Gentium S.p.A.
Form 6-K
June 26, 2008

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 June, 2008.

Commission File Number 000-51341

Gentium S.p.A.
(Translation of registrant's name into English)

Piazza XX Settembre 2, 22079 Villa Guardia (Como), Italy
(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 S Form 40-F o

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 o No S

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

The Registrant's press release and quarterly report for the period ended March 31, 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.

Exhibit	**Description**
1	Press release, dated June 26, 2008.
2	Quarterly report for the period ended March 31, 2008.

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:Chief Financial Officer

Date: June 26, 2008

INDEX TO EXHIBITS

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1	Press release, dated June 26, 2008.
2	Quarterly report for the period ended March 31, 2008.

Exhibit 1

PRESS RELEASE

FOR IMMEDIATE RELEASE

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**Gentium Reports First Quarter Financial Results;
Provides Financial and Clinical Update**

Villa Guardia (Como), Italy (June 26, 2008) - Gentium S.p.A. (NASDAQ: GENT) (the "Company") today reported financial results for the quarter ended March 31, 2008. Highlights of the first quarter of 2008 and recent weeks through June 26, 2008, include:

--Continued updates of the ongoing Phase III clinical trial in the U.S., which is evaluating the Company's lead product, Defibrotide, as a potential treatment for patients with Veno-Occlusive Disease ("VOD") with multiple organ failure ("Severe VOD"). In January the company announced the Data Safety Monitoring Board ("DSMB") conducted a safety analysis of Defibrotide as part of the interim analysis and concluded that there were no safety concerns. Additionally, the DSMB evaluated stratification between the prospective treatment and historical control arms and indicated that the groups appear to be balanced. However, the DSMB asked the Company to clarify and supplement certain trial data in order to complete the remainder of the interim analysis. After providing additional data, the Company announced in June that the DSMB had reconfirmed their previous finding regarding safety and patient stratification, but recommended reconfirmation of the patient enrollment criteria, and "data clean-up" as is stated in the trial protocol. The Company has concluded enrollment in the study with 86 patients in the historical control group and 101 patients in the treatment arm

-- Progress has been made with the Company's Phase II/III clinical trial in Europe which is evaluating Defibrotide for the prevention of VOD in children. In June, the Company announced that the DSMB concluded that there were no significant safety concerns, the prophylactic treatment arm (Defibrotide) and the control arm (no drug) were well balanced, and there was no evidence of clinical futility in the trial. Furthermore, the DSMB indicated that the results to date were satisfactory and recommended that the trial continue to accrue patients. The DSMB recommended increasing total patient enrollment to 180 patients per arm from 135 patients per arm to achieve a more statistically significant benefit of Defibrotide over the control. Currently, there are 142 patients in the treatment arm and 144 patients in the control arm. Additionally, the Company announced that following discussions with the EMEA, there is the possibility of an accelerated review for Defibrotide in this indication.

Clinical Highlights and Outlook

Commenting on Gentium's clinical progress during the quarter, Laura Ferro, M.D., Chairman and Chief Executive Officer, said, "We are working with an independent medical review committee to ensure that the proper enrollment criteria were applied when identifying historical control patients for the Defibrotide Phase III treatment trial. Additionally, we are working closely with the European clinical sites to support the recruitment of the additional patients needed for the Phase II/III pediatric prevention trial."

Dr. Ferro continued, "We look forward to announcing top-line results from the treatment trial in the fourth quarter of 2008 and top-line results from the pediatric prevention trial in the first half of 2009. We remain encouraged that Defibrotide has the potential to not only treat Severe VOD, but also prevent its occurrence."

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 March 31, 2008, €1.00 = $ 1.5812.

