Gentium S.p.A.
Form 20-F
March 31, 2008

As filed with the Securities and Exchange Commission on March 31, 2008

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

FORM 20-F

o **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended: December 31, 2007

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

o **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

000-51341
(Commission file number)

GENTIUM S.p.A.
(Exact Name of Registrant as Specified in its Charter)
NOT APPLICABLE
(Translation of Registrant's Name into English)

Italy
(Jurisdiction of incorporation or organization)

Piazza XX Settembre 2
22079 Villa Guardia (Como), Italy
+39 031 385111
(Address, including zip code, and telephone number,
including area code, of Registrant's principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Name of each exchange

Title of each class	on which registered
American Depositary Shares	The Nasdaq Global Market
Ordinary shares with a par value of €1.00 each*	The Nasdaq Global Market

(Title of Class)

Securities registered or to be registered pursuant to Section 12(g) of the Act: **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

14,946,317 ordinary shares

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l Not for trading, but only in connection with the registration of the American Depositary Shares.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes o No x

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes o No x

Note - Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of “accelerated filer and large accelerated filer” in rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer x Non-accelerated filer o

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 o Item 18 x

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No x

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

Not applicable.

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PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

GENTIUM S.P.A.

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

We have a plant in Italy where we manufacture active pharmaceutical ingredients, which are used to make the finished forms of various drugs. One of those active pharmaceutical ingredients is defibrotide. We have an affiliated company, Sirton Pharmaceuticals S.p.A., process defibrotide into the finished drug, and then we sell that finished drug in Italy to treat and prevent vascular disease with risk of thrombosis. The other active pharmaceutical ingredients that we manufacture are urokinanse, calcium heparin, sodium heparin and sulglicotide. We sell these other active pharmaceutical ingredients to other companies to be made into various drugs.

SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with "Operating and Financial Review and Prospects" and our financial statements and the related notes appearing elsewhere in this annual report. The selected financial data as of December 31, 2006 and December 31, 2007 and for each of the three years ended December 31, 2007 are derived from our audited financial statements, which are included in this annual report. The selected financial data as of December 31, 2003, December 31, 2004 and December 31, 2005 and for the years ended December 31, 2003 and December 31, 2004 has been derived from our audited financial statements, which are not included in this annual report. Our historical results are not necessarily indicative of results to be expected in any future period.

Certain reclassification of prior period amounts have been made to our financial statements to conform to the current period presentation. The convenience translation into U.S. dollars has been done solely for the benefit of the reader, and does not imply that our results would actually have been these amounts in U.S. dollars had the U.S. dollar been our functional currency.

Statement of Operations Data: *(000s omitted except per share data)*	**For the Years Ended December 31,**					
	2003	**2004**	**2005**	**2006**	**2007**	**2007[1]**
Revenues:						
Product sales to related party	€ 6,532	€ 2,870	€ 3,260	€ 3,754	€ 2,704	$ 3,949
Product sales to third parties	-	243	101	321	2,390	3,490
Total product sales	6,532	3,113	3,361	4,075	5,094	7,439
Other revenue	1,843	583	280	249	2,515	3,673
Total revenues	8,375	3,696	3,641	4,324	7,609	11,111
Operating costs and expenses:						
Cost of goods sold	2,435	2,579	2,911	3,092	3,983	5,816
Charges from related parties	1,485	1,665	1,047	854	748	1,092
Research and development	2,253	2,922	4,557	8,927	15,098	22,048
General and administrative	854	1,194	2,284	5,421	6,279	9,169
Depreciation and amortization	67	89	118	261	725	1,059
Write-down of acquired assets	-	-	-	-	13,740	20,065
	7,094	8,449	10,917	18,555	40,573	59,248
Operating income (loss)	1,281	(4,753)	(7,276)	(14,231)	(32,964)	(48,137)
Foreign currency exchange gain (loss), net	156	(55)	(249)	(627)	(4,001)	(5,843)
Interest income (expense), net	(71)	(2,192)	(4,148)	490	1,357	1,982

Pre-tax income (loss)	1,366	(7,000)	(11,673)	(14,368)	(35,608)	(51,998)
Income tax expense (benefit):						
Current	243	65	-	-	-	-
Deferred	(84)	(37)	646	-	-	-
	159	28	646	-	-	-
Net income (loss)	€ 1,207	€ (7,028)	€ (12,319)	€ (14,368)	€ (35,608)	$ (51,998)
Net income (loss) per share:						
Basic and Diluted	€ 0.24	€ (1.41)	€ (1.78)	€ (1.33)	€ (2.52)	$ (3.68)

(1) Euro amounts are translated into U.S. dollars using the Noon Buying Rate for the Euro on December 31, 2007, of US$1.4603 per Euro. No representation is made that the Euro amounts referred to in this annual report could have been or could be converted into U.S. dollars at any particular rate or at all.

The following table summarizes certain of our balance sheet data.

(000's omitted)	**2003**	**2004**	**2005**	**2006**	**2007**	**2007[(1)]**
Balance Sheet Data:						
Cash and cash equivalents	€ 23	€ 2,461	€ 12,785	€ 10,205	€ 25,964	$ 37,915
Working capital (deficit)	(3,037)	(7,611)	11,758	13,543	19,002	27,749
Property, net	4,045	8,543	8,631	9,424	11,544	16,858
Total assets	9,013	15,909	26,113	35,393	51,959	75,876
Long-term debt, net of current maturities	1,112	3,361	2,485	5,683	4,421	6,456
Shareholders' equity (deficit)	217	(2,074)	17,474	21,687	28,359	41,413
Capital stock	€ 5,000	€ 5,000	€ 9,611	€ 11,774	€ 14,946	$ 21,826
Number of shares	5,000,000	5,000,000	9,610,630	11,773,613	14,946,317	14,946,317

(1) Euro amounts are translated into U.S. dollars using the Noon Buying Rate for the Euro on December 31, 2007, of US$1.4603 per Euro. No representation is made that the Euro amounts referred to in this annual report could have been or could be converted into U.S. dollars at any particular rate or at all.

Exchange Rate Information

Fluctuations in the exchange rates between the Euro and the U.S. dollar will affect the U.S. dollar amounts received by owners of ADSs on conversion by the depositary of dividends, if any, paid in euros on the ordinary shares represented by the ADSs. Moreover, such fluctuations may also affect the U.S. dollar price of the ADSs on the Nasdaq Global Market. The following table sets forth information regarding the exchange rates of U.S. dollars per Euro for the periods indicated, calculated by using the average of the noon buying rates on the last day of each month during the periods presented.

	U.S. Dollar per Euro	
Year	**Average**	**Period End**
2003	1.1411	1.2597
2004	1.2478	1.3538
2005	1.2400	1.1842
2006	1.2661	1.3197
2007	1.3797	1.4603

Source: Federal Reserve Statistical Release H.10

The following table sets forth information regarding the high and low exchange rates of U.S. dollars per Euro for the periods indicated using the noon buying rate on each day of such period.

	U.S. Dollar per Euro	
Month	**High**	**Low**
September 2007	1.4219	1.3606
October 2007	1.4468	1.4092
November 2007	1.4682	1.4435
December 2007	1.4759	1.4344
January 2008	1.4877	1.4574

February 2008	1.5187	1.4495
March 2008 (through March 28, 2008)	1.5798	1.5195

Source: Federal Reserve Statistical Release H.10

On March 28, 2008, the noon buying rate was €1.00 to $1.5759.

We use the Euro as our functional currency for financial reporting. This annual report contains translations of euros into U.S. dollars at specified rates solely for the convenience of the reader. No representation is made that the Euro amounts referred to in this annual report could have been or could be converted into U.S. dollars at any particular rate or at all.

CAPITALIZATION AND INDEBTEDNESS

Not applicable.

REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable.

RISK FACTORS

You should carefully consider the risks described below, in conjunction with the other information and financial statements and related notes included elsewhere in this annual report, before making an investment decision. You should pay particular attention to the fact that we conduct our operations in Italy and are governed by a legal and regulatory environment that in some respects differs significantly from the environment that prevails in other countries with which you may be familiar. Our business, financial condition or results of operations could be affected materially and adversely by any or all of these risks. In that event, the market price of our ADSs could decline and you could lose all or part of your investment.

Risks Relating to Our Business

We have generated limited revenues from commercial sales of our products to date and have had significant losses in recent years and we do not know whether we will ever generate significant revenues or achieve profitability.

We are focused on product development and have generated limited revenues from commercial sales of our products to date. We had total product sales of €3.361 million**,** €4.075 million and €5.094 million in 2005, 2006 and 2007, respectively. We do not expect our total product sales to be able to fund our business unless we are able to sell our product candidates in large quantities. Even if we are successful selling our product candidates, these product candidates may have very limited markets and may not generate enough revenues to fund our business. The FDA and the European Union have designated our two most advanced product candidates, defibrotide to treat VOD and defibrotide to prevent VOD, as "orphan drugs," which generally means that fewer than 200,000 people are affected by the disease or condition.

We expect to continue to incur significant expenses as we research, develop and seek regulatory approval for our product candidates. We incurred a net loss of €12.3 million, €14.4 million and €35.6 million in 2005, 2006 and 2007, respectively. We cannot assure you that we will ever become profitable. If we fail to achieve profitability within the time frame expected by investors or securities analysts, the market price of our ADSs may decline.

We currently do not have any regulatory approvals to sell defibrotide to treat or prevent VOD or to treat multiple myeloma or to sell any of our other product candidates, and we cannot guarantee that we will ever be able to sell any of these products anywhere in the world.

We must demonstrate that our product candidates satisfy rigorous standards of safety and effectiveness before the U.S. Food and Drug Administration, or the FDA, the European Commission and other regulatory authorities will approve the products for commercial marketing. We or others must conduct clinical trials of those products which must be approved by the FDA or other regulatory agencies. These trials are time-consuming and expensive, and we cannot guarantee whether they will be successful. Currently, the only regulatory approvals we have relate to the use of defibrotide in Italy to prevent vascular disease with risk of thrombosis. We do not have approval to sell defibrotide to treat or prevent VOD or to treat multiple myeloma or to sell any of our other product candidates anywhere in the world. We will need to conduct significant additional research, preclinical testing and clinical testing before we can

file applications with the FDA, the European Commission and other regulatory authorities for approval of our product candidates. In addition, to compete effectively, our future products must be easy to use, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives and, as a result, may not be able to sell any of our product candidates anywhere in the world.

We may not successfully enroll enough patients in our current Phase III clinical trial of defibrotide to treat severe VOD or the related historical trial.

Our current Phase III clinical trial of defibrotide to treat severe VOD in the United States has two elements: the prospective arm, in which defibrotide is administered to the patients, and a historical control arm. We are not conducting a traditional control group of patients who receive no treatment for the reasons discussed in the risk factor below. The protocol for the treatment trial is extremely strict, meaning that only patients who meet very specific criteria are eligible to enroll. The protocol calls for an initial enrollment of 80 patients in the prospective arm. We may need to enroll additional patients beyond the original 80 patients. Due to the small number of patients who meet the protocol enrollment criteria, we may not be able to enroll these additional patients in a timely manner or at all.

The related historical control arm measures the historical result of patients who contracted severe VOD at the centers participating in the treatment trial in the past (prior to the start of the treatment trial) and were not treated with defibrotide. We believe that many of the centers participating in our current treatment trial treated patients with defibrotide on a compassionate use, meaning obtaining an emergency protocol, single Investigational New Drug Application, or “IND,” for several years before the treatment trial started, and as a result, there may be few patients eligible to enroll in the historical arm of this trial. The historical arm protocol calls for an initial enrollment of 80 patients. We may need to enroll additional patients beyond the original 80. Again, due to the small number of patients who meet the protocol historical enrollment criteria, we may not be able to enroll these additional patients in a timely manner or at all, or we may need to expand the number of patients we review to find additional patients who meet the enrollment criteria, which could result in additional expense to the Company.

In such events, we may have to restructure this trial, which would substantially delay the time period before we could commercialize this product. Since our other advanced product candidates are dependent in part upon approval of this lead product candidate, such a delay would also slow development of our other product candidates.

The FDA and other regulatory authorities may require us to conduct other clinical trials of defibrotide to treat severe VOD.

The Dana-Farber Cancer Institute at Harvard University conducted a Phase II clinical trial in the United States for the use of defibrotide to treat severe VOD that concluded in December 2005. Based upon a historical study conducted by Dana-Farber at three centers consisting of 38 patients, we believe that, without treatment, the complete response rate within 100 days after stem cell transplantation is approximately 11% and the survival rate for this disease is approximately 20% after 100 days. As a result of this research and belief and the fact that we believe that there are no approved treatments available at this time, the Dana-Farber clinical investigators did not establish a control group of patients who do not receive the drug, as is customarily done in the FDA approval process, on the basis that it would be unethical to refuse treatment to patients when the treatment being investigated could potentially save their lives. The FDA has stated a preference for a study that utilizes a concurrent control group of untreated patients but indicated that they would review a trial using a historical control group of untreated patients only. Our Phase III clinical trial of defibrotide to treat severe VOD that is currently underway uses a historical control group of untreated patients only. The FDA, upon reviewing this trial, may require us to conduct a new clinical trial using a concurrent control group of untreated patients and other regulatory authorities may take the same position. This could significantly delay the filing of a New Drug Application with the FDA or applications for other regulatory approval for this use because one or more of the clinical centers where the clinical trial is to be conducted may not be willing to conduct such a clinical trial, again on the basis that it is unethical to refuse treatment to patients when the treatment being investigated could potentially save their lives. The committee of clinical investigators who sponsored a Phase II/III clinical trial of defibrotide to treat VOD in Europe conducted by Consorzio Mario Negri Sud, which had a concurrent control group of untreated patients, cancelled the trial in October 2005 due to a lack of patients enrolling. We believe that patients were reluctant to enroll due to the possibility of being placed into the control group and not receiving treatment. A requirement for a concurrent control group of untreated patients would also result in the expenditure of more funds on clinical trials and delay our ability to generate revenue from this product candidate.

