Gentium S.p.A.
Form 6-K
June 08, 2007

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, 2007.

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 x 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 x

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, 2007 are attached hereto as Exhibits Numbers 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 Form S-8, File No. 333-137534 and 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 7, 2007.
2	Quarterly report for the period ended March 31, 2007.

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 7, 2007

INDEX TO EXHIBITS

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2	Quarterly report for the period ended March 31, 2007.

Exhibit 1

PRESS RELEASE

FOR IMMEDIATE RELEASE

Company Contact:
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Gentium Reports First Quarter Financial Results; Provides Financial and Clinical Update

Villa Guardia (Como), Italy (June 7, 2007) - Gentium S.p.A. (NASDAQ: GENT) (the "Company") today reported financial results for the quarter ended March 31, 2007. Highlights of the first quarter of 2007 and recent weeks as of June 7, 2007, include:

· Continued progress with the Phase III clinical trial in the U.S. evaluating Defibrotide as a potential treatment of severe Veno-Occlusive Disease (VOD) with Multiple Organ Failure (Severe VOD): this study has enrolled 39 patients.

· Progress with the Phase II/III clinical trials of Defibrotide in Europe for the prevention of VOD in children. This study is expected to be conducted in 35 centers and 130 patients have been enrolled in the trial.

· Completed Phase I of Phase I/II study of Defibrotide to treat advanced and refractory multiple myeloma patients, presented preliminary Phase I data at the Annual Meeting of Society of Hematology (ASH) 2006. The Company expects to update interim results from this trial at the upcoming International Myeloma Workshop in Kos, Greece June 25th to 30th. The Company expects to present final Phase I data in the second half of 2007.

- At the American Association of Cancer Research meeting in April, the Company presented preclinical data to support the potential mechanism for Defibrotide anti-tumor activity in multiple myeloma. Two posters presented data that suggest that Defibrotide may suppress tumor-associated angiogenesis and tumor dissemination through suppression of heparanase with a subsequent reduction in the release of stores of growth factors from the extra-cellular matrix. This, in part, may explain Defibrotide's anti-MM activity both in vitro and in vivo.

- The Company presented updated preclinical data at the World Congress of Nephrology in April which suggests that Defibrotide may have activity in diabetic nephropathy. Data demonstrated that Defibrotide not only has an effect on the down-regulation of heparanase gene expression, but also decreases its enzymatic activity in endothelial cells. Since heparanase is a critical factor in maintaining glomerular basement membrane integrity and is elevated in diabetic nephropathy, results suggest that it should be considered for the management of this disease.

    - The Company completed the acquisition of the Italian marketing authorizations for Defibrotide and related trademarks, as well as certain other related assets, from Crinos S.p.A. (Crinos) for EUR 16 million in cash and other considerations. This acquisition provides the company control over the distribution of Defibrotide, as well as enabling Gentium to market directly or seek a partner in Europe.

- The Company strengthened its cash position raising $45.2 million net proceeds through a private placement of ordinary shares in February.

Clinical Highlights and Outlook

Commenting on Gentium’s clinical and operational progress during the quarter, Laura Ferro, M.D., Chairman and Chief Executive Officer, said, “Over the past quarter the Company has undertaken a series of complementary initiatives which support progress in research, clinical, and operations activities. The clinical potential for Defibrotide continues to expand with additional data to support the elucidation of the mechanism of action for Defibrotide in cancer, VOD, as well as metabolically induced indications such as diabetic nephropathy.”

Dr. Ferro continued, “We believe that the next eighteen months will be pivotal for the Company as we expect to complete accrual and report results in both the Company’s prevention and treatment trials with Defibrotide. We remain on track to complete patient enrollment in U.S. Phase III pivotal trial of Defibrotide to treat Severe VOD this trial during the second half of 2007.”

“The acquisition of Crinos assets represented a major milestone for Gentium as it allows us to better manage this key asset in the European markets. It also gives us control over its distribution and the flexibility to market Defibrotide ourselves or alternatively seek marketing partners in the European market, both of which have long been strategic objectives. In addition, we strengthened our balance sheet by raising $45.2 million in net proceeds, which should allow us to support our clinical development programs and which we believe will provide us with the capital to complete our Phase III programs.”

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, 2007, €1.00 = $ 1.3318.

For the first quarter ended March 31, 2007 compared with the prior-year's first quarter:

- Total revenues were €1.25 million, compared with €0.95 million
- Operating costs and expenses were €5.42 million, compared with €3.94 million
- Research and development expenses, which are included in operating costs and expenses, were €3.07 million, compared with €1.67 million
- Operating loss was €4.17 million, compared with €2.99 million
- Interest income (expense), net, was €0.26 million, compared with €0.05 million
- Net loss was €4.77 million, compared with €3.10 million
- Basic and diluted net loss per share was €0.36 compared with €0.32 per share

Operating Results and Trends

The fluctuation in product sales revenues for the three-month period compared with the prior-year period is primarily due to greater demand for our products from our two main customers. Sales to affiliates represented 78% and 99% of the total product sales in the three months ended March 31, 2007 and 2006, respectively, and increased 4% to €951 thousand. Sales to third parties increased to €267 thousand mainly due to higher demand for our active pharmaceutical ingredient sulglicotide in the Korean market for €82 and due to sales of finished products for €182 directly to distributors instead of going though Sirton.

Cost of goods sold was €754 thousand for the three month period ended March 31, 2007 compared to €711 thousand for the comparable period in 2006. Cost of goods sold as a percentage of product sales was 61.9% at in the 2007 period compared to 77.7% in the 2006 period.

Research and development spending increased during the three-month periods in 2007 compared with 2006, primarily due to the costs associated with the Company's U.S. Phase III trial for the treatment of Severe VOD. Growth in headcount and outside services to support increased activity in our clinical trials, primarily contract research organization expenses and stock-based compensation expense also contributed to increased research and development expenses.

General and administrative expenses were €1.29 million and €1.3 million for the three month period ended March 31, 2007 and 2006, respectively. General and administrative expenses for the 2007 period were thus in line with the comparable period in 2006 and include personnel costs, facilities related expenses, general corporate expenses of being a public Company and stock based compensation expense of €167 thousand.

Interest income (expense), net, increased to €263 in the first quarter of 2007 over comparable period in 2006. Interest income amounted to €341 and €85 in the three months ended March 31, 2007 and 2006, respectively, an increase of €256. The increase is a result of a higher amount of invested funds as a result of the private placement in 2007. Interest expense totaled €78 and €33 in the three months ended March 31, 2007 and 2006, respectively.

The Company ended the first quarter of 2007 with €40.41 million in cash and cash equivalents, compared with cash and cash equivalents of €10.21 million as of December 31, 2006.

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 for the treatment of Severe VOD as well as the prevention of 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 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, 2006		March 31, 2007 *(unaudited)*
ASSETS				
Cash and cash equivalents	€	10,205	€	40,407
Restricted Cash		4,000		4,000
Receivables from third parties		227		162
Receivables from related parties		3,478		4,439
Inventories, net		1,499		1,846
Prepaid expenses and other current assets		1,427		1,316
Total Current Assets		20,836		52,170
Property, manufacturing facility and equipment, at cost		18,944		19,171
Less: Accumulated depreciation		9,550		9,783
Property, manufacturing facility and equipment, net		9,394		9,388
Intangible assets, net of amortization		586		665
Marketable securities		560		527
Other non-current assets		4,017		4,017
Total Assets	**€**	**35,393**	**€**	**66,767**
LIABILITIES AND SHAREHOLDERS' EQUITY				
Accounts payable	€	4,734	€	5,263
Payables to related parties		454		875
Accrued expenses and other current liabilities		1,198		1,258
Current maturities of long-term debt		140		105
Current portion of capital lease obligation		43		43
Deferred income		724		765
Total Current Liabilities		7,293		8,309
Long-term debt, net of current maturities		5,683		5,560
Capital lease obligation		48		48
Termination indemnities		682		696
Total Liabilities		13,706		14,613
Share capital (par value: €1.00; 15,100,292 and 17,454,292 shares authorized; 11,773,613 and 14,191,294 shares issued at December 31, 2006 and March 31 2007, respectively		11,774		14,191
Additional paid in capital		49,476		82,332
Other comprehensive income		32		(1)
Accumulated deficit		(39,595)		(44,368)
Total Shareholders' Equity		21,687		52,154
Total Liabilities and Shareholders' Equity	**€**	**35,393**	**€**	**66,767**

