Gentium S.p.A.
Form 6-K
December 06, 2006

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 November, 2006.

Commission File Number 000-51341

Gentium S.p.A.

(Translation of registrant's name into English)

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

(Address of principal executive office)

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

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

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

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

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

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

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

Description of events affecting the Registrant set forth in the Registrant's press release, dated November 30, 2006, attached hereto as Exhibit Number 1, and the Registrant's quarterly report for the quarterly period ended September 30, 2006, attached hereto as Exhibit 2, are each incorporated by reference herein in its entirety.

Exhibit	**Description**
1	Press release, dated November 30, 2006.
2	Quarterly report for the quarterly period ended September 30, 2006.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GENTIUM S.P.A.

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

Date: December 5, 2006

INDEX TO EXHIBITS

Exhibit	Description
1	Press release, dated November 30, 2006.
2	Quarterly report for the quarterly period ended September 30, 2006.

PRESS RELEASE

FOR IMMEDIATE RELEASE

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Gentium Reports Third Quarter Financial Results and Clinical Update

Villa Guardia (Como), Italy (November 30, 2006) - Gentium S.p.A. (NASDAQ: GENT) (the "Company") today reported financial results for the three and nine months ended September 30, 2006. Highlights of the third quarter of 2006 and recent weeks include:

- Publication of an independent study showing Defibrotide could prevent Veno-Occlusive Disease (VOD) associated with Infantile Osteopetrosis;
- Publication of two independent studies of Defibrotide to treat VOD in children;
- Presentation of data at the 16th European Congress of Immunology demonstrating that Defibrotide modulates immune functions of endothelial cells and its impact for transplantation and cancer therapy;
- Progress with the Phase III clinical trial in the U.S. with Defibrotide for the treatment of severe Veno-Occlusive Disease with Multiple Organ Failure (Severe VOD): this study is expected to be conducted at approximately 32 clinical centers; 18 centers are open for enrollment and nine patients have been enrolled;
- Progress with the Phase II/III clinical trial in Europe with Defibrotide for the prevention of VOD in children: 30 centers have IRB approval and 25 centers are open for patient enrollment; 56 patients have been enrolled;

- Progress with an investigator-sponsored Phase I/II study with Defibrotide for the treatment of advanced and refractory Multiple Myeloma: four centers are open; 24 patients have been enrolled, which completes enrollment for the Phase I segment of the study;
- Acceptance of 10 abstracts on Defibrotide for presentation at the Annual Meeting of the American Society of Hematology (ASH) in Orlando, Fla., December 9-12;
- Scheduling of two presentations on Defibrotide for the EuroTIDES, 7th Annual Conference on Oligonucleotides in Hamburg, Germany, December 4-5.

Clinical Highlights and Outlook

Commenting on Gentium's clinical progress, Laura Ferro, M.D., Chairman and Chief Executive Officer, said, "During the third quarter we continued to make substantial progress in advancing our clinical programs and in building our infrastructure to support these efforts. To date, our U.S. Phase III trial with Defibrotide for the treatment of VOD has 18 sites opened for enrollment, an increase of 12 sites, and nine patients are being treated. We continue to add centers and expect to have nearly all 32 clinical sites open for patient enrollment by year end. As each center needs to treat only 2-3 patients to reach accrual, we are confident that this trial will remain on track to reach full enrollment by third quarter 2007. In order to ensure the necessary support and expertise in managing this trial, we have engaged a leading contract research organization (CRO) to oversee implementation and to provide data management services.

"Our European Phase II/III trial for the prevention of VOD in pediatric patients is progressing, and we are in the process of determining our regulatory strategy for developing a combined U.S. and European Phase II/III trial for the prevention of VOD in adults," she added. "We believe a combined trial offers a better registration strategy for this indication that could save the Company time and money in bringing this potentially life-saving drug to market."

Dr. Ferro continued, "We were extremely pleased that the independent study of Defibrotide to treat multiple myeloma completed its Phase I trial, and is moving forward into the Phase II segment of the study. Data from this Phase I study will be among 10 presentations on Defibrotide at the annual ASH conference next month. These presentations, along with the two Defibrotide presentations at the EuroTides conference in December, underscore the potential therapeutic value of Defibrotide and testify to the hard work and dedication of our collaborating clinicians and Gentium's medical and scientific team," noted Dr. Ferro.

Financial Highlights

Gentium reports its financial condition and operating results using U.S. Generally Accepted Accounting Principles (GAAP). The Company's financial statements are prepared using the Euro as its functional currency. On September 30, 2006, €1.00 = $1.27.

For the third quarter ended September 30, 2006 compared with the prior-year's third quarter:

- Total revenues were €0.90 million, compared with €0.37 million
- Operating costs and expenses were €5.06 million, compared with €2.69 million
- Research and development expenses, which are included in operating costs and expenses, were €2.76 million, compared with €1.18 million
- Operating loss was €4.16 million, compared with €2.32 million
- Interest income (expense), net, was €0.2 million, compared with €0.05 million
- Pre-tax loss was €3.88 million, compared with €2.18 million
- Net loss was €3.88 million, compared with €2.20 million
- Net loss per share was €0.33, compared with €0.28

For the nine months ended September 30, 2006 compared with the comparable prior-year period:

- Total revenues were €3.00 million, compared with €2.21 million
- Operating costs and expenses were €13.42 million, compared with €7.44 million
- Research and development expenses, which are included in operating costs and expenses, were €6.36 million, compared with €3.12 million
- Operating loss was €10.41 million, compared with €5.23 million
- Interest income (expense), net, was €0.34 million, compared with (€4.20) million
- Pre-tax loss was €10.22 million, compared with €9.86 million
- Net loss was €10.22 million, compared with €9.91 million
- Net loss per share was €0.97, compared with €1.62
- Cash used in operating activities was €7.70 million, compared with €6.69 million
- Cash and cash equivalents were €21.55 million as of September 30, 2006

Dr. Ferro commented, "As we advance our clinical development programs, we expect proportionate increases in R&D and clinical and regulatory expenses to contribute to increasing losses for the balance of this year and next year. Our general and administrative expenses have increased substantially, with much of the higher expense a result of the costs of being a public company and the initiation of our Phase III VOD treatment clinical trial and Phase II/III VOD prevention trials. Our 2006 results also reflect a significant decline in interest expense due to the repayment and redemption of our Series A notes in June 2005 in conjunction with our initial public offering."

Operating Results and Trends

The fluctuation in total product sales for the three- and nine-month periods compared with the prior year is primarily the result of higher sales volume of the Company's active pharmaceutical ingredients defibrotide, urokinase and sulglicotide to our principal customer and affiliate, Sirton. Also contributing to the increase was an increase in sales and increases in third-party product sales, mainly due to the sales of sulglicotide to a Korean customer. Total product sales for the nine-month period ended September 30, 2006 increased by €0.81 million, or 41%, compared with the same period in 2005.

Cost of goods sold was €2.44 million for the nine-month period ended September 30, 2006, which included a €182 thousand inventory reserve attributable to slow-moving inventory, compared with cost of goods sold of €1.72 million for the comparable period in 2005. The increase in cost of goods sold was mainly due to increased sales volume in the nine-month period of 2006 compared to the same period in 2005.

Research and development spending increased during the three- and nine-month periods in 2006 compared with 2005, primarily due to the costs associated with the Company's Phase III trial in the U.S. for the treatment of Severe VOD, the Company's Phase II/III trial for prevention of VOD in children and preparations for the Phase II/III trial for the

prevention of VOD in adults. Growth in headcount and outside services to support increased activity in our clinical trials, including clinical product production costs, contract research organization expenses and stock-based compensation expense also contributed to increased research and development expenses.

The Company had 69 employees as of September 30, 2006, compared with 53 as of September 30, 2005. Other general and administrative expense increases were primarily the result of building corporate infrastructure, legal and public company expenses, an increase in internally provided administrative services to replace administrative services previously provided by affiliates and stock-based compensation expense. The increase in internally provided services accounted for the decrease in charges from affiliates between the periods. G&A expense includes a one-time charge of €104 thousand per the absorption of the fixed portion of our production costs, not otherwise included in cost of good sold, due to the partial shut-down of the manufacturing facility in July and August for the replacement of two reactors.

Interest income (expense), net, changed primarily due to the repayment and conversion of the Company's Series A senior convertible notes in June 2005, and the higher level of invested funds compared with the prior year. For the nine months ended September 30, 2005, interest expense on the Series A notes was €4.2 million, including non-cash interest expense of €3.8 million from the amortization of the issue discount and debt issue cost. These notes were converted or redeemed in June 2005. Additionally, interest income increased by €416 thousand from €56 thousand in the period ended September 30, 2005 to €472 thousand in the comparable 2006 period, as the result of a higher level of invested funds.

The Company ended the third quarter of 2006 with €21.55 million in cash and cash equivalents, compared with cash and cash equivalents of €12.79 million as of December 31, 2005.