For the first quarter ended March 31, 2008 compared with the prior year's first quarter:

- Total revenues were €2.68 million, compared with €1.25 million
- Operating costs and expenses were €7.53 million, compared with €5.42 million
- Research and development expenses, which are included in operating costs and expenses, were €3.61 million, compared with €2.74 million
- Operating loss was €4.84 million, compared with €4.16 million
- Interest income, net, was €0.1 million, compared with €0.2 million
- Pre-tax loss was €6.08 million, compared with €4.77 million
- Net loss was €6.08 million, compared with €4.77 million
- Basic and diluted net loss per share was €0.41 compared with €0.36 per share

Operating Results and Trends

The fluctuation in product sales revenues for the three month period compared with the prior-year periods is primarily due to varying demand for our products from our customers. Total product sales revenues for three months ended March 31, 2008 increased by €0.5 million, or 44%, compared with the same period in 2007. Sales to affiliates represented 30% and 77% of the total product sales in the three months ended March 31, 2008 and 2007, respectively. Sales to third parties increased to €1.20 million mainly 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 Sirton.

Other revenues were €0.9 million for the three month period ended March 31, 2008, compared to €0.04 million in 2007. The increase is mainly attributable to the reimbursement of certain costs incurred in the Company's Phase III clinical trial of Defibrotide to treat Severe VOD under a cost-sharing agreement entered into with Sigma-Tau Inc.

Cost of goods sold was €1.42 million for the three-month period ended March 31, 2008 compared to €1.08 million in 2007. Cost of goods sold as a percentage of product sales was 81% in 2008 and 89% in 2007. The increase in margin is mainly due to changes in product mix and higher sales prices.

Research and development spending increased during the three-month period in 2008 compared with 2007, primarily due to the costs 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. Growth in headcount and outside services to support increased activity in our clinical trials, including clinical product production costs, contract research organization expenses, regulatory activities, toxicology studies and stock-based compensation expenses also contributed to increased research and development expenses.

The Company had 87 employees as of March 31, 2008, compared with 81 as of March 31, 2007. Other general and administrative expense increases were primarily the result of increased headcount and facilities related expenses, general corporate expenses and stock based compensation expense.

Interest income, net, decreased to € 0.1 million in the three-month period ended March 31, 2008 over the same period in 2007. Interest income amounted to €0.2 million and € 0.3 million in the three months ended March 31, 2008 and 2007, respectively, a decrease of € 0.1 million. The decrease is due to a lower amount of invested funds and decrease in interest rates. Interest expense totaled € 0.1 million in both the three months ended March 31, 2008 and 2007.

The Company ended the first quarter of 2008 with €20.36 million in cash and cash equivalents, compared with cash and cash equivalents of €25.96 million as of December 31, 2007.

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," "potential" 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

(Tables to follow)

GENTIUM S.p.A.
Balance Sheets
(Amounts in thousands, except share and per share data)

	December 31, 2007	March 31, 2008 *(unaudited)*
ASSETS		
Cash and cash equivalents	€ 25,964	€ 20,363
Accounts receivable	805	1,084
Accounts receivable from related parties	4,149	4,816
Inventories, net	1,510	1,681
Prepaid expenses and other current assets	4,844	5,394
Total Current Assets	37,272	33,338
Property, manufacturing facility and equipment, at cost	20,590	20,810
Less: Accumulated depreciation	9,046	9,347
Property, manufacturing facility and equipment, net	11,544	11,463
Intangible assets, net of amortization	2,592	2,499
Available for sale securities	525	524
Other non-current assets	26	30
Total Assets	€ 51,959	€ 47,854
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable	€ 9,583	€ 10,443
Accounts payable to Crinos	4,000	4,000
Accounts payable to related parties	2,095	2,568
Accrued expenses and other current liabilities	1,223	1,385
Current portion of capital lease obligations	107	108
Current maturities of long-term debt	1,262	1,323
Total Current Liabilities	18,270	19,827
Long-term debt, net of current maturities	4,421	4,237
Capital lease obligation	223	207
Termination indemnities	686	671
Total Liabilities	23,600	24,942
Share capital (par value: €100; 18,454,292 shares authorized; 14,946,317 and 14,956,317 shares issued at December 31, 2007 and March 31 2008, respectively)	14,946	14,956

