

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

GENTA INC DE/  
Form 10-Q  
November 14, 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 September 30, 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 October 31, 2003, the registrant had 75,819,784 shares of common stock outstanding.

=====

Genta Incorporated  
INDEX TO FORM 10-Q

PART I. FINANCIAL INFORMATION

Page

Item 1. Financial Statements:

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

Condensed Consolidated Balance Sheets at September 30, 2003 and December 31, 2002	3
Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2003 and 2002	4
Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2003 and 2002	5
Notes to Condensed Consolidated Financial Statements	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3. Quantitative and Qualitative Disclosures about Market Risk	19
Item 4. Controls and Procedures	19
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	20
Item 4. Submission of Matters to a Vote of Security Holders	20
Item 6. Exhibits and Reports on Form 8-K	20
SIGNATURES	22
CERTIFICATIONS	24

2

### Genta Incorporated CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2003	Dec
(In thousands, except par value data)	-----	-----
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents .....	\$ 19,035	\$
Short-term investments (Note 2) .....	68,362	
Accounts receivable (Note 3) .....	11,760	
Notes receivable .....	200	
Other current assets .....	1,941	
Unallocated purchase price (Note 5) .....	13,627	
	-----	-----
Total current assets .....	114,925	
Property and equipment, net .....	4,636	
Notes receivable (Note 6) .....	3,213	
Intangibles, net .....	1,007	
Other assets .....	1,717	
	-----	-----

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

Total assets .....	\$ 125,498	\$
	=====	==
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses .....	\$ 15,936	\$
Note payable .....	--	
Deferred revenues, current portion .....	5,237	
Other current liabilities .....	--	
	-----	---
Total current liabilities .....	21,173	
Deferred revenues (Note 7) .....	37,426	
Convertible debt (Note 8) .....	10,000	
Line of credit (Note 9) .....	25,000	
	-----	---
Total liabilities .....	93,599	
	-----	---
Commitments and contingencies .....		
Stockholders' equity:		
Preferred stock, 5,000 shares authorized, Series A convertible, \$.001 par value; 600 shares authorized 261 shares issued and outstanding at September 30, 2003 and December 31, 2002, respectively; liquidation value of \$13,025 ....	--	
Common stock, \$.001 par value; 120,000 shares authorized, 75,819 and 74,168 shares issued and 75,819 and 73,775 outstanding at September 30, 2003 and December 31, 2002, respectively .....	76	
Additional paid-in capital .....	335,511	
Accumulated deficit .....	(303,376)	(
Deferred compensation .....	(335)	
Accumulated other comprehensive income .....	23	
	-----	---
Total stockholders' equity .....	31,899	
Cost of treasury stock: 0 and 393 shares at September 30, 2003 and December 31, 2002, respectively .....	--	
	-----	---
Total stockholders' equity .....	31,899	
	-----	---
Total liabilities and stockholders' equity .....	\$ 125,498	\$
	=====	==

See accompanying notes to condensed consolidated financial statements.

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

(In thousands, except per share data)	Three Months Ended September 30,		Nine Months September
	2003	2002	2003
	-----	-----	-----
<b>Revenues:</b>			
License fees and royalties (Note 7) .....	\$ 253	\$ 282	\$ 795
Development funding (Note 7) .....	1,043	1,043	3,130
	-----	-----	-----
	1,296	1,325	3,925
<b>Costs and expenses:</b>			
Research and development (Note 4) .....	9,249	13,044	14,226
Selling, general and administrative (Note 4) ..	9,287	3,602	20,198
Compensation expense related to stock options .	74	239	362
	-----	-----	-----
	18,610	16,885	34,786
	-----	-----	-----
Loss from operations .....	(17,314)	(15,560)	(30,861)
<b>Other income (expense):</b>			
Other income, principally net interest income .	393	557	1,279
Interest expense .....	(244)	(142)	(604)
Equity in net income of joint venture .....	--	33	--
	-----	-----	-----
	149	448	675
	-----	-----	-----
Net loss applicable to common shares .....	\$ (17,165)	\$ (15,112)	\$ (30,186)
	=====	=====	=====
Net loss per common share .....	\$ (0.23)	\$ (0.21)	\$ (0.40)
	=====	=====	=====
Shares used in computing net loss per common share	75,409	73,410	74,699
	=====	=====	=====

See accompanying notes to condensed consolidated financial statements.