About Gentium

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

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements." In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential" or "continue," the negative of these terms and other comparable terminology. These statements are not historical facts but instead represent the Company's belief regarding future results, many of which, by their nature, are inherently uncertain and outside the Company's control. It is possible that actual results may differ, possibly materially, from those anticipated in these forward-looking statements. For a discussion of some of the risks and important factors that could affect future results, see the discussion in our Form 20-F for the year ended December 31, 2005 under the caption "Risk Factors."

Source: Gentium

(Tables to follow)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	**2006**	**2005**	**2006**
Revenues:				
Sales to affiliates	€ 304	€ 799	€ 1,900	€ 2,652
Third party product sales	-	45	95	155
Total product sales	304	844	1,995	2,807
Royalties	-	7	-	14
Other income and revenues	70	51	210	183
Total Revenues	374	902	2,205	3,004
Operating costs and expenses:				
Cost of goods sold	426	828	1,721	2,444
Research and development	1,184	2,760	3,117	6,362
Charges from affiliates	200	251	781	632
General and administrative	844	1,138	1,738	3,787
Depreciation and amortization	35	87	78	190
	2,689	5,064	7,435	13,415
Operating loss	(2,315)	(4,162)	(5,230)	(10,411)
Foreign currency exchange gain (loss), net	85	86	(435)	(144)
Interest income (expense), net	48	198	(4,197)	338
Pre-tax loss	(2,182)	(3,878)	(9,862)	(10,217)
Income tax expense:				
Deferred	16	-	48	-
Net loss	€ (2,198)	€ (3,878)	€ (9,910)	€ (10,217)
Shares used in computing net loss per share, basic and diluted	7,977,983	11,666,013	6,104,650	10,510,315
Net loss per share:				
Basic and diluted net loss per share	€ (0.28)	€ (0.33)	€ (1.62)	€ (0.97)

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

	As of December 31, 2005	As of September 30, 2006 (Unaudited)
ASSETS		
Cash and cash equivalents	€ 12,785	€ 21,548
Receivables from third parties	8	75
Receivables from related parties	1,867	2,262
Inventories, net	1,628	1,443
Prepaid expenses and other current assets	918	1,142
Total Current Assets ……	17,206	26,470
Property, manufacturing facility and equipment, at cost	17,456	18,926
Less: Accumulated depreciation	8,825	9,440
Property, manufacturing facility and equipment, net	8,631	9,486
Intangible assets, net of amortization	267	566
Marketable securities	-	592
Other non-current assets	9	12
Total Assets	€ 26,113	€ 37,126
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable	€ 2,644	€ 4,485
Payables to related parties	542	340
Accrued expenses and other current liabilities	1,063	953
Current maturities of long-term debt	916	261
Current portion of capital lease obligation	-	50
Deferred income	283	262
Total Current Liabilities	5,448	6,351
Long-term debt, net of current maturities	2,485	5,273
Capital lease obligation	-	80
Termination indemnities	706	648
Total Liabilities	8,639	12,352
Share capital (par value: €1.00; 12,690,321 and 15,100,292 shares authorized at December 31, 2005 and September 30, 2006, respectively; 9,610,630 and 11,666,013 shares issued at December 31, 2005 and September 30, 2006, respectively	9,611	11,666
Additional paid in capital	33,090	48,489
Other comprehensive income	-	63
Accumulated deficit	(25,227)	(35,444)
Total Shareholders' Equity	17,474	24,774
Total Liabilities and Shareholders' Equity	€ 26,113	€ 37,126

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

	For the Nine Months Ended September 30,	
	2005	**2006**
Cash Flows From Operating Activities:		
Net loss	€ (9,910)	€ (10,217)
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Unrealized foreign exchange loss	575	149
Depreciation and amortization	1,107	747
(Gains) Loss on fixed assets disposal	-	(23)
Non cash interest expense	3,837	-
Amortization of debt financing cost	-	3
Inventory write off	130	182
Stock based compensation	363	665
Deferred income tax benefit	48	-
Changes in operating assets and liabilities:		
Accounts receivable	590	(462)
Inventories	(927)	3
Prepaid expenses and other current assets	56	(192)
Accounts payable and accrued expenses	(2,489)	1,522
Deferred income	(214)	(21)
Termination indemnities	145	(58)
Net cash used in operating activities	**(6,689)**	**(7,702)**
Cash Flows From Investing Activities:		
Capital expenditures	(1,024)	(1,311)
Intangible expenditures	(61)	(431)
Proceeds from sale of asset	-	23
Investment in marketable securities	-	(530)
Net cash used in investing activities	**(1,085)**	**(2,249)**
Cash Flows From Financing Activities:		
Proceeds from warrant exercises	-	884
Proceeds from long term debt, net	-	4,563
Capital contribution	3,900	-
Repayments of long-term debt	(470)	(599)
Repayment of Series A convertible Notes	(2,762)	-
Early extinguishment of long term debt	-	(1,868)
Principal payment of capital lease obligations		(20)
Repayment of affiliate's loan	(2,200)	-
Repayment of bank overdrafts and short term borrowings	(2,790)	-
Proceeds from equity offering, net	16,647	15,896
Net cash provided by financing activities	**12,325**	**18,856**
Effect of foreign exchange rate		(142)

Increase in cash and cash equivalents		4,551		8,905
Cash and cash equivalents, beginning of period		2,461		12,785
Cash and cash equivalents, end of period	€	7,012	€	21,548

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Exhibit 2

GENTIUM S.p.A.

QUARTERLY REPORT

For the quarterly period ended September 30, 2006

GENTIUM S.p.A.
QUARTERLY REPORT, SEPTEMBER 30, 2006
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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 license;
• our expectations for incurring additional capital expenditures to expand our manufacturing and 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 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.
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(in thousands, except share data)

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Total Liabilities and Shareholders' Equity	**€ 26,113**	**€ 37,126**

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

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(Unaudited, in thousands, except share data)

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Charges from affiliates	200	251	781	632
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Depreciation and amortization.	35	87	78	190
	2,689	5,064	7,435	13,415
Operating loss	(2,315)	(4,162)	(5,230)	(10,411)
Foreign currency exchange gain (loss), net	85	86	(435)	(144)
Interest income (expense), net	48	198	(4,197)	338
Pre-tax loss	(2,182)	(3,878)	(9,862)	(10,217)
Income tax expense:				
Deferred	16	-	48	-
Net loss	€ (2,198)	€ (3,878)	€ (9,910)	€ (10,217)
Shares used in computing net loss per share, basic and diluted	7,977,983	€ 11,666,013	€ 6,104,650	€ 10,510,315
Net loss per share:				
Basic and diluted net loss per share	€ (0.28)	(0.33)	(1.62)	(0.97)

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

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

	Nine Months Ended September 30,	
	2005	**2006**
Cash flows from operating activities:		
Net loss	€ (9,910)	€ (10,217)
Adjustments to reconcile net income to net cash used in operating activities:		
Unrealized foreign exchange loss	575	149
Depreciation and amortization	1,107	747
(Gains) Loss on fixed assets disposal	-	(23)
Non cash interest expense	3,837	-
Amortization of debt financing cost	-	3
Inventory write off	130	182
Stock based compensation	363	665
Changes in operating assets and liabilities:		
Accounts receivable	590	(462)
Inventories	(927)	3
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Cash flows from investing activities:		
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Repayments of long-term debt	(470)	(599)
Repayment of Series A convertible notes	(2,762)	-
Early extinguishment of long term debt	-	(1,868)
Capital contribution by shareholder	3,900	-
Principal payment of capital lease obligations	-	(20)
Repayment of affiliate's loan	(2,200)	-
Repayment of bank overdrafts and short term borrowings	(2,790)	-
Proceeds from equity offering, net	16,647	15,896
Net cash provided by financing activities	12,325	18,856
Effect of foreign exchange rate		(142)
Increase in cash and cash equivalents	4,551	8,905
Cash and cash equivalents, beginning of period	2,461	12,785
Cash and cash equivalents, end of period	€ 7,012	€ 21,548

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Supplemental disclosure of cash flow information:				
Cash paid for interest, net of capitalized amount.	€	538	€	102
Income taxes paid.	€	-	€	-
Supplemental disclosure of non-cash investing and financing activities:				
Equipment acquired under capital lease		127		150
Conversion of note payable to stockholders into ordinary shares		2,408		-
Valuation of warrant issued in connection with convertible notes		597		-
Value of beneficial conversion feature of convertible notes and warrants		5,396		-
Fair value of warrants issued with shares		-		715

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. Description of Business and Summary of Significant Accounting Policies

Description of Business

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 a pharmaceutical company 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 used to treat peptic ulcers, and other miscellaneous pharmaceutical products. All of the Company's operating assets are located in Italy, and approximately 95% of product revenue are to one affiliated customer in Italy.

The Company is domiciled in the Republic of Italy. Gentium's largest shareholder is FinSirton S.p.A. ("**FinSirton**") and an affiliate, Sirton Pharmaceuticals S.p.A. ("**Sirton**") is a subsidiary of FinSirton.

