

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

GENTA INCORPORATED /DE/  
Form 10-Q  
May 15, 2001

1

-----  
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, 2001

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 Oak Way  
Berkeley Heights  
(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.



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

Notes receivable.....	200,000
Prepaid expenses.....	1,555,419
	-----
Total current assets.....	45,412,153
	-----
Property and equipment, net.....	893,615
Intangibles, net .....	2,723,456
Restricted cash relating to office lease.....	246,626
Deposits and other assets.....	1,340
Prepaid royalties.....	1,268,347
	-----
Total assets	\$ 50,545,537
	=====

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:	
Accounts payable .....	\$ 2,201,033
Accrued compensation.....	105,075
Other accrued expenses.....	887,225
Net liabilities of liquidated foreign subsidiary.....	574,812
	-----
Total current liabilities.....	3,768,145
	-----
Stockholders' equity:	
Preferred stock; 5,000,000 shares authorized, convertible preferred shares outstanding:	
Series A convertible preferred stock, \$.001 par value; 261,200 shares issued and outstanding at March 31, 2001 and December 31, 2000, liquidation value is \$13,060,000 at March 31, 2001...	261
Common stock; \$.001 par value; 95,000,000 shares authorized, 51,508,800 and 51,085,375 shares issued and outstanding at March 31, 2001 and December 31, 2000, respectively.....	51,509
Additional paid-in capital.....	207,089,595
Accumulated deficit.....	(159,407,580)
Deferred compensation.....	(1,177,170)
Accumulated other comprehensive income.....	220,777
	-----
Total stockholders' equity.....	46,777,392
	-----
Total liabilities and stockholders' equity.....	\$ 50,545,537
	=====

See accompanying notes.

Revenues:

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

License revenues.....	\$ 70,000
Costs and expenses:	
Research and development (1).....	5,655,772
General and administrative (1).....	1,372,576
Promega settlement.....	1,000,000
Non-cash equity related compensation.....	151,750
	-----
	8,180,098
	-----
Loss from operations.....	(8,110,098)
Equity in net income of joint venture.....	--
Other income (expense):	
Interest income.....	651,289
	-----
Net loss.....	(7,458,809)
Dividends accrued on preferred stock.....	--
	-----
Net loss applicable to common shares.....	\$ (7,458,809)
	=====
Net loss per common share.....	(\$0.15)
	=====
Shares used in computing net loss per common share.....	51,131,633
	=====
(1) Excludes non-cash equity related compensation	
Research and development.....	\$ 15,867
General and administrative.....	135,883
	-----
	\$ 151,750
	=====

See accompanying notes.

4

5

GENTA INCORPORATED  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(UNAUDITED)

	THREE MONTHS EN
	-----
	2001
	-----
OPERATING ACTIVITIES	
Net loss.....	\$ (7,458,809)
Items reflected in net loss not requiring cash:	
Depreciation and amortization.....	250,899
Loss on disposal of fixed assets.....	1,736
Loss on Promega settlement.....	1,000,000
Compensation expense related to stock options.....	151,750
Changes in operating assets and liabilities.....	(471,960)
	-----
Net cash used in operating activities.....	(6,526,384)
INVESTING ACTIVITIES	

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

Purchase of available-for-sale short-term investments.....	(11,304,230)
Maturities and sales of available-for-sale short-term investments.....	6,982,310
Purchase of property and equipment.....	(188,497)
Principal payments received on notes receivable.....	--
	-----
Net cash used in investing activities.....	(4,510,417)
 FINANCING ACTIVITIES	
Issuance of common stock upon exercise of warrants and options.....	391,688
	-----
Net cash provided by financing activities.....	391,688
	-----
Decrease in cash and cash equivalents.....	(10,645,113)
Less cash at liquidated foreign subsidiary.....	--
Cash and cash equivalents at beginning of period.....	19,025,179
	-----
Cash and cash equivalents at end of period.....	\$ 8,380,066
	=====
 SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:	
Interest paid.....	\$ --
 SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING AND FINANCING ACTIVITIES:	
Preferred stock dividends accrued.....	--
Market value change of available-for-sale equity securities.....	(3,453)
Market value change of available-for-sale short-term investments.....	129,154

See accompanying notes.

5

6

GENTA INCORPORATED  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2001  
(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 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, 2000 (the "2000 Form 10-K").

The Company has experienced significant quarterly fluctuations in

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

operating results and it expects that these fluctuations will continue.

(2) DISCONTINUED OPERATIONS

On March 19, 1999, the Company entered into an Asset Purchase Agreement (the "JBL Agreement") with Promega Corporation ("Promega"), whereby a wholly owned subsidiary of Promega acquired substantially all of the assets and assumed certain liabilities of the Company's manufacturing subsidiary, JBL Scientific, Inc. ("JBL"), for approximately \$4.8 million in cash, a promissory note for \$1.2 million, and certain pharmaceutical development services in support of the Company's development activities. The closing of the sale of JBL was completed on May 10, 1999 with a gain on the sale of approximately \$1.6 million being recognized.

In connection with the sale of JBL's business, 246,000 options were granted to the former employees of JBL upon the closing of the sale of JBL's business, pursuant to an ongoing service arrangement between Promega and the Company. Those options have been accounted for pursuant to guidelines in Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock-Based Compensation," and EITF 96-18 using the Black-Scholes option pricing model. These options were granted at \$2.03 per share with a one-year vesting period and will expire two years after the date of grant. The estimated value of these options totaled \$1.9 million as of March 31, 2000 of which approximately \$970,400 is included in continuing operations for the three months ended March 31, 2000 and is based on services provided and have been charged to non-cash equity related compensation. These options were fully vested on May 9, 2000, and therefore, no expense has been charged to non-cash equity related compensation for the three months ended March 31, 2001.

(3) CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Cash and cash equivalents consisted entirely of money market funds. Marketable short-term investments consisted primarily of corporate notes, all of which are classified as available-for-sale marketable securities. The

6

7

estimated fair value of each investment security has been compared to its cost and, therefore, an unrealized gain of \$125,701 has been recognized in comprehensive loss for the three months ended March 31, 2001.