The FDA requested that we conduct an “expanded access” program in which we supply defibrotide to treat people with severe VOD who are not eligible for the Phase III clinical trial or not otherwise able to participate in the Phase III clinical trial. This expanded access program will collect usage, tolerability and safety data from the patients treated. Also, the FDA has requested that we conduct a total of four toxicology studies in connection with the Phase III clinical trial. We expect the costs of the expanded access program and the toxicology studies to be material. Additional requests from the FDA could require the expenditure of more funds by us.

Our other product candidates are at early stages of development and will require clinical trials which may not be successful.

We intend to apply for FDA and other regulatory agency approval for our other product candidates, including other uses of defibrotide, in the future, and these additional product candidates will require that we conduct clinical trials and undergo the regulatory approval process. The commencement and completion of these clinical trials could be delayed or prevented by a variety of factors, including:

· delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites or investigators;

· delays in obtaining institutional review board approval to commence a clinical trial;

· delays in obtaining FDA or other regulatory agency clearance to commence a clinical trial;

· delays in the enrollment of patients;

· lack of effectiveness of the product candidate during clinical trials; or

· adverse events in patients or safety issues.

We do not know whether these future clinical trials will be initiated or completed at all. Significant delays in clinical trials will impede our ability to commercialize these additional product candidates and generate revenue, and could significantly increase our development costs.

We may be required to suspend or discontinue clinical trials due to adverse events or other safety issues that could preclude approval of our products candidates.

Our clinical trials may be suspended at any time for a number of safety-related reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that our product candidates present an unacceptable risk to the clinical trial patients. In addition, institutional review boards or regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, including if they present an unacceptable safety risk to patients.

Administering any product candidate to humans may produce undesirable side effects. VOD is a complication associated with high dose chemotherapy and stem cell transplantation. Adverse events involving vascular disorders, coagulation, and potentially life-threatening bleeding have been reported in patients with VOD treated with defibrotide which potentially could be related to the defibrotide therapy. Hypotension has been reported as a possibly related serious adverse event in the trials of defibrotide to treat severe VOD. Also, we discontinued a 69-patient Phase I/II clinical trial of defibrotide to prevent deep vein thrombosis after hip surgery in Denmark in 2002 after three patients experienced hypotension after receiving the defibrotide intravenously. That trial was discontinued due to the hypotension and because defibrotide can also be administered orally to prevent deep vein thrombosis. These adverse events reports will be weighed by the FDA and other regulatory authorities in determining whether defibrotide can, from a risk-benefit perspective, be considered to be safe and effective to treat severe VOD, to prevent deep vein thrombosis or any other indication for which approval is sought.

It is possible that as further data are collected and analyzed, additional adverse events or safety issues could emerge which could impact conclusions relating to the safety of these product candidates. As one of our current products and most of our product candidates utilize or will utilize defibrotide, any problems that arise from the use of this drug would severely harm our business operations.

We expect to rely upon Sirton to process defibrotide both for current sales in Italy and future sales outside of Italy, and we may not be able to quickly replace Sirton if it fails in its duties.

We have hired our affiliate, Sirton Pharmaceuticals S.p.A., to process defibrotide into ampoule and capsule formulations and then we sell the finished product to Crinos, which distributes them to the Italian market to treat vascular disease with risk of thrombosis. In addition, we may hire Sirton to process additional defibrotide if and when our advanced product candidates are approved for commercialization. Sirton has experienced financial difficulties recently. If Sirton is not able to perform any processing contract for any reason, it may take us time to find a replacement processor. Such a delay could potentially put us in breach of our distribution agreement with Crinos or other contractual obligations into which we may enter, could violate local laws requiring us to deliver the product to those in need and could also impact our revenues.

One of our largest customers, Sirton, owes us a large receivable that we may not be able to collect.

The largest customer of our active pharmaceutical ingredients is our affiliate, Sirton. At December 31, 2007, Sirton owed us a receivable of €4.147 million. We also hire Sirton to process defibrotide into the finished product that we sell in Italy. At December 31, 2007, we owed Sirton a payable of €2.077 million. Sirton has experienced financial difficulties lately that may result in it being unable to pay us our receivable. FinSirton, our largest shareholder and Sirton's parent, has guaranteed Sirton's payment of a portion of this receivable equal to the receivable net of our

payable to Sirton. However, our existing agreement does not allow us to offset our payable against our receivable if Sirton went into bankruptcy. As a result, in that situation, we would be forced to pay our payable to Sirton, but we may not receive our entire receivable from either Sirton or FinSirton. At December 31, 2007, this "shortfall" exposure amounted to €2.0570 million.

Our products could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements, if and when any of our product candidates are approved.

Any product for which we obtain marketing approval, together with the manufacturing processes, post-approval commitments, and advertising and promotional activities for such product, will be subject to continued regulation by the FDA and other regulatory agencies. Later discovery of previously unknown problems with our products or their manufacture, or failure to comply with regulatory requirements, may result in:

· restrictions on such products or manufacturing processes;

· withdrawal of the products from the market;

· voluntary or mandatory recalls;

· fines;

· suspension of regulatory approvals;

· product seizures; or

· injunctions or the imposition of civil or criminal penalties.

If we are slow to adapt, or unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we may lose marketing approval for our products when and if any of them are approved.

Our manufacturing facility and the manufacturing facility of our affiliate Sirton, who processes some of our products and product candidates, are subject to continuing regulation by Italian authorities and are subject to inspection and regulation by the FDA and European regulatory authorities. These authorities could force us to stop manufacturing our products if they determine that we or Sirton are not complying with applicable regulations or require us or Sirton to complete further costly alterations to our facilities.

We manufacture active pharmaceutical ingredients at our manufacturing facility in Italy. We have hired our affiliate, Sirton, to process one of these active pharmaceutical ingredients, defibrotide, into the finished drug at Sirton's manufacturing facility. These facilities are subject to continuing regulation by the Italian Health Authority and other Italian regulatory authorities with respect to manufacturing our current products. The facilities are also subject to inspection and regulation by the FDA and European regulatory authorities with respect to manufacturing our product candidates for investigational use. Also, part of the process for obtaining approval from the FDA and European regulatory authorities for our product candidates is approval by those authorities of these manufacturing facilities compliance with current good manufacturing practices. After receiving initial approval, if any, the FDA or those European regulatory authorities will continue to inspect our manufacturing facilities, including inspecting them unannounced, to confirm whether we and Sirton are complying with the good manufacturing practices.

These regulators may require us to stop manufacturing our products and may deny us approval to manufacture our product candidates if they determine that we or Sirton are not complying with applicable regulations or require us to complete costly alterations to our facilities.

We may have difficulty obtaining raw material for our products and product candidates.

Our products and product candidates are based on either pig intestines or human urine. If our current sources of those raw materials develop safety problems or other issues that impact our supply of the raw materials, we may not be able to find alternative suppliers in a timely fashion. In that case, we would have to slow or cease our manufacture of those products and product candidates.

If our third-party clinical trial vendors fail to comply with strict regulations, the clinical trials for our product candidates may be delayed or unsuccessful.

We do not have the personnel capacity to conduct or manage all of the clinical trials that we intend for our product candidates. We rely on third parties to assist us in managing, monitoring and conducting our clinical trials. We have entered into and expect to continue to enter into clinical trial agreements with numerous centers in the United States, Canada and Israel regarding our Phase III clinical trial of defibrotide to treat severe VOD. We have entered into a co-sponsoring agreement with the European Group for Blood and Marrow Transplantation, regarding a Phase II/III clinical trial of defibrotide to prevent VOD in children in Europe. We have entered into an agreement with MDS Pharma Services (U.S.) Inc. and Parexel International to perform clinical research services in connection with clinical trials conducted in the United States and agreements with KKS-UKT, GmbH and MDS Pharma Services S.p.A. to provide such services for our clinical trials in Europe. If these third parties fail to comply with applicable regulations

or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the clinical trials for our product candidates may be delayed or unsuccessful.

Furthermore, the FDA can be expected to inspect some or all of the clinical sites participating in our clinical trials, or our third party vendors' sites, to determine if our clinical trials are being conducted according to good clinical practices. If the FDA determines that these clinical sites or our third-party vendors are not in compliance with applicable regulations, we may be required to delay, repeat or terminate the clinical trials. Any delay, repetition or termination of our clinical trials could materially harm our business.

Our failure to raise additional funds in the future may delay the development of certain of our product candidates and sale of our products.

The development and approval of our product candidates and the acquisition and development of additional products or product candidates by us, as well as the expansion of our research, regulatory and manufacturing operations, will require a commitment of substantial funds. Our future capital requirements are dependent upon many factors, some of which are beyond our control, including:

· the successful and continued development of our existing product candidates in preclinical and clinical testing;

· the costs associated with protecting and expanding our patent and other intellectual property rights;

· future payments, if any, received or made under existing or possible future collaborative arrangements;

· the costs associated with building a future commercial infrastructure;

· the costs associated with implementing any upgrades to our manufacturing facility required by the FDA, European regulators or other regulators;

· the timing of regulatory approvals needed to market our product candidates; and

· market acceptance of our products.

We will need additional funds before we have completed the development of our product candidates. We have no committed sources of additional funds. We cannot assure you that funds will be available to us in the future on favorable terms, if at all. If adequate funds are not available to us on terms that we find acceptable, or at all, we may be required to delay, reduce the scope of, or eliminate research and development efforts or clinical trials on any or all of our product candidates. We may also be forced to curtail or restructure our operations, obtain funds by entering into arrangements with collaborators on unattractive terms or relinquish rights to certain technologies or product candidates that we would not otherwise relinquish in order to continue independent operations.

We are currently dependent on third parties to market and distribute our products in finished dosage form, and we may continue to be dependent on third parties to market and distribute our products and product candidates.

Our internal ability to handle the marketing and distribution functions for our current products and our product candidates is limited and we do not expect to develop the capability to provide marketing and distribution for all of our future products. Our long-term strategy includes either developing marketing and distribution capacity internally or entering into alliances with third parties to assist in the marketing and distribution of our product candidates. We have entered into an agreement with Sigma-Tau Pharmaceuticals, Inc. to market defibrotide to treat VOD in North America, Central America and South America and we may need to develop these capabilities internally or enter into similar agreements to market and distribute our other product candidates. We face, and will continue to face, intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions, for attracting investigators and sites capable of conducting our clinical trials and for licenses of proprietary technology. Moreover, these arrangements are complex to negotiate and time-consuming to document. Our future profitability will depend in large part on our ability to enter into effective marketing agreements and our product revenues will depend on those marketers' efforts, which may not be successful.

If we are unable to attract and retain key personnel, we may be unable to successfully develop and commercialize our product candidates or otherwise manage our business effectively.

We are highly dependent on our senior management, whose services are critical to the successful implementation of our product acquisition, development and regulatory strategies. If we lose their services or the services of one or more of the other members of our senior management or other key employees, our ability to successfully commercialize our product candidates or otherwise manage our business effectively could be seriously harmed.

Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of specific skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel. In addition, under Italian law, we must pay our Italian employees a severance amount based on their salary and years of service if they leave their employment, even if we terminate them for cause or they resign.

In order to expand our operations, we will need to hire additional personnel and add corporate functions that we currently do not have. Our ability to manage our operations and growth will require us to continue to improve our operational, financial and management controls and reporting system and procedures, or contract with third parties to provide these capabilities for us.

All of our manufacturing capability is located in one facility that is vulnerable to natural disasters, telecommunication and information system failures, terrorism and similar problems, and we are not insured for losses caused by all of these incidents.

We conduct all of our manufacturing operations in one facility located in Villa Guardia, near Como, Italy. This facility could be damaged by fire, floods, earthquake, power loss, telecommunication and information system failures, terrorism or similar events. Our insurance covers losses to our facility, including the buildings, machinery, electronic equipment and goods, for approximately €15 million, but does not insure against all of the losses listed above, including terrorism and some types of flooding. Although we believe that our insurance coverage is adequate for our current and proposed operations, there can be no guarantee that it will adequately compensate us for any losses that may occur. We are not insured for business interruption and we have no replacement manufacturing facility readily available.

We sell defibrotide in Italy to treat vascular disease with risk of thrombosis, which may affect pricing of our product candidates.