In December 2000**,** Sirton contributed certain assets, including research facilities, equipment and intellectual property, to the Company in return for 98% of the Company's shares (the "**Separation**"). At that time, the Company was incorporated and in July 2001 changed its name to Gentium S.p.A. The Separation and transfer of assets was recorded at historical cost in the accompanying financial statements. The accompanying financial statements reflect the historical operations that comprised the business of research and development and manufacture of defibrotide and certain other pharmaceutical ingredients.

The financial statements include allocations of certain expenses, including centralized legal, accounting, treasury, information-technology, purchasing and logistics, controlling and reporting and other corporate services and infrastructure costs provided by the Company's largest shareholder, FinSirton, and its affiliate, Sirton. Starting in April 2005, the Company began to implement functions and activities that were previously provided by FinSirton and Sirton. As of September 30, 2006, we had established our own purchasing, logistics, quality assurance, accounting, controlling and reporting services, treasury, regulatory and information technology departments, but we continued to obtain corporate services, payroll services and quality control services from these affiliates and we are still relying on the IT infrastructure provided by Sirton.

The Company derives the majority of its revenues from its affiliate, Sirton. Despite the fact that Sirton has experienced financial difficulties which could impact the Company, management believes that the Company can continue to operate without a significant change in operations or disposal of assets. Although the Company's business plan foresees a substantial investment in research and development and continuing losses, the Company has demonstrated the ability to raise substantial third party funding based on the prospects of the Company's product candidates. The Company also has opportunities to raise capital by licensing its technology and proprietary knowledge as it has in the past. However, there can be no assurance that the Company will be able to raise additional funds in the future.

The accompanying 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, except share and per share data.

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 results could differ from those estimates.

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

Inventories: Inventories consist of raw materials, work in progress and completed products and from time to time includes products used in clinical trials, which are charged to research and development expense when consumed. 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.

Marketable Securities: The Company's marketable securities are classified as securities available for sale in non-current assets and are carried at fair value. The Company's marketable securities consist of debt securities, which have been pledged to secure the Company's repayment of a loan from 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 stockholders' 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 include upfront fees, performance milestone payments, reimbursements of development costs and continuing license and manufacturing fee arrangements if the research and development efforts 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.

Research and Development: Research and development expenditures are charged to operations as incurred. Research and development expenses consist of costs incurred for proprietary and collaborative research and development, including activities such as product registration and investigator-sponsored trials. Research and development expenses include salaries, benefits and other personnel related costs, laboratory supplies and materials, regulatory activities, 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.

Termination Indemnities: The liability for termination indemnities relates to the employees of the Company in Italy. In accordance with Italian severance pay statutes, an employee benefit is accrued for service to date and is payable immediately upon separation. The termination indemnity is calculated in accordance with local, civil and labor laws based on each employee's length of service, employment category and remuneration. The termination liability is adjusted annually by a cost-of-living index provided by the Italian Government. There is no vesting period or funding requirement associated with the liability. The liability recorded in the balance sheet is the amount that the Company's employees would be entitled to receive immediately upon separation. In accordance with EITF 88-1, "*Determination of Vested Benefit Obligation for a Defined Benefit Pension Plan"*, we record the obligation under the plan at the amount of the vested benefit obligation which is defined as the actuarial present value of the vested benefit to which the employee is entitled if the employee separates immediately. Benefits of approximately €41 and €144 were paid to employees who separated from the Company for the periods ended September 30, 2005 and 2006, respectively. The related charge to earnings was €83 and €93 for the nine months periods ended September 30, 2005 and 2006, respectively.

Share Based Compensation: Effective September 30, 2004, the Company adopted an equity incentive plan and a non-statutory share option plan (the "**Plans**") for officers, employees, consultants, directors and non-employee directors. Options to purchase an aggregate of 992,000 and 1,137,000 ordinary shares were outstanding under the Plans at December 31, 2005 and September 30, 2006, 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 equity compensation 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. Total stock based compensation expense was €363 thousand and €665 thousand for the nine month periods ended September 30, 2005 and 2006, respectively. The Company expects to continue to incur significant non-cash share based compensation expense.

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 nine month periods ended September 30, 2005 and 2006, the Company has recorded non-cash compensation expenses for options granted to non-employees and non-directors of approximately €110 thousand and €80 thousand, respectively.

Stock purchase warrants issued with Series A Senior Convertible Promissory Notes: The Company granted warrants (the "**Warrants**") in connection with the issuance of certain notes payable (the "**Notes**"). Under Accounting Principles Board Opinion No. 14, *"Accounting for Convertible Debt and Debt Issued With Stock Purchase Warrants",* the estimated fair value of such Warrants represents a discount from the face amount of the Notes. Accordingly, the related estimated fair value of the warrants was recorded in the financial statements as a discount from the face amount of the Notes. The discount on the Notes was being amortized and included in interest expense over the period to the earliest put option date using the effective interest method. Upon completion of the Company's initial public offering, convertible Note holders either received cash for their Notes or converted the Notes into equity. At that time, the remaining balance of the discount related to redeemed Notes was charged to interest expense and, for Notes converted into ordinary shares, the remaining balance was charged to additional paid-in capital.

Beneficial Conversion Feature of Series A Senior Convertible Promissory Notes: The convertible feature of the Notes and Warrants provided for a rate of conversion of the instrument into Gentium's shares that was below fair value at the time of issuance. This feature is normally characterized as a "beneficial conversion feature" ("BCF"), which represents the "intrinsic value" of the difference between the conversion price of the instrument and the underlying fair value of the Company's shares at that date. Pursuant to EITF Issue No. 98-5 *"Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratio"* and EITF No. 00-27, *"Application of EITF Issue No. 98-5 to Certain Convertible Instruments"*, the Company determined the value of the BCF, for the Notes and Warrants issued in 2004, to be approximately €3,688 ($4,643) and €459 ($578), respectively. In conjunction with Notes and Warrants issued in January 2005, the Company determined the value of the BCF to be approximately €1,111 ($1,456) and €138 ($181), for the Notes and Warrants, respectively. Accordingly, the relative fair value of the BCF related to the Notes and Warrants was recorded in the financial statements as a discount from the face amount of the Notes. The discount was being amortized to interest expense and accreted to additional paid in capital, respectively, using the effective interest method, through the earliest put option date. As of December 31, 2005, all of the Notes had either been converted or redeemed. The unamortized balance of the discount related to Notes redeemed was charged to expense and for Notes converted into ordinary shares, was charged to additional paid-in capital.
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.

Recent Accounting Pronouncement

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109" (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides related guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure. FIN 48 is effective for the Company beginning January 1, 2007. The Company is currently evaluating the potential impact of this statements on its financial statements.

In June 2006, the FASB ratified EITF No. 06-3 "How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement (That Is, Gross versus Net Presentation)" (EITF 06-3). EITF 06-3 addresses the income statement presentation of any tax collected from customers and remitted to a government authority and concludes the presentation of taxes on either a gross basis or a net basis is an accounting policy decision that should be disclosed pursuant to APB Opinion No. 22 "Disclosure of Accounting Policies." This is effective for interim and annual reporting periods beginning after December 15, 2006 and will require the financial statement disclosure of any significant taxes recognized on a gross basis. The Company is currently evaluating the potential impact of this standard on its financial statements.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108 ("SAB 108"). SAB 108 provides guidance on the consideration of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. The staff believes registrants must quantify the impact of correcting all misstatements, including both carryover and reversing effects of prior year misstatements, on the Company's current year financial statements. The staff prescribes two approaches to assessing the materially of misstatements; the "rollover" approach, which quantifies misstatements based on the amount of error originating in the current year income statement and the "iron curtain approach", which quantifies misstatements based on the effects of correcting the cumulative effect existing in the balance sheet at the end of the current year. If under either approach, misstatements are deemed material, the

Company is required to adjust its financial statements, including correcting prior year financial statements, even though such correction was and continues to be immaterial to the prior year financial statements. Correcting prior year financial statements for immaterial errors would not require the Company to amend previously filed reports, rather such corrections may be made the next time the Company files its prior year statements. The Company is currently evaluating the potential impact of this bulletin on its financial statements.

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("SFAS No. 157"). The SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This statement applies under other accounting pronouncements that require or permit fair value measurements, the FASB 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. SFAS No. 157 is effective January 1, 2008. The Company is currently evaluating the impact of this statement on its financial condition and results of operation.*:*

2. SERIES A SENIOR CONVERTIBLE PROMISSORY NOTES

From October 2004 through December 2004, the Company issued, in a private placement, $6,098 (€4,843 based on the exchange rate at the dates of subscription) of Series A senior convertible promissory notes (the "**Notes**"). In January 2005, the Company issued an additional $1,912 (€1,459 based on the exchange rate on the date of subscription) in Notes. These Notes were issued with warrants to purchase additional ordinary shares at 110% of the price per share of the Company's ordinary shares sold in its IPO. The Notes could be converted into ordinary shares at 90% of the price per share of the shares sold during the Company's IPO (but not less than $6.00 per share). The number of warrants issued with the Notes was determined by a formula that included the price per share of the shares sold in the Company's IPO. Based on the formula, the warrants were exercisable to purchase 503,298 ordinary shares at an exercise price of $9.90 per share. In October and November 2005, the Company completed a private placement that triggered an antidilution provision in warrant agreements. As a result, the exercise price of the Warrants was reduced to $9.52 per share.