MARCH 31, 2001	Amortized costs	Gross unrealized gains	Gross unrealized losses	Estimated fair value
	-----	-----	-----	-----
Corporate debt securities	\$ 35,116,710	\$ 190,346	\$ 30,388	\$ 35,276,668
	=====	=====	=====	=====

The fair value of corporate debt securities at March 31, 2001, by contractual maturity, is as follows:

Due in one year or less.....	\$ 32,388,537
Due after one year.....	2,888,131
	-----

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

\$ 35,276,668  
 =====

(4) NET LOSS PER COMMON SHARE

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

Net loss per common share for the three months ended March 31, 2000 and 2001 is based on the weighted average number of shares of common stock outstanding during the periods. Basic and diluted loss per share are the same for all periods presented as potentially dilutive securities, including options, warrants and convertible preferred stock have not been included in the calculation of the net loss per common share as their effect is antidilutive. Net loss per common share for the three months ended March 31, 2000 is also based on net loss adjusted for imputed and accrued dividends on preferred stock.

(5) COMPREHENSIVE LOSS

Comprehensive loss includes the change in the unrealized gain on available-for-sale equity and debt securities, net of tax. The following tables set forth the calculation of comprehensive loss on an interim basis:

	Three Months E
	-----
	2001
	----
Net loss.....	\$ (7,458,809)
Unrealized gain on market value change on available-for-sale short-term investments.....	125,701
	-----
Total comprehensive loss.....	\$ (7,333,108)
	=====

(6) LICENSE REVENUE

The Company has entered into various licensing agreements. In January 2001, the Company entered into a worldwide non-exclusive license agreement with Atugen AG ("Atugen") for a broad portfolio of patents and technologies that relate to antisense for therapeutic and diagnostic applications. This agreement has an initial term which expires in July 2010 and includes an upfront payment in cash and future royalties on product sales.

The Company has recognized \$70,000 of revenues for the three months ended March 31, 2001 in relation to the Atugen license agreement.

8  
 (7) STOCKHOLDERS' EQUITY

In February 2001, the Company issued 162,338 shares of common stock to a major university as consideration for an amendment to a license agreement initially executed on August 1, 1991, concerning antisense technology licensed

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

by such university. The amendment provided for a reduction in the royalty percentage rate to be paid to the university based on the volume of sales of the Company's products containing the antisense technology licensed from such university.

In March 2001, the Company issued 1,687 shares upon the cashless exercise of 4,291 warrants that were part of the warrants issued to the December 1999 private placement investors.

### (8) NOTES RECEIVABLE

The Company accepted a \$1.2 million promissory note (accruing 7% annual interest rate) from Promega as part of the sale price of JBL.

During May 2000, Promega notified Genta by letter of two claims against Genta and Genta's subsidiary, Genko Scientific, Inc. (f/k/a JBL Scientific, Inc.) ("Genko"), for indemnifiable damages in the aggregate amount of \$2,820,000 under the JBL Agreement. Promega's letter stated that it intends to reduce to zero the principal amount of the \$1.2 million promissory note it issued as partial payment for the assets of Genko (which note provided for a payment of \$700,000 on June 30, 2000) and that therefore Genta owes Promega approximately \$1.6 million. Genta believed that Promega's claims were without merit and, accordingly, on October 16, 2000 Genta filed suit in the US District Court of California against Promega for the non-payment of the \$1.2 million note plus interest. On November 6, 2000, Promega filed a countersuit against the Company with the US District Court of California.

In April 2001, Promega and the Company verbally agreed to settle this matter. The Company has agreed to reduce the \$1.2 million promissory note to \$200,000 and forgive all the accrued interest at March 31, 2001 of approximately \$158,700. Accordingly, the Company has recorded a one time cost for the Promega settlement of \$1.0 million for the three months ended March 31, 2001. The accrued interest has been recorded in full against a provision established by the Company at the time of the sale of JBL, and therefore, will not be reflected in the Company's consolidated statement of operations in fiscal 2001. The remaining balance of \$200,000 is to be repaid by Promega upon the settlement of both the Spill and Casmalia Disposal Site (See Note 10).

### (9) GENTA JAGO

On March 4, 1999, Genta and SkyePharma (on behalf of itself and its affiliates) entered into an interim agreement (the "Interim JV Agreement") pursuant to which the parties to the Joint Venture released each other from all liability relating to unpaid development costs and funding obligations of Genta Jago Technologies B.V. ("Genta Jago"), the joint venture formed by Genta and Skyepharma. SkyePharma agreed to be responsible for substantially all the obligations of the joint venture to third parties and for the further development of the joint venture's products, with any net income resulting therefrom to be allocated in agreed-upon percentages between Genta and SkyePharma as set forth in the Interim JV Agreement. In accordance with revised revenue sharing agreements, Genta reported \$502,000 in income for the three months ended March 31, 2000 for its share of net income of Genta Jago in relation to Skyepharma's royalty agreement with Elan Corporation for Genta Jago's product, Naproxen.

### (10) COMMITMENTS AND CONTINGENCIES

#### LITIGATION

In October 1996, JBL retained a chemical consulting firm to advise it with respect to an incident of soil and groundwater contamination (the "Spill"). Sampling conducted at the JBL facility revealed the presence of chloroform



and perchloroethylenes ("PCEs") in the soil and groundwater at this site. A semi-annual groundwater-monitoring program is being conducted, under the supervision of the California Regional Water Quality Control Board for the purpose of determining whether the levels of chloroform and PCEs have decreased over time. The results of the latest sampling conducted by JBL shows that PCEs and chloroform have decreased in all but one of the monitoring sites. The Company has agreed to indemnify Promega in respect of this matter. At March 31, 2001 and December 31, 2000, the Company has \$34,700 and \$49,700, respectively, accrued to cover remedial costs. Prior to 1999, such costs were not estimable and, therefore, no loss provision had been recorded. The Company believes that any costs stemming from further investigating or remediating this contamination will not have a material adverse effect on the business of the Company, although there can be no assurance thereof. In April 2001, the Company has requested closure of this matter from the California Regional Water Quality Control Board as the current sampling results shows that PCEs and chloroform have decreased in all of the monitoring sites.

JBL received notice on October 16, 1998 from Region IX of the Environmental Protection Agency (the "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. Based on volume amounts from the EPA, the Company concluded that it was probable that a liability had been incurred and accrued \$75,000 during 1998. In 1999, the EPA estimated that the Company would be required to pay approximately \$63,200 to settle their potential liability. The Company expects to receive a revised settlement proposal from the EPA during the second quarter of 2001. While the terms of the settlement with the EPA have not been finalized, they should contain standard contribution protection and release language. The Company has agreed to indemnify Promega in respect of this matter. The Company believes that any costs stemming from further investigation or remediating this contamination will not have a material adverse effect on the business of the Company, although there can be no assurance thereof.

