

Edgar Filing: Gentium S.p.A. - Form 6-K

Gentium S.p.A.  
Form 6-K  
March 10, 2009

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

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16  
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of March, 2009.

Commission File Number 000-51341

Gentium S.p.A.

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(Translation of registrant's name into English)

Piazza XX Settembre 2, 22079 Villa Guardia (Como), Italy

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(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.  
Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.  
Yes  No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b):  
82-\_\_\_\_\_.



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The Registrant's press release regarding its quarterly financial results and the quarterly report for the period ended September 30, 2008 are attached hereto as Exhibits 1 and 2 and incorporated by reference herein in their entirety. This report and the exhibits attached thereto are incorporated by reference into the registration statements of Gentium S.p.A. on Forms F-3: File No. 333-135622, File No. 333-137551, File No. 333-138202, File No. 333-139422 and File No. 333-141198 and on Forms S-8: File No. 333-137534 and File No. 333-146534.

Exhibit	Description
1	Press release, dated March 10, 2009.
2	Quarterly report for the period ended September 30, 2008.

- 2 -

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SIGNATURE

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.

GENTIUM S.P.A.

By:	/s/ Gary G. Gemignani
Name:	Gary G. Gemignani
Title:	Executive Vice President and Chief Financial Officer

Date: March 10, 2009

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INDEX TO EXHIBITS

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Exhibit 1

PRESS RELEASE

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Gentium Reports Third Quarter Financial Results;  
Provides Financial Update

Villa Guardia (Como), Italy (March 10, 2009) – Gentium S.p.A. (NASDAQ: GENT) (the “Company”) today reported financial results for the third quarter ended September 30, 2008.

Financial Highlights

The Company reports its financial condition and operating results using U.S. Generally Accepted Accounting Principles (GAAP). The Company’s financial statements are prepared using the Euro as its functional currency. On September 30, 2008, €1.00 = \$ 1.4303

For the third quarter ended September 30, 2008 compared with the prior year’s third quarter:

- Total revenues were €1.85 million, compared with €2.98 million.
- Operating costs and expenses, which include a write-down of assets of €3.05 million, were €8.86 million, compared with €7.20 million. Excluding such write-down of assets, operating costs and expenses would have been €5.81 million.
- Research and development expenses, which are included in operating costs and expenses, were €2.51 million, compared with €4.26 million.
- Operating loss was €7.02 million, compared with €4.22 million. Excluding such write-down of assets, operating loss would have been €3.97 million.
- Net loss was €5.85 million, compared with €5.46 million.
- Basic and diluted net loss per share was €0.39 compared with €0.38 per share.

For the nine months ended September 30, 2008 compared with the comparable prior-year period:

- Total revenues were €6.40 million, compared with €5.38 million.
- Operating costs and expenses were €22.89 million, compared with €32.73 million. Operating costs and expenses for the nine-month period ended September 30, 2007 include a €13.74 million write-down of the assets the Company acquired from Crinos in 2007.
- Research and development expenses, which are included in operating costs and expenses, were €7.87 million, compared with €10.29 million. 2008 research and development expenses are net of €0.79 million of government grants, in the form of a tax credit, accrued as a reduction of research and development expenses.
- Operating loss was €16.49 million, compared with €27.35 million.
- Interest income, net, was €0.17 million, compared with €1.01 million.
- Net loss was €16.46 million, compared with €29.36 million.
- Basic and diluted net loss per share was €1.10 compared with €2.12 per share.

## Operating Results

The fluctuation in product sales revenues for the nine-month period ended September 30, 2008 compared with the same period in 2007 is primarily due to varying demand for our products from our customers. Total product sales revenue for the nine-month period ended September 30, 2008 increased by €0.65 million, or 19%, compared with the same period in 2007. Sales to affiliates represented 13% and 62% of the total product sales for the nine-month period ended September 30, 2008 and 2007, respectively. Sales to third parties increased to €3.57 million primarily due to higher demand for our active pharmaceutical ingredient sulglicotide in the Korean market and due to our acquisition of the Italian marketing authorization and trademarks regarding Defibrotide, which allowed the Company to sell Defibrotide directly to distributors instead of indirectly through our affiliate, Sirton.

Other revenues were €2.28 million for the nine-month period ended September 30, 2008, compared to €1.90 million in 2007. Other revenues include reimbursement of certain costs incurred in the Company's Phase III clinical trial of Defibrotide to treat Severe VOD under a cost-sharing arrangement entered into with Sigma-Tau Pharmaceuticals, Inc.

Cost of goods sold was €4.32 million for the nine-month period ended September 30, 2008 compared to €3.13 million for the same period in 2007. Cost of goods sold as a percentage of product sales was 105% for the nine-month period in 2008 compared to 90% for the same period in 2007. The decrease in gross margin was primarily due to the non-recognition of product sales to an affiliate, Sirton, during the three-month periods ended June 30, 2008 and September 30, 2008. The Company did not recognize these product sales due to Sirton's poor financial condition, which caused concerns over the collectibility of the related receivables.

If we would have recognized the revenue from Sirton, cost of goods sold as a percentage of product sales would have been 85% for the nine-month period ended September 30, 2008 compared to 90% for the same period in 2007.

Research and development spending decreased during the nine-month period in 2008 compared with the same period in 2007, primarily due to timing and costs (including clinical production costs, contract research organization expenses, regulatory activities, and toxicology studies) associated with the Company's Phase III trial in the U.S. for the treatment of Severe VOD and the Company's Phase II/III trial in Europe for the prevention of VOD. The 2008 research and development expenses are net of €0.79 million of government grants, in the form of a tax credit, accrued as a reduction of expense. Without such netting, research and development expenses would have been €8.66 million for the nine-month period ended September 30, 2008 compared with 10.29 million for the same period in 2007.

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General and administrative expenses were €6.36 million and €4.58 million for the nine-month period ended September 30, 2008 and 2007, respectively. The increase is primarily due to an allowance for doubtful accounts of €1.77 million, general corporate expenses, legal and other professional fees, personnel and stock based compensation expense.

Write-down of assets include the write-down of acquired trademarks for Defibrotide (sold as Noravid and Prociclide in Italy), the Italian marketing authorizations for Noravid and Prociclide (the “Italian MAs”), and the Company’s patents. The trademarks for Defibrotide and the Italian MAs have been written-down due to the expiration and non-renewal by the Company of the distribution agreement with Crinos, who distributed Noravid and Prociclide in Italy to treat and prevent vascular disease with risk of thrombosis. Because the Company has decided not to distribute Noravid and Prociclide in Italy for this purpose, doubt has been raised concerning the recoverability of future cash flows expected to be derived from these assets. Therefore, the Company has impaired €1.70 million of the remaining net book value of the trademarks for Defibrotide and the Italian MAs. In addition, the Company wrote down €0.88 million of semi-finished and finished Noravid and Prociclide in its inventory, including such products expected to be returned by Crinos. As of September 30, 2008, the Company wrote down the remaining carrying value of the Company’s patents amounting to €0.48 million, because no future benefits from these patent rights are reasonably assured.

Interest income, net, was €0.17 million and €1.01 million in the nine-month period ended September 30, 2008 and 2007, respectively. Interest income amounted to €0.44 million and €1.29 million in the nine months ended September 30, 2008 and 2007, respectively, a decrease of €0.85 million. The decrease is due to a lower amount of invested funds and decrease in interest rates. Interest expense totalled €0.27 million and €0.28 million in the nine-month periods ended September 30, 2008 and 2007, respectively.

The Company ended the third quarter of 2008 with €13.58 million in cash and cash equivalents, compared with cash and cash equivalents of €25.96 million as of December 31, 2007. As of February 28, 2009, cash and cash equivalents were €6.20 million.

“We look forward to presenting data from our Phase 2/3 European pediatric prevention trial for Defibrotide at the Annual Meeting of the European Group for Blood and Marrow Transplantation at the end of March, as well as providing future updates as to the status of the Phase III treatment trial for Defibrotide,” stated Dr. Laura Ferro, CEO of Gentium S.p.A. “We believe Defibrotide has the potential to play a role in managing severe veno-occlusive disease and we remain committed to its clinical development. Additionally, in light of our financial position, we continue to evaluate our possible strategic and financing options.”

#### About VOD

Veno-occlusive disease is a potentially life-threatening condition, which typically occurs as an important complication of stem cell transplantation. Certain high-dose chemo-radiation therapy regimens used as part of SCT can damage the lining cells of hepatic blood vessels and so result in VOD, a blockage of the small veins of the liver that leads to liver failure and can result in significant dysfunction in other organs such as the kidneys and lungs (so-called severe VOD). SCT is a frequently used treatment modality following high-dose chemotherapy and radiation therapy for hematologic cancers and other conditions in both adults and children. There is currently no approved agent for the treatment or prevention of VOD in the U.S. or the EU.



## About Gentium

Gentium, S.p.A., located in Como, Italy, is a biopharmaceutical company focused on the research, discovery and development of drugs to treat and prevent a variety of vascular diseases and conditions related to cancer and cancer treatments. Defibrotide, the Company's lead product candidate, is an investigational drug that has been granted Orphan Drug status and Fast Track Designation by the U.S. FDA to treat Severe VOD and Orphan Medicinal Product Designation by the European Commission both to treat and to prevent VOD.

## Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements." In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," or "continue," the negative of these terms and other comparable terminology. These statements are not historical facts but instead represent the Company's belief regarding future results, many of which, by their nature, are inherently uncertain and outside the Company's control. It is possible that actual results may differ, possibly materially, from those anticipated in these forward-looking statements. For a discussion of some of the risks and important factors that could affect future results, see the discussion in our Form 20-F for the year ended December 31, 2007 under the caption "Risk Factors."