4

Genta Incorporated  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)

(In thousands)	Nine Months Ended Sept	2003	2002
	-----	-----	-----
<b>Operating activities</b>			
Net loss .....	\$ (30,186)	\$ (40,186)	\$ (40,186)
Items reflected in net loss not requiring cash:			
Depreciation, amortization and loss on disposal of fixed assets .....	1,668	1,668	1,668
Compensation expense related to stock options .....	362	362	362
Changes in operating assets and liabilities:			
Accounts and notes receivable (Note 3) .....	(399)	(399)	(399)
Prepays and other assets .....	(425)	(425)	(425)

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

Accounts payable, accrued expenses and other current liabilities	(21,760)	4
Net cash used in operating activities .....	(50,740)	(
Investing activities		
Purchase of available-for-sale short-term investments .....	(48,400)	
Maturities and sales of available-for-sale short-term investments .....	61,052	1
Purchase of property and equipment .....	(2,615)	(
Payment to stockholders in conjunction with Salus Acquisition (Note 5)	(56)	
Net cash provided by investing activities .....	9,981	1
Financing activities		
Issuance of common stock from private placement, net .....	--	7
Issuance of convertible debt (Note 8) .....	--	1
Proceeds from line of credit (Note 9) .....	25,000	
Purchase of treasury stock (Note 10) .....	(303)	(
Issuance of common stock upon exercise of warrants and options .....	2,397	
Net cash provided by financing activities .....	27,094	8
(Decrease) increase in cash and cash equivalents .....	(13,665)	8
Cash and cash equivalents at beginning of period .....	32,700	3
Cash and cash equivalents at end of period .....	\$ 19,035	\$ 12

See accompanying notes to condensed consolidated financial statements.

5

Genta Incorporated  
 NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
 September 30, 2003  
 (Unaudited)

(1) Basis of Presentation

The unaudited condensed 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 condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the interim

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

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.

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 series of development and commercialization agreements (collectively, 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 Genasense(TM) 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 substantially all other development, marketing, and sales costs incurred worldwide in connection with Genasense(TM). 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 (Notes 4 and 7) are being recognized over the estimated 115 months of useful life of the related first-to-expire patent.

### 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 condensed 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

6

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 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 September 30, 2003 follows (\$ in thousands):

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

	Amortization Expense
	-----
2003 .....	\$144
2004 .....	577
2005 .....	286
	-----
Total .....	\$1,007
	=====

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:

(\$ in thousands, except per share data)	Three Months Ended September 30,		Nine Months E
	2003	2002	2003
	-----	-----	-----
Net loss applicable to common shares, as reported .....	\$ (17,165)	\$ (15,112)	\$ (30,186)
Equity related employee compensation expense included in reported net income, net of related tax effects .....	74	239	362
Total stock-based employee compensation expense determined under fair values based method for all awards, net of related tax effects .....	(2,119)	(1,788)	(5,508)
	-----	-----	-----
Pro forma net loss applicable to common shares .....	\$ (19,210)	\$ (16,661)	\$ (35,332)
	=====	=====	=====

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

Net loss per common share:			
As reported: Basic and diluted .....	\$ (0.23)	\$ (0.21)	\$ (0.40)
Pro forma: Basic and diluted .....	\$ (0.25)	\$ (0.23)	\$ (0.47)

7

Pro Forma Disclosure

The fair value of options for the three months ended September 30, 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 September 30,	
	2003	2002
Risk-free interest rate .....	2.9%	2.8%
Dividend yield .....	--	--
Expected life (years) .....	4.0	5.0
Volatility .....	64.2%	65.0%

All of the options issued during the three-month periods September 30, 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 \$11.47 per share and \$6.81 per share for the three-month periods ended September 30, 2003 and 2002, respectively.

Net Loss Per Common Share

Basic and diluted loss per common share are identical for the three months and nine month periods ended September 30, 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 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 certain financial instruments including preferred securities issued in the form of shares that are mandatory redeemable; that embody an unconditional obligation requiring the issuer to redeem them by transferring its assets at a specified or determinable date (or dates) or upon an event that is certain to occur. This Statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. 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.



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

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. ("FIN") 46, Consolidation of Variable Interest Entities. The Company has no arrangements that would be subject to this interpretation.

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 September 30, 2003 is as follows (\$ in thousands):

Amortized costs .....	\$ 68,339
Gross unrealized gains .....	68
Gross unrealized losses .....	(45)
	-----
Estimated fair value .....	\$ 68,362
	=====

The estimated fair value of each marketable security has been compared to its cost, and therefore, an unrealized gain of \$0.023 million has been recognized in accumulated other comprehensive income at September 30, 2003.

