300	14,570
Notes receivable .....	200	20
Other current assets .....	2,472	1,450
	-----	-----
Total current assets .....	115,279	129,940
Property and equipment, net .....	3,251	3,250
Notes receivable .....	832	-
Intangibles, net .....	1,295	1,440
Other assets .....	1,778	1,770

Edgar Filing: GENTA INC DE/ - Form 10-Q

Total assets .....	\$ 122,435	\$ 136,41
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable .....	\$ 7,039	\$ 27,68
Note payable .....	245	49
Accrued expenses .....	5,135	4,74
Deferred revenues, current portion .....	5,237	5,23
Other current liabilities .....	212	21
	-----	-----
Total current liabilities .....	17,868	38,36
Deferred revenues (Note 5) .....	40,045	41,35
Convertible debt (Note 6) .....	10,000	10,00
Line of Credit (Note 7) .....	17,500	-
	-----	-----
Total liabilities .....	85,413	89,71
	-----	-----
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, Series A convertible preferred stock, \$.001 par value; 5,000 shares authorized, 261 shares issued and outstanding at March 31, 2003 and December 31, 2002, respectively; liquidation value of \$13,025 .....	--	-
Common stock, \$.001 par value; 120,000 shares authorized, 74,255 and 74,168 shares issued and 73,811 and 73,775 outstanding at March 31, 2003 and December 31, 2002, respectively .....	74	7
Additional paid-in capital .....	323,094	322,99
Accumulated deficit .....	(282,793)	(273,19
Deferred compensation .....	(553)	(69
Accumulated other comprehensive income .....	9	2
	-----	-----
Total stockholders' equity .....	39,831	49,20
Cost of treasury stock: 444 and 393 shares at March 31, 2003 and December 31, 2002, respectively .....	(2,809)	(2,50
	-----	-----
Total stockholders' equity .....	37,022	46,70
	-----	-----
Total liabilities and stockholders' equity .....	\$ 122,435	\$ 136,41
	=====	=====

See accompanying notes to consolidated financial statements.

Edgar Filing: GENTA INC DE/ - Form 10-Q

(In thousands, except per share data)	2003 -----	2002 -----
Revenues:		
License fees (Note 5) .....	\$ 266	\$ 5
Development funding (Note 5) .....	1,043	--
	-----	-----
	1,309	5
	-----	-----
Costs and expenses:		
Research and development (Note 4) .....	6,300	9,837
General and administrative (Note 4) .....	4,780	2,802
Compensation expense related to stock options .	144	238
	-----	-----
	11,224	12,877
	-----	-----
Loss from operations .....	(9,915)	(12,872)
	-----	-----
Other income (expense):		
Other income, principally interest income .....	452	246
Interest expense .....	(140)	--
	-----	-----
	312	246
	-----	-----
Net loss applicable to common shares .....	\$ (9,603)	\$ (12,626)
	=====	=====
Net loss per common share .....	\$ (0.13)	\$ (0.19)
	=====	=====
Shares used in computing net loss per common share	74,233	66,525
	=====	=====

See accompanying notes to consolidated financial statements.

4

Genta Incorporated  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)

(In thousands)	Three Months Ended Ma -----	2003 -----	2002 -----
Operating activities			
Net loss .....	\$ (9,603)	\$ (12,626)	\$ (12,626)
Items reflected in net loss not requiring cash:			
Depreciation and amortization .....	495	--	--
Loss on disposition of patents and equipment .....	--	144	--
Compensation expense related to stock options .....	144	--	--
Changes in operating assets and liabilities:			
Accounts and notes receivable (Note 3) .....	4,442	(1,017)	(1,017)
Prepays and other assets .....	(1,017)	(20,494)	(20,494)
Accounts payable, accrued expenses and other current liabilities	(20,494)	--	--

**Edgar Filing: GENTA INC DE/ - Form 10-Q**

Deferred revenue (Note 5) .....	(1,309)	
Net cash used in operating activities .....	(27,342)	(2)
Investing activities		
Purchase of available-for-sale short-term investments .....	(24,178)	
Maturities and sales of available-for-sale short-term investments .....	53,824	
Purchase of property and equipment .....	(345)	
Net cash provided by investing activities .....	29,301	
Financing activities		
Proceeds from line of credit (Note 7) .....	17,500	
Purchase of treasury stock (Note 8) .....	(303)	
Proceeds from exercise of warrants and options .....	97	
Net cash provided by financing activities .....	17,294	
Increase (decrease) in cash and cash equivalents .....	19,253	(1)
Cash and cash equivalents at beginning of period .....	32,700	3
Cash and cash equivalents at end of period .....	\$ 51,953	\$ 2

See accompanying notes to consolidated financial statements.