In April 2006, we issued 18,334 ordinary shares upon exercise of a warrant issued in connection with our Series A senior convertible promissory notes, at a price per share of $9.52, for proceeds of $175 thousand.

On June 21, 2005, the closing date of the Company's IPO, holders of Notes with a face value of $2,912 (€2,408 based on the exchange rate on June 21, 2005) elected to convert their promissory Notes to 359,505 of the Company's ordinary shares, and in June and July 2005, the remaining balance of the Notes with a face value of $5,098 (approximately €4,221 based on the exchange rate at the dates of redemption) were redeemed.

3. LONG TERM DEBT

Long term debt, net of current maturities consists of:

		December 31, 2005	September 30, 2006
a)	Mortgage loan bearing interest at the Euribor 6 month rate (3.63% at December 31, 2005) plus 1.0%, due February, 2006	€ 119	€ -
b)	Mortgage loan bearing interest at the Euribor 6 month rate (4.38% at December 31, 2005) plus 1.75%, due October, 2006	136	-
c)	Research loan from the Italian Ministry for University and Research, interest at 1% per annum, due January 2012	450	384
d)	Equipment loans secured by the underlying equipment pursuant to the Sabatini Law, interest at 2.1%	656	525
e)	Mortgage loan bearing interest at the Euribor 6 month rate (4.03% at December 31, 2005) plus 1.4%, due August 2010	2,000	-
	Mortgage loan bearing interest at the Euribor 6 month rate (3.52% at September 30, 2006) plus 1.0%, due June 2014	-	2,800
f)	Equipment loan secured by marketable securities, due April 2011, bearing interest at the Euribor 3 months rate (3.33% at September 30, 2006) plus 1.7%	-	1,050
g)	Equipment loan due to June 2011, bearing interest at the Euribor 3 month rate (3.33% at September 30, 2006) plus 1.20%	-	750
h)	Other	40	25
		3,401	5,534
	Less current maturities	916	261
	Total	€ 2,485	€ 5,273

a) The Company had a mortgage loan with Banca Nazionale del Lavoro ("**BNL**") that was originally granted for €1,549 in May 1999 and bore interest at the six-month Euribor rate plus 1.0%. The loan was secured by the Company's real property and was originally granted to its affiliate, Sirton, but was assumed by Gentium in 2002 as part of the Separation. This loan was repaid in full in February 2006.

b) The Company had another mortgage loan with BNL originally granted for €1,291 in November 1996 that bore interest at the six month Euribor rate plus 1.75%. The loan was secured by a mortgage on the Company's real property and was originally granted to its affiliate, Sirton, but was assumed by Gentium in 2002 as part of the Separation. On June 28, 2006, the loan was extinguished in connection with a debt restructuring agreement reached with BNL..

c) The Company received a loan commitment from the Italian Ministry for University and Research granted through San Paolo-IMI bank. The initial advance was €123 as of December 31, 2002. The loan is for financing research and development activities and bears interest at 1.0% per annum. The loan was increased to €482 as of December 31,

2003. The loan is payable in installments every six months beginning six months after the completion of the related research and development, but no later than January 2012. The balance is reflected in the table above as maturing in equal installments throughout the period until January 2012.

d) On July 9, 2004, the Company obtained a loan in the approximate amount of €487 from Cassa di Risparmio di Parma e Piacenza. The loan was obtained pursuant to Italian Law No. 1329 of 28 November 1965 (Legge Sabatini), a law that facilitates the purchase and lease of new production equipment. The loan is secured by a lien on the Company's related equipment and machinery. On August 4, 2004, the Company obtained an additional loan in the amount of €388 from Cassa di Risparmio di Parma e Piacenza under the same terms and conditions. Interest is payable quarterly at the rate of 2.1%. The principal is payable in quarterly installments of €19 and €24 thousand respectively. The principals are scheduled to be paid in full by June 2008 and July 2009, respectively.

e) On July 20, 2004, the Company obtained a mortgage loan in the amount of €2.0 million from BNL. The mortgage loan was secured by real estate owned by the Company and its affiliate, Sirton, and by a guarantee by the Company's largest shareholder, FinSirton. BNL released Sirton from its mortgage and FinSirton from its guarantee in April 2006, after we deposited €550 with BNL. On June 28, 2006, the loan was extinguished in connection with a debt restructuring agreement reached with BNL and the €550 cash escrow deposit was released back to the Company. As part of the debt restructuring agreement, BNL granted us a new loan for €2.8 million bearing interest at the six month Euribor rate plus 1.00%. The principal is payable in semi-annual installments, beginning December 28, 2007 through maturity on June 28, 2014. The interest is paid semi-annually. The loan is secured by a real estate mortgage on certain of our real estate.

f) In April 2006, the Company obtained a long term loan from Banca Intesa-Mediocredito SpA. The loan was obtained pursuant to Italian Law 598/94, a law that facilities the investment in innovation and improvements in manufacturing facilities. The loan is secured by marketable debt securities in the aggregate amount of €525 that will gradually be released back to the Company as we repay the principal of the loan, although the value of the remaining pledged securities must equal at least 50% of the remaining loan principal. The loan has a five-year term and bears interest at the three-month Euribor rate plus 1.7%. The principal is payable in eight semi-annual installments of €131 beginning October 5, 2007 through April 5, 2011. Interest is due quarterly beginning from October 5, 2006.

g) On June 30, 2006 the Company obtained a loan in the amount of €750 from San Paolo IMI Bank S.p.A. for the acquisition and installation of manufacturing equipment. The loan bears interest at the three month Euribor rate plus 1.20%. Beginning on June 15, 2008, the rate will be decreased to 1.02% if the Company completes its investment activities by January 21, 2007. The loan is payable in thirteen quarterly installments of approximately €58 beginnings on June 15, 2008 through June 15, 2011. Interest is due quarterly beginning on September 15, 2006. The agreement 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.

4. INTEREST RATE CAP AGREEMENTS

On June 28, 2006, as part of the debt restructuring agreement described above, the Company entered into an interest rate cap agreement with BNL providing protection against fluctuations in interest rates with respect to 50% of the total loan committment. The Euribor rate portion of the interest rate was capped at 4.00%. The agreement expires on June 28, 2011. At that time 50% of the principal is scheduled to be repaid.

On July 4, 2006 the Company entered into an interest rate cap agreement with San Paolo IMI Bank providing protection against fluctuations in interest rates with respect to 50% of the total loan committment. The Euribor rate portion of the interest rate was capped at 3.75%. The agreement expires on July 6, 2009. At that time 50% of the principal is scheduled to be repaid.

On July 5, 2006 the Company entered into an interest rate cap agreement with Banca Intesa S.p.A. providing protection against fluctuations in interest rates with respect to 50% of the total loan committment. The Euribor rate portion of the interest rate was capped at 3.70%. The agreement expires on July 5, 2009. At that time 50% of the principal is scheduled to be repaid.

5. SHAREHOLDERS' EQUITY

The Company had 9,610,630 and 11,666,013 ordinary shares of €1.00 par value per share issued and outstanding as of December 31, 2005 and September 30, 2006, respectively. On September 30, 2006, the authorized shares were 15,100,292. Authorized capital is as follows:

	December 31, 2005	September 30, 2006
Issued and outstanding	9,610,630	11,666,013
Reserved for exercise of warrants	1,216,816	1,571,404
Reserved for underwriters purchase option	151,200	151,200
Reserved for future planned offerings	151,675	151,675
Reserved for share option plans	1,560,000	1,560,000
	12,690,321	15,100,292

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, 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 American Depositary Shares (ADSs), each representing one (1) of its ordinary shares, at a price of $9.00 per ADS, generating gross proceeds of $21,600, and on July 27, 2005, the underwriters exercised part of their over-allotment option by purchasing an additional 300,000 ADSs generating additional gross proceeds of $2,700. The IPO underwriting discount and other offering costs amounted to €3,919 and were charged against additional paid-in capital. In connection with the IPO the Company granted the underwriters warrants to purchase 151,200 ADSs for services rendered during the IPO. All equity instruments issued to non-employees are accounted for at the estimated fair value of the equity instruments. The value of these warrants has been estimated using the Black-Scholes model. The assumption used in the calculation of the fair value were a weighted average expected life of 5 years, an expected volatility rate of 34.97% and a risk-free interest rate of 3.83%. At the time of grant, the fair market value of each warrants was $1.53. The Company applies EITF 96-18 in accounting for its warrants granted to non-employees and non-directors. The fair value of the instruments issued to the underwriters was estimated to be €190, and was included with other offering costs.