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

	Three Months Ended March 31,	
	2006	**2007**
Revenues:		
Sales to affiliates	€ 912	€ 951
Third party product sales	3	267
Total product sales	915	1,218
Other income and revenues	35	35
Total Revenues	950	1,253
Operating costs and expenses:		
Cost of goods sold	711	754
Charges from affiliates	215	226
Research and development	1,675	3,075
General and administrative	1,296	1,291
Depreciation and amortization	42	75
	(3,939)	(5,421)
Operating loss	(2,989)	(4,168)
Foreign currency exchange gain (loss), net	(168)	(868)
Interest income, net	52	263
Net loss	€ (3,105)	€ (4,773)
Net loss per share:		
Basic and diluted net loss per share	€ (0.32)	€ (0.36)
Weighted average shares used to compute basic and diluted net loss per share	9,610,630	13,117,049

GENTIUM S.p.A.
Statements of Cash Flows
(Unaudited, amounts in thousands)

		Three Months Ended March 31,		
		2006		**2007**
Cash Flows From Operating Activities:				
Net loss	**€**	**(3,105)**	**€**	**(4,773)**
Adjustments to reconcile net income to net cash used in operating activities:				
Unrealized foreign exchange loss		140		815
Depreciation and amortization		219		278
Non cash share based compensation		213		241
Deferred income		(35)		(35)
Changes in operating assets and liabilities:				
Accounts receivable		(131)		(897)
Inventories		(152)		(347)
Prepaid expenses and other current and non current assets		188		109
Accounts payable, accrued expenses and other long term liabilities.		639		1,033
Net cash used in operating activities		**(2,024)**		**(3,575)**
Cash Flows From Investing Activities				
Capital expenditures		(198)		(228)
Intangible expenditures		(274)		(120)
Net cash used in investing activities		**(472)**		**(348)**
Cash Flows From Financing Activities:				
Repayments of long-term debt		(401)		(82)
Proceeds from warrant and stock option exercise exercises		-		549
Proceeds from private placement, net		-		34,485
Net cash provided by/(used in) financing activities		**(401)**		**34,952**
Increase/(decrease) in cash and cash equivalents		(2,897)		31,029
Effect of exchange rate on cash and cash equivalents		(142)		(827)
Cash and cash equivalents, beginning of period		12,785		10,205
Cash and cash equivalents, end of period	€	**9,746**		**40,407**

Exhibit 2

GENTIUM S.p.A.

QUARTERLY REPORT

For the period ended March 31, 2007

GENTIUM S.p.A.
QUARTERLY REPORT, MARCH 31, 2007
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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 other filings with the Securities and Exchange Commission, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, those relating to:

- our expectations for increases or decreases in expenses;
- our expectations for the development, manufacturing, and approval of defibrotide or any other products we may acquire or in-license;
- our expectations for incurring additional capital expenditures to expand our research and development capabilities;
- our expectations for becoming profitable on a sustained basis;
- our expectations or ability to enter into marketing and other partnership agreements;
- our expectations or ability to enter into product acquisition and in-licensing transactions;
- our estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating and capital requirements;
- our 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 law, 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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(Unaudited, amounts in thousands except share and per share data)

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Net cash provided/(used) by/in financing activities	(401)	34,952
Increase/(decrease) in cash and cash equivalents	(2,897)	31,029
Effect of exchange rate on cash and cash equivalents	(142)	(827)
Cash and cash equivalents, beginning of period	12,785	10,205
Cash and cash equivalents, end of period	€ 9,746	€ 40,407
Supplemental disclosure of cash flow information:		
Cash paid for interest, net of capitalized amount	€ 50	€ 73
Income taxes paid	€ —	€ —

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

GENTIUM S.p.A.
Notes To 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 discovery, research and development of drugs to treat and prevent a variety of vascular diseases and conditions related to cancer and cancer treatments. The Company's core areas of focus are: i) drugs derived from DNA extracted from natural sources and ii) drugs which are synthetic oligonucleotides (molecules chemically similar to natural DNA).

In particular, we are developing our most advanced product candidates to treat and prevent Veno-Occlusive Disease ("**VOD**") and to treat multiple myeloma. Our most advanced product candidates utilize defibrotide, a drug that we discovered and currently manufacture and license to pharmaceutical companies for sale in Italy. In addition to defibrotide, we manufacture and sell urokinase and calcium heparin, which are active pharmaceutical ingredients used to make other drugs, sulglicotide, which is intended to be used to treat peptic ulcers, and other miscellaneous pharmaceutical products. We have also developed a formulation of the drug mesalazine to treat inflammatory bowel disease. All of the Company's operating assets are located in Italy, and more than 78% of product revenue in the three months ended March 31, 2007 was to one affiliated customer 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, 2006. Our accounting policies are described in the Notes to the Financial Statements in our 2006 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, 2007 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*" ("**SFAS 131**"), 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 of the Company on an aggregate basis and manage the operations of the Company as a single operating segment. 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.

Restricted Cash: As of March 31, 2007, restricted cash represents €4,000 deposited in an escrow account. The amount was deposited in connection with the acquisition of the Italian defibrotide marketing authorizations and related trademarks. The amount was subsequently released to Crinos with the transfer of the marketing authorizations, as reported in footnote 3.

Accounts Receivable: The Company extends credit to its customers in the ordinary course of business. Sirton's trade receivable outstanding as of December 31, 2006 is guaranteed by FinSirton. Trade receivables from a foreign customer are guaranteed by a letter of credit from a primary bank institution.

Inventories: Inventories consist of raw materials, semi-finished and completed 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, with the half year convention, 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 incurred during the application development stage. As of March 31, 2007, the costs incurred to develop, install, put in service and validate software amounted to €404, and include external direct costs of material and services consumed in obtaining internal-use software and our internal payroll and payroll related costs for employees who were directly associated with and who devote time to the internal-use software project. Capitalized costs of computer software obtained for internal use are 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 ten years for licenses and trademarks.

Impairment of Long-lived Assets, including Intangibles: Long-lived assets to be held and used, including intangible assets, are reviewed for impairment whenever events and circumstances indicate that the carrying amount of the assets might not be recoverable. 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. The Company's marketable securities consist of

debt securities, which have been pledged to secure the Company's repayment of a loan from Banca Intesa-Mediocredito SpA and will gradually be released from the pledge as the Company repays the principal of the loan, such that the current value of the remaining pledged securities equals at least 50% of the remaining loan principal.

The securities are held for an indefinite period of time and when gradually released from the proceeds from their sale will be used to meet the ongoing liquidity needs of the Company. 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 mainly sells its products to its affiliate, Sirton. The Company also recognizes revenue from the sale of products to third parties and from contractual arrangements. Revenues from product sales are recognized at the time of product shipment. The Company also has revenue arrangements with multiple deliverables, which 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 contracts 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 contractual arrangements with customers generally includes upfront fees, performance milestone payments, reimbursements of development 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 and certain guaranteed time based payments 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 approvals by regulatory agencies. See additional discussion under Note 4 regarding the nature of the performance milestone arrangements for the Company's significant collaborative agreements.

Government Grants: Government grants are related to the reimbursement of qualifying research and development expenses. As the research and development expenses submitted by the Company are first subject to audit and revision by the competent governmental authority and final payments are discretionary, no amount of grant reimbursement is recognized until the cash is received. Grant reimbursement costs are treated as a reduction of the qualifying expense in the accompanying financial statements.

Research and Development: Research and development expenditures are charged to operations as incurred. For the three month periods ended March 31, 2006 and 2007, research and development expenses amounted to €1,675 and €3,075, respectively. 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, and allocated facilities and overhead costs.

Clinical Trial Accruals: The Company records accruals for estimated clinical study costs. These costs can be a significant component of research and development expenses. 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.