During 1995, Genta Pharmaceuticals Europe S.A. ("Genta Europe"), a wholly-owned subsidiary of the Company, received approximately 5.4 million French Francs (as of March 31, 2001, approximately \$726,900) of funding in the form of a loan from the French government agency L'Agence Nationale de Valorisation de la Recherche ("ANVAR") towards research and development activities pursuant to an agreement (the "ANVAR Agreement") between ANVAR, Genta Europe and Genta. In October 1996, as part of the Company's restructuring program, Genta Europe terminated all scientific personnel. ANVAR asserted, in a letter dated February 13, 1998, that Genta Europe was not in compliance with the ANVAR Agreement, and that ANVAR might request the immediate repayment of such loan. On July 1, 1998, ANVAR notified Genta Europe by letter of its claim that the Company remains liable for FF4,187,423 (as of March 31, 2001, approximately \$563,700) and is required to pay this amount immediately. The Company does not believe that under the terms of the ANVAR Agreement ANVAR is entitled to request early repayment. ANVAR notified the Company that it was responsible as a guarantor of the note for the repayment. The Company's legal counsel in Europe has again notified ANVAR that the Company does not agree that the note is payable. The Company is working with ANVAR to achieve a mutually satisfactory resolution. However, there can be no assurance that such a resolution will be obtained. There can be no assurance that the Company will not incur material costs in relation to these terminations and/or assertions of default or liability.

On June 30, 1998, Marseille Aménagement, a company affiliated with the city of Marseilles, France, filed suit in France to evict Genta Europe from its

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

facilities in Marseilles and to demand payment of alleged back rent due and of a lease guarantee for nine years' rent. Following the filing of this claim and in consideration of the request for repayment of the loan from ANVAR, Genta Europe's Board of Directors directed the management to declare a "Cessation of Payment." Under this procedure, Genta Europe ceased any operations and terminated its only employee. A liquidator was appointed by the Court to take control of any assets of Genta Europe and to make payment to creditors. In December 1998, the Court in Marseilles dismissed the case against Genta Europe and indicated that it had no jurisdiction against Genta Incorporated. In August 1999, Marseille Aménagement instituted legal proceedings against the Company at the Commercial Court in France, claiming alleged back rent payment of FF663,413 (as of March 31, 2001, approximately \$89,300) and early termination payment of FF1,852,429 (as of March 31, 2001, approximately \$249,400). A court hearing has been scheduled for June 11, 2001. The Company is working with its counsel in France to achieve a mutually satisfactory resolution. However, there can be no assurance that such a resolution will be obtained. On March 31, 2001, the Company had \$574,800 of net liabilities of liquidated subsidiary recorded and, therefore, management believes no additional accrual is necessary. There can be no assurance that the Company will not incur

9

10  
material costs in relation to this claim.

### PURCHASE COMMITMENTS

In the quarter ended March 31, 2001, the Company entered into commitments relating to the Company's Gallium products franchise with various firms to develop and manufacture certain gallium-containing compounds. The Company believes that successful development of this program may yield substantial clinical and competitive advantages. The cost of these commitments is expected to be approximately \$800,000, all of which will be expensed in research and development as incurred for registration and anticipated clinical trials.

### (11) RECENT ACCOUNTING PRONOUNCEMENTS

The Company implemented SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities," as amended, on January 1, 2001 and did not have any derivative instruments that resulted in a transition adjustment.

10

11  
ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### 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, 2001, the Company has incurred a cumulative net loss of approximately \$159.4 million. The Company has experienced significant quarterly fluctuations in operating results and it expects that these fluctuations in revenues, expenses and losses will continue.

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

The unaudited condensed consolidated financial 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. Without limiting the foregoing, the words "anticipates," "believes," "expects," "intends," "may" and "plans" and similar expressions are intended to identify forward-looking statements. 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, but are subject to many risks and uncertainties, which could cause the actual results of the Company to differ materially from any future results expressed or implied by such forward-looking statements. For example, the results obtained in pre-clinical or clinical studies may not be indicative of results that will be obtained in future clinical trials, and delays in the initiation or completion of clinical trials may occur as a result of many factors. Further examples of such risks and uncertainties also include, but are not limited to: the obtaining of sufficient financing to maintain the Company's planned operations; timely development, receipt of necessary regulatory approvals, and acceptance of new products; the successful application of the Company's technology to produce new products; the obtaining of proprietary protection for any such technology and products; the impact of competitive products and pricing and reimbursement policies; and changing market conditions. The Company does not undertake to update 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.

### RESULTS OF OPERATIONS

In January 2001, the Company entered into a worldwide non-exclusive license agreement with Atugen for a broad portfolio of patents and technologies that relate to antisense for therapeutic and diagnostic applications. This agreement has an initial term which expires in July 2010 and includes an upfront payment in cash and future royalties on product sales. The Company has recognized \$70,000 of revenues for the three months ended March 31, 2001 in relation to this license agreement.

Costs and expenses totaled approximately \$8.2 million in the three months ended March 31, 2001, a decrease of approximately \$1.2 million for the same period in 2000. Costs, excluding non-cash equity related compensation and the write-down of the Promega note, increased approximately \$5.7 million for the period ended March 31, 2001, mainly due to increased drug supply costs and investigator and monitor fees for current on-going clinical studies along with increased payroll costs due to increased headcount.

Research and development expenses, excluding non-cash equity related compensation, totaled approximately \$5.7 million in the three months ended March 31, 2001, an increase of approximately \$5.2 million from the same period in 2000. The increase in research and development expenses is primarily attributable to drug supply costs and investigator and monitor fees for current on-going clinical studies, and increased payroll costs due to increased headcount.

As a result of the initiation of Phase 3 clinical trials for melanoma, chronic lymphocytic leukemia (CLL) and multiple myeloma, it is anticipated that research and development expenses will continue to increase in the future as the development program for Genasense(TM) expands and more patients are treated in

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

clinical trials. Furthermore, the Company is pursuing other opportunities for new product development candidates which pursuits, if successful, will require additional research and development expenses. There can be no assurance, however, that the trials will proceed in this manner or that the Company will initiate new development programs. There were no Phase 3 on-going clinical studies and related drug supply costs in the three months ended March 31, 2000.