On October 14, 2005, the Company completed a private placement of 1,551,125 ADSs at $7.05 per ADS. Gross proceeds from the offering were $10.9 million (€9.1 million). The private placement offering costs amounted to €1,066 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 620,450 ADSs at an exercise price of $9.69 per ADS. 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 93,068 ADSs at an exercise price of $9.69 per ADS. In April 2006, we issued 93,524 ordinary shares upon exercise of a warrant issued in connection with our October 2005 private placement, at a price per share of 9.69, for aggregate proceeds of $906 thousand.

On June 6, 2006, the Company completed a private placement of 1,943,525 ADSs at $11.39 per ADS. Gross proceeds from the offering were $22.1 million (€17.2 million). 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 ADSs at an exercise price of $14.50 per ADS. 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 ADSs at an exercise price of $17.40 per ADS.

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 September 30, 2006, no amounts are eligible to be paid as dividends and the Company has no intention to pay a dividend in the foreseeable future.

We are incorporated under the laws of the Republic of Italy. The principal laws and regulations that apply to our operations, those of Italy and the European Union, are different from those of the United States. In order to issue new equity or debt securities convertible into equity, with some exceptions, we must increase our authorized capital.

There are two ways for us to increase our authorized capital. The first way is to obtain shareholder approval. In order to do so, our board must meet and resolve to recommend to our shareholders that they approve an amendment to our bylaws to increase our capital. Our security holders must then approve that amendment to our bylaws in a formal meeting duly called, with the favorable vote of the required majority, which may change depending on whether the meeting is held on a first or subsequent call.

The second way is that our shareholders can authorize the board of directors to increase our capital, but the board may exercise such power for only five years. At the end of those five years, the authorized capital expires, and our board and shareholders would need to meet again to authorize a new capital increase. Our shareholders' authorized our board of directors to increase our capital by up to €90 million of par value for ordinary shares and €10 million for ordinary shares issuable upon conversion of convertible bonds on April 28, 2006, which our board can exercise until April 28, 2011.

In either case, these meetings take time to call. In addition, a notary public must verify the compliance of the capital increase with our bylaws and applicable Italian law. Further, under Italian law, our existing shareholders and any holders of convertible securities have preemptive rights to acquire any such shares on the same terms as are approved concurrent with the new increase of the authorized capital pro rata based on their percentage interests in our company. The shareholders or board of directors can "exclude" or limit the pre-emptive right, but only for certain specific reasons.

Italian law also provides that if the shareholders vote to increase our capital or authorize our board of directors to increase our capital, dissenting, abstaining or absent security holders representing more than 5% of the outstanding shares of our company may, for a period of 90 days following the filing of the shareholders' resolutions with the Registry of Companies, challenge such capital increase if the increase was not in compliance with Italian law. If our board of directors resolves to increase our capital, our board of statutory auditors, any member of our board of directors and any shareholder who was prejudiced may challenge that resolution for a period of 90 days following the adoption of the resolution. Finally, if a shareholders' or board of directors' meeting authorizing a capital increase was not properly called and held, any interested person may challenge the capital increase for a period of three years following the filing of the security holders' approval with the Italian Registry of Companies or 180 days following the filing of the board resolution with the Italian Registry of Companies.

Once our security holders authorize a capital increase, we must issue all of those authorized shares before the security holders may authorize a new capital increase, unless the security holders vote to cancel the previously authorized shares. These restrictions could limit our ability to issue new equity or convertible debt securities on a timely basis.

6. COLLABORATIVE AGREEMENTS

In December 2001, the Company entered into a license and supply agreement with Sigma-Tau Pharmaceuticals Inc. (as assignee of Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., hereinafter referred to as "**Sigma Tau**"). Under the multi-year agreement, Sigma Tau obtained exclusive rights to distribute, market and sell defibrotide to treat VOD in the United States. In 2005, the Company expanded Sigma-Tau's current license territory to all of North America, Central America and South America. In return for the license, Sigma-Tau agreed to pay the Company an aggregate of $4,900, of which €3,826 ($4,000) has been received to date, based on the exchange rate in effect on the date of receipt. Sigma-Tau will owe the Company an additional $350 performance milestone payment within 30 days of the end of a Phase III pivotal study, and a $550 performance milestone payment within 30 days of obtaining an FDA New Drug Application or Biologic License Application and other approvals necessary for the marketing of defibrotide in the

United States.

The amounts due for the aforementioned performance criteria will not be recognized as revenue until the performance obligations are fully satisfied. If the Company unilaterally discontinues development of defibrotide to treat VOD (after written notice to Sigma-Tau) and then resumes the development, substantially availing itself of the stages previously completed, either independently or with a third party, within 36 months of the discontinuation, then the Company will be required to promptly reimburse Sigma-Tau for the amounts received. The Company has no intention to discontinue the development of the product.

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

The Company's accounting for its performance based milestone payments is based on the guidance in SAB 104 "Revenue Recognition" which states that each of the following four criteria must be met prior to revenue being recognized:

- persuasive evidence that an arrangement exists,
- delivery has occurred or services have been rendered,
- the seller's price to the buyer is fixed or determinable, and
- collectibility is reasonably assured.

The Company believes that once it has met the performance milestone as described in the collaborative agreement, then all of the criteria have been met and that the revenue should be recognized at that date. In 2006, the Company revised the recognition period of the upfront payments to align it to the revised expected residual life of the financed research project.

7. EQUITY INCENTIVE PLANS

On September 30, 2004, the Company adopted the Gentium S.p.A 2004 Equity Incentive Plan and Italian 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 or non-statutory options, restricted share grants, share appreciation rights and share bonuses.

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 vested in full on December 15, 2004 and is exercisable for a period of five years at the lesser of $5.50 per share or 50% of the per share price of the Company's initial public offering. On March 23, 2006, the Compensation Committee agreed with him to increase the exercise price of the option from $4.50 to $5.58 to comply with an Italian law requirement, and amend the term of the option from October 2009 to September 30, 2009. We agreed to pay the officer $65 (the amount of the aggregate increase in the exercise price), subject to certain conditions, in return for amending the exercise price and the term.

On March 23, 2006, the Company granted to a consultant options to purchase an aggregate of 15,000 ordinary shares. The options were fully vested on the date of the grant and expire on September 30, 2009. The exercise price of the options granted was $12.00 per share. The market value on the date of the grant was $10.10.

On April 28, 2006, the Company issued options to purchase an aggregate of 30,000 ordinary shares to the Company's non-employee directors as a result of their re-election as directors as automatic grants under the 2004 Equity Incentive Plan. The options vest over one-twelfth on each monthly anniversary of the date of grant and expire on September 30, 2009. The exercise price of the options granted was $17.35 per share and equaled the market value on the date of grant.

On April 28, 2006, the Company issued an option to purchase 10,000 ordinary shares to one of the Company's non-employee director as result of his initial election as director as an automatic grant under the 2004 Equity Incentive Plan. The option vests over three years and is exercisable up to September 30, 2009. The exercise price of the option granted was $17.35 per share and equaled the market value on the date of grant.

On June 1, 2006, the Company issued an option to purchase 90,000 shares to an executive officer under the 2004 Equity Incentive Plan. The option vests over three years and is exercisable up to September 30, 2009. The exercise price of the option granted was $12.60 per share and equaled the market value on the date of grant.

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. As of September 30, 2005 and 2006, the compensation committee of the Company's board of directors has granted options to purchase an aggregate of 917,000 and 1,137,000 shares of the Company's ordinary shares to the Company's officers, directors and consultants, respectively. The Company recorded non cash compensation expense of €363 thousand and €665 thousand for the nine month periods ended September 30, 2005 and 2006, 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 nine month periods ended September 30, 2005 and 2006, as of the date of the grants, was $4.30 and $4.42, respectively. The assumptions used in the calculation of the fair value of options granted during the nine month periods ended September 30, 2005 and 2006, were a weighted average expected term of 5.0 and 3.05 years, respectively, a weighted average expected volatility rate of 50% and 40%, respectively, and a weighted average risk-free interest rate of 4.21% and 4.96%, 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 term 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 nine month periods ended September 30, 2005 and 2006, the Company recorded non-cash compensation expense of approximately €110 thousand and €80, respectively. As of September 30, 2005 and 2006, options issued to consultants amounted to 85,000 and 150,000, respectively.