We currently sell defibrotide in Italy to treat vascular disease with risk of thrombosis. If our product candidates that also use defibrotide are approved for sale in Europe or Italy, we may need to also obtain approval from regulators as to what price we can charge for those product candidates. The regulators may impose an artificially low cap on the defibrotide product candidate prices based on the relatively low price of our defibrotide current product.

Our industry is highly competitive and subject to rapid technological changes. As a result, we may be unable to compete successfully or to develop innovative products, which could harm our business.

Our industry is highly competitive and subject to significant and rapid technological change as researchers learn more about diseases and develop new technologies and treatments. While we are unaware of any other products or product candidates that treat or prevent VOD, we believe that other companies have products or are currently developing products to treat some of the same disorders and diseases that our other product candidates are designed to treat. These companies include Genzyme Corp., British Biotech plc, Boehringer Ingelheim, Millennium Pharmaceuticals, Inc., ARIAD Pharmaceuticals, Inc., Celgene Corp., Cell Genesys, Inc., Human Genome Sciences, Inc., Chugai Pharmaceutical Co., Ltd., Seattle Genetics, Inc., EntreMed, Inc., Xcyte Therapies, Inc., Amgen, Inc., CuraGen Corporation and Aesgen, Inc.

Many of these competitors have substantially greater research and development capabilities and experience, and greater manufacturing, marketing and financial resources, than we do. In addition, these companies' products and product candidates are in more advanced stages of development than ours or have been approved for sale by the FDA and other regulatory agencies. As a result, these companies may be able to develop their product candidates faster than we can or establish their products in the market before we can. Their products may also prove to be more effective, safer or less costly than our product candidates. This could hurt our ability to recognize any significant revenues from our product candidates.

In May 2003, the FDA designated defibrotide as an orphan drug to treat VOD. In January 2007, the FDA designated defibrotide as an orphan drug to prevent VOD as well. If the FDA approves the New Drug Applications that we intend to file before approving a New Drug Application filed by anyone else for these uses of defibrotide, the orphan drug status will provide us with limited market exclusivity for seven years from the date of the FDA's approval of our New Drug Application. However, a marketing authorization to another applicant may be granted for the same product if we give our consent to the second applicant, we are unable to supply sufficient quantities of defibrotide, or the second applicant can establish in its application that its product is safer, more effective or otherwise clinically superior to our product. In that case, our product would not have market exclusivity. Additionally, while we are not aware of any other company researching defibrotide for these uses, if another company does develop defibrotide for these uses, there is no guarantee that the FDA will approve our New Drug Application before approving the other company's defibrotide product for these uses, in which case the first product approved would have market exclusivity and our products would not be eligible for approval until that exclusivity expires.

In July 2004, the European Commission designated defibrotide as an orphan medicinal product to both treat and prevent VOD. If the European regulators grant us a marketing authorization for those uses of defibrotide, we will have limited market exclusivity for those uses for ten years after the date of the approval. However, a marketing authorization may be granted to another applicant for the same product if we give our consent to the second applicant, we are unable to supply sufficient quantities of defibrotide, or the second applicant can establish in its application that the its product is safer, more effective or otherwise clinically superior to our product. In that case, our product would not have market exclusivity.

If we are unable to adequately protect our intellectual property, our ability to compete could be impaired.

Our long-term success largely depends on our ability to create and market competitive products and to protect those creations. Our pending patent applications, or those we may file in the future, may not result in patents being issued. Until a patent is issued, the claims covered by the patent may be narrowed or removed entirely, and therefore we may not obtain adequate patent protection. As a result, we may face unanticipated competition, or conclude that without patent rights the risk of bringing products to the market is too great, thus adversely affecting our operating results.

Because of the extensive time required for the development, testing and regulatory review of a product candidate, it is possible that before any of our product candidates can be approved for sale and commercialized, our relevant patent rights may expire or remain in force for only a short period following commercialization. Our issued U.S. patents expire between 2010 and 2019, and our U.S. patents for which we have submitted applications will expire between 2021 and 2026. Our U.S. patent covering defibrotide expires in 2010. There may be no opportunities to extend these patents and thereby extend FDA and European approval exclusivity, in which case we could face increased competition for our products that are derived from defibrotide. Patent expiration could adversely affect our ability to protect future product development and, consequently, our operating results and financial position.

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. We intend to eventually license or sell our products in China, South Korea and other countries which do not have the same level of protection of intellectual property rights as exists in the United Sates and Europe. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Risks Related to Ownership of the ADSs

Our largest shareholder exercises significant control over us, which may make it more difficult for you to elect or replace directors or management and approve or reject mergers and other important corporate events.

Our largest shareholder, FinSirton, owned approximately 25% of our outstanding ordinary shares at March 31, 2008. Dr. Laura Ferro, who is our Chief Executive Officer and President and one of our directors, together with members of her family controls FinSirton. As a result, Dr. Ferro and her family, through FinSirton, may substantially control the outcome of all matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other important corporate events. They may exercise this ability in a manner that advances their best interests and not necessarily yours. In particular, Dr. Ferro may use her control over FinSirton's shareholdings in our company to resist any attempts to replace her or other members of our board of directors or management or approve or reject mergers and other important corporate events. Also, the concentration of our beneficial ownership may have the effect of delaying, deterring or preventing a change in our control, or may discourage bids for the ADSs or our ordinary shares at a premium over the market price of the ADSs. The significant concentration of share ownership may adversely affect the trading price of the ADSs due to investors' perception that conflicts of interest may exist or arise.

If a significant number of ADSs are sold into the market, the market price of the ADSs could significantly decline, even if our business is doing well.

Our outstanding ordinary shares, ordinary shares issuable upon exercise of warrants and ordinary shares issuable upon exercise of options are not subject to lock-up agreements. We have filed registration statements registering the resale of most of our outstanding ordinary shares and related ADSs and all of our ordinary shares and related ADSs issuable upon exercise of our outstanding warrants and options. Such registration and ultimate sale of the securities in the markets may adversely affect the market for the ADSs.

You may not have the same voting rights as the holders of our ordinary shares and may not receive voting materials in time to be able to exercise your right to vote.

Except as described in this annual report and in the deposit agreement for the ADSs with our depositary, holders of the ADSs will not be able to exercise voting rights attaching to the ordinary shares evidenced by the ADSs on an individual basis. Holders of the ADSs will have the right to instruct the depositary as their representative to exercise the rights attached to the ordinary shares represented by the ADSs. You may not receive voting materials in time to instruct the depositary to vote, and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

You may not be able to participate in rights offerings and may experience dilution of your holdings as a result.

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. Under our deposit agreement for the ADSs with our depositary, the depositary will not offer those rights to ADS holders unless both the rights and the underlying securities to be distributed to ADS holders are either registered under the Securities Act of 1933, as amended, or exempt from registration under the Securities Act with respect to all holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or underlying securities or to endeavor to cause such a registration statement to be declared effective. In addition, we may not be able to take advantage of any exemptions from registration under the Securities Act. Accordingly, holders of our ADSs may be unable to participate in our rights offerings and may experience dilution in their holdings as a result.

You may be subject to limitations on transfer of your ADSs.

Your ADSs represented by the ADRs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deem it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

Risks Relating to Being an Italian Corporation

The process of seeking to raise additional funds is cumbersome, subject to the verification of an Italian notary public as to compliance with our bylaws and applicable law and may require prior approval of our shareholders at an extraordinary meeting of shareholders.

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. 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, upon 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, an Italian 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, concurrently 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. This means that any warrants we issue pursuant to this authorization would have a maximum term of 5 years, and, to the degree issued after the shareholder meeting, would have a term of less than 5 years. 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.

We are restricted under Italian law as to the amount of debt securities that we may issue relative to our equity.

Italian law provides that we may not issue debt securities for an amount exceeding twice the amount of the sum of the aggregate par value of our ordinary shares (which we call our capital), our legal reserve and any other disposable reserves appearing on our latest Italian GAAP balance sheet approved by our shareholders. The legal reserve is a reserve to which we allocate 5% of our Italian GAAP net income each year until it equals at least 20% of our Italian GAAP capital. One of the other reserves that we maintain on our balance sheet is a "share premium reserve", meaning amounts paid for our ordinary shares in excess of the capital. At December 31, 2007, the sum of our capital, legal reserves and other reserves on our Italian GAAP balance sheet was €46 million. If we issue debt securities in the future, until such debt securities are repaid in full, we may not voluntarily reduce our capital or our reserves (such as by declaring dividends) if it results in the aggregate of the capital and reserves being less than half of the outstanding amount of the debt. If our equity is reduced by losses or otherwise such that the amount of the outstanding debt securities is more than twice the amount of our equity, some legal scholars are of the opinion that the ratio must be restored by a recapitalization of our company. If our equity is reduced, we could recapitalize by issuing new shares or having our shareholders contribute additional capital to our company, although there can be no assurance that we would be able to find purchasers for new shares or that any of our current shareholders would be willing to contribute additional capital.

If we suffer losses that reduce our capital to less than €120 thousand, we would need to either recapitalize, change our form of entity or be liquidated.

Italian law requires us to reduce our shareholders' equity and, in particular, our capital (aggregate par value of our ordinary shares) to reflect on-going losses. We are also required to maintain a minimum capital of €120 thousand. At December 31, 2007, our Italian GAAP capital was approximately €14.9 million. If we suffer losses from operations that reduce our capital to less than €120 thousand, then either we must increase our capital (which we could do by issuing new shares or having our shareholders contribute additional capital to our company) to at least €120 thousand or convert the form of our company into an S.r.l., which has a lower capital requirement of €10 thousand. If we did not take these steps, a court could liquidate our company.

Due to the differences between Italian and U.S. law, the depositary (on your behalf) may have fewer rights as a shareholder than you would if you were a shareholder of a U.S. company.

We are incorporated under the laws of the Republic of Italy. As a result, the rights and obligations of our shareholders are governed by Italian law and our bylaws, and are in some ways different from those that apply to U.S. corporations. Some of these differences may result in the depositary (on your behalf) having fewer rights as a shareholder than you would if you were a shareholder of a U.S. corporation. We have presented a detailed comparison of the Italian laws applicable to our company against Delaware law in "*Item 10, Additional Information, Comparison of Italian and Delaware Corporate Laws."* We compared the Italian laws applicable to our company against Delaware law because Delaware is the most common state of incorporation for U.S. public companies.

Italian labor laws could impair our flexibility to restructure our business.

In Italy, our employees are protected by various laws giving them, through local and central works councils, rights of consultation with respect to specific matters regarding their employers' business and operations, including the downsizing or closure of facilities and employee terminations. These laws and the collective bargaining agreements to which we are subject could impair our flexibility if we need to restructure our business.

FORWARD-LOOKING STATEMENTS

This annual report may contain forward-looking statements that involve substantial risks and uncertainties regarding future events or our future performance. When used in this annual report, the words "anticipate," "believe," "estimate," "may," "intent," "continue," "will," "plan," "intend," and "expect" and similar expressions identify forward-looking statements. should read statements that contain these words carefully because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other "forward-looking" information. We believe that it is important to communicate our future expectations to our investors. Although we believe that our expectations reflected in any forward-looking statements are reasonable, these expectations may not be achieved. The factors listed in the section captioned "Risk Factors," as well as any cautionary language included in this annual report or incorporated by reference, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Before you invest in our ordinary shares, you should be aware that the occurrence of the events described in the "Risk Factors" section and elsewhere in this annual report could have a material adverse effect on our business, performance, operating results and financial condition. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements set forth in this annual report. Except as required by federal securities laws, we are under no obligation to update any forward-looking statement, whether as a result of new information, future events, or otherwise.

You should rely only on the information contained in this annual report. We have not authorized anyone to provide you with information different from that contained in this annual report. The information contained in this annual report is accurate only as of the date of this annual report.

ITEM 4. INFORMATION ON THE COMPANY

HISTORY AND DEVELOPMENT OF THE COMPANY

We were originally formed in 1993 as Pharma Research S.r.L., an Italian private limited company. In December 2000, we changed from a private limited company to an Italian corporation. In July 2001, we changed our name to Gentium S.p.A. Under our current bylaws, the duration of our company will expire on December 31, 2050. We are governed by the Italian Civil Code.

We were part of a group of pharmaceutical businesses founded in Italy in 1944 that has been involved in the research and development of drugs derived from DNA and DNA molecules since the 1970s. In 1986, our founding company received approval to sell in Italy 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.

Our current primary focus is on the development of defibrotide for other uses in the United States and Europe, including to treat and prevent VOD and to treat multiple myeloma. We are also exploring the use of oligotide to treat renal disease. In addition to defibrotide, we sell urokinase, calcium heparin, sodium heparin and sulglicotide, which are active pharmaceutical ingredients used to make other drugs.

In June 2005, we consummated an initial public offering of our ADSs, which began trading on the American Stock Exchange. In May 2006, we transitioned the trading of our ADSs from the American Stock Exchange to the Nasdaq Global Market.