Genta Incorporated  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
 March 31, 2003  
 (Unaudited)

(1) Basis of Presentation

The unaudited consolidated financial statements of Genta Incorporated, a Delaware corporation ("Genta" or the "Company"), presented herein have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and note disclosures required to be presented for complete financial statements. The accompanying financial statements reflect all adjustments (consisting only of normal recurring accruals), which are, in the opinion of management, necessary for a fair presentation of the results for the interim periods presented.

The unaudited 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, 2002. Results for the interim periods are not necessarily indicative of results for the full years.

## Edgar Filing: GENTA INC DE/ - Form 10-Q

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 (the "Collaborative Agreement") with Aventis Pharmaceuticals Inc. ("Aventis"). Under the terms of the Collaborative Agreement, the Company and Aventis will jointly develop and commercialize Genasense(TM) 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. New Drug Application ("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. 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.

Initial and future funding of ongoing development received from Aventis after the achievement of certain research and development milestones (Note 4) will be recognized over the estimated useful life of the first-to-expire related patent of 115 months.

### 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(TM)-related costs, under the Collaborative Agreement (Note 4), have been recorded as a reduction to expenses in the consolidated statements of operations.

### 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

6

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 the continuing value of patents and patent applications in each financial reporting period. Through this evaluation, the Company may elect to continue to maintain these patents, seek to out-license them, or abandon them.

Future amortization expense related to intangibles at March 31, 2003 follows (\$ thousands):

	Amortization Expense -----
2003 .....	\$ 432
2004 .....	577
2005 .....	286
2006 .....	--

Edgar Filing: GENTA INC DE/ - Form 10-Q

2007 .....	--
Thereafter .....	--
	-----
Total .....	\$1,295
	=====

Stock Options

The Company accounts for stock-based compensation arrangements in accordance with provisions of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees" and complies with the disclosure provisions of Statement of Financial Accounting Standards ("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 Emerging Issues Task Force Consensus on Issue 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 Financial Accounting Standards Board ("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. In addition, this Statement amends the disclosure requirements of Statement No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results.

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,	
	2003	2002
	----	----
Net loss applicable to common shares, as reported .....	\$ (9,603)	\$ (12,626)
Equity related compensation expense included in reported net income, net of related tax effects .....	144	238
Total stock-based employee compensation expense determined under fair values based method for all awards, net of related tax effects .....	(1,548)	(1,667)
	-----	-----
Pro forma net loss .....	\$ (11,007)	\$ (14,055)
	=====	=====
Net loss per share attributable to common shareholders:		
As reported: Basic and diluted .....	\$ (0.13)	\$ (0.19)
Pro forma: Basic and diluted .....	\$ (0.15)	\$ (0.21)

## Edgar Filing: GENTA INC DE/ - Form 10-Q

### Pro Forma Disclosure

The fair value of options for the three months ended March 31, 2003 and 2002, has been estimated at the date of grant using the minimum value option pricing model with the following assumptions:

	Three Months Ended March 31,	
	2003	2002
Risk-free interest rate .....	2.8%	4.9%
Dividend yield .....	--	--
Expected life (years) .....	4.0	4.5
Volatility .....	65.0%	62.8%

All of the options issued during the three-month periods ended March 31, 2003 and 2002, were issued with an exercise price equal to market value on the date of grant. The weighted-average estimated fair value of stock options granted was \$7.62 per share and \$14.27 per share for the three-month periods ended ended March 31, 2003 and 2002, respectively.

### Net Loss Per Common Share

Basic and diluted loss per common share are identical for the three months ended March 31, 2003 and 2002 as potentially dilutive securities, including options, warrants and convertible preferred stock have been excluded in the calculation of the net loss per common share due to their anti-dilutive effect.

### Recent Accounting Pronouncements

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. The changes in SFAS No. 149 improve financial reporting by requiring that contracts with comparable characteristics be accounted for similarly. 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. Those changes will result in more consistent reporting of contracts as either derivatives or hybrid instruments. 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. Management believes that adopting this statement will not have a material impact on the Company's results of operations, financial position or cash flows.