A summary of the Company's stock option activity and related information is as follows, based on the exchange rate in effect at grant date and at each date below:

	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	-	-	-	-
Cancellations	-	-	-	-
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	-	-		-	-
Cancellations	-	-		-	-
Options outstanding at December 31, 2005	568,000	992,000	€	7.36	$8.72
Granted	(145,000)	145,000	€	10.99	$13,85
Exercised	-	-		-	-
Cancellations	-	-		-	-
Options outstanding at September 30, 2006 (unaudited)	423,000	1,137,000	€	7.40	$9.38

The following table summarizes information concerning currently outstanding and exercisable options as of September 30, 2006, based on the exchange rate in effect on September 30, 2006:

Unaudited	Options Outstanding			Options Exercisable	
Exercise Price	**Number Outstanding**	**Weighted-Average Years Remaining onContractual Life**	**Weighted Average Exercise Price**	**Number Exercisable**	**Weighted Average Exercise Price**
€4.41 ($5.58)	60,000	3.00	€ 4.41 ($5.58)	60,000	€ 4.41 ($5.58)
€5.59 ($7.08)	15,000	3.08	€ 5.59 ($7.08)	4,583	€ 5.59 ($7.08)
€6.21 ($7.90)	10,000	3.16	€ 6.21 ($7.90)	2,778	€ 6.21 ($7.90)
€6.32 ($8.00)	50,000	3.20	€ 6.32 ($8.00)	42,500	€ 6.32 ($8.00)
€7.11 (€9.00)	832,000	2.76	€ 7.11 (€9.00)	346,667	€ 7.11 (€9.00)
€7.90 ($10.00)	25,000	3.21	€ 7.90 ($10.00)	25,000	€ 7.90 ($10.00)
€9.47 ($12.00)	15,000	2.98	€ 9.47 ($12.00)	15,000	€ 9.47 ($12.00)
€9.95 ($12.60)	90,000	3.07	€ 9.95 ($12.60)	10,000	€ 9.95 ($12.60)
€13.70 ($17.35)	40,000	2.98	€ 13.70 ($17.35)	13,889	€ 13.70 ($17.35)
	1,137,000			520,417	

Warrants

Following is a summary of the Company's warrants issued as of September 30, 2006 and changes during the periods presented based on the exchange rate in effect at grant date and at each date below:

	Warrants	**Weighted Average Exercise Price**	
Balance, December 31, 2003	--		
Granted	503,298	€ 7.15	$9.52
Exercised	-	-	-
Cancellations	-	-	-
Balance, December 31, 2004	503,298	€ 7.15	$9.52
Granted	713,518	€ 8.21	$9.69
Exercised	-	-	-
Cancellations	-	-	-
Balance, December 31, 2005	1,216,816	€ 8.14	$9.61
Granted	466,446	€ 11.67	$14.98
Exercised	(111,858)	€ 7.90	$9.66

Cancellations	-		-	
Balance, September 30, 2006 (unaudited)	1,571,404	€	8.85	$11.20

In April 2006, we issued 18,334 ordinary shares upon exercise of a warrant issued in connection with our Series A senior convertible promissory notes, at a price per share of $9.52, for proceeds of $175 thousand.

In April 2006, we issued 93,524 ordinary shares upon exercise of a warrant issued in connection with our October 2005 private placement, at a price per share of 9.69, for aggregate proceeds of $906 thousand.

As part of a private placement, on June 6, 2006 the Company issued warrants for the purchase of an aggregate of 388,705 ADSs at an exercise price of $14.50 per ADS. 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 ADSs at an exercise price of $17.40 per ADS.

8. 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 diffierences between basic and diluted net loss per share for all periods presented.

9. 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 September 30, 2006, the Company had established purchasing, logistics, quality assurance, accounting, controlling and reporting departments, treasury, regulatory and information technology departments. The Company still depends on FinSirton for corporate services and payroll; and on Sirton for infrastructure costs and quality control and is still relying on the IT infrastructure provided by Sirton.

Sales to Sirton represented 95% and 94% of the total product sales for the nine month periods ended September 30, 2005 and 2006, respectively. Sirton manufactures finished products from, in part, our products, and sells those products primarily to one customer, Crinos.

For the nine and three months periods ended September 30, 2005 and 2006, the Company had the following transactions with its affiliates:

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2005	2006	2005	2006
Revenue	€ 1,900	€ 2,652	€ 304	€ 799
Expenses	781	632	200	251

As of December 31, 2005 and September 30, 2006 the Company had the following balances with its affiliates:

	December 31, 2005	September 30, 2006
Receivables	€ 1,867	€ 2,262
Payables	542	340

The receivables from related parties relates to the sales by the Company of defibrotide and other pharmaceutical ingredients to Sirton. 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, administrative, accounting, 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. The Company's inter-company contracts with FinSirton and Sirton are described below.

Organizational consulting contracts

The Company had an agreement with Sirton pursuant to which Sirton provided the Company with organizational consulting services related to implementation of strategic plans and the coordination of internal resources. The agreement expired on December 31, 2005 and it has not been renewed. Fees incurred pursuant to the agreement for the nine month period ended September 30, 2005 amounted to €54 thousand.

Regulatory consulting contracts

The Company had an agreement with Sirton pursuant to which Sirton provided the Company with its "Internal Regulatory Department," which furnishes all the services necessary to comply with the requirements of Italian pharmaceutical industry rules. The agreement expired on December 31, 2005 and it has not been renewed. The Company's fees incurred pursuant to the agreement for the nine month period ended September 30, 2005 amounted to €9 thousand.

Quality monitoring contract

The Company has an agreement with Sirton pursuant to which Sirton provides the Company with quality monitoring services related to its production process. The Company's fees are based on the number of hours of the monitoring services provided or on the costs associated with performing batch analysis. Additionally, in 2005 and until January 2006 Sirton provided Gentium with two of its employees in order to perform quality monitoring services on the Company's production and business processes. The Company's incurred fees pursuant to the agreement for the nine month periods ended September 30, 2005 and 2006 amounted to €305 thousand and €360 thousand, respectively.

Quality assurance contract

The Company had an agreement with Sirton pursuant to which Sirton provided the Company with quality monitoring services related to its production process. The Company's fees were based on the hours of the monitoring services provided. The agreement expired on December 31, 2005 and it has not been renewed. Fees incurred pursuant to the agreement for the nine month period ended September 30, 2005 amounted to €11 thousand.

Other services contracts

The Company has an agreement with Sirton pursuant to which Sirton provides Gentium with a range of services relating to purchasing and logistics, technical services for manufacturing facility revamping, consulting services, maintenance and general services. Due to the Company's establishment of some internal departments, the Company entered into a revised services agreement with Sirton in January 2006. Under the new agreement, Sirton no longer provides some of these services, as the Company provides them internally. The Company incurred fees pursuant to the agreement for the nine month periods ended September, 2005 and 2006 amounted to €136 thousand and €73 thousand, respectively.

The Company has an agreement with FinSirton to provide the Company with accounting and information technology services relating to invoicing, payments and collections and payroll processes. Due to the Company's establishment of some internal departments, the Company entered into a revised services agreement with FinSirton in January 2006. Under the new agreement, FinSirton no longer provides some of these services, as the Company provides them internally. The Company incurred fees pursuant to the agreement for the nine month periods ended September 30, 2005 and 2006 amounted to €152 thousand and €75 thousand, respectively.

Leases

On January 1, 2005, the Company entered into a lease agreement with Sirton for manufacturing space. This agreement expires on December 31, 2010. Total expenses under this operating lease for the nine month periods ended September 30, 2005 and 2006 amounted to €6 thousand in each period.

On January 1, 2005, the Company entered into a lease agreement with FinSirton to lease space for offices, laboratories and storage facilities. This agreement expires on December 31, 2010. Total expenses under this operating lease for the nine month periods ended September 30, 2005 and 2006 amounted to €117 thousand and €119 thousand, respectively.

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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 Form 20-F for the year ended December 31, 2005. 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 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. 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 used to treat peptic ulcers, and other miscellaneous pharmaceutical products.

Defibrotide for the Treatment and Prevention of VOD

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 and prevent 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 thousand 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.

Results from the Phase II trial showed 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 Phase III clinical trial in the United States and Canada for this use. We expect that this trial will include approximately 30 clinical centers. The first patient was enrolled in July 2006. The trial will be funded by us and we expect that it will receive about $800 thousand in grants from the orphan drug division of the FDA. 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.

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. 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 of defibrotide to prevent VOD in children. We expect this study to include 270 patients enrolled by several centers in Europe, who will randomly receive either defibrotide or no treatment. Fifty-six patients have been enrolled as of November 14, 2006.

We are also co-sponsoring 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. We expect this trial to include at least 370 patients enrolled by several centers in Europe beginning by the fourth quarter of 2006, who will randomly receive either defibrotide or no treatment. The total number of patients enrolled will be confirmed upon finalization of the study protocol. We are in the process of determining our regulatory strategy for combining this trial with a U.S. clinical trial for the prevention of VOD in adults.

Defibrotide for the treatment of 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 up to 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 combined 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 four centers. 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 50 consecutive patients to assess response rate and clinical efficacy. Twenty-four patients have been enrolled as of November 14, 2006.