Source: Gentium

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(Tables to follow)

## GENTIUM S.p.A.

## Balance Sheets

(Amounts in thousands of Euros, except share and per share data)

	December 31, 2007	September 30, 2008 (unaudited)
<b>ASSETS</b>		
Cash and cash equivalents	€ 25,964	€ 13,579
Accounts receivable	805	593
Accounts receivable from related parties, net	4,149	5
Inventories, net	1,510	1,154
Prepaid expenses and other current assets	4,844	3,136
<b>Total Current Assets</b>	<b>37,272</b>	<b>18,467</b>
Property, manufacturing facility and equipment, at cost	20,590	21,016
Less: Accumulated depreciation	9,046	9,939
Property, manufacturing facility and equipment, net	11,544	11,077
Intangible assets, net of amortization	2,592	113
Available for sale securities	525	519
Other non-current assets	26	24
<b>Total Assets</b>	<b>€ 51,959</b>	<b>€ 30,200</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Accounts payable	€ 9,583	€ 5,432
Accounts payable to Crinos	4,000	4,000
Accounts payable to related parties	2,095	5
Accrued expenses and other current liabilities	1,223	1,381
Current portion of capital lease obligations	107	69
Current maturities of long-term debt	1,262	1,347
<b>Total Current Liabilities</b>	<b>18,270</b>	<b>12,234</b>
Long-term debt, net of current maturities	4,421	3,605
Capital lease obligation	223	175
Termination indemnities	686	658
<b>Total Liabilities</b>	<b>23,600</b>	<b>16,672</b>
Share capital (par value: €1.00; 18,454,292 shares authorized; 14,946,317 and 14,956,317 shares issued at December 31, 2007 and September 30 2008, respectively)	14,946	14,956
Additional paid in capital	88,618	90,240
Accumulated other comprehensive income/(loss)	(2)	(8)
Accumulated deficit	(75,203)	(91,660)
<b>Total Shareholders' Equity</b>	<b>28,359</b>	<b>13,528</b>
<b>Total Liabilities and Shareholders' Equity</b>	<b>€ 51,959</b>	<b>€ 30,200</b>

GENTIUM S.p.A.  
 Statements of Operations  
 (Unaudited, amounts in thousand of Euros except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2007	2008	2007	2008
<b>Revenues:</b>				
Product sales to related party	€ 311	€ -	€ 2,147	€ 555
Product sales to third parties	852	1,210	1,328	3,565
Total product sales	1,163	1,210	3,475	4,120
Other revenues	1,819	635	1,904	2,278
Total revenues	2,982	1,845	5,379	6,398
<b>Operating costs and expenses:</b>				
Cost of goods sold	1,048	1,363	3,128	4,317
Research and development	4,258	2,505	10,289	7,873
General and administrative	1,550	1,560	4,583	6,360
Charges from related parties	124	95	526	444
Depreciation and amortization	221	286	467	845
Write-down of assets	-	3,052	13,740	3,052
	7,201	8,861	32,733	22,891
Operating loss	(4,219)	(7,016)	(27,354)	(16,493)
Interest income, net	360	15	1,009	173
Foreign currency exchange gain/(loss), net	(1,599)	1,152	(3,010)	(137)
Loss before income tax expense	(5,458)	(5,849)	(29,355)	(16,457)
Income tax expense	-	-	-	-
Net loss	€ (5,458)	€ (5,849)	€ (29,355)	€ (16,457)
<b>Net loss per share:</b>				
Basic and diluted net loss per share	€ (0.38)	€ (0.39)	€ (2.12)	€ (1.10)
Weighted average shares used to compute basic and diluted net loss per share	14,282,142	14,956,317	13,873,275	14,956,245

GENTIUM S.p.A.  
Statements of Cash Flows  
(Unaudited, amounts in thousand of Euros except share and share per data)

	Nine Months Ended September 30,	
	2007	2008
<b>Cash Flows From Operating Activities:</b>		
Net loss	€ (29,355)	€ (16,457)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Write-down of assets	13,740	2,571
Unrealized foreign exchange loss	2,930	(326)
Depreciation and amortization	1,085	1,364
Write-down of patents	-	480
Stock based compensation	1,189	1,594
Deferred income	(105)	-
Loss/(Gain) on fixed asset disposal	(14)	7
Allowance for doubtful accounts	-	1,767
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(311)	(638)
Inventories	(156)	(526)
Prepaid expenses and other current and noncurrent assets	(2,467)	(392)
Accounts payable and accrued expenses	4,255	(542)
Net cash used in operating activities	(9,209)	(11,092)
<b>Cash Flows From Investing Activities:</b>		
Capital expenditures	(1,966)	(432)
Proceeds from sales of equipment	14	-
Intangible assets expenditures	(302)	(166)
Net cash used in investing activities	(2,254)	(598)
<b>Cash Flows From Financing Activities:</b>		
Proceeds from private placements, net of offering expense	34,483	-
Proceeds from warrant and stock option exercises, net	1,365	38
Repayments of long-term debt	(300)	(731)
Proceeds/(Repayments) from/of short term borrowings	500	(279)
Principal payment of capital lease obligations	(30)	(86)
Net cash provided by (used in) financing activities	36,018	(1,058)
Increase/(decrease) in cash and cash equivalents	24,555	(12,748)
Effect of exchange rate on cash and cash equivalents	(2,913)	363
Cash and cash equivalents, beginning of period	10,205	25,964
Cash and cash equivalents, end of period	€ 31,847	€ 13,579

GENTIUM S.p.A.

QUARTERLY REPORT

For the period ended September 30, 2008

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GENTIUM S.p.A.  
QUARTERLY REPORT, SEPTEMBER 30, 2008  
TABLE OF CONTENTS

<u>CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS</u>	- 1 -
<u>PART 1. UNAUDITED FINANCIAL INFORMATION</u>	- 2 -
<u>Balance Sheets</u>	- 2 -
<u>Statements of Operations</u>	- 3 -
<u>Statements of Cash Flows</u>	- 4 -
<u>Notes To Unaudited Financial Statements</u>	- 5 -
<u>PART 2 – OPERATING AND FINANCIAL REVIEW AND PROSPECTS</u>	- 20 -

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## CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption “Operating and Financial Review and Prospects,” may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words “expect,” “anticipate,” “intend,” “plan,” “believe,” “seek,” “estimate,” and expressions are intended to identify such forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions “Operating and Financial Review and Prospects,” and elsewhere in this report, as well as factors which may be identified from time to time in our Form 20-F or other filings with the Securities and Exchange Commission, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, those relating to:

- our expectations for increases or decreases in expenses;
- our expectations for the development, manufacturing, and approval of Defibrotide or any other products we may acquire or in-license;
- our expectations for incurring additional capital expenditures to expand our research and development capabilities;
- our expectations for becoming profitable on a sustained basis;
- our expectations or ability to enter into marketing and other partnership agreements;
- our expectations or ability to enter into product acquisition and in-licensing transactions;
- our estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating and capital requirements;
- our intention to seek additional financing in order to provide funding to continue as a going concern;
- our expectations or ability to meet the continued listing requirements of the NASDAQ Stock Market;
- our expected losses; and
- our expectations for future capital requirements.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date of this report. Except as required by applicable laws, we assume no responsibility for updating any forward-looking statements.

## PART 1. FINANCIAL INFORMATION

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The accompanying notes are an integral part of these financial statements.





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GENTIUM S.p.A.  
Notes To Unaudited Financial Statements  
(Amounts in thousands, except share and per share data)

1. BUSINESS AND BASIS OF PRESENTATION

**Basis of Presentation:** Gentium S.p.A. (“Gentium”, the “Company”, “we”, or “our”) is a biopharmaceutical company focused on the research, development and manufacture of drugs to treat and prevent a variety of vascular diseases and conditions related to cancer and cancer treatments. Our primary focus is on development of Defibrotide, a DNA based drug derived from pig intestines, to treat and prevent a disease called hepatic Venous Occlusive Disease, or VOD, a condition in which some of the veins in the liver are blocked as a result of cancer treatments such as chemotherapy prior to stem cell transplantation. An acute form of VOD that results in multiple-organ failure, commonly referred to as severe VOD, is a potentially devastating complication of cancer treatments. We are sponsoring a Phase III clinical trial of Defibrotide to treat severe VOD in the United States, Canada and Israel. We are also sponsoring a Phase II/III clinical trial of Defibrotide in Europe to prevent VOD in children. In addition, we are exploring other potential uses of Defibrotide, including to treat a cancer of the plasma cell known as multiple myeloma. These uses of Defibrotide are currently in development, and we do not sell Defibrotide for these indications at this time.

We have a plant in Italy where we manufacture active pharmaceutical ingredients, which are used to make the finished forms of various drugs. One of those active pharmaceutical ingredients is Defibrotide. The other active pharmaceutical ingredients that we manufacture for sale are urokinase, calcium heparin, sodium heparin and sulglycotide. We sell these other active pharmaceutical ingredients to other companies to be made into various drugs. All of the Company’s operating assets are located in Italy.

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. These financial statements are denominated in the currency of the European Union (the Euro or €). Unless otherwise indicated, all amounts are reported in thousands of Euro or US\$, except share and per share data.

The Company has prepared its financial statements assuming that it will continue as a going concern, which contemplates realization of assets and satisfaction of liabilities in the normal course of business. The Company has incurred net operating losses since 2004 and expects to continue to incur net operating losses for the foreseeable future and may never become profitable. The Company has not generated any revenues from its primary product candidate and is dependent upon significant financing or alternative funding to provide the working capital necessary to execute its business plan. The Company currently anticipates that its cash and cash equivalents as of September 30, 2008, are sufficient to meet its anticipated working capital and operating needs through August of 2009. Accordingly, if the Company is not able to be sufficiently capitalized, the Company will not be able to continue as a going concern.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

**Use of Estimates and Reclassification:** The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual amounts and results could differ from those estimates.

In the opinion of management, the accompanying unaudited financial statements include all adjustments, consisting of only normal recurring accruals, necessary for a fair statement of our financial position, results of operations, and cash flows. The information included in this form should be read in conjunction with our financial statements and the

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accompanying notes included in our Annual Report on Form 20-F for the year ended December 31, 2007. Our accounting policies are described in the Notes to the Financial Statements in our 2007 Annual Report on Form 20-F and updated, as necessary, in this Form 6-K. The year-end balance sheet data presented for comparative purposes was derived from audited financial statements, but this Form 6-K does not contain all disclosures required by accounting principles generally accepted in the U.S. The results of operations for the nine months ended September 30, 2008 are not necessarily indicative of the operating results for the full year or for any other subsequent interim period.

Certain reclassification of prior period amounts have been made to the Company's financial statements to conform to the current period presentation.

- 5 -

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**Segment Information:** Statement of Financial Accounting Standards (“SFAS”) No. 131, “Disclosure about Segments of an Enterprise and Related Information,” establishes standards for reporting information on operating segments in interim and annual financial statements. The Company’s chief operating decision makers review the profit and loss and manage the operations of the Company on an aggregate basis. Accordingly, the Company operates in one segment, which is the biopharmaceutical industry.

**Cash and Cash Equivalents:** Cash and cash equivalents include highly liquid, temporary cash investments having original maturity dates of three months or less. For reporting purposes, cash equivalents are stated at cost plus accrued interest, which approximates fair value.

**Concentration of Credit Risk:** Financial Instruments that potentially subject the Company to concentrations of credit risks consist principally of cash, cash equivalents, marketable securities and trade receivables. The Company has cash investments policies that limit investments to short-term low risk instruments. The Company performs ongoing credit evaluations of other customers and maintains allowances for potential credit losses. Collateral is generally not required. Trade receivables from one foreign customer are guaranteed by a letter of credit from a primary bank institution.

**Inventories:** Inventories consist of raw materials, semi-finished and finished active pharmaceutical ingredients. The Company capitalizes inventory costs associated with certain by-products, based on management’s judgment of probable future commercial use and net realizable value. Inventories are stated at the lower of cost or market, cost being determined on an average cost basis. The Company periodically reviews its inventories and items that are considered outdated or obsolete are reduced to their estimated net realizable value. The Company estimates reserves for excess and obsolete inventories based on inventory levels on hand, future purchase commitments, and current and forecasted product demand. If an estimate of future product demand suggests that inventory levels are excessive, then inventories are reduced to their estimated net realizable value.

**Property, Manufacturing Facility and Equipment:** Property and equipment are carried at cost, subject to review for impairment of significant assets whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Repairs and maintenance are charged to operations as incurred, and significant expenditures for additions and improvements are capitalized if they extend the useful life or capacity of the asset. Leasehold improvements are amortized over the economic life of the asset or the lease term, whichever is shorter. Depreciation is calculated on a straight-line basis over the estimated useful life of the assets.

The cost of property, manufacturing facility and equipment also includes a proportionate share of the Company’s financing costs, as required by SFAS No. 34, “Capitalization of Interest Cost”. The amount of interest cost to be capitalized for qualifying assets is that portion of the interest cost incurred during the assets’ acquisition periods that could have been avoided if expenditures for the assets had not been made. Interest expense capitalized is amortized over the same life as the underlying constructed asset.