Income Taxes: The Company files a separate tax return in Italy on an annual basis. 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 not considered more likely than not that tax assets will 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: Effective September 30, 2004, the Company adopted an equity incentive plan and a nonstatutory share option plan (the "**Plans**") for officers, employees, consultants, directors and non-employee directors. Options to purchase an aggregate of 1,115,000 and 1,475,000 ordinary shares were outstanding under the Plans at December 31, 2006 and March 31, 2007, respectively. 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 share based compensation were unchanged. The fair value of the equity compensation for employees is determined using a single estimated expected life. Compensation expense for awards that have a vesting provision is recognized on a straight-line basis over the service period of the equity compensation award. Stock based compensation expense was €213 and €241 for the three month periods ended March 31, 2006 and 2007, respectively. The Company expects to incur significant non-cash share based compensation expense in the future.

From time to time, the Company grants options to non-employees. Grants of equity instruments to non-employees, and non-directors such as consultants are also accounted for under SFAS 123(R) and 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 non-employees 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. For the three month periods ended March 31, 2006 and 2007, the Company recorded non-cash compensation expenses for options granted to non employees and non directors of approximately €53 and nil respectively.

Fair Value of Financial Instruments: The carrying amounts of receivables, prepaid expenses and accounts payable approximate fair values due to the short-term maturities of these instruments. Substantially all of the Company's debt is floating rate debt, and therefore, the stated amount approximates fair value.

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

in OCI unrealized gains or losses in our available for sale securities. Comprehensive income for the year ended December 31, 2006 has been reflected in the Statements of Stockholders' Equity. The accumulated other comprehensive income (loss), net of tax, as of December 31, 2006 and March 31, 2007, was €32 and (€1). The only components of accumulated other comprehensive income (loss) is net unrealized gains on securities available for sale.

Recently Issued Accounting Standards:

On February 15, 2007, FASB Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115* , or SFAS 159, was issued. SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value and establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 will be effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact this standard would have on our financial statements.

On September 6, 2006, FASB Statement No 157, Fair Value Measurements, or SFAS 157, was issued. This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP), and expands disclosures about fair value measurements. This Statement applies under other accounting pronouncements that require or permit fair value measurements, the Board having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. The statement is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We are currently evaluating the impact of this standard on our financial statements.

3. ACQUISITION

Acquisition of marketing authorization and trademarks

On December 28, 2006, the Company entered into a Master Agreement with Crinos S.p.A. to acquire the Italian marketing authorizations and related trademarks known as Prociclide® and Noravid® for €16,000. The transfer of the market authorization was pending subject to approval by the Italian regulators, which occurred on April 26, 2007. As of March 31, 2007, such decree was not published, and therefore the transaction was not considered consummated as the risks and the benefits were not transferred to the Company. Additionally, the transfer of the trademarks is deferred to December 31, 2008 when the Company is obliged to pay the last installment.

As of March 31, 2007, the Company had paid €4,000 of the purchase price to Crinos and paid €4,000 into escrow. The escrowed sums were subsequently released to Crinos at the time the authorizations were transferred. Gentium is bound to pay the remaining purchase price balance of €8,000 in two equal payments of €4,000 no later than December 31, 2007 and 2008, respectively.

As part of the same transaction, the Company also entered into a Distribution and Promotion Agreement with Crinos, whereby Crinos agreed to purchase from us Prociclide and Noravid for promotion and distribution in Italy. The Distribution and Promotion Agreement is effective as of April 26, 2007 through December 31, 2008.

The Company anticipates accounting for the transaction as an asset acquisition. As such, the assets acquired will be recorded on the basis of fair value as of April 26, 2007. The Company is currently working to finalize the purchase price allocation.

4. RECEIVABLE

The Company's accounts receivable consisted of:

	December 31, 2006	March 31, 2007
Accounts receivable	€ 227	€ 162

Accounts receivable from related parties		3,478		4,439
Total	€	3,705	€	4,601

The accounts receivable relates to the sales of active pharmaceutical ingredients to Sirton Pharmaceuticals and other customers. Sirton's trade receivable outstanding as of December 31, 2006 is guaranteed by FinSirton. Trade receivables from a foreign customer are guaranteed by a letter of credit from a primary bank institution.

5. INVENTORIES

The Company's inventories consisted of:

	December 31, 2006	March 31, 2007
Raw materials	€ 293	€ 334
Semi-finished goods	689	876
Finished goods	517	636
Total	€ 1,499	€ 1,846

6. PROPERTY, MANUFACTURING FACILITY AND EQUIPMENT

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

	December 31, 2006			March 31, 2007		
	Cost	Accumulated Depreciation	Net book value	Cost	Accumulated Depreciation	Net book value
Land and building	€ 2,624	€ 1,179	€ 1,445	€ 2,653	1,197	1,456
Plant and machinery	14,075	7,402	6,673	14,091	7,578	6,513
Industrial equipment	832	598	234	860	605	255
Other	670	335	335	712	352	360
Leasehold improvements	46	9	37	137	17	120
Internally Developed Software	389	27	362	404	34	370
Construction in progress	308	—	308	314	—	314
	€ 18,944	€ 9,550	€ 9,394	€ 19,171	9,783	9,388

7. CREDIT FACILITY, LONG-TERM DEBT AND LEASES

Long term debt, net of current maturities consists of:

	December 31, 2006	March 31,2007
a) Research loan from the Italian Ministry for University and Research, interest at 1% per annum, due January 2012	351	351
b) Equipment loans secured by the underlying equipment pursuant to the Sabatini Law, interest at 2.1%.	481	437
c) Mortgage loan bearing interest at the Euribor 6 month rate plus 1.0% due June 2014 (4.8% and 5.04% at December 31, 2006 and March 31, 2007, respectively)	2,800	2,800
d) Equipment loan secured by marketable securities, bearing interest at the Euribor 3 months rate plus 1.70% due April 2011 (5.36% and 5.62% at December 31, 2006 and March 31, 2007, respectively)	1,050	1,050
e) Equipment loan bearing interest at the Euribor 3 months rate plus 1.20% due June 2011 (4.86% and 5.12% at December 31, 2006 and March 31, 2007, respectively)	750	750
f) Equipment loan bearing interest at the Euribor 3 months rate plus 0.80% due December 2011 (4.46% and 4.72% at December 31, 2006 and March 31, 2007, respectively)	230	220
g) Financing loan bearing interest at the Euribor 1 months rate plus 1.00% due December 2011 (4.60% and 4.86% at December 31, 2006 and March 31, 2007, respectively)	500	478
h) Financing loan bearing interest at the Euribor 3 months rate plus 1.00% due December 2011 (4.66% and 4.92% at December 31, 2006 and March 31, 2007, respectively)	225	225
i) Other	20	14
	6,407	6,325
Less current maturities	724	765
Total	€ 5,683	€ 5,560

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 is currently in compliance with the covenant.

The maturities of long-term debt over the next five years as of March 31, 2007 are as follows:

		March 31, 2007
2007	€	765
2008		1,091
2009		1,242
2010		1,164
2011		1,001
Thereafter		1,062
Total	€	6,325

8. SHAREHOLDERS' EQUITY

The Company had 11,773,613 and 14,191,294 ordinary shares of €1.00 par value per share issued and outstanding as of December 31, 2006 and March 31, 2007, respectively. On March 31, 2007, the authorized shares were 17,454,292. Authorized capital is as follows:

	December 31, 2006	March 31, 2007
Issued and outstanding	11,773,613	14,191,294
Reserved for exercise of warrants	1,637,004	1,591,323
Reserved for future planned offerings	151,675	151,675
Reserved for share option plans	1,538,000	1,520,000
	15,100,292	17,454,292

Gentium's largest shareholder, FinSirton and its related company, Sirton, have made periodic investments in Gentium in the past. These investments occurred via the transfer of goods or services to Gentium from one or the other of the companies. The investing company did not receive compensating goods, services or cash in return from Gentium. As such, these additional non-cash investments have been recorded in equity as it is considered to be additional paid in capital to Gentium.

In January 2005, the Company's largest shareholder, FinSirton, sold 450,000 of its Gentium ordinary shares to private investors and subsequently contributed €1,600, the approximate amount of the net proceeds, to the Company's capital. In April 2005, FinSirton sold an additional 800,000 of its Gentium ordinary shares to a private investor and subsequently contributed €2,300, the approximate amount of the net proceeds, to the Company's capital.