(3) Accounts Receivable

Included in accounts receivable and netted against operating expenses in the condensed consolidated statement of operations for the three months ended September 30, 2003, is \$11.760 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 the cost reimbursement for the three months ended September 30, 2003 is presented below (\$ in thousands):

Reimbursement to Genta:	
Third-party costs .....	\$ 8,491
Drug supply costs .....	1,759
FTE's .....	1,942
	-----
Amount due to Genta .....	12,192
Reimbursement to Aventis:	
FTE's .....	(432)
	-----
Net amount due to Genta .....	\$ 11,760
	=====

(4) Collaborative Agreement

In April 2002, the Company entered into a Collaborative Agreement with

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

Aventis. Under the terms of the Collaborative Agreement, the Company and Aventis will jointly develop and commercialize Genasense(TM) in the U.S., and Aventis will have exclusive development and marketing rights to Genasense(TM) 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 substantially all other development, marketing, and sales costs incurred worldwide in connection with Genasense(TM). An analysis of expenses reimbursable under the Collaborative Agreement (Note 1) follows:

(\$ in thousands)	Three Months Ended September 30,		Nine Months Ende
	2003	2002	2003
Research and development expenses, gross .	\$ 21,009	\$ 19,608	\$ 54,576
Less net expense reimbursement .....	(11,760)	(6,564)	(40,350)
	\$ 9,249	\$ 13,044	\$ 14,226
Research and development expenses, net ...	\$ 9,249	\$ 13,044	\$ 14,226
	=====	=====	=====
Selling, general and administrative, gross	\$ 9,287	\$ 3,763	\$ 20,198
Less expense reimbursement .....	--	(161)	--
	\$ 9,287	\$ 3,602	\$ 20,198
Selling, general and administrative, net .	\$ 9,287	\$ 3,602	\$ 20,198
	=====	=====	=====

9

As of September 30, 2003, the Company has received a total of \$214.0 million in initial and near-term funding, which included a \$10.0 million licensing fee and \$40.0 million in development funding (Note 7), \$10.0 million in convertible debt proceeds (Note 8), \$71.9 million pursuant to an at-market equity investment in the Company's common stock, \$57.1 million in paid expense reimbursements and \$25.0 million in line of credit proceeds (Note 9). A further \$11.8 million in accrued expense reimbursement is due for payment during the fourth 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) Salus Therapeutics, Inc. Acquisition

In August 2003, the Company acquired Salus Therapeutics, Inc. ("Salus"), a privately held company located in Salt Lake City, Utah. Salus specializes in the identification and development of drugs that are based on DNA or RNA, including antisense, small interfering RNAs (siRNA), and delivery systems for DNA/RNA-based drugs. Under the terms of the merger agreement, Genta issued 1.03 million shares of common stock with a fair value of approximately \$13.0 million to Salus stockholders in exchange for all of the outstanding shares of Salus common stock, including those issued pursuant to the conversion of Salus' preferred stock. Approximately thirty-five percent of the initial payment (0.36 million shares) is held in escrow and will be released on the first anniversary of the acquisition, assuming no event of default occurs as described in the merger agreement. Contingent upon the achievement of certain preclinical and clinical milestones, an additional \$17.0 million may be paid in stock or cash at Genta's option.

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

The following unaudited condensed consolidated pro forma financial information has been prepared to give effect to Genta's acquisition of Salus. The pro forma adjustments are based upon available information and assumptions that Genta believes are reasonable. The unaudited condensed consolidated pro forma financial information do not purport to represent what the consolidated results of operations or financial position of Genta would actually have been if the acquisition had occurred on the dates referred to below, nor do they purport to project the results of operations or financial position of Genta for any future period.

The unaudited condensed consolidated pro forma statement of operations data was prepared by combining Genta's statement of operations for the year ended December 31, 2002 with Salus' statement of operations for the year ended December 31, 2002, giving effect to the acquisition as though it occurred on January 1, 2002.

The unaudited condensed consolidated pro forma statement of operations data does not give effect to any restructuring costs or any potential cost savings or other operating efficiencies that could result from the acquisition, or any non-recurring charges or credits resulting from the transaction such as in-process research and development charges.

The unaudited condensed consolidated pro forma financial information should be read in conjunction with the historical financial statements of (i) Genta included in its Annual Report on Form 10-K for the year ended December 31, 2002 (filed March 31, 2003) and in this Quarterly Report on Form 10-Q, and (ii) Salus included in Genta's Form 8-K/A (filed November 4, 2003).