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations". SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS No. 143 requires that the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset. The Company adopted SFAS No. 143 effective January 1, 2003. The adoption did not have a material impact on the



Edgar Filing: GENTA INC DE/ - Form 10-Q

Company's results of operations, financial position or cash flows.

8

(2) Short-Term Investments

The carrying amounts of short-term investments approximate fair value due to the short-term nature of these instruments. The fair value of available-for-sale marketable securities at March 31, 2003 is as follows (\$ thousands):

Amortized costs .....	\$ 51,345
Gross unrealized gains .....	41
Gross unrealized losses .....	(32)
	-----
Estimated fair value .....	\$ 51,354
	=====

The estimated fair value of each marketable security has been compared to its cost, and therefore, an unrealized gain of approximately \$0.009 million has been recognized in accumulated other comprehensive income at March 31, 2003.

(3) Accounts Receivable

Included in accounts receivable and netted against operating expenses in the consolidated statement of operations for the three months ended March 31, 2003, is \$9.157 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(TM) drug supply costs. Information with respect to this cost reimbursement is presented below (\$ thousands):

	Three Months Ended March 31, 2003	Three Months Ended December 31, 2002	Total Due To Genta
	-----	-----	-----
Reimbursement to Genta:			
Third-party costs .....	\$ 6,048	\$ 134	\$ 6,182
Drug supply costs .....	2,048	--	2,048
FTE's .....	1,540	--	1,540
	-----	-----	-----
Amount due to Genta .....	\$ 9,636	\$ 134	\$ 9,770
	=====	=====	=====
Reimbursement to Aventis:			
FTE's .....	(479)	--	(479)
	-----	-----	-----
Net amount due to Genta .....	\$ 9,157	\$ 134	\$ 9,291
	=====	=====	=====

(4) Collaborative Agreement

In April 2002, the Company entered into a Collaborative Agreement with Aventis. Under the terms of the Collaborative Agreement, the Alliance will jointly develop and commercialize Genasense(TM) in the U.S., 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

## Edgar Filing: GENTA INC DE/ - Form 10-Q

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. An analysis of expenses reimbursable under the Collaborative Agreement (Note 1) follows:

(\$ thousands)	Three Months Ended March 31,	
	2003	2002
Research and development expenses, gross ....	\$ 15,457	\$ 9,837
Less net expense reimbursement .....	(9,157)	--
	-----	-----
Research and development expenses, net .....	\$ 6,300	\$ 9,837
	-----	-----
General and administrative, gross .....	\$ 4,780	\$ 2,802
Less expense reimbursement .....	--	--
	-----	-----
General and administrative, net .....	\$ 4,780	\$ 2,802
	-----	-----

9

As of March 31, 2003, the Company has received a total of \$177.7 million in initial and near-term funding, which included a \$10.0 million licensing fee and \$40.0 million in development funding (Note 5), \$10.0 million in convertible debt proceeds (Note 6), \$71.9 million pursuant to an at-market equity investment in the Company's common stock, \$28.3 million in paid expense reimbursements and \$17.5 million in line of credit proceeds (Note 7). A further \$9.3 million in accrued expense reimbursement is due for payment during the second quarter of 2003 (Note 3). 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.

(5) Deferred Revenues

As of March 31, 2003, the Company had recorded \$45.3 million in deferred revenues relating to the initial \$10.0 million licensing fee and \$40.0 million development funding received under the Collaborative Agreement (Note 4), of which \$5.2 million is included in current liabilities and \$40.1 million is classified as long-term deferred revenues, which will be recognized over the estimated useful life of the first-to-expire related 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 related patent.

(6) Convertible Debt

At March 31, 2003, the Company had \$10.0 million in convertible debt that was issued in connection with the Collaborative Agreement (Note 4). 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 (and in \$0.1 million increments thereafter). In addition, the Company may convert the Aventis Note on or prior

Edgar Filing: GENTA INC DE/ - Form 10-Q

to the Maturity Date in whole or in part (together with any accrued and unpaid interest with respect to such principal amount) in amounts of not less than \$5.0 million (and in \$1.0 million increments thereafter), into fully paid and non-assessable shares of common stock (calculated as to the nearest 1/1000 of a share). 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.