We have Italian, United States and international trademark rights in “Gentium,” United States and European Union trademark rights in “Gentide,” international and Italian trademark rights in “Oligotide” and Italian trademark rights to “Pharma Research” and “Dinelasi”. We also have a number of patent registrations issued and pending in Italy, the United States and other countries. This annual report also refers to brand names, trademarks, service marks, and trade names of other companies and organizations, and these brand names, trademarks, service marks, and trade names are the property of their respective holders.

This annual report contains market data and industry forecasts that were obtained from industry publications and third parties.

Our principal executive offices are located at Piazza XX Settembre 2, 22079 Villa Guardia (Como), Italy. Our telephone number is +39 031 385111. Our website is located at www.gentium.it. The information contained on our website is not part of this annual report. Our registered agent for service of process in New York is CT Corporation System, located at 111 Eighth Avenue, 13th Floor, New York, New York 10011, telephone number (212) 894-8940.

CAPITAL EXPENDITURES

The following table sets forth our capital expenditures for each year in the three-year period ended December 31, 2007.

	For the Year Ended December 31,		
(in thousands)	**2005**	**2006**	**2007**
Land and buildings	€ 109	€ 7	€ 162
Plant and machinery	642	793	1,839
Industrial equipment	50	254	582
Other	88	108	90
Leasehold improvements	-	46	249
Computer Software	123	259	69
Construction in progress	292	46	250
Total	€ 1,304	€ 1,513	€ 3,241

All of these capital expenditures are in Italy. We are financing these expenditures from offerings of our ordinary shares and loans from third parties.

BUSINESS OVERVIEW

We are building upon our extensive experience with defibrotide, which our founding company discovered over 20 years ago, to develop it for a variety of additional uses, including to treat and prevent VOD, a condition in which some of the veins in the liver are blocked as a result of cancer treatments such as chemotherapy prior to stem cell transplants. Severe VOD (meaning VOD that results in multiple-organ failure) is a potentially devastating complication of cancer treatments. We are sponsoring a Phase III clinical trial of defibrotide to treat severe VOD in the United States, Canada and Israel. A historical study conducted by Harvard University's Dana-Farber Cancer Institution of 38 patients in three clinical centers indicated that, without treatment, only approximately 11% of patients with severe VOD achieved a complete response to the disorder within 100 days of their stem cell transplantation, and only approximately 20% survived 100 days. By comparison, results from a Phase II clinical trial conducted by Dana-Farber of 141 evaluable patients with severe VOD who were treated with defibrotide showed a complete response rate after 100 days of approximately 46% and a survival rate after 100 days of approximately 41%. However, both the historical study and the Phase II clinical trial were based on very few patients and may not accurately show either true complete response and survival rates without treatment or the efficacy of defibrotide. We believe that there is no drug approved by the FDA or European regulators to treat or prevent VOD.

In May 2003, the FDA designated defibrotide as an orphan drug for treatment of VOD. In January 2007, the FDA designated defibrotide as an orphan drug for prevention of VOD. In July 2004, the European Commission granted us orphan medicinal product designation for the use of defibrotide to both treat and prevent VOD.

Due to the historically low complete response and survival rates and lack of treatments for this condition, we believe there is an immediate need for a drug to treat severe VOD. The FDA has a "fast track" designation program which is

designed to facilitate the development and expedite their review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The FDA has designated defibrotide to treat severe VOD occurring after stem cell transplantation by means of injection as a fast track product. The FDA approval process for defibrotide for this use remains dependent upon the successful completion of clinical trials.

If we are successful in obtaining FDA approval and/or European regulatory approval for defibrotide to treat severe VOD, we expect that the cash flow from operations generated by this use of defibrotide will contribute towards our working capital requirements and funding for the further development of defibrotide for other uses and our ultimate goal of FDA and European regulatory approval for other uses of defibrotide, including to prevent VOD and treat multiple myeloma. However, we will need to raise additional funds through debt and/or equity financings, or enter into licensing or similar collaborative arrangements, or both, in addition to cash flow we may generate from operations, to complete the development of these other uses of defibrotide.

If we are successful in bringing these product candidates to market, we intend to use the cash flow from operations generated by them and our current products to continue to discover and develop additional uses of defibrotide, and to develop other drugs, such as oligotide, which we believe may protect against damage to blood vessel wall cells caused by a particular cancer treatment and treat renal and kidney failure. These additional product candidates will be very expensive to develop, and it is likely that we will need to either raise additional funds through debt and/or equity financings, or enter into licensing or similar collaborative arrangements, or both, in addition to cash flow we may generate from operations, to complete these developments.

Our strategy, where we do not have the internal capacity, is to continue to enter into collaborative and strategic agreements to assist us in the development, manufacturing and marketing of our products and product candidates. To date, we have licensed the right to market defibrotide to treat VOD in North America, Central America and South America, upon regulatory approval, to Sigma-Tau Pharmaceuticals, Inc., which markets drug treatments for rare conditions and diseases. Sigma-Tau Pharmaceuticals, Inc. is an United States subsidiary of Sigma Tau Finanziaria S.p.A., an international family of pharmaceutical companies.

We manufacture defibrotide, calcium heparin, sodium heparin and sulglicotide at our manufacturing facility near Como, Italy, and we lease our affiliate Sirton's facility to manufacture urokinase. These products are active pharmaceutical ingredients used to make other drugs. Almost all of our revenues during the past three years have come from sales of these products to Sirton. Our revenues from the sales of these products to date have been generated primarily in Italy and, to a small degree, in South Korea and amounted to €3.4 million, €4.1 million and €5.1 million in 2005, 2006 and 2007, respectively. Since 2004, we have spent more than €10 million on upgrades to our facilities that we believe will facilitate the FDA and European regulatory approval process for our product candidates and enable our future production.

Market Overview

The American Cancer Society estimated that in 2008 approximately 1,437,180 new patients in the United States will be diagnosed with cancer and that there will be approximately 565,650 patient deaths in 2008 attributable to cancer. Cancer is a group of diseases characterized by uncontrolled growth and spread of abnormal cells. If the spread is not controlled, it can result in death. Most cancer patients will receive one or more of chemotherapy, radiation therapy and hormone therapy.

Chemotherapy, radiation therapy and hormone therapy treatments for cancer are used to target and kill cancer cells. In some cases, the therapy treats the cancer directly; in other cases, it is administered to prepare the patient for a stem cell or bone marrow transplant, which treats cancer or other diseases. Unfortunately, these therapies often have significant negative side effects, including damage to the cells that line the blood vessel walls. The damage to these cells can lead to various disorders of the vascular system. Some patients may not be able to continue with cancer treatments because they develop these vascular system complications; other patients considered at high risk of developing these vascular system complications may not receive optimal cancer treatments or any treatment at all.

VOD. One of the disorders of the vascular system that can result from chemotherapy, radiation therapy, hormone therapy and stem cell and bone marrow transplants is VOD. These therapies can cause extensive damage to the cells that line the walls of small veins in the liver. The body's natural response is to swell or clot the sites of injury, but this blocks or "occludes" the vein. This blockage of the veins is called "Veno-Occlusive Disease," or VOD. VOD can cause damage to the liver and, in its severe form, leads to failure of the liver and other organs (multiple-organ failure), which usually results in death. According to 2003 data from the International Bone Marrow Transplant Registry and the European Bone Marrow Transplant Registry, approximately 21,000 people receive bone marrow transplants, which are types of stem cell transplants, each year in the United States. Based on our review of more than 200 articles in the medical literature, we believe that approximately 14% of patients who undergo stem cell transplants develop VOD. According to a 1998 article in *Blood* magazine by Enric Carreras et. al., approximately 28% of patients who develop

VOD progress to severe VOD. Based upon a historical study conducted by Dana-Farber at three centers consisting of 38 patients, we believe that of the patients who develop severe VOD, only approximately 11% achieve a complete response within 100 days after a stem cell transplantation and only approximately 20% survive more than 100 days. VOD poses a severe risk to the victim's health. We believe that there are no FDA or European regulatory approved treatments at this time for VOD.

Multiple myeloma. Multiple myeloma is a cancer of the plasma cell. The American Cancer Society estimates that about 19,920 new cases of multiple myeloma will be diagnosed in the U.S. during 2008. Approximately 10,690 Americans are expected to die of multiple myeloma in 2008. The 5-year survival rate for patients with multiple myeloma for 1996 - 2003 was approximately 34%.

Strategy

Our goal is to research, discover, develop and manufacture drugs derived from DNA extracted from natural sources and drugs that are synthetic oligonucleotides (molecules chemically similar to natural DNA) to treat and prevent a variety of vascular diseases and conditions related to cancer and cancer treatments. The primary elements of our strategy include:

· **Obtain FDA approval to use defibrotide to treat severe VOD.** The Dana-Farber investigator presented the results from its Phase II clinical trial of defibrotide in patients with severe VOD at the 47th Annual Meeting of the American Society of Hematology held in December 2005. Results show that the complete response rate for the 141 evaluable patients was approximately 46% compared to a historical complete response rate in 38 patients of approximately 11% and the survival rate after 100 days was approximately 41% as compared to the historical 100 day survival rate of approximately 20%. The FDA has approved our application for "fast track" designation for defibrotide to treat severe VOD 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. We are sponsoring a Phase III clinical trial of defibrotide for this use in the United States.

· **Obtain European regulatory approval to use defibrotide to treat severe VOD.** We believe that we may be able to use results from U.S. clinical trials of defibrotide to treat severe VOD to apply for European regulatory approval of this product candidate without the need to replicate the clinical trials in Europe.

· **Expand approval of defibrotide to include prevention of VOD in Europe and the United States.** A preliminary study indicated that defibrotide may provide safe and effective protection against VOD. We are co-sponsoring a Phase II/III clinical trial for this use of defibrotide in children in Europe. We intend to sponsor a second Phase II/III clinical trial of defibrotide to prevent VOD in adults and children in the United States and adults in Europe upon completion of our Phase III clinical trial of defibrotide to treat severe VOD in the United States. If the clinical trials confirm the preliminary indications, we intend to pursue further development in Europe and the United States, and ultimately to apply for FDA and European regulatory approval for this use.

· **Expand approval of defibrotide to include treatment of multiple myeloma.** Based on preclinical studies conducted at the Jerome Lipper Multiple Myeloma Center at Harvard University's Dana Farber Cancer Institute, a Phase I clinical study of defibrotide to treat multiple myeloma in 24 patients at four cancer centers in Italy concluded in 2007. A Phase II clinical center is scheduled to include 50 patients in 10 cancer centers in Italy. The principal investigator for the clinical trial is Dr. Antonio Palumbo, M.D., Division of Hematology, University of Turin, Italy.

· **Discover and develop additional product candidates.** We and others have conducted preclinical studies of other uses of defibrotide and of other drugs in our pipeline. We plan to continue to develop these additional product candidates and to further expand the possible markets for our products and product candidates. If we are successful in bringing our advanced product candidates to market, our cash flow from operations will fund some of the costs needed to develop these additional product candidates. These additional product candidates will be very expensive to develop, and we will need to either raise additional funds through debt and/or equity financings, or enter into strategic partnerships, or both, to complete these developments.

· **Increase our marketing capacity, including the use of strategic partnerships.** We have entered into a strategic license agreement with Sigma-Tau Pharmaceuticals, Inc. to market defibrotide to treat VOD in North America, Central America and South America upon regulatory approval and have granted Sigma-Tau Pharmaceuticals, Inc. a right of first refusal in those territories with respect to offers made by third parties to market defibrotide to prevent VOD, to mobilize and increase the number of stem cells available for transplant and in non-intravenous forms. We intend to develop the capacity to market defibrotide in other jurisdictions and to market our other product candidates internally and/or pursue similar marketing agreements with other strategic partners.

Product Candidates

We have extensive experience developing and manufacturing drugs derived from DNA extracted from natural sources and drugs that are synthetic oligonucleotides. Most of our product candidates utilize defibrotide, a drug which our founding company discovered and we currently manufacture and license to others for sale in Italy to treat vascular disease with risk of thrombosis. Our product candidates and their stages of development are set forth below.

The FDA's designation of a product candidate as an orphan drug means that if the FDA approves our New Drug Application for that product candidate before approving a New Drug Application filed by anyone else for that product candidate, we will have limited market exclusivity for that product candidate for seven years from the date of the FDA's approval of our New Drug Application. If the FDA were to approve a New Drug Application filed by someone else for a product candidate prior to the FDA approving our New Drug Application for the product candidate, our ability to market the product candidate would be restricted by their orphan drug exclusivity. Similarly, the Commission of the European Communities designation of a product candidate as an orphan medicinal product means that if the European regulators grant us a marketing authorization for that product candidate, we will have limited market exclusivity for that product candidate for ten years after date of the approval. If the European regulators were to grant a marketing authorization filed by someone else for a product candidate prior to the European regulators granting a marketing authorization for the product candidate, our ability to market the product candidate could be restricted.

The following table sets forth the clinical trials of our product candidates completed or being conducted to date.