**Computer Software:** The Company accounts for computer software costs in accordance with AICPA Statement of Position (“SOP”) 98-1, “Accounting for the Costs of Computer Software Developed or Obtained for Internal Use”. SOP 98-1 requires the capitalization of costs relating to certain activities of developing and obtaining internal use software that were incurred during the application development stage. Capitalized costs of computer software obtained for internal use are included in property, manufacturing facility and equipment and amortized over the estimated useful life of the software.

**Intangibles:** Intangible assets are stated at cost and amortized on a straight-line basis over their expected useful life, estimated to be five years for patent rights and five to ten years for licenses and trademarks.

**Impairment of Long-lived Assets, including Intangibles:** The Company's long-lived assets consist primarily of intangible assets and property and equipment. In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," the Company evaluates its ability to recover the carrying value of long-lived assets used in its business, considering changes in the business environment or other facts and circumstances that suggest their value may be impaired. If this evaluation indicates the carrying value will not be recoverable, based on the undiscounted expected future cash flows estimated to be generated by these assets, the Company will reduce the carrying amount to the estimated fair value.

**Marketable Securities:** The Company's marketable securities are classified as securities available for sale in non-current assets and are carried at fair value based on market prices. Unrealized gains and losses (which are deemed to be temporary), if any, are reported in other comprehensive income or loss as a separate component of shareholders' equity.



A decline in the market value of any available for sale securities below cost that is deemed to be other than temporary results in a reduction in the carrying amount to fair value. The impairment would be charged to earnings and a new cost basis for the securities established. Factors evaluated to determine if an impairment is other than temporary include significant deterioration in the credit rating, asset quality, or business prospects of the issuer; adverse changes in the general market condition in which the issuer operates; the intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment; and any concerns about the issuer's ability to continue as a going concern.

**Revenue Recognition:** The Company sells its products to a related party, Sirton (see Note 3). The Company also recognizes revenue from the sale of products to third parties and from collaborative arrangements. Revenues from product sales are recognized at the time of product shipment. Collaborative arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration received from these arrangements is allocated among the separate units based on their respective fair value, and the applicable revenue recognition criteria are applied to each separate unit. Advance payments received in excess of amounts earned are classified as deferred revenue until earned. The Company's revenue recognition policies for its various types of revenue streams are as follows:

The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred and title passes to the customer, the price is fixed and determinable, collectibility is reasonably assured, and the Company has no further obligations. Costs incurred by the Company for shipping and handling are included in cost of goods sold.

The Company recognizes revenue from royalties based on the licensees' sales of the Company's products or technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reliably measured and collectibility is reasonably assured.

Revenues from collaborative arrangements generally includes upfront fees, performance milestone payments, reimbursement of research costs and continuing license and manufacturing fee arrangements if the research and development efforts ever reach the commercialization phase.

Sales of licensing rights for which no further performance obligations exist are recognized as revenues on the earlier of when the payment is received or collection is assured. Nonrefundable upfront licensing fees that require the Company's continuing involvement in the form of research and development or manufacturing efforts are recognized as revenues:

- ratably over the development period if the development risk is significant,
- ratably over the manufacturing period or estimated product useful life if development risk has been substantially eliminated, or
- based upon the level of research services performed during the period of the research contract.

Performance based milestone payments are recognized as revenue when the performance obligation, as defined in the contract, is achieved. Performance obligations typically consist of significant milestones in the development life cycle of the related technology, such as initiation of clinical trials, filing for approval with regulatory agencies and obtaining such approvals.

Revenues are recorded net of applicable allowance for contractual adjustments entered into with customers. We establish a reserve for this discount, which is classified in accrued expenses and other current liabilities in our balance sheet and as a reduction of gross product revenue. Our product revenue reserve is based on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual requirements, and forecasted customer buying patterns. If actual results vary, we may need to adjust these estimates, which could have an effect on earnings in the period of the adjustment.

**Research and Development:** Research and development expenditures are charged to operations as incurred. Research and development expenses consist of costs incurred for proprietary and collaborative research and development, including activities such as product registration and investigator-sponsored trials. Research and development expenses include salaries, benefits and other personnel related costs, clinical trial and related trial product manufacturing costs, contract and other outside service fees, employee stock based compensation expenses and allocated facilities and overhead costs.

**Clinical Trial Accruals:** The Company accrues for the costs of clinical studies conducted by contract research organizations based on the estimated costs and contractual progress over the life of the individual study. These costs can be a significant component of research and development expenses.

**Income Taxes:** The Company uses the liability method of accounting for income taxes, as set forth in SFAS No. 109, "Accounting for Income Taxes." Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences related to the temporary differences between the carrying amounts and the tax basis of assets and liabilities and net operating loss carry-forwards, all calculated using presently enacted tax rates. Valuation allowances are established when necessary to reduce deferred tax assets when it is considered more likely than not that tax assets will not be recoverable.

**Foreign currency transactions:** The Company has no foreign subsidiaries and, therefore, has no translation adjustment in the financial statements. However, net realized and unrealized gains and losses resulting from foreign currency transactions that are denominated in a currency other than the Company's functional currency, the Euro, are included in the statements of operations.

**Share Based Compensation:** The Company has always accounted for share based compensation on the basis of fair value, previously under SFAS 123 and as of July 1, 2005, under SFAS 123(R), "Share Based Payments". The adoption of SFAS 123R did not have a significant impact on the Company as the fair valuations previously used to estimate the fair value of stock based compensation were unchanged. Compensation expense for awards that are ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period of the equity compensation award, which is generally the vesting period. From time to time, the Company grants options to persons other than officers, employees and directors, such as consultants. Grants of equity instruments to such persons are also accounted for under EITF 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services". Under the EITF, equity instruments granted to such persons require the measuring of the fair value of that instrument at the earlier of either i) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached (a "performance commitment"); or ii) the date at which the counterparty's performance is complete. Fair value of the option grant is estimated on the grant date using the Black-Scholes option-pricing model. The Black-Scholes model takes into account volatility in the price of the Company's stock, the risk-free interest rate, the estimated life of the option, the closing market price of the Company's stock and the exercise price.

**Comprehensive Income:** Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income, or SFAS130, requires us to display comprehensive income (loss) and its components as part of our financial statements. Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income or (loss) (or "OCI"). OCI includes certain changes in stockholders' equity that are excluded from net loss. Specifically, we include only unrealized gains or losses on our available for sale securities in OCI. Other comprehensive income (loss), net of tax, for the three and nine-month periods ended September 30, 2007 and 2008, were €(5,460) and €(5,858), respectively and €(29,388) and €(16,463), respectively.

#### Recently Issued Accounting Standards:

In March 2008, the FASB issued SFAS No. 161, Disclosure About Derivate Instruments and Hedging Activities- an amendment of FASB Statement No. 133, which enhances the disclosure requirements for derivatives instruments and hedging activities. This Standard is effective January 1, 2009. We are currently evaluating the effects, if any, that FAS 161 will have on our financial statements.

In April 2008, the FASB issued FSP 142-3, "Determination of the Useful Life of Intangible Assets," which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FAS 142, "Goodwill and Other Intangible Assets." This change is intended to improve the consistency between the useful life of a recognized intangible asset under FAS 142 and the period of expected cash flows used to measure the fair value of the asset under FAS 141R and other generally accepted accounting principles. The requirement for determining useful lives must be applied prospectively to intangible assets

acquired after the effective date and the disclosure requirements must be applied prospectively to all intangible assets recognized as of, and subsequent to, the effective date. FSP 142-3 is effective for fiscal years beginning after December 15, 2008. We are currently evaluating the effects, if any, that FSP 142-3 will have on our financial statements.

In June 2008, the FASB issued EITF Issue No. 03-6-1, "Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities," which clarifies that all outstanding unvested share-based payment awards that contain rights to nonforfeitable dividends, whether paid or unpaid, participate in undistributed earnings with common stockholders. Awards of this nature are considered participating securities and the two-class method of computing basic and diluted earnings per share must be applied. EITF Issue No. 03-6-1 is effective for us on January 1, 2009 with retrospective application. We do not expect the implementation of EITF Issue No. 03-6-1 to have a material impact on our financial position and results of operations.

In June 2008, the FASB ratified EITF Issue No. 07-5, "Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity's Own Stock," which provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. It also clarifies the impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. EITF Issue No. 07-5 is effective for fiscal years beginning after December 15, 2008. We do not expect the implementation of EITF Issue No. 07-5 to have a material impact on our financial position and results of operations.

### 3. RELATED PARTIES

The Company has relationships with two privately owned Italian companies, FinSirton S.p.A. ("FinSirton") and its wholly owned subsidiary, Sirton Pharmaceuticals S.p.A. ("Sirton"). FinSirton, the parent company of several businesses, is the Company's largest shareholder (approximately 25% ownership at September 30, 2008) and was originally the Company's sole shareholder. The Company's Chief Executive Officer serves in the same capacity for FinSirton and is a member of FinSirton's Board of Directors.

Historically, FinSirton and Sirton have provided the Company with a number of business services such as purchasing, logistics, quality assurance, quality control, analytical assistance for research and development, and regulatory services as well as office space, personnel, administrative services, information technology systems and accounting services. Although the Company has substantially reduced the functions and activities provided by FinSirton and Sirton, the Company still depends on FinSirton for certain corporate services and on Sirton for certain infrastructure costs and quality control. These service agreements have recurring one year terms that may be terminated by either party upon written notice to the other party at least one month prior to the expiration of the term. The cost of such services are included in charges from related parties in the accompanying statements of operations.

The Company has historically sold the active pharmaceutical ingredient form of Defibrotide and other active pharmaceutical ingredients to Sirton, who then manufactured and sold the finished products primarily to one customer, Crinos S.p.A. ("Crinos"). As a result, approximately 62% and 13% of the Company's product sales for the nine-month periods ended September 30, 2007 and 2008, respectively, have been to Sirton. In connection with the Company's 2006 distribution agreement with Crinos regarding Defibrotide, the Company entered into an agreement with Sirton, pursuant to which Sirton manufactures the finished Defibrotide ampoules and capsules that the Company then sells to Crinos. This agreement with Sirton was terminated in November 2008.

Sirton also manufactures finished Defibrotide ampoules from the active pharmaceutical form of Defibrotide for the Company's clinical trials pursuant to purchase orders from the Company. These costs have been classified as research and development costs.

Finally, the Company leases space for manufacturing, offices, laboratories and storage facilities from Sirton and FinSirton. These agreements expire on December 31, 2010 and 2013. Total expense under these operating leases for the three and nine-month period ended September 30, 2007 and 2008 amounted to €49 and €50, respectively and €149 and €152, respectively. See Note 13 for such operating lease commitments.