(7) Aventis Line of Credit

At March 31, 2003, the Company had \$17.5 million outstanding on a line of credit that was issued in connection with an amendment, dated March 14, 2003, to the Collaborative Agreement (Note 4) that established a \$40.0 million line of credit related to the development, manufacturing and commercialization of Genasense(TM) ("Aventis Credit Line"). The amendment provides Genta the immediate availability of up to \$40.0 million in cash. This revolving debt will be considered an advance against both past and future costs and will be secured by reimbursable development expenses from Aventis, as well as drug inventory. At the time of Genasense(TM) 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 Credit Line provide for a favorable interest rate, which is set two days prior to the first day of each calendar quarter. The Aventis Credit Line terminates upon the earlier of (1) the receipt of Genasense(TM) NDA approval in the U.S., (2) notice given by either Genta or Aventis of the termination of the Collaborative Agreement, (3) notice given by Genta of the termination of the Aventis Credit Line, (4) various default provisions or (5) December 31, 2004. Depending upon the circumstances, repayment is due immediately or up to six months after the termination of the Aventis Credit Line.

(8) Treasury Stock

In June 2002 the Company commenced a stock repurchase program, whereby up to 5.0 million shares of its common stock may be repurchased by the Company at prices deemed desirable by the Company. As of March 31, 2003, the Company had repurchased 444,200 shares of common stock in open-market transactions as follows:

10

	Shares Repurchased	Average price per share
	-----	-----
At December 31, 2002	392,700	\$6.3807
Three Months Ended March 31, 2003	51,500	5.8927
	-----	-----
	444,200	\$6.3242
	=====	=====

(9) Comprehensive Loss

An analysis of comprehensive loss is presented below:

(\$ thousands)

Three Months Ended March 31,	
2003	2002
-----	-----

Edgar Filing: GENTA INC DE/ - Form 10-Q

Net loss .....	\$ (9,603)	\$ (12,626)
Change in market value change on available-for-sale short-term investments .....	(16)	(56)
	-----	-----
Total comprehensive loss .....	\$ (9,619)	\$ (12,682)
	=====	=====

(10) Supplemental Disclosure of Cash Flows Information and Non-cash Investing and Financing Activities

(\$ thousands)	Three Months Ended March 31	
	-----	-----
	2003	2002
	----	----
Market value change on available-for-sale Short-term investments...	\$ (16)	\$ (56)

No interest was paid for the three months ended March 31, 2003 and 2002.

(11) Commitments and Contingencies

Litigation and Potential Claims

JBL

The sale of JBL Scientific, Inc. ("JBL"), the Company's manufacturing subsidiary, was completed on May 10, 1999. JBL was notified on October 1998 from Region IX of the Environmental Protection Agency ("EPA") that it had been identified as a potentially responsible party ("PRP") at the Casmalia Disposal Site, which is located in Santa Barbara, California. JBL has been designated as a de minimis PRP by the EPA. In December 2001, Genta received a revised settlement proposal from the EPA in the amount of \$0.033 million, the terms of the settlement with the EPA containing standard contribution protection and release language. In January 2002, the Company accepted the proposal and paid the \$0.033 million as an offer to settle this matter. There can be no assurance, however, that the EPA will not reject our settlement offer if there is not a sufficient number of PRPs settling with the EPA.

Genta Europe

During 1995, Genta Pharmaceuticals Europe S.A. ("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 also believes it to be unlikely that Genta will incur any liability in this matter, although there can be no assurance thereof. At March 31, 2003, the Company has accrued a net liability of \$0.212 million related to this matter, which management believes is adequate to provide for this contingency.

University of Pennsylvania

In October 2002, a licensing officer from the University of Pennsylvania ("UPenn") asserted a claim to a portion of the initial \$40.0 million development funding (Note 5) the Company received from Aventis pursuant to the Collaborative Agreement. The Company has disputed this claim and has filed a petition for binding arbitration for this matter, as provided in the original licensing agreement between the Company and UPenn. At the current time the Company cannot reasonably estimate the outcome of this claim; however, the Company does not believe that this claim will have a material adverse impact on the Company's financial results and liquidity. As such, the Company has not reserved any amount for royalty payments that could be due to UPenn as a result of binding arbitration.