On June 21, 2005, the Company completed an IPO of 2,400,000 ordinary shares at a price of $9.00 per share, generating gross proceeds of $21,600 (€17,863), and on July 27, 2005, the underwriters exercised part of their over-allotment option by purchasing an additional 300,000 ordinary shares generating additional gross proceeds of $2,700 (€2,252). The IPO underwriting discount and other offering costs amounted to €3,919 and were charged against additional paid-in capital.

On October 14, 2005, the Company completed a private placement of 1,551,125 ordinary shares at $7.05 per ordinary share. Gross proceeds from the offering were $10,900 (€9,100). The private placement offering cost amounted to €1,066 and was charged against additional paid in capital. As part of the 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 have a term of exercise of five years. 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. In April 2006, we issued 93,524 ordinary shares upon exercise of a warrant, at a price per share of 9.69, for aggregate proceeds of $906 (€744).

On June 6, 2006, the Company completed a private placement of 1,943,525 ordinary shares at $11.39 per ordinary share. Gross proceeds from the offering were $22,100 (€17,200). The private placement offering costs amounted to €1,333 and were charged against additional paid-in capital. As part of the 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. The warrants have a term of five years. 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. In December 2006, we issued 10,000 ordinary shares upon exercise of a warrant, at a price per share of $14.50, for proceeds of $145 (€110). In January 2007, we issued 31,920 ordinary shares upon exercise of warrants, at a price per share of $14.50, for proceeds of $463 (€354).

On December 15, 2006, the Company issued warrants to purchase an aggregate of 151,200 ordinary shares to the underwriters of the Company's initial public offering. As of March 31, 2007, 88,628 warrants were exercised at a price per share of $11.25, for proceeds of $997 (€756).

On February 9, 2007, the Company completed a private placement of 2,354,000 ordinary shares at $20.17 per ordinary share. Gross proceeds from the offering were $47,500 (€36,504). The private placement offering costs amounted to €2,019 and were charged against additional paid-in capital.

Italian law restricts the amount of dividends that can be paid on an annual basis. Before dividends can be paid out of net income in any year, an amount equal to 5% of such net income must be allocated to the statutory legal reserve until such reserve is at least equal to one-fifth of the par value of the issued shares. If the capital account is reduced as a result of statutory losses, no amounts can be paid until the capital account is restored. Dividends can only be declared on the basis of the statutory equity available, which can be substantially different from the US GAAP equity reported herein. In addition to restrictions on the amount of dividends, Italian law also prescribes the procedures required if a company's aggregate par value falls below a certain level. The law states that if the aggregate par value is reduced by more than one third, then the shareholders must take action, which could include a recapitalization of the company. Based on our statutory equity at March 31, 2007, no amounts are eligible to be paid as dividends and the Company has no intention to pay a dividend in the foreseeable future.

Warrants

A summary of the status of the Company's warrants issued as of March 31, 2007 and changes during the periods stated is presented below, based on the exchange rate in effect on March 31, 2007:

	Warrants	Weighted Average Exercise Price		
Balance, December 31, 2004	503,298	€	7.15	$ 9.52
Granted	713,518	€	8.21	$ 9.69
Exercised	—		—	—
Cancelled	—		—	—]
Balance, December 31 2005	1,216,816	€	8.14	$ 9.61
Granted	617,646	€	12.13	$ 14.07
Exercised	(197,458)	€	8.29	$ 10.52
Cancelled	—			
Balance, December 31, 2006	1,637,004	€	9.63	$ $11.18
Granted	—		—	—
Exercised	(45,681)	€	10.36	$ $13.49
Cancelled	—		—	—
Balance, March 31, 2007	1,591,323	€	9.61	$ 11.11

9. EQUITY INCENTIVE PLANS.

2004 Equity Incentive Plan

On September 30, 2004, the Company adopted the Gentium S.p.A 2004 Equity Incentive Plan and Italy Stock Award Plan. The Plans provide for the issue of incentives awards for up to 1.5 million ordinary shares to employees, consultants, directors, and non-employee directors. Awards may be in the form of either incentive and non-qualified options, restricted share grants, share appreciate rights and share bonuses. Our compensation committee determines the price of share options granted under the incentive plan, provided that the exercise price for an incentive share option cannot be less than 100% of the fair market value of our ordinary shares on the date of grant. The term of share options granted under the incentive plan generally may not exceed ten years, although the capital increase relating to the ordinary shares issuable upon exercise of such options expires on September 30, 2009. On April 27, 2007, shareholders approved (i) to extend the term of the capital increase of the resolution adopted by the extraordinary shareholders' meeting of the Company on September 30, 2004 from September 30, 2009 to September 30, 2019 and (ii) to amend the 2004 Equity Incentive Plan determining that options granted under the plan shall terminate at the earlier of (a) ten (10) years after the date of grant, (b) September 30, 2019. As of March 31, 2007, stock option agreements outstanding have not been amended to reflect such changes.

Options granted under the incentive plan vest at the rate determined by our compensation committee. Typically, options granted under the incentive plan vest over three years, at the rate of one-third of the shares covered by the option vesting each year.

Each director who is not otherwise one of our employees or consultants (with one exception) automatically was granted a nonstatutory share option for 10,000 ordinary shares upon his or her initial election or appointment to our board of directors. These grants vest one-third one year after the date of grant and the remainder in twenty-four equal monthly installments beginning one year and one month from the date of grant, provided that the person is still serving as a non-employee director on each such vesting date. Upon the conclusion of each regular annual meeting of our shareholders, each non-employee director receives a nonstatutory share option for 5,000 ordinary shares. These grants vest in twelve equal monthly installments beginning one month from the date of grant, provided that the person is still serving as a non-employee director on each such vesting date. The exercise price of the options granted to

non-employee directors is equal to the fair market value of our ordinary shares on the date of grant and the term ends on September 30, 2009. Future grants will end on the earlier of ten years from the date of grant and September 30, 2019.

2004 Italy Stock Award Sub-Plan

Our Amended and Restated 2004 Italy Stock Award Sub-Plan is a part of our Amended and Restated 2004 Equity Incentive Plan and provides for the grant of share options and the issuance of share grants to certain of our employees who reside in the Republic of Italy and who are liable for income tax in the Republic of Italy. Generally, the exercise price for a share option under the Italy sub-plan cannot be less than the average of the closing price of our ordinary shares listed on the American Stock Exchange or The Nasdaq Global Market System, as applicable, over the 30 days preceding the date of grant. The Italy sub-plan, which was originally scheduled to terminate on September 30, 2009, was amended by shareholders on April 27, 2007 and it will terminate by September 30, 2019.

2004 Nonstatutory Share Option Plan and Agreement

On September 30, 2004, the Company adopted a Non-Statutory Stock Option Plan and Agreement for 60,000 shares of its ordinary shares and on October 1, 2004, granted to an officer of the Company a non-qualified option to purchase 60,000 shares. The option has a term ending on September 30, 2009.

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 and is recognized as expense over the service period. During the three month periods ended March 31, 2006 and 2007, the compensation committee of the Company's board of directors granted options to purchase 15,000 and 378,000 ordinary shares, respectively, to the Company's officers, directors and consultants. The Company recorded non cash compensation expense of €213 and €24for the three month periods ended March 31, 2006 and 2007, respectively. The Company expects to incur significant non-cash compensation expense for option grants in the future.

The fair value of each option grant is estimated on the grant date using the Black-Scholes option-pricing model. The weighted average fair market value of options granted to officers, directors and consultants for the three month periods ended March 31, 2006 and 2007, as of the date of the grants, was $2.96 and $10.49, respectively. The assumptions used in the calculation of the fair value of options granted during the three month periods ended March 31, 2006 and 2007, were a weighted average assumed term of 3.53 and 5.0 years, a weighted average assumed volatility rate of 40% and 60% and a weighted average risk-free interest rate of 4.93% and 4.55%, respectively.