Product candidate	Orphan drug designation	Territory and status of clinical trial	Sponsor of clinical trial	Number of centers that participated or are expected to participate in clinical trial	Number of patients that participated or are expected to participate in clinical trial
Defibrotide to treat severe VOD	United States and Europe	Europe, "Compassionate use" study, results published in 2000	Committee of clinical investigators	5	40
		United States, Phase I/II, results published in 2002	Investigator at Dana-Farber Cancer Institute at Harvard University	11	88
		Europe, "Compassionate use" study, results published in 2004	Investigator at University of Ulm, German	12	45
		United States, Phase II, results published in December 2005	Investigator at Dana-Farber Cancer Institute at Harvard University	9	141 evaluable patients
		United States, Canada and Israel, Phase III, currently enrolling patients	Gentium	35	160
Defibrotide to prevent VOD	United States and Europe	Switzerland, preliminary pilot clinical study completed	University Hospital of Geneva	1	157
		Europe and Israel, Phase II/III, pediatric	Gentium and European Group for Blood and Marrow Transplantation	35	270
				4 in Phase I, 10 in Phase II	

Defibrotide to treat multiple myeloma	Italy, Phase I completed, Phase II pending	Investigator at the University of Turin	24 in the Phase I and 50 in the Phase II

Defibrotide to treat severe VOD

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

In 2000, the *British Journal of Hematology* published the results of a 40 patient "compassionate use" study of defibrotide to treat VOD conducted in 19 centers in Europe from December 1997 to June 1999. Twenty-two patients, or 55%, showed a complete response. Nineteen patients, or 47%, survived more than 100 days after stem cell transplantation. The publication indicated that four patients 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. Ten of the 28 "poor risk" patients, or 36%, showed a complete response within 100 days after stem cell transplantation, all of whom also survived for at least 100 days. This publication stated that defibrotide was generally safely administered with no significant side-effects.

In 2002, the results from 88 patients with severe VOD 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 32 patients, or 36%, showed a complete response within 100 days after stem cell transplantation, and 31 patients, or 35%, of those patients survived at least 100 days after stem cell transplantation 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 last 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.

In 2004, the results from 45 children and adolescents with VOD following stem cell transplants who were treated with defibrotide were published in *Bone Marrow Transplantation*. Twenty-two of the 45 patients had severe VOD. Thirty-four of the 45 patients, or 76%, had a complete response within 100 days after stem cell transplantation and 29 patients, or 64%, survived at least 100 days after stem cell transplantation. Of the 22 patients with severe VOD, 11 patients, or 50%, had a complete response and 8 patients, or 36%, survived at least 100 days after stem cell transplantation. The report stated that defibrotide was well tolerated; about one-third of the patients had a form of coagulopathy, and treatment was discontinued in two cases where a severe bleeding disorder was observed, although the events could not be clearly attributed to defibrotide.

The Dana-Farber investigator also sponsored, under his Investigational New Drug Application, a Phase II clinical trial in the United States of defibrotide which enrolled 150 stem cell transplant patients with severe VOD, of whom 141 were evaluable, at nine 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 severe VOD, the effective dosage and potential adverse side effects. The primary endpoint was complete response, with survival after 100 days as a secondary endpoint. The Dana-Farber investigator presented the results from this Phase II clinical trial at the 47th Annual Meeting of the American Society of Hematology on December 12, 2005. Results show that of 141 patients evaluable for response, 65 patients, or 46%, showed a complete response within 100 days after stem cell transplantation and 62 patients, or 41%, survived at least 100 days after stem cell transplantation, with minimal adverse events. We do not have information about the survival rate after 100 days.

We started a historically controlled Phase III clinical trial in the United States, Canada and Israel for this use in December 2005 in patients with severe VOD. The primary endpoint is complete response within 100 days after stem cell transplantation and survival after 100 days and after six months is a secondary endpoint. 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.

We have also instituted an expanded access program for patients diagnosed with severe VOD who are not eligible to participate in or otherwise lack access to the Phase III clinical trial. Under an expanded access program, the FDA allows early access to investigational drugs that are being developed to treat serious diseases for which there is no satisfactory alternative therapy. We decided to undertake this expanded access program due to the large numbers of requests for compassionate use Investigational New Drug Application received for the use of defibrotide, and the corresponding burden that sites and investigators have been undergoing to obtain institutional review board and FDA approval for such compassionate use requests. We will collect additional usage tolerability and safety data from these patients to support our planned New Drug Application for this use of defibrotide.

The FDA has designated defibrotide to treat severe VOD occurring after stem cell transplantation by means of injection as a fast track product. 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.

Defibrotide to prevent VOD

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

In 2002, the results of a study on defibrotide in patients at high risk of VOD were published in Blood magazine. One of 57 patients who received defibrotide as a preventative agent developed VOD. No patients experienced significant bleeding.

In 2004, results of a study on defibrotide in patients who received chemotherapy and stem cell transplants were published in *Blood* magazine. Eight of 44 patients, or 18%, who received defibrotide developed VOD, of which three patients, or 7%, developed severe VOD. By comparison, four of 16 control group patients, or 25%, who received

heparin instead of defibrotide, developed VOD, of which two, or 12.5%, developed severe VOD. There were no serious adverse events attributed to the use of defibrotide.

In 2006, the results from a preliminary pilot clinical study in Switzerland by the University Hospital of Geneva on defibrotide, in patients at high risk of VOD was published in *Blood* magazine. The results suggested that defibrotide may provide effective and safe prevention against VOD. The study tested patients who received stem cell transplants. None of 157 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.

In 2007, the results of a study on defibrotide in patients who received stem cell transplants, a majority of who received reduced intensity cancer treatments but had other risk factors for VOD, were published in *Bone Marrow Transplant* magazine. None of the 58 patients who received defibrotide as a preventative agent developed VOD. No serious adverse events were reported.

In 2007, the results of a study on defibrotide in patients who received stem cell transplants and had elevated risks for VOD were reported in *Blood* magazine. One of 39 evaluable patients who received defibrotide as a preventative agent developed VOD. No serious adverse events were reported.

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

We also plan to sponsor a second Phase II/III clinical trial of defibrotide to prevent VOD in adults and children in the United States and adults in Europe upon completion of our Phase III clinical trial of defibrotide to treat severe VOD in the United States.

Defibrotide to treat multiple myeloma

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

An independent Phase I/II clinical study of defibrotide to treat multiple myeloma in combination with melphalan, prednisone, and thalidomide (MPT) started in December 2005. The Phase I portion included 24 patients in four cancer centers in Italy and concluded in 2007. The Phase II portion is scheduled to include 50 patients in 10 cancer centers in Italy. The principal investigator for the clinical trial is Dr. Antonio Palumbo, 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 multiple myeloma 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 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.

Oligotide

We are developing oligotide, another product derived from natural DNA, to treat diabetic nephropathy. Diabetic nephropathy is a complication of diabetes that causes the kidney to cease functioning properly. Each kidney has many tufts of blood vessels called glomerulus. The glomerulus filters blood and forms urine. Diabetic nephropathy causes the glomerulus to thicken, partly through the action of an enzyme called heparanase. As a result, the kidney allows too much protein to pass into the urine. Eventually, the kidneys can fail, which results in death. We performed an in vitro pre-clinical study of obligotide, which indicated that oligotide may slow heparanase from damaging the glomerulus, and thus slow or stop diabetic nephropathy. We may pursue clinical trials of this indication at some point in the future.

Current Products

Our current products are all active pharmaceutical products ingredients used to make other drugs. The principal market for these products is Italy. In 2006, 7.5% of our product sales were in South Korea and in 2007, 13.4% of our product sales were in South Korea. Our revenues from the sales of our current products were €6.5 million, €3.1 million, €3.4 million, €4.1 million and €5.1 million in 2003, 2004, 2005, 2006 and 2007, respectively.

Defibrotide

Currently, we manufacture defibrotide to treat and prevent vascular disease with risk of thrombosis in Italy. We hire Sirton to process the drug into ampoule and capsule formulations and then we sell the finished ampoules to hospitals and the finished capsules to the retail market in Italy through a distribution agreement with Crinos.

Urokinase

Urokinase is made from human urine and has the potential to dissolve fibrin clots and, as such, is used to treat various vascular disorders such as deep vein thrombosis and pulmonary embolisms. We sell urokinase to Sirton, who uses it as an ingredient in the manufacture of generic drugs.

Calcium Heparin and Sodium Heparin

Calcium heparin and sodium heparin are made from pig intestines and prevents the blood from clotting. Decreasing clot formation diminishes the likelihood of strokes and heart attacks. Calcium heparin and sodium heparin have numerous uses, including the treatment of certain types of lung, blood vessel, and heart disorders, and administration during or after certain types of surgery, such as open heart and bypass surgeries. Other uses include the flushing of catheters and other medical equipment. Calcium heparin and sodium heparin are also part of many topical preparations to treat various inflammatory disorders. We sell calcium heparin and sodium heparin to Sirton, who uses them as an ingredient in the manufacture of generic drugs. Sirton sells the final formulated generic drugs to other companies, which then sell the drugs to hospitals and pharmacies.

Sulglicotide

Sulglicotide is developed from swine duodenum and appears to have ulcer healing and gastrointestinal protective properties. We sell sulglicotide to Samil, a South Korean company, for use in manufacturing a product of Samil's in South Korea. We also sell sulglicotide to Sirton for use in contract manufacturing of Gliptide, a drug marketed in Italy to treat peptic ulcers. The effects of this drug have prompted us to commission a preclinical investigation by Epistem Ltd., a United Kingdom contract research organization specializing in studies of mucositis caused by anticancer or radiation therapies, into its function in potential prevention and treatment of mucous membrane damage.

Seasonality

Seasonality does not affect our business, although the timing of manufacturer orders can cause variability in sales.

Regulatory Matters

Overview

The preclinical and clinical testing, manufacture, labeling, storage, distribution, promotion, sale, import and export, reporting and record-keeping of our product candidates are subject to extensive regulation by governmental authorities in the United States, principally the FDA and corresponding state agencies, and regulatory agencies in foreign countries.

Non-compliance with applicable regulatory requirements can result in, among other things, injunctions, seizure of products, total or partial suspension of product manufacturing and marketing, failure of the government to grant approval, withdrawal of marketing approvals, civil penalty actions and criminal prosecution. Except as discussed below, we believe that we are in substantial compliance in all material respects with each of the currently applicable laws, rules and regulations mentioned in this section. During the most recent biannual inspection of our manufacturing facility by the Italian Health Authority in February 2007, the Italian Health Authority noted by way of observations certain deficiencies in regard to the operation of our facility. We have corrected all of the deficiencies. Also, a regional Italian regulatory inspector, during an April 2005 inspection of our manufacturing facility, requested that we install an exhaust vent on one of our machines. We have installed this device. In order to obtain FDA approval for the sale of any of our product candidates, the FDA must determine that this facility meets their current good manufacturing practices, or GMP, including requirements for equipment verification and validation of our manufacturing and

cleaning processes. The FDA has not yet inspected our facility, but since 2004 we spent over €10 million in upgrades to our facility in anticipation of such an inspection. We are not aware of any other situation that could be characterized as an incidence of non-compliance in the last three years.

United States Regulatory Approval

FDA regulations require us to undertake a long and rigorous process before any of our product candidates may be marketed or sold in the United States. This regulatory process typically includes the following general steps:

- our performance of satisfactory preclinical laboratory and animal studies under the FDA's good laboratory practices regulations;

- our submission to and acceptance by the FDA of an IND which must become effective before human clinical trials may begin in the United States;

- our obtaining the approval of independent Institutional Review Boards at each clinical site to protect the welfare and rights of human subjects in clinical trials;

- our successful completion of a series of adequate and well-controlled human clinical trials to establish the safety, purity, potency and effectiveness of any product candidate for its intended use;

- our submission to, and review and approval by, the FDA of a marketing application prior to any commercial sale or shipment of a product; and

- our development and demonstration of manufacturing processes which conform to FDA-mandated current good manufacturing practices.

This process requires a substantial amount of time and financial resources. In 2002, the FDA announced a reorganization that has resulted in the shift of the oversight and approval process for certain therapeutic biologic drugs and the related staff from the Center for Biologics Evaluation and Research to the Center for Drug Evaluation and Research. Our initial product candidate, defibrotide to treat severe VOD, is being regulated through the latter.

Preclinical Testing

Preclinical tests generally include laboratory evaluation of a product candidate, its chemistry, formulation, stability and toxicity, as well as certain animal studies to assess its potential safety and effectiveness. We must submit the results of these preclinical tests, together with manufacturing information, analytical data and the clinical trial protocol, to the FDA as part of an Investigational New Drug Application, which must become effective before we may begin any human clinical trials. An application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within this 30-day time period, raises concerns or questions about the intended conduct of the trials and imposes what is referred to as a clinical hold. If one or more of our products is placed on clinical hold, we would be required to resolve any outstanding issues to the satisfaction of the FDA before we could begin clinical trials. Preclinical studies generally take several years to complete, and there is no guarantee that an Investigational New Drug Application based on those studies will become effective, allowing clinical testing to begin.