### Condensed Consolidated Pro Forma Statement of Operations Data (In thousands, except per share data)

	For the year ended December 31, 2002				
	Genta	Salus	Adjustments	F/N	Pro Forma
Revenues .....	\$ 3,559	\$ 386	\$--		\$ 3,945
Net loss .....	\$(74,528)	\$ (1,193)	\$--		\$(75,721)
Net loss per basic and diluted share	\$ (1.05)				\$ (1.07)

	For the three months ended September 30, 2003				
	Genta	Salus	Adjustments	F/N	Pro Forma
Revenues .....	\$ 1,296	\$20	\$ --		\$ 1,316
Net loss .....	\$(17,165)	\$ (782)	\$ 231	1	\$(17,716)
Net loss per basic and diluted share	\$ (0.23)				\$ (0.23)

	For the three months ended September 30, 2002				
	Genta	Salus	Adjustments	F/N	Pro Forma
Revenues .....	\$ 1,325	\$ 90	\$--		\$ 1,415
Net loss .....	\$(15,112)	\$ (272)	\$--		\$(15,384)
Net loss per basic and diluted share	\$ (0.21)				\$ (0.21)

For the nine months ended September 30, 2003

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

	Genta	Salus	Adjustments	F/N	Pro Forma
Revenues .....	\$ 3,925	\$ 194	\$ --		\$ 4,119
Net loss .....	\$ (30,186)	\$ (1,471)	\$ 231	1	\$ (31,426)
Net loss per basic and diluted share	\$ (0.40)				\$ (0.42)

	For the nine months ended September 30, 2002				
	Genta	Salus	Adjustments	F/N	Pro Forma
Revenues .....	\$ 2,240	\$ 300	\$--		\$ 2,540
Net loss .....	\$ (44,808)	\$ (785)	\$--		\$ (45,593)
Net loss per basic and diluted share	\$ (0.64)				\$ (0.65)

(1) An adjustment was made to eliminate the revenues and net losses recorded twice in the table above during the period from August 21, 2003, the date Genta purchased Salus, through September 30, 2003 ("Consolidation Period"). During that period, Salus' financial information was consolidated into Genta; however, to accurately depict the financial position of both entities for the three and nine months ended September 30, 2003, both revenues and net loss were shown on a 'stand alone' basis, and properly adjusted for by backing out the amounts during the Consolidation Period to determine the pro forma information.

Since the estimated fair value of the assets acquired is not readily determinable at September 30, 2003, the aggregate purchase price is being shown as unallocated purchase price. Management believes that a large portion of the unallocated purchase price will be valued as in-process research and development and will be written off. Information with respect to the unallocated purchase price at September 30, 2003 is presented below (\$ in thousands):

Market value of 1.03 million shares of common stock issued .....	\$12,985
Legal and accounting fees directly associated with the acquisition .....	642
	-----
	\$13,627
	=====

(6) Note Receivable

At September 30, 2003, the Company had recorded \$3.2 million as a note receivable relating to advance financing provided to Avecia Biotechnology, Inc. ("Avecia") for facility expansion, which will be recovered with interest through future payments determined as a function of drug substance purchases to be made by the Company in the future. Final repayment terms of this note receivable are pursuant to the Supply Agreement (Note 13). Information with respect to the note receivable at September 30, 2003 is presented below (\$ in thousands):

Advance funding for facility expansion	\$ 3,274
Interest recorded .....	44
Payments received .....	(105)
	-----
	\$ 3,213
	=====

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

### (7) Deferred Revenues

As of September 30, 2003, the Company had recorded \$42.6 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 \$37.4 million is classified as long-term deferred revenues. These revenues are being recognized over the estimated 115 months of useful life of the related first-to-expire patent. 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.

### (8) Convertible Debt

At September 30, 2003, the Company had \$10.0 million outstanding in a convertible promissory note ("Aventis Note") that was issued in connection with the Collaborative Agreement (Note 4). 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 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.

### (9) Aventis Line of Credit

At September 30, 2003, the Company had \$25.0 million outstanding on a line of credit that was issued in connection with an amendment, dated March 14, 2003, to the Collaborative Agreement (Note 4) that established an up to \$40.0 million line of credit related to the development, manufacturing and commercialization of Genasense(TM) ("Aventis Line of Credit"). 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 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(TM) NDA approval in the U.S., ii) notice given by either Genta or Aventis of the termination of the Collaborative Agreement (Note 4), (iii) notice given by Genta of the termination of the Aventis Line of Credit, (iv) various default provisions or (v) December 31, 2004. Depending upon the circumstances, repayment is due immediately or up to six months after the termination of the Aventis Line of Credit.