Additional paid in capital		88,618		89,245
Accumulated other comprehensive income/(loss)		(2)		(4)
Accumulated deficit		(75,203)		(81,285)
Total Shareholders' Equity		28,359		22,912
Total Liabilities and Shareholders' Equity	€	51,959	€	47,854

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

	Three Months Ended March 31,	
	2007	**2008**
Revenues:		
Product sales to related party	€ 951	€ 555
Product sales to third parties	267	1,199
Total product sales	1,218	1,754
Other revenues	35	935
Total revenues	1,253	2,689
Operating costs and expenses:		
Cost of goods sold	1,088	1,429
Research and development	2,741	3,611
General and administrative	1,291	2,020
Depreciation and amortization	75	277
Charges from related parties	226	195
	5,421	7,532
Operating loss	(4,168)	(4,843)
Interest income, net	263	124
Foreign currency exchange (loss), net	(868)	(1,363)
Loss before income tax expense	(4,773)	(6,082)
Income tax expense	-	-
Net loss	€ (4,773)	€ (6,082)
Net loss per share:		
Basic and diluted net loss per share	€ (0.36)	€ (0.41)
Weighted average shares used to compute basic and diluted net loss per share	13,117,049	14,956,096

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

	Three Months Ended March 31, 2007	2008
Cash Flows From Operating Activities:		
Net loss	€ (4,773)	€ (6,082)
Adjustments to reconcile net loss to net cash used in operating activities:		
Unrealized foreign exchange loss	815	1,396
Depreciation and amortization	278	459
Stock based compensation	241	599
Deferred income	(35)	-
Loss on fixed asset disposal	-	7
Changes in operating assets and liabilities:		
Accounts receivable	(897)	(946)
Inventories	(347)	(171)
Prepaid expenses and other current and noncurrent assets	109	(554)
Accounts payable and accrued expenses	1,034	1,340
Net cash used in operating activities	**(3,575)**	**(3,952)**
Cash Flows From Investing Activities:		
Capital expenditures	(228)	(227)
Intangible assets expenditures	(120)	(66)
Net cash used in investing activities	**(348)**	**(293)**
Cash Flows From Financing Activities:		
Proceeds from private placements, net of offering expense	34,485	-
Proceeds from warrant and stock option exercises, net	549	38
Repayments of long-term debt	(82)	(124)
Proceeds from short term borrowings	-	217
Principal payment of capital lease obligations	-	(15)
Net cash provided by financing activities	**34,952**	**116**
Increase/(decrease) in cash and cash equivalents	31,029	(4,129)
Effect of exchange rate on cash and cash equivalents	(827)	(1,472)
Cash and cash equivalents, beginning of period	10,205	25,964
Cash and cash equivalents, end of period	€ 40,407	€ 20,363

Exhibit 2

GENTIUM S.p.A.

QUARTERLY REPORT

For the period ended March 31, 2008

GENTIUM S.p.A.
QUARTERLY REPORT, MARCH 31, 2008
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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 mayacquire 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 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

GENTIUM S.p.A.
Balance Sheets
(Amounts in thousands except share and per share data)

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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**" or "**we**") 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 Veno-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 exploring other potential uses of defibrotide, including to treat a cancer of the plasma cell known as multiple myeloma. In addition, we are exploring a potential use of oligotide, another product derived from natural DNA, to treat diabetic nephropathy. These uses of defibrotide and oligotide are currently in development, and we do not sell defibrotide or oligotide 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. We have an affiliated company, Sirton Pharmaceuticals S.p.A. (Sirton), who processes defibrotide into the finished drug, and then we sell that finished drug in Italy to treat and prevent vascular disease with risk of thrombosis. The other active pharmaceutical ingredients that we manufacture are urokinanse, calcium heparin, sodium heparin and sulglicotide. 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.

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 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 three months ended March 31, 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.