For the three- and nine- month periods ended September 30, 2007 and 2008, the Company had the following transactions with FinSirton and Sirton:

	Three-month period ended September 30,		Nine-month period ended September 30	
	2007	2008	2007	2008
<b>Revenues</b>				
Products Sales	€ 311	-	€ 2,147	€ 555
<b>Expenses</b>				
Cost of goods sold	101	119	101	319
Research and Development	75	-	98	145
Charges from related parties	124	95	526	444
Total	€ 300	214	€ 725	€ 908

As of December 31, 2007 and September 30, 2008, the Company had the following balances with FinSirton and Sirton:

	December 31, 2007		September 30, 2008	
Accounts Receivable - Sirton	€ 4,147	€ 1,772		
Accounts Receivable - FinSirton	2	-		
	4,149	1,772		
Allowance of doubtful accounts	-	(1,767)		
Accounts Receivable, net	4,149	5		
Accounts Payable - Sirton	2,077	5		
Accounts Payable - FinSirton	18	-		
	€ 2,095	€ 5		

Sirton has been unable to make timely payments on outstanding receivables. FinSirton, our largest shareholder and Sirton's parent, has guaranteed Sirton's payment of its outstanding trade payable to us as of December 31, 2007, net of our accounts payable to Sirton, recognizing itself as joint debtor. As of September 30, 2008, proceeds from collections of our accounts receivable from Sirton amounted to €901. Additionally, as of the date of this report, the Company and Sirton formally offset €3,227 of payables due to Sirton against the same amount of receivables due from Sirton. As reported in footnote 15, Subsequent Events, €1,160 of such offset was recorded as if it occurred as of September 30, 2008, even though such payables were formally offset subsequent to September 2008.

We have been advised that FinSirton and Sirton are seeking to raise funds for payment of the amounts owed, including through the sale of real property or other assets; however, as of today, none of the actions planned have been successful, raising doubt about the realization of the net receivable. While the Company is pursuing the collection of such net receivable, we have established an allowance for doubtful accounts of €1,767 and we have not recognized revenue from product sales to Sirton that occurred in the second and third quarter of 2008, because one of the criteria ("collectibility is reasonably assured"), indicated by SAB 104, was not met. As a result, the Company has significantly eliminated its ongoing activities which result in additional receivables from Sirton and is entering into agreements with alternative customers and contract manufacturers.

The Company is also party to a License and Supply Agreement with Sigma-Tau Pharmaceuticals, Inc. pursuant to which we have licensed the right to market Defibrotide to treat VOD in North America, Central America and South America to Sigma-Tau Pharmaceuticals, Inc. and pursuant to which Sigma-Tau Pharmaceuticals, Inc. has agreed to purchase Defibrotide for this use from us. Sigma-Tau Pharmaceuticals, Inc. is an affiliate of several of our large shareholders, including Sigma Tau Industrie Farmaceutie S.p.A. One of our board members, Marco Codella, is the Chief Financial Officer of Sigma Tau Industrie Farmaceutice Riunite S.p.A., which is a wholly-owned subsidiary of Sigma-Tau Finanziaria S.p.A.

The accounting policies applied to transactions with affiliates are consistent with those applied in transactions with independent third parties and management believes that all related party agreements are negotiated on an arm's length basis.

#### 4. COLLABORATIVE ARRANGEMENTS

In December 2001, the Company entered into a license and supply agreement with Sigma-Tau Pharmaceuticals Inc. (as assignee of Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., hereinafter referred to as "Sigma Tau"). Under the multi-year agreement, Sigma Tau obtained exclusive rights to distribute, market and sell Defibrotide to treat VOD in the United States. In 2005, the Company expanded Sigma-Tau's current license territory to all of North America, Central America and South America. This license expires on the later of the eighth year of the Company's launch of the product or the expiration of the U.S. patent regarding the product, which expires in 2010. In return for the license, Sigma-Tau agreed to pay the Company an aggregate of \$4,900, of which €3,826 (\$4,000) has been received to date, based on the exchange rate in effect on the date of receipt. Sigma-Tau will owe the Company an additional \$350 performance milestone payment within 30 days of the end of a Phase III pivotal study, and a \$550 performance milestone payment within 30 days of obtaining an FDA New Drug Application or Biologic License Application and other approvals necessary for the marketing of Defibrotide in the United States, if and when these events occur. The agreement also envisions that the Company will produce and supply Defibrotide to Sigma Tau for marketing and distribution in the United States if and when the drug is approved by the FDA.

If the Company unilaterally discontinues development of Defibrotide to treat VOD (after written notice to Sigma-Tau) and then resumes the development, substantially availing itself of the stages previously completed, either independently or with a third party, within 36 months of the discontinuation, then the Company will be required to promptly reimburse Sigma-Tau for the amounts received. The Company has no intention to discontinue the development of the product.

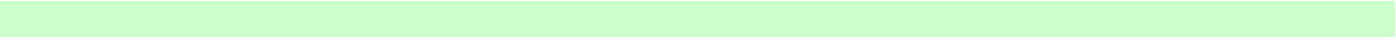
If during the drug development stages the Company realizes that the activities to bring the product to completion would require a material increase of expenditures, the parties will discuss the increased costs and revisions to the terms of the agreement; if the parties are unable to mutually agree on such revisions, either party can terminate the agreement. If the Company or Sigma-Tau terminates the agreement for that reason and the Company then resumes the development, substantially availing itself of the stages previously completed, either independently or with a third party, within 36 months of the termination, the Company will be required to promptly reimburse Sigma-Tau for the amounts received.

On October 12, 2007, the Company and Sigma-Tau entered into a cost sharing agreement to address the need for additional funding not included in the original license and supply agreement. Under this agreement Sigma-Tau will reimburse the Company for 50% of certain costs incurred in the Company's ongoing Phase III clinical trial of Defibrotide to treat severe VOD. We recognize the reimbursement of research and development expenses as revenue when we incur the costs subject to reimbursement.

In conjunction with our agreement with Sigma Tau, we recognized the following amounts as other revenue in the accompanying financial statements:

	Three months ended September 30, 2007	Three months ended September 30, 2008	Nine months ended September 30, 2007	Nine months ended September 30, 2008
Research and development cost reimbursement	€ 1,784	€ 199	€ 1,784	€ 1,839
Upfront payments recognized ratably	35	-	105	-





Total	€	1,819	€	199	€	1,889	€	1,839
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- 11 -

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## 5. INVENTORIES

The Company's inventories consisted of:

	December 31, 2007		September 30, 2008	
Raw materials	€	385	€	432
Semi-finished goods		845		561
Finished goods		280		161
Total	€	1,510	€	1,154

As of December 31, 2007 and September 30, 2008, the Company reserved €547 and €553, respectively, to adjust a by-product cost to its net realizable value and to account for excess inventory compared with forecasted sales. Additionally, as reported in footnote 15 (Subsequent Events), the Company, in connection with the expiration and non-renewal of the distribution agreement entered into with Crinos, wrote down €877 of semi-finished and finished Noravid and Prociclide in our inventory, including such products expected to be returned by Crinos.

## 6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

The Company's prepaid expenses and other current assets consisted of:

	December 31, 2007		September 30, 2008	
VAT receivables	€	3,776	€	1,052
Tax credit		-		791
Other prepaid expenses and current assets		1,068		1,293
Total prepaid expenses and current assets	€	4,844	€	3,136

The value added tax (or "VAT") amounts represent a tax on the value of consumption. VAT has no effect on the Company's operating results, as payments and receipts are allowed to be netted against each other in periodic filings with the tax authorities. The VAT payment system is a "custodial" relationship. VAT liabilities are generated when the Company invoices customers, including the VAT amount, and VAT receivables are created when the Company purchases goods and services subject to VAT. The decrease in VAT receivable is primarily due to the assignment, on June 23, 2008, of €2,100 VAT credit to Crinos. As a result of the assignment of such VAT credit to Crinos, the Company offset an equivalent amount of accounts payable due to Crinos. Additionally, in 2008, we obtained from the Italian Tax Authorities reimbursement of VAT credit in the amount of €738.

At December 31, 2007 and September 30, 2008, other prepaid expenses and current assets include the accrual of €794 and €516 in receivables, respectively, that Sigma-Tau Pharmaceuticals, Inc. has agreed to pay as a reimbursement of costs incurred on Phase III trial for the treatment of severe VOD pursuant to a cost-sharing letter agreement between the Company and Sigma-Tau.

The tax credit includes €791 of government grants received, in the form of a tax credit, for 2007 research and development activities. These benefits have been accounted for in the first half of 2008 based on reliable estimates of the amount of tax credit to which the Company is entitled. The credit was accounted for in compliance with Law 244/07 and Law 296/06 enacted by the Italian Parliament which established a tax credit in the measure of 10% of the research and development costs incurred in taxable year 2007/2009 (increased to 40% of the costs incurred on

contracts entered into with University and Public Research Centre). The tax credit, disclosed in the annual tax return, could have been utilized automatically to offset any tax disbursement (including VAT and withholding taxes). As of December 31, 2008, €492 was utilized to offset social securities and withholding taxes.

On January 28, 2009, Decree N. 185/2008, released by the Italian Authorities, which amended Law 244/07 and Law 296/06 regarding the utilization of the tax credit, was converted into Law N. 2/2009. The new law indicates that preventive approval (so called “nulla osta”) by the Tax Authority is now required for the utilization of the tax credit and that filing the annual tax return is not alone sufficient to claim the utilization of such credit. As of today, the qualification for the tax credit is not clear, because the law provides for different procedures and treatment based on the commencement date of research and development activities. Specifically, it is not clear whether such preventive approval by the Tax Authority will affect the Company’s ability to receive a tax credit on research and development activities commenced prior to November 29, 2008. For these reasons, the tax credit on 2008 research and development activities, amounting to €433, has not been recognized as of September 30, 2008.

## 7. PROPERTY, MANUFACTURING FACILITY AND EQUIPMENT

The Company's property, manufacturing facility and equipment consisted of:

	December 31, 2007			September 30, 2008		
	Cost	Accumulated Depreciation	Net book value	Cost	Accumulated Depreciation	Net book value
Land and building	€ 2,683	1,185	1,498	€ 2,683	1,235	1,448
Plant and machinery	14,434	6,700	7,734	14,621	7,357	7,264
Industrial equipment	1,085	635	450	1,264	680	584
Other	1,047	380	667	1,054	450	604
Leasehold improvements	295	78	217	322	135	187
Internally Developed Software	458	68	390	458	82	376
Construction in progress	588	-	588	614	-	614
	€ 20,590	9,046	11,544	€ 21,016	9,939	11,077

As of December 31, 2007 and September 30, 2008 property, manufacturing facility and equipment include €460 of lab instruments acquired under capital lease agreements. The related accumulated depreciation at December 31, 2007 and September 30, 2008 was €47 and €81, respectively.

## 8. INTANGIBLE ASSETS

The Company's intangible assets consisted of:

	December 31, 2007			September 30, 2008			
	Cost	Accum. amortiz.	Net book value	Cost	Accum. amortiz.	Impairm.	Net book value
Patent rights	€ 1,093	595	€ 498	€ 1,230	€ 750	€ 480	€ -
License and trademarks	1,280	184	1,096	1,312	352	847	113
Marketing authorizations	1,131	133	998	1,131	283	848	-
Total	€ 3,504	912	€ 2,592	€ 3,673	€ 1,385	€ 2,175	€ 113

As reported in footnote 15, Subsequent Events, the distribution agreement entered into with Crinos expired on December 31, 2008 and the Company has chosen not to renew this agreement. In addition, the Company plans to submit a request for the withdrawal of Noravid and Procyclide (also known as Defibrotide) from the Italian market. Such plan raised doubt concerning the recoverability of future cash flows expected to be derived from these assets, which has required the Company to write-down the remaining net book value of the trademark and Italian marketing authorizations for Noravid and Procyclide (the "Italian MAs") amounting to €847 and €848, respectively.