Clinical Trials

In addition to FDA review of an application, each clinical institution that desires to participate in a proposed clinical trial must have the clinical protocol reviewed and approved by an independent Institutional Review Board. The independent Institutional Review Boards consider, among other things, ethical factors, informed consent and the selection and safety of human subjects. Clinical trials must also be conducted in accordance with the FDA's good clinical practices requirements. Prior to commencement of each clinical trial, the sponsor must submit to the FDA a clinical plan, or protocol, accompanied by the approval of the committee responsible for overseeing clinical trials at one of the clinical trial sites. The FDA, and/or the Institutional Review Board at each institution at which a clinical trial is being performed, may order the temporary or permanent discontinuation of a clinical trial at any time if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients.

Human clinical trials are typically conducted in three sequential phases that may overlap, including the following:

Phase I

In Phase I clinical trials, a product candidate is typically given to either healthy people or patients with the medical condition for which the new drug is intended to be used. The main purpose of the trial is to assess a product candidate's safety and the ability of the human body to tolerate the product candidate, and may also assess the dosage, absorption, distribution, excretion and metabolism of the product candidate.

Phase II

During Phase II, a product candidate is given to a limited number of patients with the disease or medical condition for which it is intended to be used in order to:

- further identify any possible adverse side effects and safety risks;
- assess the preliminary or potential effectiveness of the product candidate for the specific targeted disease or medical condition; and
- assess dosage tolerance and determine the optimal dose for a Phase III trial.

Phase III

If and when one or more Phase II trials demonstrate that a specific dose or range of doses of a product candidate is likely to be effective and has an acceptable safety profile, one or more Phase III trials are generally undertaken to demonstrate clinical effectiveness and to further test for safety in an expanded patient population with the goal of evaluating the product's efficacy and its overall risk-benefit relationship of the product candidate. The successful demonstration of clinical effectiveness and safety in one or more Phase III trials is typically a prerequisite to the filing of an application for FDA approval of a product candidate.

After approval, the FDA may also require a Phase IV clinical trial to continue to monitor the safety and effectiveness of the product candidate.

The sponsor must submit to the FDA the results of the pre-clinical and clinical trials, together with, among other things, detailed information on the manufacturing and composition of the product, in the form of New Drug Application or a Biologics License Application. Once the submission has been accepted for filing, the FDA has 180 days to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification.

Post-Approval Regulations

If a product candidate receives regulatory approval, the approval is typically limited to specific clinical uses. Subsequent discovery of previously unknown problems with a product may result in restrictions on its use or even complete withdrawal of the product from the market. Any FDA-approved products manufactured or distributed by us are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse events or experiences. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies, and are subject to periodic inspections by the FDA and state agencies for compliance with current good manufacturing practices, or GMPs, which impose rigorous procedural and documentation requirements upon us and our contract manufacturers. Failure to comply with these requirements may result in, among other things, total or partial suspension of production activities, failure of the FDA to grant approval for marketing, and withdrawal, suspension, or revocation of marketing approvals.

If the FDA approves one or more of our product candidates, we and our contract manufacturers must provide certain updated safety and effectiveness information. Product changes, as well as changes in the manufacturing process or facilities where the manufacturing occurs or other post-approval changes, may necessitate additional FDA review and approval. The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA requirements which include, among others, standards and regulations for direct-to-consumer advertising, communication of information relating to off-label uses, industry sponsored scientific and educational activities and promotional activities involving the Internet. The FDA has very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing a company to correct deviations from regulatory standards and enforcement actions that can include seizures, fines, injunctions and criminal prosecution.

Fast track and orphan drug designation

The FDA has a “fast track” program that provides the potential for expedited review of an application. However, there is no assurance that the FDA will, in fact, accelerate the review process for a fast track product candidate. Fast track status is provided only for new and novel therapies that are intended to treat persons with life-threatening and severely debilitating diseases, where there is a defined unmet medical need, especially where no satisfactory alternative therapy exists or the new therapy is significantly superior to alternative therapies. During the development of product candidates that qualify for this status, the FDA may expedite consultations and reviews of these experimental therapies. Furthermore, an accelerated approval process is potentially available to product candidates that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses. The FDA can base approval of a marketing application for a fast track product on an effect on a clinical endpoint, or on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may condition the approval of an application for certain fast track products on additional post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Fast track status also provides the potential for a product candidate to have a “priority review.” A priority review allows for portions of the application to be submitted to the FDA for review prior to the completion of the entire application, which could result in a reduction in the length of time it would otherwise take the FDA to complete its review of the application. Fast track status may be revoked by the FDA at any time if the clinical results

of a trial fail to continue to support the assertion that the respective product candidate has the potential to address an unmet medical need. A product approved under a “fast track” designation is subject to expedited withdrawal procedures and to enhanced scrutiny by the FDA of promotional materials.

The FDA may grant orphan drug status to drugs intended to treat a “rare disease or condition,” which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. If and when the FDA grants orphan drug status, the generic name and trade name of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Aside from guidance concerning the non-clinical laboratory studies and clinical investigations necessary for approval of the application, orphan drug status does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The FDA may grant orphan drug designations to multiple competing product candidates targeting the same uses. A product that has been designated as an orphan drug that subsequently receives the first FDA approval for the designated orphan use is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years from the date of FDA approval. Orphan drug status may also provide certain tax benefits. Finally, the FDA may fund the development of orphan drugs through its grants program for clinical studies.

The FDA has designated defibrotide as an orphan drug both to treat VOD and to prevent VOD and has provided funding for clinical studies for defibrotide to treat VOD. The FDA has approved the Company's application for "fast track" designation for defibrotide to treat severe VOD 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. If our other product candidates meet the criteria, we may also apply for orphan drug status and fast track status for such products.

Market Exclusivity

In addition to orphan drug exclusivity, a product regulated by the FDA as a "new drug" is potentially entitled to non-patent and/or patent exclusivity under the Federal Food, Drug and Cosmetic Act, or FFDCA, against a third party obtaining an abbreviated approval of a generic product during the exclusivity period. An abbreviated approval allows an applicant to obtain FDA approval without generating, or obtaining a right of reference to, the basic safety and effectiveness data necessary to support the initial approval of the drug product or active ingredient. In the case of a new chemical entity (an active ingredient which has not been previously approved with respect to any drug product) non-patent exclusivity precludes an applicant for abbreviated approval from submitting an abbreviated application until five years after the approval of the new chemical entity. In the case of any drug substance (active ingredient), drug product (formulation and composition) and method of use patents listed with the FDA, patent exclusivity under the FFDCA precludes FDA from granting effective approval of an abbreviated application of a generic product until the relevant patent(s) expire, unless the abbreviated applicant certifies that the relevant listed patents are invalid, not infringed or unenforceable and the NDA/patent holder does not bring an infringement action within 45 days of receipt of notification of the certification or an infringement action is brought within 45 days and a court determines that the relevant patent(s) are invalid, not infringed or unenforceable or 30 months have elapsed without a court decision of infringement.

User Fees

A New Drug Application for a prescription drug product that has been designated as an orphan drug is not subject to the payment of user fees to the FDA unless the application includes an indication other than the orphan indication.

A supplement proposing to include a new indication for a designated orphan disease or condition in an application is also not subject to a user fee, if the drug has been designated an orphan drug with regard to the indication proposed in such supplement.

There is no specific exemption for orphan drug products from annual product and establishment fees. However, sponsors of orphan drugs can request a waiver of such fees on hardship or other grounds.

HIPAA

Other federal legislation may affect our ability to obtain certain health information in conjunction with our research activities. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, mandates, among other things, the adoption of standards designed to safeguard the privacy and security of individually identifiable health information. In relevant part, the U.S. Department of Health and Human Services, or HHS, has released two rules to date mandating the use of new standards with respect to such health information. The first rule imposes new standards relating to the privacy of individually identifiable health information. These standards restrict the manner and circumstances under which covered entities may use and disclose protected health information so as to protect the privacy of that information. The second rule released by HHS establishes minimum standards for the security of electronic health information. While we do not believe we are directly regulated as a covered entity under HIPAA, the HIPAA standards impose requirements on covered entities conducting research activities regarding the use and

disclosure of individually identifiable health information collected in the course of conducting the research. As a result, unless they meet these HIPAA requirements, covered entities conducting clinical trials for us may not be able to share with us any results from clinical trials that include such health information.

Foreign Regulatory Approval

Outside of the United States, our ability to market our product candidates will also be contingent upon our receiving marketing authorizations from the appropriate foreign regulatory authorities whether or not FDA approval has been obtained. The foreign regulatory approval process in most industrialized countries generally includes risks that are similar with the FDA approval process we have described herein. The requirements governing conduct of clinical trials and marketing authorizations, and the time required to obtain requisite approvals may vary widely from country to country and differ from that required for FDA approval.

European Union Regulatory Approval

Under the current European Union regulatory system, applications for marketing authorizations may be submitted either under a centralized or decentralized procedure. The centralized procedure (which is compulsory for certain categories of drugs) provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization that is obtained in accordance with the procedure and requirements applicable in the member state concerned may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. The mutual recognition process results in separate national marketing authorizations in the reference member state and each concerned member state.

The centralized procedure

An applicant under the centralized procedure must be a person who is domiciled in the European Union or an entity established in the European Union. The applicant must file a preliminary request containing the information regarding the product candidate, including its description and the location of the production plant, as well as the payment of the application fees. The European Agency for the Evaluation of Medicinal Products (an European Union statutory entity) formally evaluates the preliminary request and indicates either an initial approval to review a full application or a rejection. If the European Agency indicates an initial approval to review a full application, the applicant must submit the application to the European Agency. This application must indicate certain specific information regarding the product candidate, including the composition (quality and quantity) of all the substances contained in the product, therapeutic indications and adverse events, modalities of use, the results of physical, chemical, biological and microbiological tests, pharmacological and toxicity tests, clinical tests, a description of production and related control procedures, a summary of the characteristics of the product as required by the European legislation and samples of labels and information to consumers. The applicant must also file copies of marketing authorizations obtained, applications filed and denials received for the same product in other countries, and must prove that the manufacturer of the product candidate is duly authorized to produce it in its country.

The European Agency (through its internal Committee for Proprietary Medicinal Products) examines the documents and information filed and may carry out technical tests regarding the product, request information from the member state concerned with regard to the manufacturer of the product candidate and, when it deems necessary, inspect the manufacturing facility in order to verify that the manufacturing facility is consistent with the specifications of the product candidate, as indicated in the application.

The Committee generates and submits its final opinion to the European Commission, the member states and the applicant. The Commission then issues its decision, which is binding on all member states. However, if the Commission approves the application, member states still have authority to determine the pricing of the product in their territories before it can be actually marketed.

The European Agency may reject the application if the Agency decides that the quality, safety and effectiveness of the product candidate have not been adequately and sufficiently proved by the applicant, or if the information and documents filed are incomplete, or where the labeling and packaging information proposed by the applicant do not comply with the relevant European rules.

The European Agency has also established an accelerated evaluation procedure applying to product candidates aimed at serious diseases or conditions for which no suitable therapy exists, if it is possible to predict a substantial beneficial effect for patients.

The marketing authorization is valid for five years and may be renewed, upon application, for further five year terms. After the issue of the authorization the holder must constantly take into consideration scientific and technical progress so that the product is manufactured and controlled in accordance with scientific methods generally accepted.

We plan to apply for approvals for our product candidates under the centralized procedure. We believe that the centralized procedure will result in a quicker approval of our product candidates than the decentralized procedure due to the fact that we intend to market our product candidates in many European Union member states, rather than just one.

The decentralized procedure

The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization—obtained in accordance with the procedure and requirements applicable in

the member state concerned (see the description below for Italy)—may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. The mutual recognition process results in separate national marketing authorizations in the reference member state and each concerned member state.

An application under the decentralized procedure begins with the applicant obtaining a national marketing authorization. An example of the process for obtaining a national marketing authorization in Italy is set forth below. The applicant then submits an application for authorization in other member states and the European Agency. If any of the member states refuses to recognize the authorization by the original member state, the matter is deferred to arbitration proceedings, unless the applicant withdraws its request in the member state refusing recognition. The characteristics of the product in the new applications must be identical to those approved in the original member state.

Italian Regulatory Approval

An application for marketing authorization in Italy must be filed with the competent office of the Italian Agency for the Evaluation of Medical Products ("AIFA") and must contain certain specific information, including the composition (quality and quantity) of all the substances contained in the product, therapeutic indications and adverse events, modalities of use, the results of physical, chemical, biological and microbiological tests, pharmacological and toxicity tests, clinical tests, a description of production and related control procedures and samples of labels and information to consumers. Italian legislation (in accordance with European laws) regulates in great detail the information to be indicated on the packaging. Marketing authorization includes a 10-year protection period during which no one else may use the results of the clinical trials included in the application to apply for a substantially similar drug. This period may be extended where there are new therapeutic indications for the same product, which require new complete clinical studies and justify the same protection as that granted to a new drug.

The AIFA may grant or deny the national authorization after a review of the contents of the application, both from a formal and substantial viewpoint. If an authorization is granted, it is valid for an initial period of five years and, upon application, may be renewed for subsequent five year terms. In particular, the AIFA examines the quality, effectiveness and safety of the product. The AIFA may also order further tests prior to granting or denying the authorization regarding the suitability of the production and control methods described in the application. The AIFA may reject the authorization if the ordinary use of the drug has adverse events, the quality and quantity of the ingredients of the drugs do not correspond to the data indicated in the application, there is a lack, either total or partial, of beneficial therapeutic effects or the information and the documents included in the application do not comply with the requirements provided by law. After the AIFA grants a national authorization, the AIFA may temporarily suspend or revoke the authorization if the information disclosed in the relevant application turns out to be incorrect, the drug no longer meets the necessary quality, effectiveness or safety requirements, or adequate production controls have not been carried out.