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. To mitigate the credit risks associated with our largest customer, Sirton, we obtained a guarantee from its parent company, FinSirton and we monitor the credit worthiness of FinSirton. 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 primarily 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 requires 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 month periods ended March 31, 2007 and 2008, was €(4,806) and €(6,084), respectively.

Recently Adopted Accounting Pronouncements

In June 2007, the Accounting Standards Board ("FSAB") ratified EITF Issue No. 07-3, "*Accounting for Nonrefundable Advance Payments of Goods or Services Received for Use in Future Research and Development Activities*" (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods and services that will be used or rendered in future R&D activities pursuant to executory contractual arrangements be deferred and recognized as an expense in the period that the related goods are delivered or services are performed. EITF 07-3 was effective for us beginning on January 1, 2008. The implementation of this standard did not have a material impact on our financial position, results of operations or cash flows.

In September 2006, the FASB issued SFAS No. 157, "*Fair Value Measurements*" (FAS 157), which provides enhanced guidance for using fair value to measure assets and liabilities. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new circumstances. FAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. FAS 157 was effective for us beginning January 1, 2008. The implementation of this standard did not have a material impact on our financial position, results of operations or cash flows.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities - Including an Amendment of FASB Statement No. 115* ("SFAS No. 159"). SFAS No. 159 permits, but does not require, entities to choose to measure certain financial instruments and other assets and liabilities at fair value on an instrument-by-instrument basis. The objective of SFAS No. 159 is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. In adopting SFAS No. 159, we did not elect to measure any new

assets or liabilities at their respective fair values, and therefore, the adoption of SFAS No.159 did not have an impact on our results of operations and financial position.

Recently Issued Accounting Standards:

In December 2007, the FASB ratified the final consensuses in Emerging Issues Task Force (EITF) Issue No. 07-1, "*Accounting for Collaborative Arrangements*" (EITF 07-1), which provides guidance for the income statement presentation of transactions with third parties and payments between parties to a collaborative arrangement, along with disclosure of the nature and purpose of the arrangement. EITF 07-1 is effective for us beginning January 1, 2009. We do not expect this pronouncement to have a material effect on our financial statements.

In December 2007, the FSAB issued Statement of Financial Accounting Standards (SFAS) No. 141R, *Business Combinations*, which will significantly change the accounting for business combinations. SFAS 141R is effective for fiscal years beginning after December 15, 2008. We are currently evaluating the effects, if any, that FAS 141R will have on our financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements- An Amendment of ARB No. 51,* which established new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS No. 160 is effective for the Company beginning January 1, 2009. We do not expect this pronouncement to have a material effect on our financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosure About Derivate Instruments and Hedging Activities- an amendment of SFAB Statement No. 133,* which enhances the disclosure requirements for derivates 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.

3. RELATED PARTIES

The Company has significant relationships with two privately owned Italian companies, FinSirton and its wholly owned subsidiary, Sirton. FinSirton, the parent company of several businesses, is the Company's largest shareholder (approximately 25% ownership at March 31, 2008) and originally the sole shareholder. The Company's Chief Executive Officer serves in the same capacity for FinSirton and is a member of the 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 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. As a result, approximately 78% and 32% of the Company's product sales for the three month period ended March 31, 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, which expires on November 30, 2009, pursuant to which Sirton manufactures the finished defibrotide ampoules and capsules that the Company then sells to Crinos. Accordingly, the Company expects that product sales to Sirton will continue to decrease.

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 month period ended March 31, 2007 and 2008 amounted to €50 and €51, respectively. See Note 13 for such operating lease commitments.

For the three month period ended March 31, 2007 and 2008, the Company had the following transactions with FinSirton and Sirton:

	March 31, 2007	March 31, 2008
Revenues		
Products Sales	€ 951	€ 555
Expenses		
Cost of goods sold	-	98
Research and Development	-	25
Charges from related parties	226	195
Total	€ 226	€ 318

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

	December 31, 2007	March 31, 2008
Accounts Receivable - Sirton	€ 4,147	€ 4,813
Accounts Receivable - FinSirton	2	3
	4,149	4,816
Accounts Payable - Sirton	2,077	2,555
Accounts Payable - FinSirton	18	13
	€ 2,095	€ 2,568

Sirton has been unable to make timely payments on outstanding receivables. As a result, 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 account payable to Sirton, recognizing itself as joint debtor. Subsequent to March 31, proceeds from accounts receivables from Sirton amounted to €900 thousand.