As reported in footnote 15, in connection with the expiration and non-renewal of the distribution agreement with Crinos and the Company's plan to withdraw Noravid and Procyclide from the Italian market, the Company revised the asset value of the capitalized cost of patents for which no future benefits are reasonably assured. Changes in the carrying value are the result of the lack of future benefits from these assets. The impact of the change resulted in an increase of net loss of €480, which has been included in the write-down of assets in the statement of operations.



## 9. CREDIT FACILITY and LONG-TERM DEBT

Long term debt, net of current maturities consists of:

	December 31, 2007	September 30, 2008
a) Mortgage loan bearing interest at the Euribor 6 month rate plus 1.0% due June 2014 (5.71% and 6.38% at December 31, 2007 and September 30, 2008, respectively)	2,600	2,400
b) Equipment loan secured by marketable securities, bearing interest at the Euribor 3 months rate plus 1.70% due April 2011 (6.38% and 6.98% at December 31, 2007 and September 30, 2008, respectively)	919	788
c) Equipment loan bearing interest at the Euribor 3 months rate plus 1.20% due June 2011 (4.86% and 6.48% at December 31, 2007 and September 30, 2008 respectively)	750	687
d) Financing loan bearing interest at the Euribor 1 months rate plus 1.00% due December 2011 (5.29% and 6.05% at December 31, 2007 and September 30, 2008, respectively)	409	338
e) Equipment loans secured by the underlying equipment pursuant to the Sabatini Law, interest at 2.1%	306	175
f) Research loan from the Italian Ministry for University and Research, interest at 1% per annum, due January 2012	318	250
g) Financing loan bearing interest at the Euribor 3 months rate plus 1.00% due December 2011 (4.68% and 6.28% at December 31, 2007 and September 30, 2008, respectively)	193	159
h) Equipment loan bearing interest at the Euribor 3 months rate plus 0.80% due December 2011 (5.48% and 6.08% at December 31, 2007 and September 30, 2008, respectively)	188	155
	5,683	4,952
Less current maturities	1,262	1,347
Total	€ 4,421	€ 3,605

The equipment loan in the amount of €750 requires the Company to maintain a minimum level of net shareholders' equity determined in accordance with Italian generally accepted accounting principles. The Company was in compliance with the covenant at December 31, 2007 and September 30, 2008.

The Company's marketable securities consist of debt securities, which have been pledged to secure the Company's repayment of the loan from Banca Intesa-Mediocredito S.p.A. The loan agreement requires that pledged securities equal at least 50% of the remaining loan principal at all times. Accordingly, such securities will gradually be released from the pledge as the Company repays the principal of the loan.

The maturities of long-term debt over the next five years as of September 30, 2008 are as follows:

September	
2008	€ 1,347
2009	1,184
2010	1,131
2011	490

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2012	400
Thereafter	400
	€ 4,952

- 14 -

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## 10. SHAREHOLDERS' EQUITY

The Company had 14,946,317 and 14,956,317 ordinary shares of €1.00 par value per share issued and outstanding as of December 31, 2007 and September 30, 2008, respectively. On September 30, 2008, the authorized shares were 18,454,292. Authorized capital is as follows:

	December 31, 2007	September 30, 2008
Issued and outstanding	14,946,317	14,956,317
Reserved for share option plans	2,510,000	2,500,000
Reserved for exercise of warrants	846,300	846,300
Reserved for future offerings	151,675	151,675
	18,454,292	18,454,292

In conjunction with the convertible promissory notes sold in a private placement from October 2004 to January 2005, the Company issued warrants for the purchase of an aggregate of 503,298 ordinary shares at a purchase price (as adjusted) of \$9.52 per share. The warrants are fully vested, exercisable at the option of the holder, in whole or in part, and expire five years from the date of grant. Through September 30, 2008, the Company issued 22,734 ordinary shares upon exercise of these warrants for proceeds of \$216 (€170).

In connection with its initial public offering ("IPO"), the Company granted warrants to purchase 151,200 ordinary shares to the underwriters for services rendered during the IPO. The warrants are fully vested, exercisable at the option of the holder, in whole or in part, and expire five years from the date of grant. Through September 30, 2008, we had issued 107,990 ordinary shares upon exercise of these warrants at a price per share of \$11.25, for proceeds of \$1,215 (€914).

In connection with a private placement in 2005, the Company issued warrants for the purchase of an aggregate of 620,450 ordinary shares at an exercise price of \$9.69 per ordinary share. The warrants are fully vested, exercisable at the option of the holder, in whole or in part, and expire five years from the date of grant. In addition, the Company issued to one of the placement agents a five year warrant for the purchase of 93,068 ordinary shares at an exercise price of \$9.69 per ordinary share. As of September 30, 2008, all of the warrants had been exercised and the Company had issued 713,518 ordinary shares underlying these warrants for aggregate proceeds of \$6,914 (€5,000).

In connection with a private placement in 2006, the Company issued warrants for the purchase of an aggregate of 388,705 ordinary shares at an exercise price of \$14.50 per ordinary share. In addition, the Company issued to one of the placement agents a five year warrant for the purchase of 77,741 ordinary shares at an exercise price of \$17.40 per ordinary share. The warrants are fully vested, exercisable at the option of the holder, in whole or in part, and expire five years from the date of grant. Through September 30, 2008, we had issued 143,920 ordinary shares upon exercise of these warrants for proceeds of \$2,087 (€1,490).

The following is a summary of outstanding warrants as of September 30, 2008:

	Number of warrants issued	Number of warrants exercised	Number of warrants outstanding
Warrant issued in conjunction with Promissory note	503,298	22,734	480,564



Initial Public Offering	151,200	107,990	43,210
2005 Private placement	713,518	713,518	-
2006 private placement	466,446	143,920	322,526
Total	1,834,462	988,162	846,300

#### 11. EQUITY INCENTIVE PLANS.

The Company currently has three option plans in place: an Amended and Restated 2004 Equity Incentive Plan, which includes an Amended and Restated 2004 Italy Stock Award Sub-Plan, an Amended and Restated Nonstatutory Stock Option Plan and Agreement, and a 2007 Stock Option Plan (collectively, the Plans”). The following table lists the balance available by the Plans at September 30, 2008.

- 15 -

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	Amended and Restated Nonstatutory Plan and Agreement	Amended and Restated 2004 Stock Option Plan	2007 Stock Option Plan
Number of shares authorized	60,000	1,500,000	1,000,000
Number of option granted since inception	60,000	1,500,000	327,178
Number of options exercised	60,000	-	-
Number of shares cancelled/expired	-	-	30,000
Number of shares available for grant	-	-	642,822

There were no options granted in the three months ended September 30, 2007 and 2008. The weighted average grant-date fair market value of options granted to officers, employees, directors and consultants for the nine months ended September 30, 2007 and 2008 were \$10.30 and \$5.37, respectively. The fair value of each option grant is estimated on the grant date using the Black-Scholes option-pricing model. The valuation of options granted was based on the following weighted average assumptions:

	Three months ended September 30, 2007	Three months ended September 30, 2008	Nine months ended September 30, 2007	Nine months ended September 30, 2008
Risk free interest rate	-	-	4.60%	2.60%
Expected dividend yield	-	-	-	-
Expected stock price volatility	-	-	60.00%	60.65%
Expected term	-	-	4.83	5.62

In accordance with the provision of SFAS No. 123R, stock-based compensation cost is measured at the grant date based on the fair value of the award ultimately expected to vest and is recognized as an expense over the service period, which is generally the vesting period. The Company recorded non-cash compensation expense of €1,594 and €1,189 for the nine-month period ended September 30, 2008 and 2007, respectively, as follows:

	Three months ended September 30, 2007	Three months ended September 30, 2008	Nine months ended September 30, 2007	Nine months ended September 30, 2008
Cost of goods sold	13	15	39	71
Research and development	101	69	262	317
General and administrative	358	343	888	1,206
Total employee stock-based compensation expense	472	427	1,189	1,594

Stock-based compensation expense recognized in the statement of operations is based on awards ultimately expected to vest, reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeiture percentage was estimated to be approximately zero. If pre-vesting forfeitures occur in the future, the Company will record the effect of such forfeitures as the forfeitures occur.

All of the Company's stock options vest ratably through continued employment over the vesting period. The number of options expected to vest is based on estimated forfeitures of options that were outstanding at September 30, 2008. Once vested, options become exercisable immediately.

The Black-Scholes model takes into account volatility in the price of the Company's stock, the risk-free interest rate, the estimated life of the option, the closing market price of the Company's stock and the exercise price. Some of these inputs are highly subjective assumptions and these assumptions can vary over time. Additionally the Company has limited historical information available to support its estimate of certain assumptions required to value employee stock options. In developing its estimate of expected term, due to the limited history, the existing historical share option exercise experience is not a particularly relevant indicator of future exercise patterns. Additionally, due to the limited period that there has been a public market for the Company's securities, the historical volatility of the Company's ordinary shares may not be representative of the expected volatility. Finally, the use of implied volatility, the volatility assumption inherent in the market price of a company's traded options, is not practicable because the Company has no publicly traded options. In order to determine the expected volatility, the Company analyzed other available information, including the historical experience of a group of stocks in the Company's industry having similar traits. The risk-free rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant. The Company assumed that no dividends would be paid during the expected term of the options.

The Company expects to incur significant non-cash compensation expense for option grants in the future. As of September 30, 2008, total compensation cost not yet recognized was €2,658, which is expected to be expensed over a remaining weighted average vesting period of 36 months.

The Company applies EITF 96-18 in accounting for options granted to consultants. As of September 30, 2007 and 2008, options outstanding to consultants amounted to 110,000 and 105,000, respectively. As of September 30, 2008, there were 10,000 non employee share options exercised. Cash received on stock options exercised amounted to \$56 (€38).

## 12. NET LOSS PER SHARE

Net loss per share is computed using the weighted average number of ordinary shares outstanding during the applicable period. Because the effect is antidilutive, the Company has excluded from the calculation of diluted net loss per share the impact of the ordinary equivalent shares resulting from the assumed exercise of stock options and warrants under the treasury stock method. There is no difference between basic and diluted net loss per share for all periods presented.

## 13. FAIR VALUE MEASUREMENT

Effective January 1, 2008, we implemented SFAS 157, "Fair Value Measurements," for our financial assets and liabilities that are re-measured and reported at fair value at each reporting period. The adoption of FAS 157 to our financial assets and liabilities did not have a material impact on our financial position and results of operations.

SFAS 157 defines fair value, provides a framework for measuring fair value, and requires expanded disclosures regarding fair value measurements. SFAS 157 does not require assets and liabilities that were previously recorded at cost to be recorded at fair value. For assets and liabilities that are already required to be disclosed at fair value, SFAS 157 introduced, or reiterated, a number of key concepts which form the foundation of the fair value measurement approach to be used for financial reporting purposes. The statement indicates, among other things, that a fair value measurement assumes that the transaction to sell an asset or transfer a liability occurs in the principal market for the asset or liability or, in the absence of a principal market, the most advantageous market for the asset or liability. SFAS 157 defines fair value based upon an exit price model.