Purchase Commitments

Per an agreement entered into with Avecia Biotechnology, Inc. ("Avecia") in December 2002 (the "Supply Agreement") the Company is obligated for up to \$27.5 million in drug substance purchases during 2003. Pursuant to the Collaborative Agreement with Aventis (Note 4), the Company anticipates that it will be reimbursed for at least 75% of these purchase commitments after the drug is shipped to the clinical sites. As of March 31, 2003, no 2003 purchases of drug substance have been made, primarily due to the significant amount of drug substance purchased in the fourth quarter of 2002. In addition, the Company has committed up to \$5.0 million of advance financing to Avecia for facility expansion, which would be recovered with interest through future payments determined as a function of drug substance purchases to be made by Genta in the future. As of April 2003, the Company paid \$0.829 million in advance financing.

12

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:

- o the Company's ability to develop, manufacture and sell its products;
- o the potential efficacy of the Company's products;
- o the commencement and completion of pre-clinical and clinical trials;
- o the Company's ability to obtain necessary regulatory approvals;
- o the Company's contractual collaborative arrangements;
- o the adequacy of the Company's capital resources;
- o the ability to obtain sufficient financing to maintain the Company's planned operations;

## Edgar Filing: GENTA INC DE/ - Form 10-Q

- o the possibility and effect of patent infringement claims;
- o the impact of competitive products and market conditions; and
- o other risks described under Certain Risks and Uncertainties Related to the Company's Business in the Company's annual report on Form 10-K for the year ended December 31, 2002.

The Company does not undertake to update any forward-looking statements. Although the Company believes that the forward-looking statements contained herein are reasonable, it can give no assurances that the Company's expectations are correct.

### Overview

Since its inception in February 1988, the Company has devoted its principal efforts toward drug discovery and research and development. The Company has been unprofitable to date and expects to incur substantial operating losses for the next several years due to continued requirements for ongoing research and development activities, preclinical and clinical testing activities, regulatory activities, possible establishment of manufacturing activities and a sales and marketing organization. From the period since its inception to March 31, 2003, the Company has incurred a cumulative net loss of approximately \$282.8 million. The Company has experienced significant quarterly fluctuations in operating results and it expects that these fluctuations in revenues, expenses and losses will continue.

A full description of the Company's business, R&D programs and products can be seen the Annual Report on Form 10K for the period ended December 31, 2002.

13

### Results of Operations

#### Summary Operating Results For the three months ended March 31,

(\$ thousands)	Increase (Decrease)			2002
	2003	\$	%	
Revenues:				
License fees	\$ 266	\$ 261	5,220%	\$ 5
Development funding	1,043	1,043	N/A	--
	-----	-----	-----	-----
	1,309	1,304		5
Costs and expenses:				
Research and development	15,457	5,620	57%	9,837
General and administrative	4,780	1,978	71%	2,802
Compensation expense related to stock options	144	(94)	(39)%	238
Less: Expense reimbursement	9,157	9,157	N/A	--
	-----	-----	-----	-----
	11,224	(1,653)	(13)%	12,877
	-----	-----	-----	-----
Loss from operations	(9,915)	(2,957)	(23)%	(12,872)

Edgar Filing: GENTA INC DE/ - Form 10-Q

Other income, principally net interest income.....	452	206	84%	246
Less: Interest expense	140	140	N/A	--
	-----	-----	-----	-----
Net loss from continuing operations	\$ (9,603)	\$ (3,023)	(24)%	\$ (12,626)
	=====	=====	=====	=====

Revenues. Licensing fees and development funding for the three months ended March 31, 2003 increased \$1.304 million over the comparable period in 2002. This increase reflects the amortization of the up-front licensing fee and development funding received from Aventis (Note 5), which are being recognized over the estimated useful life of the first-to-expire related patent of 115 months.

Research and development expenses. Research and development expenses before reimbursement for the three months ended March 31, 2003 increased \$5.620 million or 57% over the comparable period in 2002. The increase in research and development expenses is primarily attributable to the costs of the Genasense(TM) Phase 3 clinical trials and NDA preparation activities, offset by lower drug substance purchases in the quarter. Of the \$15.457 million in research and development expenses for the three months ended March 31, 2003, \$11.062 million and \$1.340 million were reimbursable at 75% and 100%, respectively, pursuant to the Collaborative Agreement (Note 4), of which the net amount of \$9.636 million will be reimbursed. Certain of the research and development expenses relating to drug manufacturing not currently reimbursable will be at least 75% reimbursed after the drug is shipped to the clinical sites.