### (10) 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 September 30, 2003, the Company had repurchased 444,200 shares of common stock in open-market transactions as follows:

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

	Shares Repurchased	Average price per share
	-----	-----
At December 31, 2002 .....	392,700	\$6.3807
Nine Months Ended September 30, 2003 .....	51,500	5.8927
	-----	-----
	444,200	\$6.3242
	=====	=====

11

In September 2003, the Company retired the 444,200 shares of treasury stock.

(11) Comprehensive Loss

An analysis of comprehensive loss is presented below:

(\$ in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
	-----	-----	-----	-----
Net loss .....	\$(17,165)	\$(15,112)	\$(30,186)	\$(44,800)
Change in market value on available-for-sale short-term investments .....	42	6	(2)	6
	-----	-----	-----	-----
Total comprehensive loss .....	\$(17,123)	\$(15,106)	\$(30,188)	\$(44,794)
	=====	=====	=====	=====

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

No interest was paid for the nine months ended September 30, 2003 and 2002.

The market value of common stock issued for the purchase of Salus (Note 5) was \$12.985 million.

The value of treasury stock (Note 10) retired was \$2.809 million.

(13) 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

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

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. During the quarter ended September 30, 2003, the Company reversed the accrued net liability of \$0.212 million related to this matter, as management no longer believes that a loss is probable.

12

### 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 7) the Company received from Aventis pursuant to the Collaborative Agreement (Note 4). In October 2003, the Company reached a settlement with UPenn with respect to this claim. Under the terms of the settlement agreement, in exchange for an agreement by UPenn 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 (Note 4), Genta has agreed to make the following payments to UPenn: (i) \$0.750 million on November 5, 2003, (ii) \$0.250 million on February 2, 2004, (iii) \$1.5 million upon the first NDA or foreign equivalent approval of Genasense(TM), and (iv) provided that the first NDA or foreign equivalent approval of Genasense(TM) has been received by Genta, \$0.750 million on the earlier of (a) the second NDA or foreign equivalent approval of Genasense(TM) or (b) December 30, 2004. As of September 30, 2003, the Company has reserved for the royalty payments that are due to UPenn per the settlement agreement.

### Purchase Commitments

Per an agreement entered into with Avecia in December 2002 (the "Supply Agreement") the Company is obligated to purchase up to \$27.5 million in drug substance each year in 2003 and 2004. The Company expects the 2003 obligation and purchases to be below that level. Pursuant to the Collaborative Agreement (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. No drug substance purchases were made in the first half of 2003, primarily due to the significant amount of drug substance purchased in the fourth quarter of 2002. For the three months ended September 30, 2003, the Company purchased approximately \$2.5 million of drug substance. 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 the Company in the future (Note 6).

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

### (14) Subsequent Event

On November 4, 2003 the Company filed a Form S-1 registration statement with the SEC to register the 0.67 million shares issued to former Salus stockholders in connection with the Company's acquisition of Salus. Upon the registration statement being declared effective, the former Salus stockholders will have the option to retain their shares or sell them during quarterly window periods.

13

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

#### Certain Factors Affecting Forward-Looking Statements - Safe Harbor Statement

We have made statements in this quarterly report on Form 10-Q that 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. We intend that all forward-looking statements be subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify these statements by forward-looking words such as "may", "might", "will", "should", "expects", "plans", "anticipates", "believes", "estimates", "predicts", "potential" or "continue", the negative of these terms and other comparable terminology.

These forward-looking statements reflect our 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. Factors that may cause actual results to differ materially from those contemplated by the forward-looking statements include, among others, those listed under the caption entitled "Risk Factors" and the following:

- o U.S. Food and Drug Administration, ("FDA") approval or failure to approve Genasense(TM);
- o our ability to develop, manufacture and sell our products or to enter into collaborative arrangements with third parties to manufacture or sell our products;
- o the safety and efficacy of our products;
- o the commencement and completion of pre-clinical and clinical trials;
- o our ability to obtain necessary regulatory approvals;
- o our contractual collaborative arrangements;
- o the adequacy of our capital resources;
- o the ability to obtain sufficient financing to maintain our planned operations;
- o the possibility and effect of patent infringement claims; and
- o the impact of competitive products and market conditions.

Although we believe the expectations reflected in the forward-looking statements



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

are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. We are under no duty to update any of these forward-looking statements after the date of this prospectus to conform our prior statements to actual results or revised expectations.

### 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. 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, research and development programs and products is set forth in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002 and Form S-1 Statement filed on November 4, 2003.