Overview

We manufacture defibrotide at our facility. Currently, we sell the defibrotide to our affiliate, Sirton. Sirton focuses on processing the defibrotide for either oral administration or intra-venous administration and sells the finished products to Crinos S.p.A., a subsidiary of Stada Arzneimittel AG. Crinos markets defibrotide in Italy to both treat and prevent vascular disease with thrombosis under license agreements 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 used to treat peptic ulcers. We sell sulglicotide to unrelated third parties and are actively working on developing other customers for these products. We also manufacture a variety of other miscellaneous pharmaceutical products.

Sirton sells its finished products, including calcium heparin, primarily to one customer, Crinos, which sells them to the retail market. As a result, Sirton's demand for these products depend on Crinos purchasing policy and market penetration. Despite the fact that Sirton has recently experienced financial difficulties which could impact our business, we believe that we can continue to operate without a significant change in our operations or any disposal of our assets.

We have also generated revenue from the receipt of research grants, 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 and professional fees and other corporate expenses, including public company expenses. Some of these services are 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

Currently, our primary source of revenue is 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 due to our most significant customer also being an affiliate. 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 €20 thousand and €28 thousand for the nine month periods ended September 30, 2005 and 2006, 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 forecasted 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, laboratory supplies and materials, regulatory activities, 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 billing 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. We often rely on judgments to determine the date on which certain services commence, the level of service performed on or before a given date, and the cost of such service. We make these judgments based on the facts and circumstances known to us. 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 nine month periods ended September 30, 2005 and 2006, we have incurred research and development expenses of €3,117 thousand and €6,362 thousand, respectively. As of September 30, 2006, we had €2.2 million of future payables under outstanding contracts with various contract research organizations. 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. We have used a weighted average 40% factor based on what we believe is a representative sample of similar biopharmaceutical companies. However, this sample is not perfect as it omits, for example, Italian companies, due to the fact that there are a limited number of companies such as ourselves publicly traded in the U.S. market. If we increased our volatility factor to 80%, the fair value of our stock options granted in 2005 and in 2006 would have increased by $1.816 million and $443 thousand, respectively, and would have resulted in $140 thousand and $120 thousand in additional compensation expense for the nine month period ended as of September 30, 2005 and 2006, respectively. Therefore, significant changes to these estimates could have a material impact on the results of our operations. Additionally, FAS No. 123(R) requires the application of an estimated forfeiture rate to current period expense to recognize compensation expense only for those awards expected to vest. Because of a lack of history, we have estimated no forfeitures and we will adjust our estimate of forfeitures if actual forfeitures differ or are expected to differ from such estimate. Subsequent changes in estimated forfeitures will be recognized through a cumulative adjustment in the period of change and will also impact the amount of stock based compensation expense in future periods.

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.

Results of Operations

The following tables set forth our results of operations,:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2006	2005	2006
Revenues:				
Sales to affiliates	€ 304	€ 799	€ 1,900	€ 2,652
Third party product sales	-	45	95	155
Total product sales	304	844	1,995	2,807
Royalties	-	7	-	14
Other income and revenues.	70	51	210	183
Total Revenues	374	902	2,205	3,004
Operating costs and expenses:				
Cost of goods sold.	426	828	1,721	2,444
Research and development	1,184	2,760	3,117	6,362
Charges from affiliates	200	251	781	632
General and administrative	844	1,138	1,738	3,787
Depreciation and amortization	35	87	78	190
	2,689	5,064	7,435	13,415
Operating loss	(2,315)	(4,162)	(5,230)	(10,411)
Foreign currency exchange gain (loss), net	85	86	(435)	(144)
Interest income (expense), net.	48	198	(4,197)	338
Pre-tax loss	(2,182)	(3,878)	(9,862)	(10,217)
Income tax expense:				
Deferred	16	-	48	-
Net loss	€ (2,198)	€ (3,878)	€ (9,910)	€ (10,217)

Three Months Ended September 30, 2006 Compared to Three Months Ended September 30, 2005

Product sales.

Our product sales were €844 thousand for the three month period ended September 30, 2006, compared to €304 thousand for the comparable period in 2005, an increase of 178% or €540 thousand. The timing of manufacturer orders, which we do not control, can cause variability in sales. The fluctuation was primarily due to higher sales volume of the Company's active pharmaceutical ingredients defibrotide, urokinase and sulglicotide to our principal customer and affiliate, Sirton Also contributing to the increase was an increase in third party product sales mainly due to the sales of sulglicotide to a Korean customer.

Cost of goods sold.

Our cost of goods sold was €828 thousand for the three month period ended September 30, 2006 compared to €426 thousand for the comparable period in 2005. The increase in cost of goods sold was mainly due to increased sales volume compared to the same period in 2005. Cost of goods sold was 140% of product sales in the 2005 period and

98% of product sales in the 2006 period.

Other income and revenues.

Our other income and revenues was €51 thousand for the three month period ended September 30, 2006, compared to €70 thousand for the comparable period in 2005. 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. In 2006, the Company revised the recognition period of the upfront payments to align it to the revised period of the underlying research project.

Research and development expenses.

We incurred research and development expenses of €2.760 million for the three month period ended September 30, 2006 compared to €1.184 million for the comparable period in 2005. The expenses were primarily for the development of defibrotide to treat and prevent VOD. The difference between the periods is primarily due to the timing and expenses incurred for clinical trials, including clinical research organizations charges, regulatory activities, costs associated with the set-up, initiation of our Phase III clinical trial of defibrotide to treat VOD, our Phase II/III clinical trial of defibrotide to prevent VOD and manufacturing expenses costs. Also contributing to the increase was an increase in outside services to support increased activity in our clinical trials and stock based compensation of €83 thousand.

General and administrative expenses.

Our general and administrative expenses were €1.138 million for the three month period ended September 30, 2006 compared to €844 thousand for the comparable period in 2005. G&A include one time charge of €104 thousand per the absorption of the fixed portion of our production costs, not otherwise included in cost of good sold, due to the partial shut-down of the manufacturing facility in July and August for the replacement of two reactors. Contributing to the increase was also professional fees for outside services and stock based compensation of 166 thousand.

Depreciation and amortization.

Depreciation and amortization amounted to €87 thousand for the three month period ended September 30, 2006 compared to €35 thousand for the comparable period in 2005. The increase is primarily attributable to deprecation of the information technology infrastructure and amortization of the intellectual property portfolio. Depreciation expense excludes depreciation on our manufacturing facilities which is included in cost of goods sold.

Interest income (expense) and Other income, net

For the three months ended September 30, 2006, the components of interest income (expense) on a net basis have changed primarily due to the higher level of invested funds available to the Company partilally offset by an increase in interest expense resulting from €4.600 million in new borrowings.

Net loss.

Our net loss was €3.878 million for the three month period ended September 30, 2006 compared to a net loss of €2.198 million for the comparable 2005 period. The difference was primarily due to a decrease in interest expense in 2006 offset by increases in general and administrative expenses, research and development expenses, and stock based compensation.

Nine Months Ended September 30, 2006 Compared to Nine Months Ended September 30, 2005

Product sales.

Our product sales were €2.807 million for the nine month period ended September 30, 2006, compared to €1.995 million for the comparable period in 2005, an increase of 41% or €812 thousand. The timing of manufacturer orders, which we do not control, can cause variability in sales. During the nine month period ended September 30, 2006, the increase in product sales was primarily due to higher sales volume of the Company's active pharmaceutical ingredients defibrotide, urokinase and sulglicotide to our principal customer and affiliate, Sirton. Also contributing to the increase was an increase in sales and increase in third party product sales mainly due to the sales of sulglicotide to a Korean customer.

Cost of goods sold.

Our cost of goods sold was €2.444 million for the nine month period ended September 30, 2006 which included a €182 thousand of inventory reserve attributable to slow-moving inventory compared to €1.721 million and 130 thousand for the comparable period in 2005..The increase in cost of goods sold was mainly due to increased sales volume in the nine months periods of 2006 compared to the same period in 2005.

Other income and revenues.

Our other income and revenues was €183 thousand for the nine month period ended September 30, 2006, relatively unchanged from the comparable period in 2005 of €210 thousand. 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. In 2006, the Company revised the recognition period of the upfront payments to align it to the revised period of the underlying research project.

Research and development expenses.

We incurred research and development expenses of €6.362 million for the nine month period ended September 30, 2006 compared to €3.117 million for the comparable period in 2005. The expenses were primarily for the development of defibrotide to treat and prevent VOD. The difference between the periods is primarily due to the timing 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, our Phase II/III clinical trial of defibrotide to prevent VOD and manufacturing expenses costs. 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 €220 thousand.

General and administrative expenses.

Our general and administrative expenses were €3.787 million for the nine month period ended September 30, 2006 compared to €1.738 million for the comparable period in 2005. The increase was primarily related to our increased headcount and higher expenses as a result of being a public company, legal and other professionals fees and increased administrative costs resulting from performing administrative function internally as opposed to through affiliated administrative service agreements and stock based compensation of €445 thousand.

Depreciation and amortization.

Depreciation and amortization amounted to €190 thousand for the nine month period ended September 30, 2006 compared to €78 thousand for the comparable period in 2005. 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 is included in cost of goods sold.