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 Reunite 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. 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.

The following table outlines the nature and amount of other revenue recognized under the agreement in the accompanying financial statements:

		March 31, 2007		March 31, 2008
Research and development cost reimbursement	€	-	€	903
Upfront payments recognized ratably		35		-
Total	€	35	€	903

5. INVENTORIES

The Company's inventories consisted of:

		December 31, 2007		March 31, 2008
Raw materials	€	385	€	358
Semi-finished goods		845		785
Finished goods		280		538
Total	€	1,510	€	1,681

As of December 31, 2007 and March 31, 2008, the Company reserved €547 to adjust a by-product cost to its net realizable value and to account for excess inventory compared with forecasted sales.

6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	December 31, 2007	March 31, 2008
VAT receivables	€ 3,776	€ 3,531
Other prepaid expenses and current assets	1,068	1,863
Total prepaid expenses and current assets	€ 4,844	€ 5,394

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.

At December 31, 2007 and March 31, 2008, other prepaid expenses and current assets include the accrual of a €794 and €1,520, respectively, receivable 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. Subsequent to March 31, reimbursements from Sigma-Tau Inc. amounted to €1,030.

7. PROPERTY, MANUFACTURING FACILITY AND EQUIPMENT

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

	December 31, 2007			March 31, 2008		
	Cost	Accumulated Depreciation	Net book value	Cost	Accumulated Depreciation	Net book value
Land and building	€ 2,683	1,185	1,498	€ 2,683	1,202	1,481
Plant and machinery	14,434	6,700	7,734	14,498	6,918	7,580
Industrial equipment	1,085	635	450	1,263	650	613
Other	1,047	380	667	1,053	404	649
Leasehold improvements	295	78	217	312	96	216
Internally Developed Software	458	68	390	484	77	407
Construction in progress	588	-	588	517	-	517
	€ 20,590	9,046	11,544	€ 20,810	9,347	11,463

Property, manufacturing facility and equipment include €460 and €460 at December 31, 2007 and March 31, 2008, respectively, of lab instruments acquired under capital lease agreements. The related accumulated depreciation at December 31, 2007 and March 31, 2008 was €47 and €58, respectively.

8. CREDIT FACILITY, LONG-TERM DEBT AND LEASES

Long term debt, net of current maturities consists of:

	December 31, 2007	March 31, 2008
a) Mortgage loan bearing interest at the Euribor 6 month rate plus 1.0% due June 2014 (5.71% and 5.73% at December 31, 2007 and March 31, 2008, respectively)	2,600	2,600
b) Equipment loan secured by marketable securities, bearing interest at the Euribor 3 months rate plus 1.70% due April 2011 (6.38% and 6.43% at December 31, 2007 and March 31, 2008, respectively)	919	919
c) Equipment loan bearing interest at the Euribor 3 months rate plus 1.20% due June 2011 (4.86% and 5.93% at December 31, 2007 and March 31, 2008 respectively)	750	750
d) Financing loan bearing interest at the Euribor 1 months rate plus 1.00% due December 2011 (5.29% and 5.36% at December 31, 2007 and March 31, 2008, respectively)	409	387
e) Equipment loans secured by the underlying equipment pursuant to the Sabatini Law, interest at 2.1%	306	262
f) Research loan from the Italian Ministry for University and Research, interest at 1% per annum, due January 2012	318	283
g) Financing loan bearing interest at the Euribor 3 months rate plus 1.00% due December 2011 (4.68% and 5.36% at December 31, 2007 and March 31, 2008, respectively)	193	182
h) Equipment loan bearing interest at the Euribor 3 months rate plus 0.80% due December 2011 (5.48% and 5.53% at December 31, 2007 and March 31, 2008, respectively)	188	177
	5,683	5,560
Less current maturities	1,262	1,323
Total	€ 4,421	€ 4,237