General and administrative expenses, excluding non-cash equity related compensation, were approximately \$1.4 million for the three months ended March 31, 2001, an increase of \$0.5 million from the same period in 2000. The increase is primarily related to payroll costs resulting from additional headcount and increased marketing-related spending.

In April 2001, the Company verbally agreed to settle its lawsuit with Promega (See Note 2). The Company agreed to reduce the \$1.2 million promissory note to \$200,000 and forgive all the accrued interest at March 31, 2001 of approximately \$158,700. The Company has recorded a one time cost for the Promega settlement of \$1.0 million for the three months ended March 31, 2001. The accrued interest has been recorded in full against a provision established by the Company at the time of the sale of JBL, and, therefore, will not be reflected in the Company's consolidated statement of operations in fiscal 2001. The remaining balance of \$200,000 is to be repaid by Promega upon the settlement of both the Spill and Casmalia Disposal Site (See Note 10).

Non-cash equity related compensation totaled approximately \$0.2 million in the three months ended March 31, 2001, decreasing approximately \$7.8 million from the same period in 2000. The decrease is primarily attributable to the acceleration of stock options for retiring Board members in fiscal 2000.

On March 4, 1999, the Company and SkyePharma (on behalf of itself and its affiliates) entered into the Interim JV Agreement pursuant to which the Company was released from all liability relating to unpaid development costs and funding obligations of Genta Jago. SkyePharma agreed to be responsible for substantially all the obligations of the joint venture to third parties and for the further development of the joint venture's products, with any net income resulting therefrom to be allocated in agreed-upon percentages between the Company and SkyePharma. As a result of the Interim JV Agreement, the Company wrote off its equity interest in the net loss of the joint venture and, as such, recorded a gain of approximately \$2.3 million for the three months ended March 31, 1999. In accordance with revised revenue sharing agreements, the Company recorded \$502,000 in income for the three months ended March 31, 2000 for its share of net income of Genta Jago in relation to SkyePharma's royalty agreement with Elan Corporation for Genta Jago's product, Naproxen.

The Company's net loss from operations before accrued dividends totaled approximately \$7.5 million, or \$0.15 per common share, for the three months ended March 31, 2001 compared to a net loss from continuing operations of approximately \$8.7 million, or \$0.31 per common share, for the same period in 2000. During the three months ended March 31, 2000, as a result of accrued dividends on the Company's preferred stock of approximately \$3.4 million, the Company's net loss per common share was \$0.44. As a result of the mandatory conversion of Series D Convertible Preferred Stock in June 2000, no dividends were required to be paid beyond January 29, 2000, and therefore, there were no accrued dividends during the three months ended March 31, 2001. The Company's net loss applicable to common shares for the three months ended March 31, 2001 was less than those reported for the comparable period of 2000 primarily as a result of higher non-cash stock compensation charges and dividends accrued on preferred stock in fiscal 2000.

Interest income has fluctuated significantly each year and is anticipated to continue to fluctuate primarily due to changes in the levels of cash, investments and interest rates for each period.

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

### LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed its operations primarily from private and public offerings of its

12

13

equity securities. Cash provided from these offerings totaled approximately \$175.6 million through March 31, 2001, including net proceeds of \$40.0 million received in 2000 and \$10.4 million received in 1999. At March 31, 2001, the Company had cash, cash equivalents and short-term investments totaling \$43.6 million compared to approximately \$49.6 million at December 31, 2000. Management believes that at the current rate of spending, the Company will have sufficient cash funds to maintain its present operations into the second quarter of 2002.

The Company entered into the JBL Agreement with Promega on March 19, 1999. Under the agreement, a wholly owned subsidiary of Promega acquired substantially all of the assets and assumed certain liabilities of JBL for approximately \$4.8 million in cash, a promissory note for \$1.2 million at a 7% annual interest rate maturing on the later of June 30, 2000 or the Environmental Compliance Date, and certain pharmaceutical development services in support of the Company's development activities. The closing of the sale of JBL was completed on May 10, 1999. As previously discussed, the Company verbally agreed to settle this matter. The Company has agreed to reduce the \$1.2 million promissory note to \$200,000 and forgive all the accrued interest at March 31, 2001 of approximately \$158,700. The Company has recorded a one time cost for the Promega settlement of \$1.0 million for the three months ended March 31, 2001. The accrued interest has been recorded in full against a provision established by the Company at the time of the sale of JBL, and therefore, will not be reflected in the Company's consolidated statement of operations in fiscal 2001. The remaining balance of \$200,000 is to be repaid by Promega upon the settlement of both the Spill and Casmalia Disposal Site (See Note 10).

The Company's major source of expenditures relates to its research and development activities, which includes the Company's current and on-going clinical trials. The Company expects this to continue in the future until the lead anti-cancer drug, Genasense(TM), is approved for commercialization.

In the quarter ended March 31, 2001, the Company entered into commitments relating to the Company's Gallium products franchise with various firms to develop and manufacture certain gallium-containing compounds. The Company believes that successful development of this program may yield substantial clinical and competitive advantages. The cost of these commitments is expected to be approximately \$800,000, all of which will be expensed in research and development as incurred for registration and anticipated clinical trials.

The Company will need substantial additional funds before it can expect to realize significant product revenue. To the extent that the Company is successful in accelerating its development of Genasense(TM) or in expanding its development portfolio or acquiring or adding new development candidates, the current cash resources would be consumed at a greater rate. Certain parties with whom the Company has agreements have claimed default and, should the Company be obligated to pay these claims or should the Company engage legal services to defend or negotiate its positions or both, its ability to continue operations could be significantly reduced or shortened. See "MD&A -- Certain Trends and Uncertainties -- Claims of Genta's Default Under Various Agreements." The Company anticipates that significant additional sources of financing, including equity financing, will be required in order for the Company to continue its planned operations beyond the second quarter of 2002. The Company also

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

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 preclinical 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. See "MD&A -- Certain Trends and Uncertainties -- Our Business Will Suffer if We Fail to Obtain Timely Funding."

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

13

14

### RECENT ACCOUNTING PRONOUNCEMENTS

The Company implemented SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," as amended, on January 1, 2001 and did not have any derivative instruments that resulted in a transition adjustment.