14

On October 6, 2003, the Company began marketing its first commercial product, Ganite(TM), which was approved by the FDA, for the treatment of cancer-related hypercalcemia. The drug is being marketed and sold exclusively by Genta in the United States by a dedicated sales force that currently consists of 18 regional representatives. Ganite(TM) is currently undergoing clinical testing for use as a cancer chemotherapy drug, especially in patients with non-Hodgkin's lymphoma, or NHL.

In September 2003, Genta reported Phase 3 clinical data for Genasense(TM) in patients with advanced malignant melanoma. The Company plans to include these data in its NDA for Genasense(TM), which was initiated on a rolling basis (i.e. in several sections) in August 2003. Management expects that the NDA filing for the use of Genasense(TM) in combination with chemotherapy for patients with advanced malignant melanoma will be completed in 2003.

In August 2003, the Company acquired Salus (Note 5), a privately held company located in Salt Lake City, Utah. Salus specializes in the identification and development of drugs that are based on DNA or RNA, including antisense, small interfering RNAs (siRNA), and delivery systems for DNA/RNA-based drugs.

Genasense(TM) is being tested as a drug that can increase the effectiveness of current types of cancer therapy. Patient enrollment has been completed in two additional randomized Phase 3 trials that test the efficacy of Genasense(TM) in patients with multiple myeloma and chronic lymphocytic leukemia, or CLL. Genasense(TM) is also being tested in earlier stage clinical trials for treating more than ten other cancer types. Genasense(TM) has received designations as "Fast Track" and "Orphan Drug" from the FDA in the advanced malignant melanoma, multiple myeloma and CLL indications.

Results of Operations for the Three Months Ended September 30, 2003 and 2002

Summary Operating Results

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

(\$ in thousands)

For the Three Months Ended September 30,

	2003	Increase (Decrease)		2002
		\$	%	
Revenues:				
Licensing fees and royalties .....	\$ 253	\$ (29)	(10)%	\$ 282
Development funding .....	1,043	--	--	1,043
	1,296	(29)	(2)%	1,325
Costs and expenses:				
Research and development .....	21,009	1,401	7%	19,608
Selling, general and administrative	9,287	5,524	147%	3,763
Compensation expense related to				
stock options .....	74	(165)	(69)%	239
Less: Aventis reimbursement .....	11,760	5,035	75%	6,725
	18,610	1,725	10%	16,885
Loss from operations .....	(17,314)	1,754	11%	(19,068)
Other income, principally net interest				
income .....	393	(197)	(33)%	590
Less: Interest expense .....	244	102	72%	142
Net loss applicable to common shares ..	\$(17,165)	\$ 2,053	14%	\$(15,112)

Revenues. Licensing fees, development funding and royalties for the three months ended September 30, 2003 decreased \$0.029 million over the comparable period in 2002, reflecting the final annual installments of licensing fees recorded in 2002 that were not required in 2003.

Research and development expenses. Research and development expenses before reimbursement for the three months ended September 30, 2003 increased \$1.401 million or 7% over the comparable period in 2002. The increase in

15

research and development expenses is primarily attributable to the costs of the Genasense(TM) Phase 3 clinical trials and NDA preparation activities for Genasense(TM), offset by lower drug substance purchases in the quarter. Of the \$21.009 million in research and development expenses for the three months ended September 30, 2003, \$13.340 million and \$1.755 million were reimbursable at 75% and 100%, respectively, pursuant to the Collaborative Agreement (Note 4), of which the net amount of \$11.760 million is expected to be reimbursed in the fourth quarter of 2003.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended September 30, 2003 increased \$5.524 million or 147% over the comparable period in 2002. The increase in selling, general and administrative expenses is primarily attributable to costs associated with Ganite(TM) pre-launch activities, royalty payments due to UPenn per the settlement agreement (Note 13) and general corporate expenses driven by business growth. There were no sales and marketing related expenses reimbursable at 100% pursuant to the Collaborative Agreement (Note 4) for the three months ended September 30, 2003, as sales and marketing related expenses related to

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

Genasense(TM) are mainly being billed to, and paid for, directly by Aventis.