Relative to SFAS 157, the FASB issued FASB Staff Positions (FSP) 157-1 and 157-2. FSP 157-1 amends SFAS 157 to exclude SFAS No. 13, "Accounting for Leases," (SFAS 13) and its related interpretive accounting pronouncements that address leasing transactions, while FSP 157-2 delays the effective date of the application of SFAS 157 to fiscal years beginning after November 15, 2008 for all non-financial assets and non-financial liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis. In October 2008, the FASB issued FASB Staff Position (FSP) No. 157-3, Determining the Fair Value of a Financial Asset When the Market for that Asset is Not Active, that clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key consideration in determining the fair value of a financial asset when the market for that financial asset is not active. We are evaluating the impact, if any, this Standard will have on our non-financial assets and liabilities.

- 17 -

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SFAS 157 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows:

Level 1 inputs, which include quoted prices in active markets for identical assets or liabilities.

Level 2 inputs, which include observable inputs other than Level 1 inputs, such as quoted prices for similar assets and liabilities; quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability; and

Level 3 inputs, which include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Level 3 assets or liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table sets forth our financial assets that were accounted for at fair value on a recurring basis as of September 30, 2008:

	Fair Value Measurements at September 30, 2008 using			
	Total Carrying Value at September 30, 2008	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash and cash equivalents	€ 13,579	€ 13,579	€ —	€ —
Available for sale securities	519	519	—	—
Total	€ 14,098	€ 14,098	€ -	€ -

The fair values of our cash and cash equivalents and available for sale securities are determined through market, observable and corroborated sources. There were no changes in valuation techniques due for the three-month period ended September 30, 2008.

The carrying amounts of accounts receivables, prepaid expenses, other current assets, accounts payable and accrued expenses approximate fair values due to the short-term maturities of these instruments.

#### 14. COMMITMENTS AND CONTINGENCIES

Future minimum lease payments that are non-cancellable under operating and capital leases as of September 30, 2008 are:

	Operating Lease	Capital Leases
September 30, 2009	€ 199	80
September 30, 2010	199	73
September 30, 2011	193	73
September 30, 2012	71	40
September 30, 2013	30	-
Thereafter	8	-

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Total minimum lease payments	€	700	266
Less: imputed interest			(22)
Present value of net minimum lease payment			244
Less: Current portion of capital lease payment			(69)
Long term portion of capital lease payment			175

- 18 -

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As of September 30, 2008, we had €1,543 of future payables under outstanding contracts with various contract research organizations that are not revocable. Most of these contracts are on a cost plus or actual cost basis.

#### 15. SUBSEQUENT EVENT

After September 2008, considering the existing concerns regarding the ability of Sirton to operate as a going concern, the company revisited Sirton's ability to pay its outstanding receivable to the Company. None of the actions planned for the third quarter to raise additional funds have been completed by Sirton; therefore, additional doubt arose concerning the collectibility of the outstanding accounts receivable and the realization of sales transactions recorded in the second and third quarter of 2008. As a result, the Company treated Sirton's financial condition as a Type 1 subsequent event under Section 560 of Statement on Auditing Standards No. 1, Codification of Auditing Standards and Procedures, because the debtor's poor financial condition existed as of September 30, 2008 requiring an accounting recognition and valuation at September 30, 2008. For these reasons, the Company established a provision for doubtful accounts of €1,767 and did not recognize revenue from the product sales to Sirton during the periods ended June 30 and September 30, 2008, since one of the criteria ("collectibility is reasonably assured"), as indicated by SAB 104, was not met. Additionally, the Company and Sirton formally offset €1,160 of payables due to Sirton against the same amount of receivables due from Sirton. We recorded such transactions as if the offsets occurred as of September 30, 2008, even though such payables were formally offset in October and December 2008.

Because the Company knew that the distribution agreement with Crinos was going to expire on December 31, 2008 and the Company was not going to renew such agreement, doubt was raised concerning the recoverability of future cash flows expected to be derived from the acquired Defibrotide trademarks and Italian MAs, and the Company wrote down the remaining net book value of such assets amounting to €847 and €848, respectively. In addition, the Company wrote down €877 of the book value of semi-finished and finished Noravid and Prociclide in our inventory, including such products expected to be returned by Crinos. These write-downs are included within the write-down of assets in the statement of operations.

In connection with the withdrawal of Defibrotide in the Italian market, the Company revised the asset value of the capitalized cost of patents for which no future benefits are reasonably assured. Changes in the carrying value are the result of the lack of future benefits from these assets. The impact of the change resulted in an increase of net loss of €480, which has been included in the write-down of assets in the statement of operations.

The Company treated the write-down of the intangible assets, patents and the inventory as a Type 1 subsequent event under Section 560 of Statement on Auditing Standards No. 1, Codification of Auditing Standards and Procedures, because the uncertainty of the recoverability of assets existed as of September 30, 2008 requiring an accounting recognition and valuation at September 30, 2008.

In December 2008 we received a loan from the Ministry for University and Research ("MURST") for €147 granted through IntesaSanpaolo. The loan is for financing research and development activities and bears interest at 1.00 % per annum. The loan is payable in installments every six months until the final maturity in January 2012. Additionally, the MURST granted a non refundable contribution for €18.

In January 2009, we obtained from the Italian Tax Authorities a reimbursement of VAT credit in the amount of €244 and paid the last installment of €4,000 pursuant to the Master Agreement entered into with Crinos.

## PART 2 – OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion together with the financial statements, related notes and other financial information included elsewhere in this report and in conjunction with management's operating and financial review and prospects and our audited annual financial statements and related notes included in our Form 20-F. This discussion may contain predictions, estimates and other forward-looking statements that involve risks and uncertainties. These risks could cause our actual results to differ materially from any future performance suggested below.

All amounts are in thousands except per share data.

### Overview

We are a biopharmaceutical company focused on the research, development and manufacture of drugs to treat and prevent a variety of vascular diseases and conditions related to cancer and cancer treatments. Our primary focus is on development of Defibrotide, a DNA based drug derived from pig intestines, to treat and prevent a disease called hepatic Venous Occlusive Disease, or VOD, a condition in which some of the veins in the liver are blocked as a result of cancer treatments such as chemotherapy prior to stem cell transplantation. An acute form of VOD that results in multiple-organ failure, commonly referred to as severe VOD, is a potentially devastating complication of cancer treatments. We are sponsoring a Phase III clinical trial of Defibrotide to treat severe VOD in the United States, Canada and Israel. We are also sponsoring a Phase II/III clinical trial of Defibrotide in Europe to prevent VOD in children. In addition, we are exploring other potential uses of Defibrotide, including to treat a cancer of the plasma cell known as multiple myeloma. These uses of Defibrotide are currently in development, and we do not sell Defibrotide for these indications at this time.

We have a plant in Italy where we manufacture active pharmaceutical ingredients, which are used to make the finished forms of various drugs. One of those active pharmaceutical ingredients is Defibrotide. The other active pharmaceutical ingredients that we manufacture for sale are urokinase, calcium heparin, sodium heparin and sulglucotide. We sell these other active pharmaceutical ingredients to other companies to be made into various drugs. All of the Company's operating assets are located in Italy.

Historically, we have also generated revenue from research and development agreements with co-development partners, from the sale of rights to our intellectual property, and from licensing agreements. Our licensing agreements have included up-front payments (some of which are paid based on achieving defined milestones), reimbursement of research and development expenses, and royalties from product sales in the licensed territories.

Our cost of goods sold consists of material costs, direct labor and related benefits and payroll burden, utilities, quality control expenses, depreciation of our facility and other indirect costs of our facility. Cost of goods sold include costs charged from Sirton for manufacturing activities performed to finalize and package product distributed in the Italian market under a distribution agreement with Crinos.

We expect to continue to incur net losses as we continue the development of our product candidate, apply for regulatory approvals and expand our operations. Until we become profitable, our ability to continue as a going concern will be dependent upon obtaining sufficient funding.

### Research and Development Expenses

Our research and development expenses consist primarily of costs associated with research, preclinical development contract research organization charges, regulatory activities, laboratory supplies and materials, manufacturing costs,



contracted service and clinical trials for our product candidates, offset by research and development tax credit due from the Italian Government. Development timelines and costs are difficult to estimate and may vary significantly for each product candidate and from quarter to quarter. The process of seeking regulatory approvals, and the subsequent compliance with applicable regulations, requires the expenditure of substantial resources.

The successful development of our product candidates is highly uncertain. We cannot estimate with certainty or know the exact nature, timing and estimated costs of the efforts necessary to complete the development of Defibrotide to treat or prevent VOD or the other uses for which we are developing Defibrotide or the date of completion of these development efforts. We do not anticipate that we will generate any new revenues from our product candidates until 2010, at the earliest, and we cannot reasonably estimate when we may have material net cash inflows from sales of Defibrotide to treat or prevent VOD or the other uses for which we are developing Defibrotide, if ever. We cannot estimate with certainty any of the foregoing due to the numerous risks and uncertainties associated with development, including:

- the possibility of delays in the collection of clinical trial data and the uncertainty of the timing of any interim analysis of any clinical trial that may be permitted by FDA;

- the uncertainty of clinical trial results; and
- extensive governmental regulation, both foreign and domestic, for approval of new therapies.

If we fail to complete the development of Defibrotide to treat or prevent VOD, it will have a material adverse effect on our future operating results and financial condition. In addition, any failure by us to obtain, or any delay in obtaining, regulatory approvals will also have a material adverse effect on our results of operations and financial condition.

As part of our development of Defibrotide, we expect to continue to incur significant costs related to the following:

- § Phase III clinical study of Defibrotide to treat VOD in the United States.
- § Phase II/III clinical trial of Defibrotide to prevent VOD in children in Europe;
- § Toxicology studies related to our Phase III clinical study of Defibrotide to treat VOD in the United States; and
- § The expanded access program of Defibrotide to treat VOD in the United States.

In addition, we expect to incur substantial costs when and if we initiate a Phase III clinical trial of Defibrotide to prevent VOD in adults and children in the United States and adults in Europe after we complete our Phase III trial of Defibrotide to treat VOD in the United States.

#### Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates.

We believe the following policies to be critical to understand our financial conditions and results of operations because they require us to make estimates, assumptions and judgments about matters that are inherently uncertain.

#### Revenue Recognition

Our primary source of revenue was from the sale of products and from collaborative arrangements. We recognize revenue from product sales when ownership of the product is transferred to and accepted by the customer, the sales price is fixed and determinable, and collectibility is reasonably assured. Provisions for returns and other adjustments related to sales are provided in the same period the related sales are recorded on the basis of historical rates of return. Historically, our returns have been insignificant.

Collaborative arrangements generally contemplate that our technology or intellectual property will be utilized to commercialize or produce certain pharmaceutical products and that we will receive certain revenues pursuant to these agreements. We recognize revenue from our collaborative arrangements according to Staff Accounting Bulletin No. 104, "Revenue Recognition." When necessary, we divide such agreements into separate units of accounting as required by Emerging Issues Task Force No. 00-21, "Revenue Arrangements with Multiple Deliverables" before using the applicable revenue recognition policy for each element within the agreement. Accordingly, we recognize revenues on performance milestones only when we have met specific targets or milestones as set forth in the contracts. We defer and recognize as revenue non-refundable payments received in advance that are related to the future

performance over the life of the related research project. We recognize reimbursements to fund research and development efforts as the qualified expenditures are made. Finally, royalty revenues are recognized when earned when the applicable sales are made.