### CERTAIN TRENDS AND UNCERTAINTIES

In addition to the other information contained in this Quarterly Report on Form 10-Q, the following factors should be considered carefully.

The Company may be unsuccessful in our efforts to commercialize our pharmaceutical products, such as Ganite(TM) and Genasense(TM).

The commercialization of our pharmaceutical products involves a number of significant challenges. In particular, our ability to commercialize products, such as Ganite(TM) and Genasense(TM), depends, in large part, on the success of our clinical development programs, and our sales and marketing efforts to physicians, patients and third-party payors. A number of factors could impact these efforts, including our ability to demonstrate clinically that our products have utility beyond current indications, delays by regulatory authorities in granting marketing approvals, our limited financial resources and sales and marketing experience relative to our competitors, perceived differences between our products and those of our competitors, the availability and level of reimbursement of our products by third-party payors, incidents of adverse reactions, side effects or misuse of our products and the unfavorable publicity that could result, or the occurrence of manufacturing, supply or distribution disruptions. In particular, the Company has said that it intends to be a direct marketer of its products in the United States. Our inability to build a sales force capable of marketing our pharmaceutical products will adversely affect our sales and limit the commercial success of our products.

Ultimately, our efforts may not prove to be as effective as the efforts of our competitors. In the United States and elsewhere, our products face significant competition in the marketplace. The conditions that our products treat, and some of the other disorders for which we are conducting additional studies, are currently treated with several drugs, many of which have been available for a number of years or are available in inexpensive generic forms. Thus, we will need to demonstrate to physicians, patients and third party payors

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

that the cost of our products is reasonable and appropriate in light of their safety and efficacy, the price of competing products and the related health care benefits to the patient. Even if we are able to increase sales over the next several years, we cannot be sure that such sales and other revenue will reach a level at which we will attain profitability.

Our business will suffer if we fail to obtain timely funding.

Our Company's operations to date have consumed substantial amounts of cash. Based on our current operating plan, we believe that our available resources, including the proceeds from two private offerings in September and November 2000, will be adequate to satisfy our capital needs into the second quarter of 2002. Our future capital requirements will depend on the results of our research and development activities, pre-clinical studies and bioequivalence and clinical trials, competitive and technological advances, and regulatory processes of the FDA and other regulatory authority. If our operations do not become profitable before we exhaust existing resources, we will need to raise additional financing in order to continue our operations. We may seek additional financing through public and private resources, including debt or equity financing, or through collaborative or other arrangements with research institutions and corporate partners. We may not be able to obtain adequate funds for our operations from these sources when needed or on acceptable terms. If we raise additional capital by issuing equity, or securities convertible into equity, the ownership interest of existing Genta stockholders will be subject to further dilution and share prices may decline. If we are unable to raise additional financing, we will need to do the following:

- delay, scale back or eliminate some or all of our research and product development programs;
- license third parties to commercialize products or technologies that we would otherwise seek to develop ourselves;
- sell Genta to a third party;

14

15

- to cease operations; or
- declare bankruptcy.

Many of our products are in an early stage of development.

Most of our resources have been dedicated to applying molecular biology and medicinal chemistry to the research and development of potential antisense pharmaceutical products based upon oligonucleotide technology. While we have demonstrated the activity of antisense oligonucleotide technology in model systems in vitro in animals, only one of these potential antisense oligonucleotide products, Genasense(TM), has been tested in humans. Results obtained in preclinical studies or early clinical investigations are not necessarily indicative of results that will be obtained in extended human clinical trials. Our products may prove to have undesirable and unintended side effects or other characteristics that may prevent our obtaining FDA or foreign regulatory approval for any indication. In addition, it is possible that research and discoveries by others will render our oligonucleotide technology obsolete or noncompetitive.

Clinical trials are costly and time consuming and are subject to delays.

Clinical trials are very costly and time-consuming. How quickly we are

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

able to complete a clinical study depends upon several factors, including the size of the patient population, how easily patients can get to the site of the clinical study, and the criteria for determining which patients are eligible to join the study. Delays in patient enrollment could delay completion of a clinical study and increase its costs, and could also delay the commercial sale of the drug that is the subject of the clinical trial.

Our commencement and rate of completion of clinical trials also may be delayed by many other factors, including the following:

- inability to obtain sufficient quantities of materials used for clinical trials;
- inability to adequately monitor patient progress after treatment;
- unforeseen safety issues;
- the failure of the products to perform well during clinical trials; and
- government or regulatory delays.

We cannot market and sell our products in the United States or in other countries if we fail to obtain the necessary regulatory approvals.

The United States Food and Drug Administration and comparable agencies in foreign countries impose substantial premarket approval requirements on the introduction of pharmaceutical products through lengthy and detailed preclinical and clinical testing procedures and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more depending upon the type, complexity and novelty of the product. While limited trials of our products have produced favorable results, we cannot apply for FDA approval to market any of our products under development until the product successfully completes its preclinical and clinical trials. Several factors could prevent successful completion or cause significant delays of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that the product is safe and effective for use in humans. If safety concerns develop, the FDA could stop our trials before completion. If we are not able to obtain regulatory approvals for use of our products under development, or if the patient populations for which they are approved are not sufficiently broad, the commercial success of our products could be limited.

We may be unable to obtain or enforce patents and other proprietary rights to protect our business.

15

16

Our success will depend to a large extent on our ability to (1) obtain U.S. and foreign patent or other proprietary protection for our technologies, products and processes, (2) preserve trade secrets and (3) operate without infringing the patent and other proprietary rights of third parties. Legal standards relating to the validity of patents covering pharmaceutical and biotechnological inventions and the scope of claims made under such patents are still developing. There is no consistent policy regarding the breadth of claims allowed in biotechnology patents. As a result, our ability to obtain and enforce patents that protect our drugs is highly uncertain and involves complex legal and factual questions.

We have more than 74 U.S. and international patents to aspects of our technology, which includes novel compositions of matter, methods of large-scale synthesis and methods of controlling gene expression. We may not receive any



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

issued patents based on pending or future applications. Our issued patents may not contain claims sufficiently broad to protect us against competitors with similar technology. Additionally, our patents, our partners' patents and patents for which we have license rights may be challenged, narrowed, invalidated or circumvented. Furthermore, rights granted under our patents may not cover commercially valuable drugs or processes and may not provide us with any competitive advantage.