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 historical share option exercise experience is not a particularly relevant indicator of future exercise patterns. The Company has assumed for purposes of the Black-Scholes calculation that an option will be exercised after it fully vests for officers and directors and based on contractual terms for options granted to consultants. Additionally, due to the limited period that there has been a public market for the Company's securities, the implied volatility of the Company's ordinary shares may not be representative of the expected volatility. Implied volatility is the volatility assumption inherent in the market price of a company's traded options. Therefore, since the Company has no publicly traded options, in determining the expected volatility the Company took into account other available information, including the historical experience of a group of stocks in the Company's industry having similar traits. For purposes of the calculation, the Company assumed that no dividends would be paid during the expected term of the options.

The Company applies EITF 96-18 in accounting for options granted to consultants. For the three month periods ended March 31, 2006 and 2007, the Company recorded non-cash compensation expense of approximately €53 andnil, respectively. As of March 31, 2006 and 2007, options outstanding to consultants amounted to 150,000 and 110,000, respectively.

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	Shares Available for Grant	Shares	Weighted Average Exercise Price
Options available upon plan adoption	1,560,000	—	
Granted	(85,000)	85,000	€ 5.12 $ 6.82
Exercised	—	—	— —
Cancelled	—	—	— —
Options outstanding at December 31, 2004	1,475,000	85,000	€ 5.12 $ 6.82
Granted	(907,000)	907,000	€ 7.51 $ 8.90
Exercised	—	—	— —
Cancelled	—	—	— —
Options outstanding at December 31, 2005	568,000	992,000	€ 7.36 $ 8.72
Granted	(145,000)	145,000	€ 10.12 $ 13.45
Exercised	—	(22,000)	€ 4.23 $ 5.58
Cancelled	—	—	— —
Options outstanding at December 31, 2006	423,000	1,115,000	€ 7.15 $ 9.45
Granted	(378,000)	378,000	€ 14.29 $ 18,95
Exercised	—	(18,000)	€ 4.24 $ 5.58
Cancelled	—	—	— —
Options outstanding at March 31, 2007	45,000	1,475,000	€ 8.96 $ 11.93

A summary of the Company's stock option activity and related information is as follows, based on the exchange rate in effect on March 31, 2007:

The following table summarizes outstanding and exercisable options as of March 31, 2007, based on the exchange rate in effect on March 31, 2007:

	Options Outstanding			Options Exercisable	
Exercise Price	Number Outstanding	Weighted-Average Years Remaining on Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
€4.19 ($5.58)	20,000	2.75	€ 4.19 ($5.58)	20,000	€ 4.19 ($5.58))
€5.32 ($7.08)	15,000	2.82	€ 5.32 ($7.08)	7,083	€ 5.32 ($7.08)
€5.93 ($7.90)	10,000	2.91	€ 5.93 ($7.90)	4,444	€ 5.93 ($7.90)
€6.01 ($8.00)	50,000	2.95	€ 6.01 ($8.00)	50,000	€ 6.01 ($8.00)
€6.76 (€9.00)	832,000	2.51	€ 6.76 (€9.00)	485,333	€ 6.76 (€9.00)
€7.51 ($10.00)	25,000	2.96	€ 7.51 ($10.00)	25,000	€ 7.51 ($10.00)
€9.01 ($12.00)	15,000	2.72	€ 9.01 ($12.00)	15,000	€ 9.01 ($12.00)
€9.46 ($12.60)	90,000	2.72	€ 9.46 ($12.60)	25,000	€ 9.46 ($12.60)
€13.03 ($17.35)	40,000	2.72	€ 13.03($17.35)	30,556	€ 13.03 ($17.35)
€14.23($18.35)	378,000	9.99	€ 14.23($18.35)	1,680	€ 14.23($18.35)
	1,475,000			664,097	

10. NET LOSS PER SHARE

Net loss per share is computed using the weighted average number of shares of common stock outstanding during the applicable period. Shares associated with stock options and warrants are not included because they are antidilutive. There are no differences between basic and diluted net loss per share for all periods presented.

11. COMMITMENTS AND CONTINGENCIES

Legal

The Company is not involved in any legal proceedings.

Raw material contracts

We extract many of our products and product candidates from the DNA of pig intestines through well-established processes used by others to manufacture many other drugs. In particular, we extract defibrotide and calcium heparin from swine intestinal mucosa and sulglicotide from swine duodenum. In 2004, we entered into supply agreements with La.bu.nat. S.r.l. for La.bu.nat. to supply us with the swine intestinal mucosa and swine duodenum we need to produce defibrotide, calcium heparin and sulglicotide. We believe La.bu.nat can meet our current and near-term supply needs.

The initial contract term of the swine intestinal mucosa supply agreement expires on December 31, 2007, with automatically renewable three year periods, unless either party notifies the other party in writing six months prior to the annual date of termination. We must give written purchase orders to La.bu.nat at least two months in advance of the date of delivery. For the year ending as of December 31, 2007, the purchase price has been determined at €0.1757 per kg. After December 31, 2007, both parties may request renegotiation of the price with reference to market trends and manufacturing costs. In the event that the parties cannot agree on a renegotiated price, an arbitrator will determine the new price.

The initial contract term of the swine duodenum supply agreement expires on December 31, 2007, with automatically renewable three year periods, unless either party notifies the other party in writing six months prior to the annual date of termination. We must give written purchase orders to La.bu.nat at least four months in advance of the date of delivery. For the year ending as of December 31, 2007, the purchase price has been determined at €1.0157 per kg subject to a 5% discount for quantities purchased over 90,000 kg.

While we have no current arrangements with any other supplier of our critical raw material, we believe there are suitable alternative sources of pig intestine. The FDA and other regulatory bodies may evaluate La.bu.nat.'s or any other supplier's processing centers as part of approving our product candidates and the ongoing production of our products.

Other contracts

In connection with our purchase of the Italian marketing rights to defibrotide and the related trademarks from Crinos, we paid Crinos €4,000 in 2006, placed another €4,000 in escrow, which were released to Crinos at the time the authorizations were transferred, and agreed to pay Crinos two additional installments of €4,000 each by December 31, 2007 and December 31, 2008.

12. RELATED PARTY TRANSACTIONS

The Company's largest shareholder is FinSirton. Historically, FinSirton has provided the Company with office space, personnel, administrative services, information technology systems and accounting services. Sirton, which is a wholly owned subsidiary of FinSirton, purchases products from the Company. Sales to Sirton account for most of the Company's existing product sales. Sirton has also historically 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. Beginning in April 2005, the Company started to build-up internal functions and activities that were previously provided by FinSirton and Sirton. As of March 31, 2007, the Company had established purchasing, logistics, quality assurance, accounting, controlling and reporting departments, information technology departments treasury and regulatory. The Company still depends on FinSirton for corporate services and payroll and on Sirton for infrastructure costs and quality control. The Company is planning to internalize some of these services in 2007.

Approximately 99% and 78% of the Company's sales for the three month periods ended March 31, 2006 and 2007, respectively, have been to Sirton. Sirton manufactures finished products from, in part, our products, and sells those products primarily to one customer, Crinos. We expect that product sales to Sirton will decrease in 2007 because we are planning to sell defibrotide directly to Crinos who will market it in Italy under a distribution agreement with us.

For the three month periods ended March 31, 2006 and 2007, the Company had the following transactions with its affiliates:

	For the Three Months Ended March 31,	
	2006	2007
Revenues	€ 912	€ 951
Expenses	215	226

As of December 31, 2006 and March 31, 2007 the Company had the following balances with its affiliates:

	December 31, 2006	March 31, 2007
Receivables	€ 3,478	€ 4,439
Payables	454	875

The receivable from related parties relates to the sales by the Company of defibrotide and other pharmaceutical ingredients to Sirton. FinSirton guaranteed the Sirton's trade receivable outstanding as of December 31, 2006. The payables relate to services provided to the Company by Sirton and FinSirton according to agreements with these affiliates. These agreements involve a range of services, such as general management, human resources, payroll and quality monitoring services. The agreements each have recurring one year terms, and 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 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.

Leases

The Company entered into three lease agreements with Sirton and FinSirton to lease space for manufacturing, offices, laboratories and storage facilities. These agreements expire on December 31, 2010 and 2013. Total expenses under these operating leases for the three month periods ended March 31, 2006 and 2007 amounted to €41 and €50, respectively.