#### Inventories

We state inventories at the lower of cost or market, determining cost on an average cost basis. We periodically review inventories and reduce items that we consider outdated or obsolete to their estimated net realizable value. We estimate reserves for excess and obsolete inventories based on inventory levels on hand, future purchase commitments, and current and forecast product demand. Our reserve level and as a result our overall profitability, is therefore subject to our ability to reasonably forecast future sales levels versus quantities on hand and existing purchase commitments. Forecasting of demand and resource planning are subject to extensive assumptions that we must make regarding, among other variables, expected market changes, overall demand, pricing incentives and raw material availability. Significant changes in these estimates could indicate that inventory levels are excessive, which would require us to reduce inventories to their estimated net realizable value. We also capitalize inventory costs associated with certain by-products, based on management's judgment of probable future commercial use and net realizable value.

In the highly regulated industry in which we operate, raw materials, work in progress and finished goods inventories have expiration dates that must be factored into our judgments about the recoverability of inventory cost. Additionally, if our estimate of a product's demand and pricing is such that we may not fully recover the cost of inventory, we must consider that in our judgment as well. In the context of reflecting inventory at the lower of cost or market, we will record an inventory reserve as soon as a need for such a reduction in net realizable value is determined.

#### Impairment of Long-lived Assets

Our long-lived assets consist primarily of product rights and property and equipment. In accordance with Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" (SFAS 144), we evaluate our ability to recover the carrying value of long-lived assets used in our business, considering changes in the business environment or other facts and circumstances that suggest their value may be impaired.

If, based on the preceding discussion, our management has concluded that impairment indicators exist, we will initially review by assessing the undiscounted cash flows expected to be derived from the asset or group of assets, comparing the lowest level of total expected undiscounted cash flow to the carrying value. If the carrying value of the asset or the group of assets exceeds the sum of the undiscounted cash flows, impairment is considered to exist. An impairment charge is assessed by comparing the assets' fair value to the carrying value. Fair value can be calculated by a number of different approaches, including discounted cash flow, comparables, market valuations or quoted market prices. The process and steps required to assess the possible impairments of assets, including the identification of possible impairment indicators, assessing undiscounted cash flows, selecting the appropriate discount rate, the calculation of the weighted average cost of capital and the discounts or premiums inherent in market prices requires a substantial amount of management discretion and judgment. If actual results differ from these estimates, or if we adjust these estimates in future periods, operating results could be significantly affected.

#### Research and Development Expenses

We have several activities, and their related costs, that are included in research and development expenses. These activities include primarily salaries and benefits of our direct employees, employee stock based compensation expense, facility costs, overhead costs, clinical trial costs and related trial product manufacturing costs, contracted services and subcontractor costs. Clinical trial costs include costs associated with contract research organizations. The billings that we receive from contract research organizations for services rendered may not be received for several months following the service. We accrue the estimated costs of the contract research organizations related services based on our estimate of management fees, site management and monitoring costs and data management costs. Our research and development department is in continuous communication with our contract research organizations to assess both their progress on the underlying study and the reasonableness of their cost estimates. Differences between estimated trial costs and actual have not been material to date, and any changes have been made when they become known. Under this policy, research and development expense can vary due to accrual adjustments related to the underlying clinical trials and the expenses incurred by the contract research organizations. As of September 30, 2008, we had €1,543 thousand of future payables under outstanding contracts with various contract research organizations that are not revocable. Most of these contracts are on a cost plus or actual cost basis.

#### Stock-Based Compensation

Under the provisions of Statement of Financial Accounting Standards (FAS) No. 123(R), "Share-Based Payment" (FAS 123R), employee stock-based compensation is estimated at the date of grant based on the employee stock award's fair value using the Black-Scholes option-pricing model and is recognized as expense ratably over the requisite service period, which is generally the vesting period, in a manner similar to other forms of compensation paid to employees.

The Black-Scholes option-pricing model requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock, the expected term of the award and the expected forfeiture rate. When establishing an estimate of the expected term of an award, we consider the vesting period of the award, our recent historical experience of employee stock option exercise, the expected volatility and a comparison to relevant peer group data.

We review our assumptions periodically and, as a result, we may change our assumptions used to value share based awards granted in future periods. Such changes may lead to a significant change in the expense we recognize in connection with share based payments.

In using the option pricing model that we have selected, changes in the underlying assumptions have the following effect on the resulting fair value output:

- 22 -

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An increase to the:	Results in a fair value estimate that is:
Price of the underlying share	Higher
Exercise price of option	Lower
Expected volatility of stock	Higher
Risk-free interest rate	Higher
Expected term of option	Higher

In our current valuation, we consider the volatility factor to be important factor in determining the fair value of the options granted. We have used 60.65% factor based on what we believe is a representative sample of similar biopharmaceutical companies. However, this sample is not perfect as it omits, for example, Italian companies, due to the fact that there are a limited number of companies such as ourselves publicly traded in the U.S. market. Significant changes to these estimates could have a material impact on the results of our operations.

#### Recent Accounting Pronouncements

Refer to Note 2, Recently Issued Accounting Standards in Summary of Significant Accounting Policies, for a discussion of new accounting standards.

## Results of Operations

The following table sets forth our results of operations:

(Unaudited, amounts in thousand of Euros except shares and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2007	2008	2007	2008
<b>Revenues:</b>				
Product sales to related party	€ 311	€ -	€ 2,147	€ 555
Product sales to third parties	852	1,210	1,328	3,565
Total product sales	1,163	1,210	3,475	4,120
Other revenues	1,819	635	1,904	2,278
Total revenues	2,982	1,845	5,379	6,398
<b>Operating costs and expenses:</b>				
Cost of goods sold	1,048	1,363	3,128	4,317
Research and development	4,258	2,505	10,289	7,873
General and administrative	1,550	1,560	4,583	6,360
Charges from related parties	124	95	526	444
Depreciation and amortization	221	286	467	845
Write-down of assets	-	3,052	13,740	3,052
	7,201	8,861	32,733	22,891
Operating loss	(4,219)	(7,016)	(27,354)	(16,493)
Interest income, net	360	15	1,009	173
Foreign currency exchange gain/(loss), net	(1,599)	1,152	(3,010)	(137)
Loss before income tax expense	(5,458)	(5,849)	(29,355)	(16,457)
Income tax expense	-	-	-	-
Net loss	€ (5,458)	€ (5,849)	€ (29,355)	€ (16,457)
<b>Net loss per share:</b>				
Basic and diluted net loss per share	€ (0.38)	€ (0.39)	€ (2.12)	€ (1.10)
Weighted average shares used to compute basic and diluted net loss per share	14,282,142	14,956,317	13,873,275	14,956,245

Three Months Ended September 30, 2008 Compared to Three Months Ended September 30, 2007

## Product sales

Our product sales were €1,210 for the three-month period ended September 30, 2008 compared to €1,163 for the comparable period in 2007, an increase of €47 or 4%. The increase was primarily due to an increase in demand for our products from our customers. Sales to a related party for the three-month period ended September 30, 2008 and 2007 represented 0% and 27% of the total product sales, respectively. The decrease in sales to a related party is primarily due to the fact that we did not recognize product sales to a related party for the three-month period ended September

30, 2008, amounting to €384, because one of the criteria stated by SAB 104 (“collectibility is reasonably assured”) was not met. Sales to third parties increased to €1,210 for the three-month period ended September 30, 2008 due to higher sales volume of sulglicotide. Sulglicotide is used by a South Korean manufacturer to produce a finished product.

Other revenues

Our other revenues were €635 and €1,819 for the three-month periods ended September 30, 2008 and 2007, respectively. Fluctuation versus the prior-year period is primarily due to timing on the recognition of reimbursement from Sigma Tau, under a cost sharing arrangement entered into during the third quarter of 2007, of certain costs incurred in our ongoing phase III clinical trial of Defibrotide to treat severe VOD.



#### Cost of goods sold

Our cost of goods sold was €1,363 for the three months ended September 30, 2008 compared to €1,048 for the comparable period in 2007. Cost of goods sold as a percentage of product sales was 113% for the three-month period ended September 30, 2008 compared to 90% for the same period in 2007. The decrease in gross margin was primarily due to the non-recognition of product sales to a related party, Sirton, during the three-month period ended as of September 30, 2008. The Company did not recognize product sales due to Sirton's poor financial condition, which caused concerns over the collectibility of such receivables.

If we would have recognized such revenue, cost of goods sold as a percentage of product sales would have been 86% for the three-month period ended September 30, 2008 compared to 90% for the same period in 2007. The increase in gross margin would have been primarily due to change in product mix.

#### Research and development expenses

We incurred research and development expenses of €2,505 during the three-month period ended September 30, 2008 compared to €4,258 for the comparable period in 2007. Research and development expenses were primarily for the development of Defibrotide to treat and prevent VOD. The decrease from the comparable period in 2007 is the timing of performance of clinical research organizations and regulatory activities. Also contributing to the research and development expenses was stock based compensation of €69 for the three-month period ended September 30, 2008 compared to €101 for the comparable period in 2007.

#### General and administrative expenses

Our general and administrative expenses were €1,560 and €1,550 for the three-month period ended September 30, 2008 and 2007, respectively. The 2008 general and administrative expenses reflect the establishment of an allowance for doubtful accounts of €263. General and administrative expenses include general corporate expenses, legal and other professionals fees and stock based compensation expense of €343 for the period ended September 30, 2008 compared to €358 for the comparable period in 2007.

#### Depreciation and amortization expense

Depreciation and amortization expense was €286 for the three-month period ended September 30, 2008 compared to €221 for the comparable period in 2007. Depreciation expense excludes depreciation of our manufacturing facilities which are included in cost of goods sold.

#### Write-down of assets

Write-down of assets include the write-down of acquired trademarks for Defibrotide (sold as Noravid and Prociclide in Italy), the Italian marketing authorizations for Noravid and Prociclide (the "Italian MAs"), and the Company's patents. The trademarks for Defibrotide and the Italian MAs have been written-down due to the expiration and non-renewal by the Company of the distribution agreement with Crinos, who distributed Noravid and Prociclide in Italy to treat and prevent vascular disease with risk of thrombosis. Because the Company has decided not to distribute Noravid and Prociclide in Italy for this purpose, doubt has been raised concerning the recoverability of future cash flows expected to be derived from these assets. Therefore, the Company has impaired the remaining net book value of the trademarks for Defibrotide and Italian MAs amounting to €847 and €848, respectively. In addition, the Company wrote down €877 of the book value of semi-finished and finished Noravid and Prociclide in our inventory, including such products expected to be returned by Crinos. As of September 30, 2008, we wrote down the remaining carrying value of the Company's patents amounting to €480, because no future benefits from these patent rights are reasonably

assured.

Foreign currency exchange gain (loss)

Our foreign currency exchange gain (loss) is primarily due to remeasurement at September 30, 2008 of U.S. dollar cash balances.

Interest income, net

Interest income, net amounted to €15 and €360 for the three-month period ended September 30, 2008 and 2007, respectively. Gross interest income amounted to €101 and €458 for the three-month period ended September 30, 2008 and 2007, respectively, a decrease of €357. The decrease is a result of a lower amount of invested funds in the 2008 period and decrease in interest rates. Interest expense totaled €86 and €98 for the three-month period ended September 30, 2008 and 2007.