Clinical Trials

Italy has implemented European legislation regarding good practices in drug clinical trials. As a result, clinical trials are now governed in great detail and failure to comply with these rules means that the results of the trials will not be taken into consideration in evaluating an application for a marketing authorization.

Prior to starting any clinical trial, the organizing and/or financing entity must obtain the approval of the competent health authorities (which vary depending on the type of drug concerned) and obtain the favorable opinion of the Ethical Committee, an independent body. Good practice rules include the following principles:

- the predictable risks and inconveniences shall not outweigh the beneficial effects for the person subject to the trials and for the other current and future patients;

- the person participating in the trials must have been duly informed of all the relevant circumstances and in particular of the right to interrupt the experimentation at any time without any prejudicial consequence, and must have given consent after having been properly informed;

- the right of the participants to their physical and mental integrity, as well as their right to privacy, shall be respected;

- the entity organizing the trial must have obtained adequate insurance coverage for any damage that may derive to the participants because of the trial;

    - the name of a person to be contacted for any information must be communicated to the participant; and

- the trial must be conducted by suitably qualified medical personnel.

The trial must be constantly monitored, in particular with regard to serious adverse events which are not envisaged in the approved clinical protocol. Whenever the safety of the participants is in danger due to unexpected serious adverse events, the AIFA must be promptly informed by the entity organizing the trials. Italian legislation provides sanctions (criminal sanctions and administrative fines) in case of violation of specific good practice rules.

Post-approval issues

There are many national legislative instruments (implementing European Union rules) governing controls on drugs in the post-authorization phase. For instance, the holder of the national marketing authorization must promptly record in detail and notify any adverse reaction to the drug of which it becomes aware, regardless of the country where the reaction occurs, also preparing periodic update reports on these adverse events. For these and other purposes, the holder of the authorization must hire and maintain in its organization a person expert in the field and responsible for all drug controlling and reporting activities.

Moreover, any form of information and advertising aimed at promoting the sale of drugs is governed by specific national legislation (also implementing European Union rules), which provides for the requirements and limitations of advertising messages in general, as well as of other particular promotional activities, such as the organization of conferences regarding certain drugs and the distribution of free samples.

The export of drugs from Italy is not subject to authorization (except for plasma and blood-related products), but the import into Italy from non-European Union countries must be authorized by the Ministry of Health, on the basis of the adequacy of the quality controls to be carried out on the imported drugs.

European orphan drug status

European legislation provides for a particular procedure for the designation of medicinal products as orphan drugs. Such designation may include incentives for the research, development and marketing of these orphan drugs and, in case of a subsequent successful application for a marketing authorization regarding the same therapeutic indications, grants a substantial period of market exclusivity.

A medicinal product - at any stage of its development but in any case prior to the filing of any application for the marketing authorization - may be designated as an orphan drug if the person/entity that has applied for the designation can establish that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than five persons out of every ten thousand persons in the European Union, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the medicinal product would generate sufficient income to cover the necessary investments. Moreover, the sponsor must prove that there is no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition.

In order to obtain the designation of a medicinal product as an orphan drug, the sponsor shall submit an application to the European Agency for the Evaluation of Medical Products, which must describe the indication of the active ingredients of the medicinal product, the proposed therapeutic indications and proof that the criteria established by the relevant European legislation are met.

The European Agency reviews the application and prepares a summary report to a special Committee for Orphan Medicinal Products, which issues an opinion within 90 days of the receipt of the application. The European Commission must adopt a decision within 30 days of the receipt of the committee's opinion. If the European Commission approves the application, the designated medicinal product is entered in the European Register of Orphan Medicinal Products and the product is eligible for incentives made available by the European Union and by member states to support research into, and development and availability of, orphan drugs.

After the registration, the sponsor must submit to the European Agency an annual report on the state of development of the designated orphan drug. A designated orphan drug may be removed from the Register of Orphan Medicinal Products in three cases:

- at the request of the sponsor;
- if it is established, before the market authorization is granted, that the requirements provided for in the European orphan drug legislation are no longer met; or
- at the end of the period of market exclusivity (as explained below).

Orphan drug market exclusivity means that the European Union shall not, for a period of 10 years from the grant of the marketing authorization for an orphan drug, accept any other application for a marketing authorization, grant a marketing authorization or accept an application to extend an existing marketing authorization, for the same product. This period, however, may be reduced to six years if at the end of the fifth year it is established that the criteria laid down in the legislation are no longer met by the orphan drug, or where the available evidence shows that the orphan drug is sufficiently profitable, so that market exclusivity is no longer justified.

However, as an exception to orphan drug market exclusivity, a marketing authorization may be granted for the same therapeutic indications to a similar medicinal product if:

- the holder of the marketing authorization for the orphan drug has given his consent to the second applicant;
- the holder of the marketing authorization for the orphan drug is unable to supply sufficient quantities of the latter; or
- the second applicant can establish in its application that the second medicinal product, although similar to the authorized orphan drug, is safer, more effective or otherwise clinically superior.

Raw Materials

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

The contract term of the swine intestinal mucosa supply agreement expires on December 31, 2010, with automatically renewable three year periods, unless either party notifies the other party in writing six months prior to the annual date of termination. We must give written purchase orders to La.bu.nat at least two months in advance of the date of delivery.

The contract term of the swine duodenum supply agreement expires on December 31, 2010, with automatically renewable three year periods, unless either party notifies the other party in writing six months prior to the annual date of termination. We must give written purchase orders to La.bu.nat at least four months in advance of the date of delivery.

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

Our other product, urokinase, is derived from human urine, which is subject to similar regulatory review. While we currently purchase the urine from only one supplier of urine and do not have a fixed supply agreement with that supplier, we believe there are suitable alternative sources of the material.

Historically, there has been no significant price volatility for any of our raw materials. It is possible that widespread illness or destruction of pigs could result in volatility of the price of pig intestines.

Competition

Our industry is highly competitive and characterized by rapid technological change. Significant competitive factors in our industry include:

- controlling the manufacturing costs;
- the effectiveness and safety of products;
- the timing and scope of regulatory approvals;
- the willingness of private insurance companies and government sponsored health care programs to reimburse patients or otherwise pay for the drugs and the related treatments;
- the availability of alternative treatments for the disorders as well as the availability of alternatives to the treatments which cause or contribute to these disorders (such as chemotherapy, radiation therapy, stem cell transplants, etc.);
- the ability to perform clinical trials, independently or with others;

- intellectual property and patent rights and their protection; and
- sales and marketing capabilities.

We face competition in both the development and marketing of our product candidates. During development alternative treatments for similar or completely different disorders may limit our ability to get participants or co-sponsors for clinical trials with our product candidates. Any product candidates that we successfully develop that are approved for sale by the FDA or similar regulatory authorities in other countries may compete with products currently being used or that may become available in the future. Many organizations, including large pharmaceutical and biopharmaceutical companies, as well as academic and research organizations and government agencies, may be interested in pursuing the research and development of drug therapies that target the blood vessel wall. Many of these organizations have substantially greater capital resources than we have, and greater capabilities and resources for basic research, conducting preclinical studies and clinical trials, regulatory affairs, manufacturing, marketing and sales. As a result, our competitors may develop or license products or other novel technologies that are more effective, safer or less costly than our existing products or products that are being developed by us, or may obtain regulatory approval for products before we do. Clinical development by others may render our products or product candidates noncompetitive.

While we are unaware of any other products or product candidates that treat or prevent VOD or the apoptosis that our product candidate oligotide is designed to treat, we believe that other companies have products or are currently developing products to treat some of the same disorders and diseases that our other product candidates are designed to treat.

Our statements above are based on our general knowledge of and familiarity with our competitors.

Legal Proceedings

Currently, we are not a party to or engaged in any material legal proceedings.

ORGANIZATIONAL STRUCTURE

We were part of a group of pharmaceutical businesses founded in Italy in 1944 that has been involved in the research and development of drugs derived from DNA and DNA molecules since the 1970's. In 1993, FinSirton formed our company as Pharma Research S.r.L., an Italian private limited company, to pursue research and development activities of prospective pharmaceutical specialty products. FinSirton is our largest shareholder, and is controlled by Dr. Laura Ferro, who is our Chief Executive Officer and President and one of our directors, together with her family. In December 2000, we changed from a private limited company to a corporation and in July 2001 we changed our name to Gentium S.p.A. Under our current bylaws, the duration of our company will expire on December 31, 2050. We have no subsidiaries.

PROPERTY, PLANT AND EQUIPMENT

Manufacturing and Facilities

We own a manufacturing facility near Como, Italy which, at December 31, 2007, is subject to a mortgage securing repayment of an aggregate of €2.6 million of debt owed to Banca Nazionale del Lavoro. The manufacturing facility is 2,350 square meters in size. In order to obtain FDA approval for the sale of any of our product candidates, the FDA must determine that this facility meets their current good manufacturing practices, or GMP, including requirements for equipment verification and validation of our manufacturing and cleaning processes. The FDA has not yet inspected our facility, but since 2004 we have spent more than €10 million for upgrades to our facility in anticipation of such an inspection.

We raised the money to fund these improvements from our sale of our Series A notes and our initial public offering, and we may also use some of the net proceeds of our initial public offering and our October 2005 private placement, June 2006 private placement and February 2007 private placement to pay for future improvements.

We produce defibrotide, sulglicotide, calcium heparin and sodium heparin at this facility. Defibrotide, calcium heparin and sodium heparin are produced simultaneously. In 2006, we replaced a principal reactor in the defibrotide production line and separated the defibrotide production line from the sulglicotide line by installing an additional reactor. These improvements allow us to produce both defibrotide and sulglicotide simultaneously and to double our potential capacity to manufacture defibrotide and sulglicotide.

We typically operate our manufacturing facility on two eight hour shifts per day. Our estimated current production, our production capacity and percentage of utilization for defibrotide and calcium heparin for the fiscal year 2008 are set forth below:

Product	Estimated Current	Maximum Production	Percentage of Utilization

	Production Levels (kilograms/year)	Capacity With Two Eight Hour Shifts (kilograms/year)	
Defibrotide	4,200	4,400	95%

Product	Estimated Current Production Levels (millions of units/year)	Maximum Production Capacity With Two Eight Hour Shifts (millions of units/year)	Percentage of Utilization
calcium heparin and sodium heparin	49,000	49,000	100%

We currently manufacture defibrotide to treat and prevent vascular disease with risk of thrombosis in Italy. Compared to the dosage necessary to treat and prevent VOD and to treat multiple myeloma, the treatment for this current use is significantly longer and therefore the overall amount of defibrotide is much larger than would be used to treat or prevent VOD or to treat multiple myeloma. Accordingly, if we obtain FDA or European regulatory approvals for those new uses, a smaller portion of our maximum capacity would be required for the manufacture of defibrotide for those additional uses.

Our estimated current production, production capacity and percentage of utilization for sulglicotide for the fiscal year 2008 are set forth below:

Product	Estimated Current Production Level (kilograms/year)	Maximum Production Capacity With Two Eight Hour Shifts (kilograms/year)	Percentage of Utilization
Sulglicotide	4,700	4,700	100%

Our estimated current production, production capacity and percentage of utilization for urokinase for the fiscal year 2008 are set forth below:

Product	Estimated Current Production Level (millions of units/year)	Maximum Production Capacity With One Eight Hour Shift (millions of units/year)	Percentage of Utilization
Urokinase	27.3	37	74%

Our facility is subject to customary regulation by regional agencies regarding worker health and safety, fire department, water, air, noise and environmental pollution and protection by Azienda Sanitaria Locale and Agenzia Regionale Prevenzione e Ambiente. We have engaged Lariana Depur, a consortium that specializes in the treatment of waste water, to treat our waste water. We monitor our waste water to control the levels of nitrogen, chlorides and chemical oxygen before delivering the waste water to Lariana Depur for additional treatment. We do not expect any difficulties in complying with these regulations. Also, we installed two scrubbers to reduce the odors and chemicals released into the air by the facility to comply with Italian regulations.

In 2007 we continued with the work of implementation and subsequent approval of environmental management system as per International Standard ISO 14001 and the EMAS European regulation for manufacturing plants and laboratories. The environmental management system was certified under the UNI EN ISO 14001 Standard on April 20, 2007 and the EMAS certification was obtained on July 26, 2007. We defined our environmental policy to be in compliance with current regulations on environmental protection, to provide for continuous improvement of our manufacturing performance, to protect our employees' health, to protect the safety of people working at our location and to respect the safety of people living close to our plant and the surrounding community.

We lease 2,350 square meters of office and laboratory space from FinSirton. We also lease 100 square meters of laboratory and manufacturing space for urokinase from Sirton.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. 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 annual report. This discussion may contain predictions, estimates and other forward-looking statements that involve risks and uncertainties, including those discussed under "Risk Factors" and elsewhere in this annual report. These risks could cause our actual results to differ materially from any future performance suggested below.