Expense reimbursement. Expense reimbursement for the three months ended September 30, 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 (\$ in thousands):

Reimbursement to Genta:	
Third-party costs .....	\$ 8,491
Drug supply costs .....	1,759
FTE's .....	1,942
	-----
Amount due to Genta .....	12,192
Reimbursement to Aventis:	
FTE's .....	(432)
	-----
Net amount due to Genta .....	\$ 11,760
	=====

Other income less interest expense. Net other income for the three months ended September 30, 2003 decreased \$0.299 million or 67% from the comparable period in 2002, as a result of both lower interest income, resulting from a lower aggregate balance for cash, cash equivalents and short-term investments and interest expense on the \$10.0 million Aventis Note (Note 8) and \$25.0 million borrowed from Aventis under the Aventis Line of Credit (Note 9).

Net Loss. Genta incurred a net loss of \$17.165 million, or \$0.23 per share, for the three months ended September 30, 2003, compared with a net loss of \$15.112 million, or \$0.21 per share, for the three months ended September 30, 2002. The increase in net loss, and per share net loss to common shareholders, was primarily due to increased expenses primarily related to third-party costs for current Genasense(TM) on-going clinical studies, expenses attributable to the NDA preparation for Genasense(TM), general corporate legal fees, personnel costs and Ganite(TM) marketing-related spending, offset by an increase of the expense reimbursement pursuant to the Collaborative Agreement (Note 4).

Results of Operations for the Nine Months Ended September 30, 2003 and 2002

(\$ in thousands)	Summary Operating Results For the Nine Months Ended September 30,			
	2003	Increase (Decrease)		2002
		\$	%	
	-----	-----	-----	-----
Revenues:				
Licensing fees and royalties .....	\$ 795	\$ 294	59%	\$
Development funding .....	3,130	1,391	80%	1,
	-----	-----	-----	-----
	3,925	1,685	75%	2,
Costs and expenses:				
Research and development .....	54,576	8,690	19%	45,
Selling, general and administrative	20,198	4,962	33%	15,
Compensation expense related to				

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

stock options .....	362	(354)	(49)%	
Less: Aventis reimbursement .....	40,350	26,453	190%	13,
	-----	-----	-----	-----
	34,786	(13,155)	(27)%	47,
	-----	-----	-----	-----
Loss from operations .....	(30,861)	(14,840)	(32)%	(45,
Other income, principally net interest				
income .....	1,279	144	13%	1,
Less: Interest expense .....	604	362	150%	
	-----	-----	-----	-----
Net loss applicable to common shares ..	\$ (30,186)	\$ (14,622)	(33)%	\$ (44,
	=====	=====	=====	=====

Revenues. Licensing fees, development funding and royalties for the nine months ended September 30, 2003 increased \$1.685 million over the comparable period in 2002. This increase reflects the amortization, for nine months in 2003 compared to five months in 2002, of the up-front licensing fee and development funding received from Aventis (Note 7), which are being recognized over the estimated 115 months of useful life of the related first-to-expire patent.

Research and development expenses. Research and development expenses before reimbursement for the nine months ended September 30, 2003 increased \$8.690 million or 19% 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 for Genasense(TM), offset by lower drug substance purchases in the nine months. Of the \$54.576 million in research and development expenses for the nine months ended September 30, 2003, \$48.641 million and \$3.869 million were reimbursable at 75% and 100%, respectively, pursuant to the Collaborative Agreement (Note 4), of which the net amount of \$11,760 million related to the three months ended September 30, 2003, is expected to be reimbursed in the fourth quarter of 2003.

Selling, general and administrative expenses. Selling, general and administrative expenses for the nine months ended September 30, 2003 increased \$4.962 million or 33% over the comparable period in 2002. The increase is primarily related to costs associated with Ganite(TM) pre-launch activities, royalty payments due to UPenn per the settlement agreement (Note 13) and general corporate expenses driven by business growth. There were no sales and marketing related expenses reimbursable at 100% pursuant to the Collaborative Agreement (Note 4) for the nine months ended September 30, 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 nine months ended September 30, 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 (\$ in thousands):

Reimbursement to Genta:	
Third-party costs .....	\$ 23,361
Drug supply costs .....	12,999
FTE's .....	5,275
	-----
Reimbursement to Genta .....	41,635
Reimbursement to Aventis:	

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

FTE's .....	(1,285)
	-----
Net reimbursement to Genta .....	\$ 40,350
	=====

Other income less interest expense. Net other income for the nine months ended September 30, 2003 decreased \$0.218 million or 24% from the comparable period in 2002, principally as a result of interest expense on the \$10.0 million Aventis Note (Note 8) and \$25.0 million borrowed from Aventis under the Aventis Line of Credit (Note 9).