- 25 -

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#### Net loss

Our net loss was €5,849 for the three-month period ended September 30, 2008 compared to €5,458 for the comparable period in 2007. The difference is primarily due to the write-down of assets amounting to €3,052 and a reduction in reimbursement of research and development costs under a cost sharing agreement entered into with Sigma-Tau, offset by foreign exchange gain and lower research and development expenses.

#### Nine Months Ended September 30, 2008 Compared to Nine Months Ended September 30, 2007

#### Product sales

Our product sales were €4,120 for the nine-month period ended September 30, 2008 compared to €3,475 for the comparable period in 2007, an increase of €645 or 19%. The increase was primarily due to an increased demand for our products from our customers. Sales to a related party for the nine-month periods ended September 30, 2008 and 2007 represented 13% and 62% of the total product sales, respectively, and decreased 74% to €555. The decrease in sales to a related party is primarily due to the fact that we did not recognize product sales to a related party for the quarters ended June and September 30, 2008, amounting to €934 because one of the criteria stated by SAB 104 (“collectibility is reasonably assured”) was not met. Sales to third parties increased to €3,565 for the nine-month period ended September 30, 2008 due to higher sales volume of sulglicotide. Sulglicotide is used by a South Korean manufacturer to produce a finished product.

#### Other revenues

Our other revenues were €2,278 and €1,904 for the nine-month period ended September 30, 2008 and 2007, respectively. Other revenues primarily refers to a cost sharing arrangement with Sigma-Tau, entered into in 2007, under which Sigma-Tau agreed to reimburse us for 50% of certain costs incurred in our ongoing phase III clinical trial of Defibrotide to treat severe VOD.

#### Cost of goods sold

Our cost of goods sold was €4,317 for the nine months ended September 30, 2008 compared to €3,128 for the comparable period in 2007. Cost of goods sold as percent of product sales was 105% for the nine-month period ended September 30, 2008 compared to 90% for the same period in 2007. The decrease in gross margin was primarily due to the non-recognition of product sales to a related party, Sirton, during the three-month periods ended as of June 30 and September 30, 2008. The Company did not recognize product sales due to Sirton’s poor financial condition, which caused concerns over the collectibility of such receivables.

If we would have recognized such revenue, cost of goods sold as percentage of product sales would have been 85% for the nine-month period ended September 30, 2008 compared to 90% for the same period in 2007.

#### Research and development expenses

We incurred research and development expenses of €7,873 during the nine-month period ended September 30, 2008 compared to €10,289 for the comparable period in 2007. Research and development expenses for the period ended September 30, 2008 are net of €791 government grants accrued as a reduction of expense. Excluding such grants, research and development expenses would have been €8,664 and €10,289 for the nine-month periods ended September 30, 2008 and 2007, respectively. The expenses were primarily for the development of Defibrotide to treat and prevent VOD. The difference between the periods is primarily due to the timing on performing research and development activities such as costs for our clinical trials including clinical research organization charges, toxicology studies and

other costs associated with the screening and enrollment of patients for our Phase III clinical trial of Defibrotide to treat VOD. Also contributing to the variance was stock based compensation of €317 for the nine-month period ended September 30, 2008 compared to €262 for the comparable period in 2007.

#### General and administrative expenses

Our general and administrative expenses were €6,360 and €4,583 for the nine-month period ended September 30, 2008 and 2007, respectively. The 2008 general and administrative expenses reflect the establishment of an allowance for doubtful accounts of €1,767. Excluding such allowance, general and administrative expense would have been €4,593. General and administrative expense include general corporate expenses, personnel, legal and other professionals fees and stock based compensation expense of €1,206 for the period ended September 30, 2008 compared to €888 for the comparable period in 2007.

#### Depreciation and amortization expense

Depreciation and amortization expense was €845 for the nine-month period ended September 30, 2008 compared to €467 for the comparable period in 2007. Depreciation expense excludes depreciation of our manufacturing facilities which are included in the cost of goods sold.

#### Write-down of assets

Write-down of assets include the write-down of acquired trademarks for Defibrotide (sold as Noravid and Prociclide in Italy), the Italian marketing authorizations for Noravid and Prociclide (the “Italian MAs”), and the Company’s patents. The trademarks for Defibrotide and the Italian MAs have been written-down due to the expiration and non-renewal by the Company of the distribution agreement with Crinos, who distributed Noravid and Prociclide in Italy to treat and prevent vascular disease with risk of thrombosis. Because the Company has decided not to distribute Noravid and Prociclide in Italy for this purpose, doubt has been raised concerning the recoverability of future cash flows expected to be derived from these assets. Therefore, the Company has impaired the remaining book value of the trademarks for Defibrotide and Italian MAs amounting to €847 and €848, respectively. In addition, the Company wrote down €877 of the book value of semi-finished and finished Noravid and Prociclide in our inventory, including such products expected to be returned by Crinos. As of September 30, 2008, we wrote down the remaining carrying value of the Company’s patents amounting to €480, because no future benefits from these patent rights are reasonably assured.

#### Foreign currency exchange gain (loss)

Our foreign currency exchange gain (loss) is primarily due to remeasurement at September 30, 2008 of U.S. dollar cash balances.

#### Interest income, net

Interest income, net amounted to €173 and €1,009 for the nine-month period ended September 30, 2008 and 2007, respectively. Gross interest income amounted to €437 and €1,285 for the nine-month period ended September 30, 2008 and 2007, respectively, a decrease of €848. The decrease is a result of a lower amount of invested funds in the 2008 period and decrease in interest rates. Interest expense totaled €264 and €276 for the nine-month period ended September 30, 2008 and 2007, respectively.

#### Net loss

Our net loss was €16,457 for the nine-month period ended September 30, 2008 compared to €29,355 for the comparable period in 2007. The difference was primarily due to write-down of assets acquired from Crinos amounting to €13,740, foreign exchange gain, and lower research and development expenses, offset by an increase in general and administrative expenses due to the allowance for doubtful accounts of €1,767.

#### Liquidity and Capital Resources

During the nine-month period ended September 30, 2008, we used approximately €11,092 of cash to fund operations and working capital requirements and approximately €598 for capital expenditures and acquisition of intangible assets. We funded these amounts from the following sources:

- €6,398 in gross revenues; and
- €25,964 from cash available at December 31, 2007.

At September 30, 2008, we had an aggregate of €4,952 in debt outstanding.

- 27 -

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We expect to devote substantial resources to continue our research and development efforts, on regulatory expenses, and to expand our licensing and collaboration efforts. Our funding requirements will depend on numerous factors including:

- the scope and results of our clinical trials;
- whether we are able to commercialize and sell Defibrotide for the uses for which we are developing;
  - advancement of other product candidates in development;
  - the timing of, and the costs involved in, obtaining regulatory approvals;
  - the cost of manufacturing activities;
  - the costs associated with building a future commercial infrastructure;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and results of such litigation; and
  - our ability to establish and maintain additional collaborative arrangements.

We do not expect our revenues to increase significantly until we successfully obtain FDA and European regulatory marketing approval for, and begin selling, Defibrotide for the treatment or prevention of VOD. We believe that some of the key factors that will affect our internal and external sources of cash are:

- our ability to obtain FDA and European regulatory marketing approval for and to commercially launch Defibrotide to treat severe VOD;
- the success of our other clinical and pre-clinical development programs, including development of Defibrotide to prevent VOD and to treat multiple myeloma;
  - the receptivity of the capital markets to financings of biotechnology companies;
- our ability to enter into additional collaborative arrangements with corporate and academic collaborators and the success of such relationships; and
- Sirton's ability to make payments of accounts receivable owed to us and our ability to enforce the related guaranty received from FinSirton.

We have incurred net losses since 2004 and we expect to generate losses from operations for the foreseeable future, primarily due to research and development costs for Defibrotide to treat and prevent VOD. We have not generated any revenues from our planned principal operations and we are dependent upon significant financing or alternative funding to provide the working capital necessary to develop and commercialize Defibrotide. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approval for Defibrotide, successfully complete any post-approval regulatory obligations, and successfully commercialize Defibrotide. We may continue to incur substantial operating losses even if we begin to generate revenues from Defibrotide, if approved, and we may never become profitable. As of September 30, 2008 we had €13,579 in cash and cash equivalents. Our existing cash and cash equivalents and securities available for sale are not sufficient to fund our planned operations beyond the second quarter of 2009. Accordingly, we implemented a cost

savings initiative to reduce operating expenses and we continue to seek additional areas where we can reduce costs. However, we will also need to raise additional funds. Financing or alternative means of funding may not be available on acceptable terms, or at all, and our failure to raise capital will negatively impact our ability to continue as a going concern, our growth plans, and our financial condition and results of operations. Furthermore, additional equity financing may be dilutive to our shareholders, and debt financing, if available, may involve significant cash payment obligations and covenants and/or financial ratios that would restrict our ability to operate our business. In addition, alternative funding, such as strategic partnerships, may not be available. If we are unable to obtain sufficient capital, we may be required to cease conducting business, or reduce the scope of, or delay or eliminate some or all of our planned development and commercialization activities.

Italian law provides for limits and restrictions on our issuance of debt securities, described in our risk factor in our Form 20-F for the year ended December 31, 2007 entitled, “We are restricted under Italian law as to the amount of debt securities that we may issue relative to our equity.” In order to issue new equity or debt securities convertible into equity, with some exceptions, we must increase our authorized capital through a process described in our risk factor in our Form 20-F for the year ended December 31, 2007 entitled, “The process of seeking to raise additional funds is cumbersome, subject to the verification of a notary public as to compliance with our bylaws and applicable law and may require prior approval of our shareholders at an extraordinary meeting.”



#### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

#### Contractual Obligations and Commitments

During the period ended September 30, 2008, there have been no material changes outside the ordinary course of our business to our major contractual obligations and commitments set forth in our annual report on Form 20-F.

#### Quantitative and Qualitative Disclosures about Market Risk

Market risk represents the risk of loss arising from adverse changes in market rates and foreign exchange rates. The carrying amounts of cash and cash equivalents, accounts receivable and other receivables, and the interest rate on our debt with floating rates represents our principal exposure to credit risk in relation to our financial assets.

As of September 30, 2008, substantially all of our cash and cash equivalents were held in accounts at financial institutions located in the Republic of Italy and the United States, that we believe are of acceptable credit quality. We invest our cash in liquid instruments that meet high credit quality standards and generally have maturity at the date of purchase of less than three months. We are exposed to exchange rate risk with respect to certain of our cash balances that are denominated in U.S. dollar. As of September 30, 2008, we held a cash balance of \$11,620 that was denominated in U.S. dollars. This dollar-based cash balance is available to be used for future acquisitions and other liquidity requirements that may be denominated in such currency. We are exposed to unfavorable and potentially volatile fluctuations of the U.S. dollar against the Euro (our functional currency).

Substantially all of our current revenue generating operations are transacted in, and substantially all of our assets and liabilities are denominated in, the Euro. In the future, we expect to transact business in the United States dollar and other currencies. The value of the Euro against the United States dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions. Any change in the value of the Euro relative to other currencies that we transact business with in the future could materially and adversely affect our cash flows, revenues and financial condition. To the extent we hold assets denominated in United States dollars, any appreciation of the Euro against the United States dollar could result in a charge to our operating results and a reduction in the value of our United States dollar denominated assets upon remeasurement.