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 March 31, 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 March 31, 2008 are as follows:

March 31,	
2008	€ 1,323
2009	1,247
2010	1,170
2011	820
2012	400
Thereafter	600
Total	€ 5,560

9. 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 March 31, 2008, respectively. On March 31, 2008, the authorized shares were 18,454,292. Authorized capital is as follows:

	December 31, 2007	March 31, 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 March 31, 2008, the Company issued 22,734 ordinary shares upon exercise of these warrants for proceeds of $216 (€170).

In connection with the 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 March 31, 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 the 2005 private placement, 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 March 31, 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 the 2006 private placement, 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 March 31, 2008, we had issued 143,920 ordinary shares upon exercise of these warrants for proceeds of $2,087 (€1,490).

The followings is a summary of outstanding warrants as of March 31, 2008:

	Number of warrant issued	Number of warrant exercised	Number of warrant 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	988,612	846,300

10. 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 March 31, 2008.

	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	221,060
Number of options exercised	60,000	-	-
Number of shares cancelled/expired	-	-	4,000
Number of shares available for grant	-	-	774,940

The Company issued 114,560 stock options in the first quarter of 2008. The weighted average grant-date fair market value of options granted to officers, employees, directors and consultants for the three months ended March 31, 2007 and 2008 were $10.49 and $7.65, 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 March 31, 2007	Three months ended March 31, 2008
Risk free interest rate	4.55%	2.60%
Expected dividend yield	-	-
Expected stock price volatility	60.00%	60.65%
Expected term	5.00	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 expense over the service period, which is generally the vesting period. The Company recorded non-cash compensation expense of €241 and €599 for the three months ended March 31, 2007 and 2008, respectively, as follows:

	March 31, 2007	March 31, 2008
Cost of goods sold	14	28
Research and development	60	124
General and administrative	167	446
Total employee stock-based compensation expense	241	599

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 March 31, 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 March 31, 2008, total compensation cost not yet recognized was €3,412, 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 March 31, 2007 and 2008, options outstanding to consultants amounted to 110,000 and 105,000, respectively. There were 10,000 non-employee share options exercised during the quarter ended March 31, 2008. Cash received on stock options exercised amounted to $56 (€38).

11. 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 14,171 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.

12. FAIR VALUE MEASUREMENT

Effective January 1, 2008, we implemented FAS 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.

FAS 157 defines fair value, provides a framework for measuring fair value, and requires expanded disclosures regarding fair value measurements. FAS 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, FAS 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. We are evaluating the impact, if any, this Standard will have on our non-financial assets and liabilities.

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 are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. 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 March 31, 2008:

(in thousands of euro)	Total Carrying Value at March 31, 2008	Fair Value Measurements at March 31, 2008 using Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash and cash equivalents	€ 20,363	€ 20,363	€ —	€ —
Available for sale securities	524	524	—	—
Total	€ 20,887	€ 20,887	€ -	€ -

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 March 31, 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.

13. COMMITMENTS AND CONTINGENCIES

Future minimum lease payments that are non-cancellable under operating and capital leases as of March 31, 2008 are:

	Operating Leases	Capital Leases
March 31, 2009	€ 199	123
March 31, 2010	199	73
March 31, 2011	197	73
March 31, 2012	151	73
March 31, 2013	30	3
Thereafter	23	-
Total minimum lease payments	€ 799	345
Less: imputed interest		30
Present value of net minimum lease payment		315
Less: Current portion of capital lease payment		108
Long term portion of capital lease payment		207

As of March 31, 2008, we had €1,312 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.