Future minimum lease payment non-cancellable under operating leases as of March 31, 2007 are:

	Operating Leases
2007	€ 78
2008	193
2009	193
2010	193
2011	30
Thereafter	60
Total minimum lease payments	€ 747

13. SUBSEQUENT TRANSACTIONS

In April 2007, the official transfer of the Italian marketing authorizations that we purchased from Crinos was published in the Italian Official Gazette, which means that such transfer is now effective. We subsequently released to Crinos the €4,000 that had been held in escrow pending this publication.

On April 27, 2007, the Company's shareholders approved a new 2007 Stock Option Plan providing for options that may be granted to the Company's directors, employees and consultants to purchase up to 1,000,000 ordinary shares, and a related a capital increase of the Company in cash for a maximum amount of €1,000 of par value for such shares.

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.

Background

We are a biopharmaceutical company engaged in the research, development and manufacture of drugs to treat and prevent a variety of vascular diseases and conditions related to cancer and cancer treatments. In 1986, our founding company received approval to sell in Italy a drug called "defibrotide" to treat deep vein thrombosis, and, in 1993, it received approval to manufacture and sell defibrotide to both treat and prevent all vascular disease with risk of thrombosis. In addition to defibrotide, we sell urokinase and calcium heparin, which are active pharmaceutical ingredients used to make other drugs, sulglicotide, which is intended to be used to treat peptic ulcers, and other miscellaneous pharmaceutical products.

Defibrotide to treat VOD with multiple-organ failure

Our leading product candidate is defibrotide to treat VOD, and in particular VOD with multiple-organ failure. In May 2003, the FDA designated defibrotide as an orphan drug to treat VOD. In July 2004, the Commission of the European Communities designated defibrotide to treat VOD as an orphan medicinal product, which is similar to being designated an orphan drug by the FDA.

In 2000, the British Journal of Hematology published the results of a 40 patient "compassionate use" study of defibrotide to treat VOD conducted in 19 centers in Europe from December 1997 to June 1999. Nineteen patients, or 47.5%, survived more than 100 days. The publication indicated that four of the 19 patients who survived more than 100 days subsequently died. Twenty-eight patients were judged likely to die or had evidence of multiple-organ failure, and 10, or 36%, of these patients survived more than 100 days. The 100 day survival rate is a milestone generally used to determine transplant success. This publication stated that the defibrotide was generally safely administered with no significant side-effects.

In 2002, the results from 88 patients with VOD with multiple-organ failure following stem cell transplants who were treated with defibrotide from March 1995 to May 2001 were published in *Blood*, the Journal of the American Society of Hematology. This publication reported data on 19 patients treated under individual Investigational New Drug Applications and on a subsequent 69 patient multi-center Phase I/II clinical trial that was conducted under an Investigational New Drug Application filed by a Dana-Farber investigator. The primary goal of the trial was the assessment of the potential effectiveness of the drug and its side effects, if any. All patients in the clinical trial received defibrotide on an emergency basis. This publication stated that 31 patients, or 35.2%, of those patients survived at least 100 days after stem cell transplant with minimal adverse side effects, primarily transient mild hypotension. Thirteen of those 31 patients who had survived more than 100 days had died by October 2001, the latest date for which survival information was available. No mortality from VOD or other toxicity related to the cancer treatment was seen more than 134 days after treatment with defibrotide, with the most common cause of later death being relapse.

The Dana-Farber investigator also sponsored, under its Investigational New Drug Application, a Phase II clinical trial in the United States of defibrotide which enrolled 150 stem cell transplant patients with VOD with multiple-organ failure at eight cancer centers. This trial was funded by us and $525 in grants from the orphan drug division of the FDA. The purpose of this trial was to evaluate the effectiveness of this drug, including the effect of the drug on the survival rate of patients with VOD with multiple-organ failure, the effective dosage and potential adverse side effects.

The Dana-Farber investigator presented the results from this Phase II clinical trial at the 47th Annual Meeting of the American Society of Hematology on December 12, 2005. Results show that the survival rate after 100 days for the 150 patients treated was approximately 41% after 100 days with minimal adverse events as compared to the historical 100 day survival rate of approximately 20%. We do not have information about the survival rate after 100 days.

The FDA has approved our application for “fast track” designation for defibrotide to treat VOD with multiple-organ failure occurring after stem cell transplantation by means of injection. The FDA approval process for defibrotide for this use remains dependent upon the successful completion of clinical trials. Fast track designation may shorten and facilitate the approval process.

We started a historically controlled Phase III clinical trial in the United States, Canada and Israel for this use in December 2005 in patients with severe VOD. We are the sponsor and will conduct the Phase III clinical trial and any additional clinical trials required by the FDA under our own Investigational New Drug Application that we submitted to the FDA in December 2003. Sponsoring and conducting the additional clinical trials under our own Investigational New Drug Application will allow us to communicate directly with the FDA regarding the development of this drug for marketing approval. In 2006, the FDA agreed to make additional grants aggregating up to $800 to Dana-Farber supporting this research, which is being applied against the costs of our Phase III clinical trial of this product candidate that we would otherwise have to pay.

Consorzio Mario Negri Sud had been conducting a multi-center Phase II/III clinical trial in Europe and Israel of defibrotide to treat VOD after stem cell transplants that was sponsored by a committee of clinical investigators. The trial was scheduled to include approximately 340 patients, of which approximately 60 had been enrolled at December 31, 2004. We were funding the costs of this clinical trial. The committee of clinical investigators cancelled the trial in October 2005 due to a lack of patients enrolled in the trial. This trial included a randomly selected control group. We believe that patients may have been reluctant to enroll due to the possibility of being placed in the control group and not receiving treatment.

Defibrotide to prevent VOD

We believe there is a significant market opportunity for defibrotide to prevent VOD for patients at risk of developing VOD. Based on our experience researching VOD, we believe that many recipients of high doses of chemotherapy, radiation therapy or hormone therapy or of therapies that prepare for stem cell transplants have an elevated risk of developing VOD. In January 2007, the FDA designated defibrotide as an orphan drug to prevent VOD. In July 2004, the Commission of European communities designated defibrotide to prevent VOD, an orphan medicinal product, which is similar to being designated an orphan drug by the FDA. We believe that there are no FDA or European regulatory approved drugs to prevent VOD at this time.

A preliminary pilot clinical study in Switzerland by the University Hospital of Geneva on defibrotide, in patients at high risk of VOD, suggested that defibrotide may provide effective and safe prevention against VOD. The study tested patients who received stem cell transplants. None of 52 successive transplant patients who received defibrotide as a preventative agent developed VOD. By comparison, 10 of 52 patients who underwent transplants in the same center before the study developed VOD, which was fatal in three cases. The study report indicated that mild to moderate toxicity such as mild nausea, fever and abdominal cramps was documented, although the report stated that it was difficult to determine whether the toxicity was directly attributable to the defibrotide, the chemotherapy that preceded the stem cell transplants or other drugs used during the stem cell transplants. The study report did not indicate the number of patients who experienced this toxicity.

We are co-sponsoring with the European Group for Blood and Marrow Transplantation, a not-for-profit scientific society, a Phase II/III clinical trial in Europe and Israel of defibrotide to prevent VOD in children. We expect this study, which began enrollment in the first quarter of 2006, to include 270 patients enrolled by several centers in Europe, who will randomly receive either defibrotide or no treatment.

We also plan to co-sponsor with the European Group for Blood and Marrow Transplantation a second Phase II/III clinical trial in Europe of defibrotide to prevent VOD and transplant associated microangiopathy in adults and sponsor a Phase II/III clinical trial of defibrotide to prevent VOD in the United States upon completion of our Phase III clinical

trial of defibrotide to treat VOD in the United States.

Defibrotide to treat multiple myeloma

Preclinical studies conducted by the Myeloma Center of the Dana-Farber Cancer Institute at Harvard University on human multiple myeloma in rodents suggests that defibrotide's effect on the cells of blood vessel walls may help increase the effectiveness of other treatments for multiple myeloma. In particular, the overall survival rate of rodents with human multiple myeloma increased and tumor volume decreased when the animals were administered defibrotide in combination with other chemotherapy agents. The Myeloma Center of Dana-Farber is conducting additional preclinical studies of defibrotide's effects on multiple myeloma.