General and administrative expenses. General and administrative expenses for the three months ended March 31, 2003 increased \$1.978 million or 71% over the comparable period in 2002. The increase is primarily related to costs associated with Ganite(TM) pre-launch activities and general corporate expenses driven by business growth. There were no sales and marketing related expenses reimbursable at 100% pursuant to the Collaborative Agreement for the three months ended March 31, 2003, as sales and marketing related expenses related to Genasense(TM) are mainly being billed to and paid for directly by Aventis.

Expense reimbursement. Expense reimbursement for the three months ended March 31, 2003 relate to various third-party, FTE and drug supply costs that Aventis is required to reimburse under the Collaborative Agreement (Note 4), as follows (\$ thousands):

14

Reimbursement to Genta:	
Third-party costs .....	\$ 6,048
Drug supply costs .....	2,048
FTE's .....	1,540
	-----
Amount due to Genta .....	\$ 9,636
	=====
Reimbursement to Aventis:	
FTE's .....	(479)
	-----
Net amount due to Genta .....	\$ 9,157
	=====

Other Income. Net other income for the three months ended March 31, 2003 increased \$0.066 million or 27% over the comparable period in 2002, principally

## Edgar Filing: GENTA INC DE/ - Form 10-Q

as a result of higher investment balances on investments. Interest expense is attributable to interest being accrued on the \$10.0 million Aventis Note (Note 6) and \$17.5 million Aventis Credit Line (Note 7).

Net Loss. Genta incurred a net loss of \$9.603 million, or \$0.13 per share, for the three months ended March 31, 2003, compared with a net loss of \$12.626 million, or \$0.19 per share, for the three months ended March 31, 2002. The decrease in net loss, and per share net loss to common shareholders, was primarily due to the expense reimbursement pursuant to the Collaborative Agreement (Note 4) of \$9.157 million or \$0.12 per share, offset by increased expenses primarily related to third-party costs for current Genasense(TM) on-going clinical studies, expenses attributable to the NDA preparation, general corporate legal fees, personnel costs and Ganite(TM) marketing-related spending.

### Liquidity and Capital Resources

Since its inception, the Company has financed its operations primarily from private placements and public offerings of its equity securities. Cash received from these equity offerings totaled approximately \$279.7 million through March 31, 2003, including net proceeds of \$71.0 million received in 2002. At March 31, 2003, the Company had cash, cash equivalents and short-term investments totaling \$103.3 million compared to \$113.7 million at December 31, 2002.

As reflected in Note 4 to the consolidated financial statements, in April 2002, Genta entered into a Collaborative Agreement with Aventis. Under the terms of the Collaborative Agreement, the Alliance will jointly develop and commercialize Genasense(TM) in the U.S., 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, the Company is entitled to royalties on worldwide sales of Genasense(TM) from which the Company is required to pay third-party pass-through royalties to UPenn and The National Institutes of Health ("NIH") based on net worldwide sales of Genasense(TM). 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. Genta has received a total of \$177.7 million in initial and near-term funding, which included a \$10.0 million licensing fee and \$40.0 million in development funding (Note 5), \$10.0 million in convertible debt proceeds (Note 6), \$71.9 million pursuant to an at-market equity investment in the Company's common stock, \$28.3 million in paid expense reimbursements and \$17.5 million in line of credit proceeds (Note 7). A further \$9.3 million in accrued expense reimbursement is due for payment during the second quarter of 2003 (Note 3).

Contingent upon the achievement of certain research and development milestones, and included in the Collaborative Agreement's collective amount of \$476.9 million, the Company could receive up to \$280.0 million in cash and up to \$65.0 million in convertible note proceeds.

The Company's principal expenditures relate to its research and development activities, which include the Company's on-going and future clinical



## Edgar Filing: GENTA INC DE/ - Form 10-Q

trials. The Company expects these expenditures to continue. The Company expects increased total expenditures, prior to expense reimbursement, for clinical trials and drug supply related to Genasense(TM) as a result of the Collaboration Agreement with Aventis. In addition, expenditures associated with other products under development by the Company may increase as research and development activities become more focused and as other clinical trials are initiated.

The Company anticipates seeking additional product development opportunities from external sources. Such acquisitions may consume cash reserves or require additional cash or equity. The Company's working capital and additional funding requirements will depend upon numerous factors, including: (i) the progress of the Company's research and development programs; (ii) the timing and results of pre-clinical testing and clinical trials; (iii) the level of resources that the Company devotes to sales and marketing capabilities; (iv) technological advances; (v) the activities of competitors; and (vi) the ability of the Company 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.