We may have to initiate arbitration or litigation to enforce our patent and license rights. If our competitors file patent applications that claim technology also claimed by us, we may have to participate in interference or opposition proceedings to determine the priority of invention. An adverse outcome could subject us to significant liabilities to third parties and require us to cease using the technology or to license the disputed rights from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all.

The cost to us of any litigation or proceeding relating to patent rights, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of any pending patent or related litigation could have a material adverse effect on our ability to compete in the marketplace.

We rely on our contractual collaborative arrangements with research institutions and corporate partners for development and commercialization of our products.

Our business strategy depends in part on our continued ability to develop and maintain relationships with leading academic and research institutions and independent researchers. The competition for such relationships is intense, and we can give no assurances that we will be able to develop and maintain such relationships on acceptable terms. We have entered into a number of collaborative relationships relating to specific disease targets and other research activities in order to augment our internal research capabilities and to obtain access to specialized knowledge and expertise. The loss of any of these collaborative relationships could have a material adverse effect on our business.

Similarly, strategic alliances with corporate partners, primarily pharmaceutical and biotechnology companies, may help us develop and commercialize drugs. Various problems can arise in strategic alliances. A partner responsible for conducting clinical trials and obtaining regulatory approval may fail to develop a marketable drug. A partner may decide to pursue an alternative strategy or alternative partners. A partner that has been granted marketing rights for a certain drug within a geographic area may fail to market the drug successfully. Consequently, strategic alliances that we may enter into in the future may not be scientifically or commercially successful. We may be unable to negotiate advantageous strategic alliances in the future. The absence of, or failure of, strategic alliances could harm our efforts to develop and commercialize our drugs.

The raw materials for our products are produced by a limited number of suppliers.

The raw materials that we require to manufacture our drugs, particularly oligonucleotides, are available from only a few suppliers, namely those with access to our patented technology. If these few suppliers cease to provide us with the necessary raw materials or fail to provide us with adequate supply of materials at an acceptable price and

quality, we could be materially adversely affected.

The successful commercialization of our products will depend on obtaining coverage and reimbursement for use of our products from third-party payors.

Our ability to commercialize drugs successfully will depend in part on the extent to which various third parties are willing to reimburse patients for the costs of our drugs and related treatments. These third parties include government authorities, private health insurers, and other organizations, such as health maintenance organizations. Third-party payors often challenge the prices charged for medical products and services. Accordingly, if less costly drugs are available, third-party payors may not authorize or may limit reimbursement for our drugs, even if they are safer or more effective than the alternatives. In addition, the federal government and private insurers have considered ways to change, and have changed, the manner in which health care services are provided and paid for in the United States. In particular, these third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products. In the future, it is possible that the government may institute price controls and further limits on Medicare and Medicaid spending. These controls and limits could affect the payments we collect from sales of our products. Internationally, medical reimbursement systems vary significantly, with some medical centers having fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third-party reimbursement. Even if we or our partners succeed in bringing therapeutic products to market, uncertainties regarding future health care policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at profitable prices.

We could become involved in time-consuming and expensive patent litigation and adverse decisions in patent litigation could cause us to incur additional costs and experience delays in bringing new drugs to market.

The pharmaceutical and biotechnology industries have been characterized by time-consuming and extremely expensive litigation regarding patents and other intellectual property rights. We may be required to commence, or may be made a party to, litigation relating to the scope and validity of our intellectual property rights, or the intellectual property rights of others. Such litigation could result in adverse decisions regarding the patentability of our inventions and products, or the enforceability, validity, or scope of protection offered by our patents. Such decisions could make us liable for substantial money damages, or could bar us from the manufacture, use, or sale of certain products, resulting in additional costs and delays in bringing drugs to market. We may not have sufficient resources to bring any such proceedings to a successful conclusion. It may be that entry into a licensing arrangement would allow us to avoid any such proceedings. We may not be able, however, to enter into any such licensing arrangement on terms acceptable to us, or at all.

We also may be required to participate in interference proceedings declared by the U.S. Patent and Trademark Office and in International Trade Commission proceedings aimed at preventing the importing of drugs that would compete unfairly with our drugs. Such proceedings could cause us to incur considerable costs.

Our business exposes us to potential product liability which may have a negative effect on our financial performance.

The administration of drugs to humans, whether in clinical trials or

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

commercially, exposes us to potential product and professional liability risks, which are inherent in the testing, production, marketing and sale of human therapeutic products. Product liability claims can be expensive to defend and may result in large judgments or settlements against us, which could have a negative effect on our financial performance. We maintain product liability insurance (subject to various deductibles), but our insurance coverage may not be sufficient to cover claims. Furthermore, we cannot be certain that we will always be able to purchase sufficient insurance at an affordable price. Even if a product liability claim is not successful, the adverse publicity and time and expense of defending such a claim may interfere with our business.

17

18

If we cease doing business and liquidate our assets, we are required to distribute proceeds to holders of our preferred stock before we distribute proceeds to holders of our common stock.

In the event of a dissolution or liquidation of Genta, holders of Genta common stock will not receive any proceeds until holders of 261,200 outstanding shares of Genta Series A preferred stock are paid a \$13.1 million dollar liquidation preference.

There currently exist certain interlocking relationships and potential conflicts of interest.

Certain of our affiliates, Aries Domestic Fund, LP, Aries Domestic Fund II, LP, and Aries Trust (together the "Aries Funds") have the contractual right, which expires January 1, 2002, to appoint a majority of the members of the Board of Directors of the Company. Paramount Capital Asset Management, Inc. ("PCAM") is the investment manager of The Aries Funds. The Aries Funds have the right to convert and exercise their securities into a significant portion of the outstanding Common Stock. Dr. Lindsay A. Rosenwald, the Chairman and sole stockholder of PCAM, is also the Chairman of Paramount Capital, Inc. and of Paramount Capital Investments LLC ("PCI"), a New York-based merchant banking and venture capital firm specializing in biotechnology companies. PCAM, PCI and its affiliates collectively control approximately 38% of the Company's Common Stock when calculated on a fully diluted basis. In the regular course of its business, PCI identifies, evaluates and pursues investment opportunities in biomedical and pharmaceutical products, technologies and companies. Generally, the law requires that any transactions between Genta and any of its affiliates be on terms that, when taken as a whole, are substantially as favorable to us as those then reasonably obtainable from a person who is not an affiliate in an arms-length transaction. Nevertheless, our affiliates including PCAM and PCI are not obligated pursuant to any agreement or understanding with the Company to make any additional products or technologies available to the Company, nor can there be any assurance, and we do not expect and you should not expect, that any biomedical or pharmaceutical product or technology developed by any affiliate in the future will be made available to us. In addition, some of our officers and directors of the Company or certain of any officers or directors of the Company hereafter appointed may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies. We cannot assure you that these other companies will not have interests in conflict with ours.