An independent Phase I/II clinical study of defibrotide to treat multiple myeloma in combination with melphalan, prednisone, and thalidomide (MPT) started in December 2005 which we expect to include approximately 10 cancer centers in Italy. The principal investigator for the clinical trial is Dr. Mario Boccadoro, M.D., Division of Hematology, University of Turin, Italy. We will pay part of the costs of this trial. The trial is scheduled to be a dose-escalating, multi-center, non-comparative, open label study designed to assess the safety and the efficacy of Defibrotide with MPT regimen as a salvage treatment in advanced refractory MM patients. The Phase I component of the trial will combine oral MPT with escalating doses of defibrotide to determine the maximum tolerated dosage of defibrotide combined with MPT in 24 patients (three cohorts of eight patients). In the Phase II component of the trial, the oral MPT regimen will be combined with the maximum tolerated dosage of defibrotide and administered to consecutive patients to assess response rate and clinical efficacy.

Overview

We manufacture defibrotide at our facility. We expect that by the second quarter of 2007, we will engage our affiliate, Sirton, to process the defibrotide and then we will sell the finished product to Crinos S.p.A., a subsidiary of Stada Arzneimittel AG. Currently, we sell the defibrotide to Sirton, which processes it and sells the finished products to Crinos. Crinos markets defibrotide in Italy to both treat and prevent vascular disease with thrombosis under a distribution agreement with us. We also manufacture and sell to Sirton two active pharmaceutical ingredients, urokinase and calcium heparin, used by Sirton to make generic drugs, and sulglicotide, which is intended to be used to treat peptic ulcers. We sell sulglicotide to unrelated third parties. We also manufacture a variety of other miscellaneous pharmaceutical products.

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 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.

The gross margin from our current revenues contributes towards our general and administrative expenses, research and development expenses, and capital expenditures. Our general and administrative expenses include compensation for our executive officers, office facilities, accounting and human resources, information technology services, professional fees and other corporate expenses, including public company expenses. Some of these services were provided pursuant to contracts with Sirton and FinSirton.

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 2008, 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.

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 and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Actual results could differ from those estimates.

We believe the following policies to be the most critical to an understanding of 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

Through the three month period ended March 31, 2007, 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. However, given our intent to grow our non-affiliate revenues, we expect that in the future we will be required to periodically estimate the amount of goods subject to return.

Licensing and royalty agreements generally contemplate that our technology or intellectual property will be utilized to commercialize or produce certain pharmaceutical products and that we will receive certain fees pursuant to these agreements. Up-front payments related to licensing agreements are deferred and recognized ratably over the life of the agreement. Royalty revenues are recognized in proportion to the underlying sales. We also derive revenues from research and development agreements with co-development partners. We initially defer milestone revenues on such arrangements and subsequently recognize them as income in proportion to the costs incurred for the related development phase and in accordance with the contract terms. Performance milestone payments are not subject to forfeiture. We recognize revenue from these contractual arrangements according to Staff Accounting Bulletin No. 104, “Revenue Recognition.” When necessary, we divide our 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 arrangement within the agreement. Accordingly, we recognize revenues on performance milestones contracts only when we have met specific targets or milestones 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 have used and expect to continue to enter into arrangements that have multiple deliverables. The timing and amount of revenue recognition is subject to our estimates of the relative fair values of the individual components of an agreement. In connection with recording revenue, we must make estimates and assumptions determining the expected conversion of the revenue streams to cash collected. The cash conversion estimation process requires that our management make assumptions based on historical results, future expectations, the economic and competitive environment and changes in the credit worthiness of customers, and other relevant factors. If these assumptions prove to be incorrect, our actual conversion rate of recorded revenue to cash may be lower than expected and we would be required to increase our allowance for doubtful accounts.

Our current estimate of bad debt expense is zero, as approximately 95% of our product sales are with one affiliate. If we increased our estimate of bad debt to 1% of sales, our operating results would have been lower by approximately €9 and €12 for the three month periods ended March 31, 2006 and 2007, respectively. These amounts would have a material impact on our results of operation and our shareholder's equity, but no impact on our cash flow in those periods.

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 capitalize inventory costs associated with certain by-products, based on management's judgment of probable future commercial use and net realizable value. We could be required to permanently write down previously capitalized costs related to commercial inventory upon change in such judgment, a delay in commercialization, delay of approval by regulatory bodies, or other potential factors. 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 a permanent inventory write-down as soon as a need for such a write down 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.

To assess impairment of property, manufacturing facility and equipment and amortizing intangible assets for purposes of U.S. generally accepted accounting principles, we use the guidance outlined in SFAS 144. If, based on the preceding discussion, our management has concluded that impairment indicators exist, we will initially review by assessing the undiscounted cash flows expected to be derived from the asset or group of assets, comparing the lowest level of total expected undiscounted cash flow to the carrying value. If the carrying value of the asset or the group of assets exceeds the sum of the undiscounted cash flows, impairment is considered to exist. An impairment charge is assessed by comparing the assets' fair value to the carrying value. Fair value can be calculated by a number of different approaches, including discounted cash flow, comparables, market valuations or quoted market prices. The process and steps required to assess the possible impairments of assets, including the identification of possible impairment indicators, assessing undiscounted cash flows, selecting the appropriate discount rate, the calculation of the weighted average cost of capital and the discounts or premiums inherent in market prices requires a substantial amount of management discretion and judgment. If actual results differ from these estimates, or if we adjust these estimates in future periods, operating results could be significantly affected.

Research and Development Expenses

We have several activities and cost drivers that we collectively refer to as "research and development." These activities include salaries and benefits of our direct employees, facility costs, overhead costs, clinical trial costs and related trial product manufacturing costs, contracted services, subcontractor costs and other research and or developmental related costs. Research and development costs, including any upfront payments and milestones paid to collaborators, are expensed as incurred. The timing of upfront fees and milestone payments in the future may cause variability in future research and development expenses. Clinical trial costs include costs associated with contract research organizations. The billings that we receive from contract research organizations for services rendered can lag for several months. 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 suppliers 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. For the three month periods ended March 31, 2006 and 2007, we have incurred research and development expenses of €1,675 and €3,075, respectively. As of March 31, 2007, we had €8,608 of future payables under outstanding contracts with various contract research organizations that are not revocable. Most of these contracts are on a cost plus basis or actual cost basis.

Share-Based Compensation

We have adopted the fair value based method of accounting for share-based employee compensation in accordance with the provisions of Statement of Financial Accounting Standards No. 123R, "Share Based Payment" (SFAS 123R). SFAS 123R requires us to estimate a significant number of variables in order to derive a fair value of an equity based instrument. For example, the risk of the underlying deliverable equity instruments (i.e., our ordinary shares) as compared to the market as a whole, is generally reflected in our unique "Beta". This is a unique measurement to each company, and requires several assumptions. The most common and generally accepted valuation models related to option pricing also include many significant assumptions related to such variables as dividend yields, share prices and the estimated life of the option before being exercised. The actual selection of which valuation model to use requires judgment, as there are several models to choose from.

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
Expected dividends on stock	Lower
Risk-free interest rate	Higher
Expected term of option	Higher

In our current valuation, we consider the volatility factor to be critical. For stock options issued in 2006 and 2007, which we assume will be exercised in three and five years, respectively, we have used a weighted average 40% factor of 40% and 60%. 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. If we increased our volatility factor to 80%, the fair value of our stock options outstanding as of March 31, 2006 and 2007 would have increased by $1,881 and $3,116, respectively, and would have resulted in $196 and $216 in additional compensation expense for the three month periods ended March 31, 2006 and 2007, respectively. Therefore, significant changes to these estimates could have a material impact on the results of our operations.

Accounting for income taxes

We use the liability method of accounting for income taxes, as set forth in Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes." Under this method, we recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities and net operating loss carry-forwards, all of which we calculate using presently enacted tax rates. We establish valuation allowances when necessary to reduce deferred tax assets to the amount that we expect to be realized.