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 the Company's audited annual financial statements and related notes included in its 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 Veno-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 exploring other potential uses of defibrotide, including to treat a cancer of the plasma cell known as multiple myeloma. In addition, we are exploring a potential use of oligotide, another product derived from natural DNA, to treat diabetic nephropathy. These uses of defibrotide and oligotide are currently in development, and we do not sell defibrotide or oligotide 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. We have an affiliated company, Sirton Pharmaceuticals S.p.A., who processes defibrotide into the finished drug, and then we sell that finished drug in Italy to treat and prevent vascular disease with risk of thrombosis. The other active pharmaceutical ingredients that we manufacture are urokinanse, calcium heparin, sodium heparin and sulglicotide. We sell these other active pharmaceutical ingredients to other companies to be made into various drugs.

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 S.p.A

We expect to continue to incur net losses as we continue the development of our product candidates, apply for regulatory approvals and expand our operations.

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. 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 VOD or to 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 in 2008:

- § 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 to our affiliate, Sirton. 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 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.

Valuation of Acquired Intangible Assets

In 2007, we acquired intangible assets in the form of Italian marketing authorizations and trademarks from Crinos S.p.A. When significant identifiable intangible assets are acquired, we determine the fair values of these assets as of the acquisition date using valuation techniques such as discounted cash flow models. These models require the use of significant estimates and assumptions including, but not limited, to determining the estimated future cash flows from product sales.

We believe that the fair value assigned to the intangible assets acquired are based on reasonable estimates and assumptions, given the available facts and circumstances as of the acquisition date. We will continually evaluate whether any intangible asset values have been impaired.

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 March 31, 2008, we had €1,312 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:

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 thousands except share and per share data)

	Three Months Ended March 31,	
	2007	**2008**
Revenues:		
Product sales to related party	€ 951	€ 555
Product sales to third parties	267	1,199
Total product sales	1,218	1,754
Other revenues	35	935
Total revenues	1,253	2,689
Operating costs and expenses:		
Cost of goods sold	1,088	1,429
Research and development	2,741	3,611
General and administrative	1,291	2,020
Depreciation and amortization	75	277
Charges from related parties	226	195
	5,421	7,532
Operating loss	(4,168)	(4,843)
Interest income, net	263	124
Foreign currency exchange (loss), net	(868)	(1,363)
Loss before income tax expense	(4,773	(6,082)
Income tax expense	-	-
Net loss.	€ (4,773)	€ (6,082)
Net loss per share:		
Basic and diluted net loss per share	€ (0.36)	€ (0.41)
Weighted average shares used to compute basic and diluted net loss per share	13,117,049	14,956,096

Three Months Ended March 31, 2007 Compared to Three Months Ended March 31, 2008

Product sales

Our product sales were €1,754 for the three month period ended March 31, 2008 compared to €1,218 for the comparable period in 2007, an increase of €536 or 44%. The increase was mainly due to increased demand for our products from our customers. Sales to a related party for the three month period ended March 31, 2008 and 2007 represented 32% and 78% of the total product sales, respectively, and decreased 42% to €555. The decrease in sales to a related party is mainly due to the fact that in July 2007, in connection with our acquisition of the Italian marketing authorizations and trademarks regarding pharmaceutical products known in the Italian market as Prociclide and Noravid from Crinos S.p.A., we started selling defibrotide as a finished product to Crinos as our distributor, rather than to our related party, Sirton Pharmaceuticals S.p.A. Sales to third parties increased to €1,199 for the three month period ended March 31, 2008 due to this change and also due to higher sales volume of sulglicotide. Sulglicotide is used by a South Korean manufacturer to produce a finished product. We expect future growth in sulglicotide revenue due to higher penetration

and positioning of the finished product in the South Korean market.

Other revenues

Our other revenues were €935 and €35 for the three month period ended March 31, 2008 and 2007, respectively. Other revenues are primarily due to reimbursement of research and development expenses and upfront payments recognized ratably over the expected life of the research period under our license agreement with Sigma-Tau.