Concentration of ownership of our stock could lead to a delay or prevent a change of control.

Our directors, executive officers and principal stockholders and their affiliates own a significant percentage of our outstanding common stock and preferred stock. They also own, through the exercise of options and warrants, the right to acquire even more common stock and preferred stock. As a result, these stockholders, if acting together, have the ability to influence the

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

outcome of corporate actions requiring stockholder approval. This concentration of ownership may have the effect of delaying or preventing a change in control of Genta.

Anti-takeover provisions in our certificate of incorporation and Delaware law may prevent our stockholders from receiving a premium for their shares.

Our certificate of incorporation and by-laws include provisions that could discourage takeover attempts and impede stockholders ability to change management. The approval of 66-2/3% of our voting stock is required to approve certain transactions and to take certain stockholder actions, including the amendment of the by-laws and the amendment, if any, of the anti-takeover provisions contained in our certificate of incorporation.

We anticipate that we will incur additional losses.

The Company has not been profitable to date, incurring substantial operating losses associated with ongoing research and development activities, preclinical testing, clinical trials and manufacturing activities. From the period since its inception to March 31, 2001, the Company has incurred a cumulative net loss of \$159.4 million. We expect to continue to incur losses until such time as product and other revenue exceed expenses of operating our business. While we seek to attain profitability, we cannot be sure that we will ever achieve product and other revenue sufficient for us to attain this objective.

18

19

Claims of Genta's Default Under Various Agreements.

During 1995, Genta Pharmaceuticals Europe S.A. ("Genta Europe"), a wholly-owned subsidiary of the Company, received approximately 5.4 million French Francs (as of March 31, 2001, approximately \$726,900) of funding in the form of a loan from the French government agency L'Agence Nationale de Valorisation de la Recherche ("ANVAR") towards research and development activities pursuant to an agreement (the "ANVAR Agreement") between ANVAR, Genta Europe and Genta. In October 1996, as part of the Company's restructuring program, Genta Europe terminated all scientific personnel. ANVAR asserted, in a letter dated February 13, 1998, that Genta Europe was not in compliance with the ANVAR Agreement, and that ANVAR might request the immediate repayment of such loan. On July 1, 1998, ANVAR notified Genta Europe by letter of its claim that the Company remains liable for FF4,187,423 (as of March 31, 2001, approximately \$563,700) and is required to pay this amount immediately. The Company does not believe that under the terms of the ANVAR Agreement ANVAR is entitled to request early repayment. ANVAR notified the Company that it was responsible as a guarantor of the note for the repayment. The Company's legal counsel in Europe has again notified ANVAR that the Company does not agree that the note is payable. The Company is working with ANVAR to achieve a mutually satisfactory resolution. However, there can be no assurance that such a resolution will be obtained. There can be no assurance that the Company will not incur material costs in relation to these terminations and/or assertions of default or liability.

On June 30, 1998, Marseille Aménagement, a company affiliated with the city of Marseilles, France, filed suit in France to evict Genta Europe from its facilities in Marseilles and to demand payment of alleged back rent due and of a lease guarantee for nine years' rent. Following the filing of this claim and in consideration of the request for repayment of the loan from ANVAR, Genta Europe's Board of Directors directed the management to declare a "Cessation of Payment." Under this procedure, Genta Europe ceased any operations and terminated its only employee. A liquidator was appointed by the Court to take

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

control of any assets of Genta Europe and to make payment to creditors. In December 1998, the Court in Marseilles dismissed the case against Genta Europe and indicated that it had no jurisdiction against Genta Incorporated. In August 1999, Marseille Aménagement instituted legal proceedings against the Company at the Commercial Court in France, claiming alleged back rent payment of FF663,413 (as of March 31, 2001, approximately \$89,300) and early termination payment of FF1,852,429 (as of March 31, 2001, approximately \$249,400). A court hearing has been scheduled for June 11, 2001. The Company is working with its counsel in France to achieve a mutually satisfactory resolution. However, there can be no assurance that such a resolution will be obtained. On March 31, 2001, the Company has \$574,800 of net liabilities of liquidated subsidiary recorded and, therefore, management believes no additional accrual is necessary. There can be no assurance that the Company will not incur material costs in relation to this claim.

### Dividends.

The Company has never paid cash dividends on its common stock and does not anticipate paying any such dividends in the foreseeable future. As a result of the mandatory conversion of Series D Convertible Preferred Stock in June 2000, no dividends were required to be paid beyond January 29, 2000. The Company currently intends to retain its earnings, if any, for the development of its business.

The Company is dependent on key executives and scientists.

The Company's success is highly dependent on the hiring and retention of key personnel and scientific staff. The loss of key personnel or the failure to recruit necessary additional personnel or both is likely further to impede the achievement of development objectives. There is intense competition for qualified personnel in the areas of the Company's activities, and there can be no assurance that Genta will be able to attract and retain the qualified personnel necessary for the development of its business.

Volatility of Stock Price; Market Overhang from Outstanding Convertible Securities and Warrants.

The market price of the Company's common stock, like that of the common stock of many other

19

20

biopharmaceutical companies, has been highly volatile and may be so in the future. Factors such as, among other things, the results of pre-clinical studies and clinical trials by the Company or its competitors, other evidence of the safety or efficacy of products of the Company or its competitors, announcements of technological innovations or new therapeutic products by the Company or its competitors, governmental regulation, developments in patent or other proprietary rights of the Company or its respective competitors, including litigation, fluctuations in the Company's operating results, and market conditions for biopharmaceutical stocks in general could have a significant impact on the future price of the common stock. As of May 7, 2001, the Company had 52,710,330 shares of common stock outstanding. Future sales of shares of common stock by existing stockholders, holders of preferred stock who might convert such preferred stock into common stock, and option and warrant holders also could adversely affect the market price of the common stock.