Net Loss. Genta incurred a net loss of \$30.186 million, or \$0.40 per share, for the nine months ended September 30, 2003, compared with a net loss of \$44.808 million, or \$0.64 per share, for the nine months ended September 30, 2002. The increase in net loss, and per share net loss to common shareholders, was primarily due to expenses 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

At September 30, 2003, the Company had cash, cash equivalents and short-term investments totaling \$87.4 million compared to \$113.7 million at December 31, 2002.

As reflected in Note 4 to the condensed consolidated financial statements, contingent upon the achievement of certain research and development milestones, the Company could still receive, pursuant to the Collaborative Agreement (Note 4), up to an additional \$280.0 million in cash and up to \$65.0 million in convertible note proceeds. In March 2003, Genta and Aventis negotiated a line of credit (Note 9) 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(TM) or December 31, 2004. Loans under the Aventis Line of Credit (Note 9) are subject to repayment six months after termination. As of November 14, 2003, up to \$15.0 million remained available under the Aventis Line of Credit (Note 9). FDA approval of Genasense(TM) would trigger a milestone payment from Aventis of \$75.0 million. Management believes that at the current rate of spending, primarily in support of on-going 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 to the end of 2004.

The Company's principal expenditures relate to its research and development activities, which include the Company's on-going and future clinical 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 Collaborative Agreement (Note 4). 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. Any 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

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

obtain regulatory approvals and, if such approvals are obtained, to manufacture and market products.

18

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 financings 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 condensed 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

As required by Rules 13a-15(b) or 15d-15(b), Genta's Chief Executive Officer and Chief Financial Officer conducted an evaluation as of the end of the period covered by this report of the effectiveness of the Company's "disclosure controls and procedures" (as defined in Exchange Act Rule 13a-15(e) or 15d-15(e)). Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of the end of the period covered by this report.

As required by Rules 13a-15(d) or 15d-15(d), Genta's Chief Executive Officer and Chief Financial Officer also conducted an evaluation of the Company's internal control over financial reporting to determine whether any changes occurred during the quarter covered by this report that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. Based on that evaluation, there has been no such change during the quarter covered by this report.

19

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

#### 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

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

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. During the quarter ended September 30, 2003, the Company reversed the accrued net liability of \$0.212 million related to this matter, as management no longer believes that a loss is probable.

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 7) the Company received from Aventis pursuant to the Collaborative Agreement (Note 4). In October 2003, the Company reached a settlement with UPenn with respect to this claim. Under the terms of the settlement agreement, in exchange for an agreement by UPenn 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 (Note 4), Genta has agreed to make the following payments to UPenn: (i) \$0.750 million on November 5, 2003, (ii) \$0.250 million on February 2, 2004, (iii) \$1.5 million upon the first NDA or foreign equivalent approval of Genasense(TM), and (iv) provided that the first NDA or foreign equivalent approval of Genasense(TM) has been received by Genta, \$0.750 million on the earlier of (a) the second NDA or foreign equivalent approval of Genasense(TM) or (b) December 30, 2004. As of September 30, 2003, the Company has reserved for the royalty payments that are due to UPenn per the settlement agreement.

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

None.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits.

- 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

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

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 filed on November 4, 2003, Reg. 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 filed on November 4, 2003, Reg. 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 the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification by the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification by the 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 the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K.

On August 18, 2003, the Company filed a Current Report on Form 8-K under Item 5 disclosing a press release issued on August 14, 2003, regarding the Company's agreement to acquire Salus Therapeutics, Inc. On November 4, 2003, the Company filed a Current Report on Form 8-K /A to amend its Form 8-K Report dated August 14, 2003, to provide financial statements and pro forma financial information of business acquired,



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

regarding the Company's acquisition of Salus Therapeutics, Inc.

On September 15, 2003, the Company filed a Current Report on Form 8-K under Item 5 disclosing a press release issued on September 10, 2003, regarding the Company's results from their Phase 3 clinical study of Genasense(TM) plus chemotherapy in patients with malignant melanoma and the submission of the first portion of the NDA to the FDA for Genasense(TM) in this indication.

On September 18, 2003, the Company filed a Current Report on Form 8-K under Item 5 disclosing a press release issued on September 18, 2003, regarding the Company's approval from the FDA to market Ganite(TM) for the treatment of cancer-related hypercalcemia that is resistant to hydration and the initiation of an assistance program to facilitate patient access to Ganite(TM) treatment.

21

### 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  
Corporate Secretary

Date: November 14, 2003

22

### EXHIBIT INDEX

Exhibit Number	Description	Sequence Number
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	

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

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 filed on November 4, 2003, Reg. 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 filed on November 4, 2003, Reg. 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 the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification by the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification by the 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 the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