Cost of goods sold

Our cost of goods sold was €1,429 for the three months ended March 31, 2008 compared to €1,088 for the comparable period in 2007. Cost of goods sold as percent of product sales was 81% in 2008 period compared to 89% in the 2007 period. Increase in margin was mainly due to change in the product mix and higher sales prices.

Research and development expenses

We incurred research and development expenses of €3,611 during the three month period ended March 31, 2008 compared to €2,741 for the comparable period in 2007. The expenses were primarily for the development of defibrotide to treat and prevent VOD and increased headcount. The difference between the periods is primarily due to increased costs for our clinical trials, and in particular clinical research organizations charges, regulatory activities, 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 increase was stock based compensation of €124 for the three month period ended March 31, 2008 compared to €60 for the comparable period in 2007.

General and administrative expenses

Our general and administrative expenses were €2,020 and €1,291 for the three month period ended March 31, 2008 and 2007, respectively. The increase is primarily due to increased headcount and facilities related expenses, general corporate expenses, legal and other professionals fees and stock based compensation expense of €446 for the period ended March 31, 2008 compared to €167 for the comparable period in 2007.

Depreciation and amortization expense

Depreciation and amortization expense was €277 for the three month period ended March 31, 2008 compared to €75 for the comparable period in 2007. The increase is primarily attributable to €100 of amortization of our Italian marketing authorizations and trademarks acquired in 2007. Depreciation expense excludes depreciation of our manufacturing facilities which are included in cost of goods sold.

Foreign currency exchange gain (loss)

Our foreign currency exchange losses are primarily due to remeasurement at March 31, 2008 of U.S. dollar cash balances.

Interest income, net

Interest income, net amounted to €124 and €263 for the three month period ended March 31, 2008 and 2007, respectively. Gross interest income amounted to €227 and €341 for the three month period ended March 31, 2008 and 2007, respectively, a decrease of €114. The decrease is a result of a lower amount of invested funds in the 2008 period and decrease in interest rates. Interest expense totaled €104 and €78 for the three month period ended March 31, 2008 and 2007, respectively, an increase of €26 attributable to an increase in long term debt.

Net loss.

Our net loss was €6,082 for the three month period ended March 31, 2008 compared to €4,773 for the comparable period in 2007. The difference was primarily due to increases in research and development expenses, general and administrative expenses and foreign exchange loss, partially offset by an increase in revenues.

Liquidity and Capital Resources

During the three month period ended March 31, 2008, we used approximately €3,952 thousand of cash to fund operations and working capital requirements and approximately €293 thousand for capital expenditures and acquisition of intangible assets. We funded these amounts from the following sources:

- €2,689 thousand in gross revenues;
- €217 thousand in short term borrowing; and
- €25,964 thousand from cash available at December 31, 2007.

At March 31, 2008, we had an aggregate of €5,560 thousand in debt outstanding. Additional information about the maturity and repayment obligations for this debt and interest rate structure and our material commitments for capital expenditures is provided below under "Contractual Obligations and Commitments."

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 it;
- 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 to treat severe 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; and
-

our ability to enter into additional collaborative arrangements with corporate and academic collaborators and the success of such relationships.

We believe that our capital resources are sufficient to fund our operations into 2009. Changes in our operating plans, delays in obtaining approval to market our product candidates, lower than anticipated revenues, increased expenses or other events, including those described in our "Risk Factors" in our from 20-F for the year ended December 31, 2007, may cause us to seek additional debt or equity financing on an accelerated basis. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could negatively impact our growth plans and our financial condition and results of operations. Additional equity financing may be dilutive to the holders of our ordinary shares and debt financing, if available, may involve significant cash payment obligations and covenants and/or financial ratios that restrict our ability to operate our business.

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.*"

If we are unable to obtain additional financing, we may be required to reduce the scope of, or delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our financing condition and operating results.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations and Commitments

During the period ended March 31, 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 March 31, 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 March 31, 2008, we held a cash balance of $31,582 thousand that was denominated in U.S. dollar. 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.