If the Company successfully secures sufficient levels of collaborative revenues and other sources of financing, it expects to use such revenues and the proceeds of any such financing to continue and expand its ongoing research and development activities, preclinical and clinical testing activities, manufacturing and/or market introduction of potential products and expansion of its administrative activities.

### Recent Accounting Pronouncements

See Note 1 to the consolidated financial statements.

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

The Company does not utilize financial instruments for trading purposes and holds no derivative financial instruments, which could expose the Company to significant market risk. The Company'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.

### Item 4. Controls and Procedures

Explanation 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-14(c) and 15-d and 14(c)) as of a date (the "Evaluation Date") within 90 days of the filing of this quarterly report, have concluded that as of the Evaluation Date, the Company's 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 subsequent to the Evaluation Date.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

## Edgar Filing: GENTA INC DE/ - Form 10-Q

### JBL

The sale of JBL, the Company's manufacturing subsidiary, was completed on May 10, 1999. JBL was notified on October 1998 from Region IX of the EPA that it had been identified as a PRP at the Casmalia Disposal Site, which is located in Santa Barbara, California. JBL has been designated as a de minimis PRP by the EPA. In December 2001, Genta received a revised settlement proposal from the EPA in the amount of \$0.033 million, the terms of the settlement with the EPA containing standard contribution protection and release language. In January 2002, the Company accepted the proposal and paid the \$0.033 million as an offer to settle this matter. There can be no assurance, however, that the EPA will not reject our settlement offer if there is not a sufficient number of PRPs settling with the EPA.

### Genta Europe

During 1995, 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 also believes it to be unlikely that Genta will incur any liability in this matter, although there can be no assurance thereof. At March 31, 2003, the Company has accrued a net liability of \$0.212 million related to this matter, which management believes is adequate to provide for this contingency.

### University of Pennsylvania

In October 2002, a licensing officer from the UPenn asserted a claim to a portion of the initial \$40.0 million development funding (Note 5) the Company received from Aventis pursuant to the Collaborative Agreement. The Company has disputed this claim and has filed a petition for binding arbitration for this matter, as provided in the original licensing agreement between the Company and UPenn. At the current time the Company cannot reasonably estimate the outcome of this claim; however, the Company does not believe that this claim will have a material adverse impact on the Company's financial results and liquidity. As such, the Company has not reserved any amount for royalty payments that could be due to UPenn as a result of binding arbitration.

### Item 4. Submission of Matters to a Vote of Security Holders

None.

17

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

#### (a) Exhibits.

- |         |  |
|---------|--|
| 10.1(1) | Amendment to U.S. Commercialization Agreement dated March 14, 2003, by and between Genta Incorporated and Aventis Pharmaceuticals Inc. |
| 99.1    | Certification by the Chief Executive Officer Relating  |

Edgar Filing: GENTA INC DE/ - Form 10-Q

to a Periodic Report Containing Financial Statements.

99.2 Certification by the Chief Financial Officer Relating to a Periodic Report Containing Financial Statements.

(1) Confidential treatment has been requested for portions of such exhibit.

(b) Reports on Form 8-K.

None.

18

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  
(Registrant)

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

-----  
Name: Raymond P. Warrell, Jr., M.D.  
Title: Chairman, President, Chief Executive Officer  
and Principal Executive Officer

By: /s/ WILLIAM P. KEANE

-----  
Name: William P. Keane  
Title: Vice President, Chief Financial Officer and  
Principal Accounting Officer

Date: May 15, 2003

19

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Raymond P. Warrell, Jr., M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Genta Incorporated;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly represent in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

Edgar Filing: GENTA INC DE/ - Form 10-Q

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
- a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
- a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003

/s/ RAYMOND P. WARRELL, JR., M.D.

-----  
Name: Raymond P. Warrell, Jr., M.D.  
Title: Chief Executive Officer

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, William P. Keane, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Genta Incorporated;
- 2. Based on my knowledge, this quarterly report does not contain any untrue

Edgar Filing: GENTA INC DE/ - Form 10-Q

statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly represent in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003

/s/ WILLIAM P. KEANE

-----  
Name: William P. Keane  
Title: Chief Financial Officer