Interest income (expense) and Other income, net

The components of interest income (expense) on a net basis have changed primarily due to the effects of the repayment and conversion of our Series A senior convertible notes in 2005 and the amount of invested funds we had following our initial public offering in June 2005. For the nine months ended September 30, 2005, interest expense on the Series A notes was €4.095 million, including non-cash interest expense of €3.837 million from the amortization of the issue discount and debt issue cost. These notes were converted or redeemed in June 2005. Additionally, interest income increased to €472 thousand as the result of a higher level of invested funds.

Net loss.

Our net loss was €10.217 million for the nine month period ended September 30, 2006 compared to a net loss of €9.910 million for the comparable 2005 period. The difference was primarily due to a decrease in interest expense in 2006 compared to the 2005 period and an increase in revenue partially offset by increases in general and administrative expenses, research and development expenses, and stock based compensation.

Liquidity and Capital Resources

For the nine month period ended September 30, 2006, we used approximately €7.7 million of cash in operating activities, approximately €2.2 million for investing activities, including capital expenditures and purchase of marketable securities, and we repaid approximately €2.5 million of debt, for a total use of cash of €12.4 million. As of September 30, 2006, we had cash of €21.548 million.

In June 2006, we completed a private placement of 1,943,525 of our ADSs together with warrants to purchase 466,446 ADSs, for aggregate gross proceeds of $22.1 million (€17.2 million). In addition, during the nine month period we had warrants exercised for 111,858 ADSs generating additional gross proceeds of $1.08 million (€884 thousand).

Given the resources needed to continue to fund our operating costs, including our clinical and pre-clinical research and development, we intend to fund these activities through issuing equity or debt securities and obtaining medium-long term bank credit lines.

As of September 30, 2006, we received total proceeds of €4.6 million under different financing facilities. In April 2006, the Company obtained a €1.0 million long term loan from Intesa-Mediocredito S.p.A.. The financing facility has a five-year term and bears interest at the three-month Euribor rate plus 1.7%. The loan will be reimbursed in eight semi-annual installments of €131,250 starting from October 5, 2007 throughout April 5, 2011. Interest is due quarterly starting from October 5, 2006.

On June 28, 2006, we entered into a Loan Contract with Banca Nazionale del Lavoro ("BNL") S.p.A. pursuant to which we restructured our two outstanding loans. Pursuant to the Loan Contract, the two existing loans, which had an outstanding principal balance of €1.9 million, were extinguished and BNL granted us a new loan for €2.8 million that bears interest at the six month Euribor rate plus 1.00%. The principal will be repaid in 14 semi-annual installments starting from December 28, 2007 through final maturity on June 28, 2014. Interest is due semi-annually starting from June 28, 2006.

On June 30, 2006 the Company obtained a loan in the amount of €750 thousand from San Paolo IMI Bank SpA for the acquisition and the installation of manufacturing equipment. The loan bears interest at the three month Euribor rate plus 1.20%. The parties agreed that, starting from June 15, 2008, such spread would be decreased to 1.02% if the Company completes its installation of manufacturing equipment by January 21, 2007. The loan is payable in thirteen quarterly installments of approximately €58 thousand beginning on June 15, 2008 throughout June 15, 2011. Interest is due quarterly starting from September 15, 2006. The agreement requires the Company to maintain a minimum level of net shareholders' equity determined according with Italian generally accepted accounting principles. The Company is currently in compliance with the covenant and provisions of the loan agreement.

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 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 will need to raise additional financing and/or enter into collaborative or licensing agreements in the future to fund continuing research and development for our product candidates, as well as any mergers or acquisitions in which we may engage. Changes in our operating plans, delays in obtaining approval to market our product candidates, lower than anticipated revenues, increased expenses or other events, 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.

In order to issue new equity or debt securities convertible into equity, with some exceptions, we must increase our authorized capital. In order to do so, our board must meet and resolve to recommend to our shareholders that they approve an amendment to our bylaws to increase our capital. Our shareholders must then approve that amendment to our bylaws in a formal meeting duly called, with the favorable vote of the required majority, which may change depending on whether the meeting is held on a first or subsequent call. These meetings take time to call. In addition, a notary public must verify the compliance of the capital increase with our bylaws and applicable Italian law. Further, under Italian law, our existing shareholders and any holders of convertible securities sometimes have preemptive rights to acquire any such shares on the same terms as are approved concurrent with the new increase of the authorized capital pro rata based on their percentage interests in our company. Also, our shareholders can authorize the board of directors to increase our capital, but the board may exercise such power for only five years. If the authorized capital is not issued by the end of those five years, the authorized capital expires, and our board and shareholders would need to meet again to authorize a new capital increase. Our shareholders authorized our board of directors to increase our capital by up to €90 million of par value for ordinary shares and €10 million for ordinary shares issuable upon conversion of convertible bonds on April 28, 2006. Italian law also provides that if the shareholders vote to increase our capital, dissenting, abstaining or absent shareholders representing more than 5% of the outstanding shares of our company may, for a period of 90 days following the filing of the shareholders' approval with the Registry of Companies, challenge such capital increase if the increase was not in compliance with Italian law. In certain cases (if, for example, a shareholders' meeting was not called), any interested person may challenge the capital increase for a period of 180 days following the filing of the shareholders' approval with the Registry of Companies. Finally, once our shareholders authorize a capital increase, we must issue all of those authorized shares before the shareholders may authorize a new capital increase, unless the shareholders vote to cancel the previously authorized shares. These restrictions could limit our ability to issue new equity or convertible debt securities on a timely basis.

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

Our major contractual obligations and commitments relate to our real estate mortgages, other financing from banks and financial institutions, and various service agreements (including those related to our clinical trials).

Quantitative and Qualitative Disclosures about Market Risk

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

As of September 30, 2006, substantially all of our cash and cash equivalents were held in accounts at financial institutions located in the Republic of Italy and the United States that we believe are of acceptable credit quality. We invest our cash in liquid instruments that meet high credit quality standards and generally have maturity at the date of purchase of less than three months. We are exposed to exchange rate risk with respect to certain of our cash balance that are denominated in US dollar. As of September 30, 2006, we held a cash balance of $23.5 million that was denominated in $. This dollars-based cash balance is available to be used for future acquisitions and other liquidity requirements that may be denominated in such currency. We are exposed to unfavorable and potentially volatile fluctuations of the U.S. dollar against the Euro (our functionally currency). Any increase (decrease) in the value of the U.S. dollar against the Euro will cause to experience unrealized foreign currency translation losses (gains) with respect to Euro. 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.

In addition, we are exposed to foreign currency risk to the extent that we enter into transactions denominated in currencies other than our functional currency, such as investments, programming costs, payable that are denominated in a currency other than our functional currency. Changes in exchange rates with respect to these items will result in unrealized or realized foreign currency transaction gains and losses upon settlement of the transactions.

We are exposed to changes in interest rate primarily as a result of our borrowings. Our primary exposure to variable rate debt is through the EURIBOR and we have entered into various derivative transaction to manage exposure to movements in interest rates. We use interest rate cap agreements that lock in a maximum interest rate should variable rate rises, but which enable it to otherwise pay lower market rates.

Trends

Currently, our primary source of revenue is from the sale of products to our affiliate, Sirton. Sirton manufactures finished products from, in part, our products, and sells those products primarily to one customer, Crinos. Sirton sells its finished products, including calcium heparin, primarily to one customer, Crinos, which sells them to the retail market. As a result, Sirton's demand for these products depends on Crinos purchasing policy and market penetration.

On November 11, 2003, we entered into a Supply Agreement with Samil Pharm. Co., Ltd., a Korean corporation. Under this agreement, we supply Samil with sulglicotide, and Samil has the following purchase obligations:

Period	Purchase Amount
June 20, 2005 to June 20, 2006	at least 2,600 kilograms
June 20, 2006 to June 20, 2007	at least 3,400 kilograms
After June 20, 2007	to be renegotiated

In any given period, excess purchases by Samil may be applied as a reduction of the immediately following period's minimum purchases or as compensation for a failure to purchase the immediately preceding period's minimum purchase, at Samil's choice. Samil launched its product in early 2006. As of September 30, 2005 and 2006, we sold nil and 382kg of sulglicotide to Samil. We expect future growth in sulglicotide revenue due to the expected penetration of the Samil's product in the Korean market. However, we cannot be certain that the Samil will be successful on its efforts.

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, the American Stock Exchange and the Nasdaq National 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.

During the second quarter of 2006, the Company began to transition certain activities of our business and financial systems to a new integrated accounting system, which will be utilized to produce financial information contained in this quarterly report. Implementation of the new systems involves changes to our procedures for control over financial reporting. The new systems were subjected to testing prior to its implementation and are functioning to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange

Commission's rules and forms. The Company has not experienced any significant difficulties to date in connection with the implementation or operation of the new system. The Company is planning to full implement the information system by the end of 2006.