In our accompanying financial statements we have reserved for all of our deferred tax assets as we currently believe that it is more likely than not that the assets will not be recoverable during their estimated life. In establishing our deferred tax position, in particular deferred tax assets, we only establish the tax asset if we believe that it is probable that this asset will be an allowable deduction in our tax jurisdiction. The assessment of the "recoverability" of that asset is a separate exercise, which uses the "more likely than not" criteria. In Italy, which is currently the only taxing jurisdiction where we are required to file a tax return, we have assessed that due to the limited lives of our net operating losses (limited to 5 years), we believe that these assets will not be recoverable before expiration. Although

we have paid some corporate income taxes in the past, the significant amount of other tax assets in conjunction with the higher level of expected expenditures, the already existing net operating losses and limited taxable income expected in the near future resulted in our estimating that a complete valuation allowance was necessary. Significant changes either to the underlying facts, such as an increase in the net operating loss life in Italy, or our estimates, such as our ability to generate meaningful taxable income, could result in changes to our existing valuation allowance. Such changes could have a material impact on our results of operations or financial position.

Recent Accounting Pronouncements

On February 15, 2007, FASB Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115* , or SFAS 159, was issued. SFAS 159 permits companies to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value and establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 will be effective for fiscal years beginning after November 15, 2007. We are currently evaluating the impact this standard would have on our financial statements.

On September 6, 2006, FASB Statement No 157, *Fair Value Measurements*, or SFAS 157, was issued. This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP), and expands disclosures about fair value measurements. This Statement applies under other accounting pronouncements that require or permit fair value measurements, the Board having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. The statement is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We are currently evaluating the impact of this standard on our financial statements.

Results of Operations

The following table sets forth our results of operations:

	Three Months Ended March 31,	
Unaudited, amounts in thousands	**2006**	**2007**
Sales to affiliates	€ 912	€ 951
Third party product sales	3	267
Total product sales	915	1,218
Other income and revenues.	35	35
Total Revenues	950	1,253
Operating costs and expenses:		
Cost of goods sold	711	754
Charges from affiliates	215	226
Research and development	1,675	3,075
General and administrative	1,296	1,291
Depreciation and amortization	42	75
	(3,939)	(5,421)
Operating loss	(2,989)	(4,168)
Foreign currency exchange gain (loss), net	(168)	(868)
Interest income (expense) and other income, net	52	263
Net loss	€ (3,105)	€ (4,773)

Three Months Ended March 31, 2006 Compared to Three Months Ended March 31, 2007

Product sales.

Our product sales were €1,218 for the three month period ended March 31, 2007, compared to €915 for the comparable period in 2006, an increase of 33% or €303. The increase in product sales is mainly due to greater demand for our products from our two main customers. Sales to affiliates represented 78% and 99% of the total product sales in the three months ended March 31, 2007 and 2006, respectively, and increased 4% to €951. Sales to third parties increased to €267 mainly due to higher demand for our active pharmaceutical ingredient sulglicotide in the Korean market for €82 and due to sales of finished products for €182 directly to distributors instead of going through Sirton.

Other income and revenues

Our other income and revenues was €35 for the three month period ended March 31, 2007 and 2006. Other income is primarily due to our recognition of revenues for performance milestone payments received under our license agreement with Sigma-Tau and upfront payments recognized ratably over the expected life of the research period.

Cost of goods sold.

Our cost of goods sold was €754 for the three month period ended March 31, 2007 compared to €711 for the comparable period in 2006. Cost of goods sold as a percentage of product sales was 61.9% in the 2007 period compared to 77.7% in the 2006 period. The decrease was due to the fact that, because of the timing of our manufacturing programs and purchase orders from our customers, during the 2007 period, we had more semifinished and finished inventory stockpiled for sale than during the 2006 period. We deferred the costs of this unsold inventory in each period, but since we had a greater amount of deferred costs in 2007 than 2006, it reduced the costs of goods as a percentage of products sold for 2007 compared to 2006.

Research and development expenses.

We incurred research and development expenses of €3,075 in the three month period ended March 31, 2007 compared to €1,675 in the comparable period in 2006. The expenses were primarily for the development of defibrotide to treat VOD and increased headcount. The difference between the periods is primarily due to the timing and expenses incurred for clinical trials, including clinical research organizations charges, regulatory activities, costs associated with the set-up, initiation and execution of our Phase III clinical trial of defibrotide to treat VOD and manufacturing expenses. Also contributing to the increase was an increase in headcount and outside services to support increased activity in our clinical trials and stock based compensation of €75.

General and administrative expenses.

Our general and administrative expenses were €1,291 and €1,296 for the three month period ended March 31, 2007 and 2006, respectively. General and administrative expenses for the 2007 period were thus in line with the comparable period in 2006 and include personnel costs, facilities related expenses, general corporate expenses of being a public company, legal and other professionals fees and stock based compensation expense of €167.

Depreciation and amortization expense.

Depreciation and amortization expense was €75 for the three month period ended March 31, 2007 compared to €42 for the comparable period in 2006. The increase is primarily attributable to capital expenditures for an infrastructure upgrade and amortization of the intellectual property portfolio. Depreciation expense excludes depreciation on our manufacturing facilities which are included in cost of goods sold.

Interest income (expense), net.

Interest income (expense), net, increased to €263 in the first quarter of 2007 over the comparable period in 2006. Interest income amounted to €341 and €85 in the three months ended March 31, 2007 and 2006, respectively, an increase of €256. The increase is a result of a higher amount of invested funds in the 2007 period. Interest expenses totaled €78 and €33 in the three months ended March 31, 2007 and 2006, respectively, an increase of €45. Interest expense increased due to the higher amount of long term debt outstanding as of March 31, 2007 for which there was no similar expense in 2006.

Net loss.

Our net loss was €4,773 for the three month period ended March 31, 2007 compared to €3,105 in the comparable period in 2006. The difference was primarily due to increases in research and development expenses and foreign exchange loss in the 2007 period, partially offset by increases in interest income, net and product sales.

Liquidity and Capital Resources

During the three month period ended March 31, 2007, we used €3,575 of cash to fund operations and working capital requirements, including research development and incurred capital expenditures and expenditures on other intangibles of €348 and we funded these amounts from the following sources:

- $47,500 (€36,504) in gross proceeds from a private placement of 2,354,000 of our ordinary shares;
- $700 (€549) in gross proceeds from exercise of warrants and stock options; and
- €10,205 from cash available at December 31, 2006.

At March 31, 2007, we had an aggregate of €6,325 in debt outstanding.

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:

- whether we are able to commercialize and sell defibrotide for the uses for which we are developing it;
- the scope and results of our clinical trials;
- 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 VOD with multiple-organ failure. 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 VOD with multiple-organ failure;
- 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 strategic agreements with corporate and academic collaborators and the success of such relationships.

We believe that our working capital is sufficient for our present needs. 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 "Risk Factors" in our Form 20-F for the year ended December 31, 2006 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, 2006 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, 2006 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, 2007, 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, 2007, 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 use interest rate swaps on our floating rate mortgage debt to hedge the risk of rising rates. We do not believe we are exposed to material risks due to changes in interest rates, although our future interest income may fluctuate in line with changes in interest rates. The risk associated with fluctuating interest rates is principally confined to our cash deposits in banks and our floating rate debt (to the extent we are not protected by interest rate hedges) and, therefore, we believe that our current exposure to interest rate risk is minimal.

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.

Trends

As a public reporting company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as new rules subsequently implemented by the Securities and Exchange Commission and the Nasdaq Global Market System, have required changes in corporate governance practices of public companies. We expect these new rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect these new rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance.

In connection with our purchase of the Italian marketing rights to defibrotide and related trademarks from Crinos, we paid Crinos €4,000 in 2006, placed another €4,000 in escrow, which was released to Crinos in the second quarter of 2007, and agreed to pay Crinos two additional installments of €4,000 by December 31, 2007 and December 31, 2008.

We expect our costs for the following current clinical trials and historical trials to increase substantially in 2007 compared to 2006 as we enroll patients and pay the related clinical trial centers and clinical research organizations:

- Phase III clinical trial of defibrotide to treat VOD in the United States;
- Historical trial of defibrotide to treat VOD in the United States; and
- Phase II/III clinical trial of defibrotide to prevent VOD in children in Europe.

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 in the United States and Europe after we complete our Phase III trial of defibrotide to treat VOD in the United States.