No predictions can be made of the effect that future market sales of the shares of common stock underlying the convertible securities and warrants referred to under the caption "MD&A -- Certain Trends and Uncertainties -- If we cease doing business and liquidate our assets, we are required to distribute

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

proceeds to holders of our preferred stock before we distribute proceeds to holders of our common stock," or the availability of such securities for sale, will have on the market price of the Common Stock prevailing from time to time. Sales of substantial amounts of Common Stock, or the perception that such sales might occur, could adversely affect prevailing market prices.

20

21

### PART II. OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

In October 1996, JBL retained a chemical consulting firm to advise it with respect to an incident of soil and groundwater contamination (the "Spill"). Sampling conducted at the JBL facility revealed the presence of chloroform and perchloroethylenes ("PCEs") in the soil and groundwater at this site. A semi-annual groundwater-monitoring program is being conducted, under the supervision of the California Regional Water Quality Control Board for the purpose of determining whether the levels of chloroform and PCEs have decreased over time. The results of the latest sampling conducted by JBL shows that PCEs and chloroform have decreased in all but one of the monitoring sites. The Company has agreed to indemnify Promega in respect of this matter. Based on an estimate provided to the Company by the consulting firm, at December 31, 2000 and March 31, 2001 the Company has \$49,700 and \$34,700, respectively, accrued to cover remedial costs. Prior to 1999, such costs were not estimable and, therefore, no loss provision had been recorded. The Company believes that any costs stemming from further investigating or remediating this contamination will not have a material adverse effect on the business of the Company, although there can be no assurance thereof.

JBL received notice on October 16, 1998 from Region IX of the Environmental Protection Agency (the "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. Based on volume amounts from the EPA, the Company concluded that it was probable that a liability had been incurred and accrued \$75,000 during 1998. In 1999, the EPA estimated that the Company would be required to pay approximately \$63,200 to settle their potential liability. The Company expects to receive a revised settlement proposal from the EPA during the second quarter of 2001. While the terms of the settlement with the EPA have not been finalized, they should contain standard contribution protection and release language. The Company has agreed to indemnify Promega in respect of this matter. The Company believes that any costs stemming from further investigation or remediating this contamination will not have a material adverse effect on the business of the Company, although there can be no assurance thereof.

During May 2000, Promega notified Genta by letter of two claims against Genta and Genta's subsidiary, Genko Scientific, Inc. (f/k/a JBL Scientific, Inc.) ("Genko"), for indemnifiable damages in the aggregate amount of \$2,820,000 under the JBL Agreement. Promega's letter stated that it intends to reduce to zero the principal amount of the \$1.2 million promissory note it issued as partial payment for the assets of Genko (which note provided for a payment of \$700,000 on June 30, 2000) and that therefore Genta owes Promega approximately \$1.6 million. Genta believed that Promega's claims were without merit and, accordingly, on October 16, 2000 Genta filed suit in the US District Court of California against Promega for the non-payment of the \$1.2 million note plus interest. On November 6, 2000, Promega filed a countersuit alleging indemnifiable damages in the aggregate amount of \$2,820,000. In April 2001, the Company came to a verbal settlement with Promega regarding the unpaid note of \$1.2 million (See Note 8). Under the tentative agreement, the Company has agreed to the following (i) write-off the accrued interest (ii) write down the \$1.2

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

million note receivable to \$200,000, which is to be repaid upon the settlement of both the Spill and Casmalia Disposal Site (See Note 10).

During 1995, Genta Pharmaceuticals Europe S.A. ("Genta Europe"), a wholly-owned subsidiary of the Company, received approximately 5.4 million French Francs (as of March 31, 2001, approximately \$726,900) of funding in the form of a loan from the French government agency L'Agence Nationale de Valorisation de la Recherche ("ANVAR") towards research and development activities pursuant to an agreement (the "ANVAR Agreement") between ANVAR, Genta Europe and Genta. In October 1996, as part of the Company's restructuring program, Genta Europe terminated all scientific personnel. ANVAR asserted, in a letter dated February 13, 1998, that Genta Europe was not in compliance with the ANVAR Agreement, and that ANVAR might request the immediate repayment of such loan. On July 1, 1998, ANVAR notified Genta Europe by letter of its claim that the Company remains liable for FF4,187,423 (as of March 31, 2001, approximately \$563,700) and is required to pay this amount immediately. The Company does not believe that under the terms of the ANVAR Agreement ANVAR is entitled to request early repayment. ANVAR notified the Company that it was responsible as a guarantor of the note for the repayment. The Company's legal counsel in Europe has again notified ANVAR that the Company does not

21

22

agree that the note is payable. The Company is working with ANVAR to achieve a mutually satisfactory resolution. However, there can be no assurance that such a resolution will be obtained. There can be no assurance that the Company will not incur material costs in relation to these terminations and/or assertions of default or liability.

On June 30, 1998, Marseille Amenagement, a company affiliated with the city of Marseilles, France, filed suit in France to evict Genta Europe from its facilities in Marseilles and to demand payment of alleged back rent due and of a lease guarantee for nine years' rent. Following the filing of this claim and in consideration of the request for repayment of the loan from ANVAR, Genta Europe's Board of Directors directed the management to declare a "Cessation of Payment." Under this procedure, Genta Europe ceased any operations and terminated its only employee. A liquidator was appointed by the Court to take control of any assets of Genta Europe and to make payment to creditors. In December 1998, the Court in Marseilles dismissed the case against Genta Europe and indicated that it had no jurisdiction against Genta Incorporated. In August 1999, Marseille Amenagement instituted legal proceedings against the Company at the Commercial Court in France, claiming alleged back rent payment of FF663,413 (as of March 31, 2001, approximately \$89,300) and early termination payment of FF1,852,429 (as of March 31, 2001, approximately \$249,400). A court hearing has been scheduled for June 11, 2001. The Company is working with its counsel in France to achieve a mutually satisfactory resolution. However, there can be no assurance that such a resolution will be obtained. On March 31, 2001, the Company has \$574,800 of net liabilities of liquidated subsidiary recorded and, therefore, management believes no additional accrual is necessary. There can be no assurance that the Company will not incur material costs in relation to this claim.

#### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

#### ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits.

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

None.

(b) Reports on Form 8-K.

None.

22

23

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/ Gerald M. Schimmoeller  
-----

Name: Gerald M. Schimmoeller  
Title: Vice President, Chief Financial Officer  
and Principal Accounting Officer

Date: May 15, 2001

23