OPERATING RESULTS

Overview

We manufacture defibrotide as an active pharmaceutical ingredient at our facility. In the third quarter of 2007, we engaged our affiliate, Sirton, to process the defibrotide into ampoule and capsule form and then we sell the finished product 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 a distribution agreement with us. We also manufacture and sell urokinase, calcium heparin, sodium heparin and sulglicotide, which are additional active pharmaceutical ingredients used to make other drugs.

For each of the five years ended December 31, 2007, the sale of defibrotide, urokinase, calcium heparin, sodium heparin and sulglicotide to Sirton amounted to approximately 100%, 92%, 97%, 92% and 53%, respectively, of our total product sales. The price of defibrotide to Sirton was based on comparable sale prices in years prior to 2002 to unrelated third parties. The price for urokinase, calcium heparin, sodium heparin and sulglicotide is based on comparable market prices charged by other manufacturers.

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

	For The Years Ended December 31,		
(in thousands)	**2005**	**2006**	**2007**
Product sales:			
Defibrotide	€ 2,476	€ 2,316	€ 2,756
Urokinase	684	1,271	1,461
Sulglicotide	53	375	764
Other	148	113	113
Total product sales	3,361	4,075	5,094
Other revenue	280	249	2,515
Total revenue	€ 3,641	€ 4,324	€ 7,609

Of our product sales in the periods shown in the table above, all were sales in Italy except for 7.5% during the year ended December 31, 2006 and 13.4% during the year ended December 31, 2007 which were sales of sulglicotide in South Korea. Substantially all of our other revenue was for reimbursement of research and development expenses under a collaborative arrangement for the development and sale of our product candidates in the United States and Canada.

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

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

As of December 31, 2007, substantially all of our cash and cash equivalents were held in accounts at financial institutions located in the Republic of Italy and the United States, that we believe are of acceptable credit quality. We invest our cash in liquid instruments that meet high credit quality standards and generally have maturity at the date of purchase of less than three months. We are exposed to exchange rate risk with respect to certain of our cash balances that are denominated in U.S. dollars. As of December 31, 2007, we held a cash balance of $34.6 million that was denominated in U.S. dollars. This dollar-based cash balance is available to be used for future purchases and other liquidity requirements that may be denominated in such currency. We are exposed to unfavorable and potentially volatile fluctuations of the U.S. dollar against the Euro (our functional currency).

Any increase (decrease) in the value of the U.S. dollar against the Euro will result in unrealized foreign currency translation losses (gains) with respect to the Euro. The value of the Euro against the U.S. 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 effect our cash flows, revenues and financial condition. To the extent we hold assets denominated in U.S. dollars, any appreciation of the Euro against the U.S. dollar could result in a non-cash charge to our operating results and a reduction in the value of our U.S. dollar denominated assets upon remeasurement.

In addition, we are exposed to foreign currency risks to the extent that we enter into transactions denominated in currencies other than our functional currency, such as investments, programming costs and accounts payable. 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 rates primarily as a result of our borrowings. Our primary exposure to variable rate debt is through the EURIBOR and we have entered into interest rate cap agreement to manage exposure to movements in interest rates. Interest rate cap agreements lock in a maximum interest rate should variable rates rise, but enable us to benefit from lower interest rates.

Critical Accounting Policies and Estimates

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

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

Revenue Recognition

Our primary source of revenue 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.

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

Inventories

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

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

Impairment of Long-lived Assets

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

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

Valuation of Acquired Intangible Assets

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

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

Research and Development Expenses

We have several activities, and their related costs, that are included in research and development expenses. These activities include primarily salaries and benefits of our direct employees, employee stock based compensation expense, facility costs, overhead costs, clinical trial costs and related trial product manufacturing costs, contracted services and subcontractor costs. Clinical trial costs include costs associated with contract research organizations. The billings that we receive from contract research organizations for services rendered may not be received for several months following the service. We accrue the estimated costs of the contract research organizations related services based on our estimate of management fees, site management and monitoring costs and data management costs. Our research and development department is in continuous communication with our contract research organizations to assess both their progress on the underlying study and the reasonableness of their cost estimates. Differences between estimated trial costs and actual have not been material to date, and any changes have been made when they become known. Under this policy, research and development expense can vary due to accrual adjustments related to the underlying clinical trials and the expenses incurred by the contract research organizations. As of December 31, 2007, we had €3.934 million of future payables under outstanding contracts with various contract research organizations that are not revocable. Most of these contracts are on a cost plus or actual cost basis.

Share-Based Compensation

Under the provisions of Statement of Financial Accounting Standards (FAS) No. 123(R), "*Share-Based Payment*" (FAS 123R), employee share-based compensation is estimated at the date of grant based on the employee stock award's fair value using the Black-Scholes option-pricing model and is recognized as expense ratably over the requisite service period, which is generally the vesting period, in a manner similar to other forms of compensation paid to employees. The Black-Scholes option-pricing model requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock, the expected term of the award and the expected forfeiture rate. When establishing an estimate of the expected term of an award, we consider the vesting period of the award, our recent historical experience of employee stock option exercise, the expected volatility and a comparison to relevant peer group data.

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

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

An increase to the:	**Results in a fair value estimate that is:**

Price of the underlying share	Higher
Exercise price of option	Lower
Expected volatility of stock	Higher
Risk-free interest rate	Higher
Expected term of option	Higher

In our current valuation, we consider the volatility factor to be important factor in determining the fair value of the otions granted. We have used a 60% factor based on what we believe is a representative sample of similar biopharmaceutical companies. However, this sample is not perfect as it omits, for example, Italian companies, due to the fact that there are a limited number of companies such as ourselves publicly traded in the U.S. market. Significant changes to these estimates could have a material impact on the results of our operations.

Recent Accounting Pronouncements

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

In June 2007, the FASB ratified EITF Issue No. 07-3, "*Accounting for Nonrefundable Advance Payments of Goods or Services Received for Use in Future Research and Development Activities*" (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods and services that will be used or rendered in future research and development activities pursuant to executory contractual arrangements be deferred and recognized as an expense in the period that the related goods are delivered or services are performed. EITF 07-3 is effective for us beginning on January 1, 2008. We do not expect this pronoucement to have a material effect on our financial statements.

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

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities-Including an Amendment of FASB Statement No. 115* ("SFAS No. 159"). SFAS No. 159 permits entities to chose to measure many financial instruments and certain other items at fair value. The objective of SFAS No. 159 is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. SFAS No. 159 is effective for us beginning January 1, 2008. We do not believe that SFAS No. 159 will have a material impact on our financial statements.

Effective January 1, 2007, we adopted FASB Interpretation No. 48 (FIN 48), "*Accounting for Uncertainty in Income Taxes*". FIN 48 prescribes a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We had no material unrecognized tax benefits before or after the adoption of FIN 48.

Results of Operations

The following tables set forth our results of operations:

	For The Years Ended December 31,		
	2005	**2006**	**2007**
Amounts in thousands except share and per share data			
Revenues:			
Product sales to related party	€ 3,260	€ 3,754	€ 2,704
Product sales to third parties	101	321	2,390
Total product sales	3,361	4,075	5,094
Other revenues	280	249	2,515
Total Revenues	3,641	4,324	7,609
Operating costs and expenses:			
Cost of goods sold	2,911	3,092	3,983
Research and development	4,557	8,927	15,098
General and administrative	2,284	5,421	6,279
Depreciation and amortization	118	261	725
Charges from related parties	1,047	854	748
Write-down of acquired assets	-	-	13,740
Total operating costs and expenses:	10,917	18,555	40,573
Operating loss	(7,276)	(14,231)	(32,964)
Foreign currency exchange loss, net	(249)	(627)	(4,001)
Interest income (expense), net	(4,148)	490	1,357
Loss before income tax expense	(11,673)	(14,368)	(35,608)
Income tax expense	646	-	-
Net loss	€ (12,319)	€ (14,368)	€ (35,608)
Net loss per share:			
Basic and diluted net loss per share	(1.78)	(1.33)	(2.52)
Weighted average shares used to compute basic and diluted net loss per share	6,933,104	10,808,890	14,105,128

Year Ended December 31, 2007 Compared to Year Ended December 31, 2006

Product sales.

Our product sales were €5.09 million for 2007 compared to €4.08 million in 2006, an increase of €1.01 million or 25%. The increase was mainly due to increased demand for our products from our customers. Sales to a related party in 2007 and 2006 represented 53% and 92% of the total product sales, respectively and decreased 29% to €2.70 million. The decrease in sales to a related party is mainly due to the fact that in July 2007, in connection with our acquisition of the Italian marketing authorizations and trademarks regarding pharmaceutical products known in the Italian market as Prociclide and Noravid from Crinos S.p.A., we started selling defibrotide as finished product to Crinos as our distributor, rather than to our related party, Sirton Pharmaceuticals S.p.A. Sales to third parties increased to €2.39

million due to this change and also due to higher sales volume of sulglicotide. Sulglicotide is used by a South Korean manufacturer to produce a finished product. We expect future growth in sulglicotide revenue due to higher penetration and positioning of the finished product in the South Korean market.

Other income and revenues

Our revenues were €2.515 million for 2007 compared to €249 thousand in 2006. Other revenue are primarily due to reimbursement of research and development expenses and upfront payments recognized ratably over the expected life of the research period under our license agreement with Sigma-Tau. Other income and revenues also includes royalties recognized under license agreements with Crinos S.p.A., which expired in December 2006, and gains on fixed asset disposals.

Cost of goods sold.

Our cost of goods sold was €3.98 million for 2007 compared to €3.09 million in 2006. Cost of goods sold as percent of product sales was 78.2% in 2007 compared to 75.9% in 2006.

Research and development expenses.

We incurred research and development expenses of €15.1 million for 2007 compared to €8.93 million in 2006. The expenses were primarily for the development of defibrotide to treat and prevent VOD and increased headcount. The difference between the periods is primarily due to increased costs for our clinical trials, and in particular clinical research organizations charges, regulatory activities and other costs associated with the screening and enrollment of patients for our Phase III clinical trial of defibrotide to treat VOD. Also contributing to the increase was stock based compensation of €444 thousand in 2007 compared to €288 thousand in 2006.

Write-down of assets acquired from Crinos

In 2007, we recorded an impairment charge of €13.74 million regarding the Italian marketing authorizations and related trademarks for defibrotide that we acquired from Crinos S.p.A. The charge reflects the total consideration paid (€16 million) in excess of the present value of the cash flow we expect to receive from these assets over the next five years.

General and administrative expenses.

Our general and administrative expenses were €6.28 million in 2007 compared to €5.42 million in 2006. The increase in 2007 was primarily due to increased headcount and facilities related expenses, cost incurred on Sarbanes-Oxley internal control implementation, general corporate expenses, legal and other professionals fees and stock based compensation expense of €1.36 million in 2007 compared to €619 thousand in 2006.

Depreciation and amortization expense.

Depreciation and amortization expense was €725 thousand in 2007 compared to €261 thousand in 2006. The increase is primarily attributable to €266 thousand of amortization of our Italian marketing authorizations and trademarks acquired in 2007.. Depreciation expense excludes depreciation of our manufacturing facilities which are included in cost of goods sold.

Foreign currency exchange gain (loss)

Our foreign currency exchange losses are primarily due to converting or translating U.S. dollar cash balances to Euros.

Interest income, net.

Interest income (expense), net amounted to €1.36 million and €490 thousand in 2007 and 2006, respectively. Gross interest income amounted to €1.67 million and €708 thousand in 2007 and 2006, respectively, an increase of €966 thousand. The increase is a result of higher amount of invested funds in the 2007 period. Interest expense totaled €316 thousand and €218 thousand in 2007 and 2006, respectively, an increase of €100 thousand attributable to an increase in long term debt.

Net loss.

Our net loss was €35.6 million in 2007 compared to €14.4 million in 2006. The difference was primarily due to the write-down of the Italian marketing authorizations and related trademarks for defibrotide that we acquired from

Crinos S.p.A. in the amount of €13.74 million and to increases in research and development expenses and foreign exchange loss in 2007, partially offset by an increase in interest income, net.

Year Ended December 31, 2006 Compared to Year Ended December 31, 2005

Product sales.

Our sales were €4.08 million for 2006 compared to €3.36 million in 2005, or an increase of 21.2%. Sales to affiliates represented 92% of the total product sales and increased 15% to €3.75 million. The increase in sales to affiliates was mainly due to the higher sales volume of our active pharmaceutical ingredient urokinase, which represents 31% (or €1.27 million) and 20% (or €684 million) of the total product sales in 2006 and 2005, respectively. Sales to third parties increased to €321 thousand mainly due to higher sales volume of the active pharmaceutical ingredient sulglicotide in the South Korean market. We expect future growth in sulglicotide revenue due to higher penetration and positioning of the finished product in the South Korean market.

Other income and revenues.

Our other income and revenues was €249 thousand for 2006 compared to €280 thousand in 2005. Other income is primarily due to upfront payments recognized ratably over the expected life of the research period under our license agreement with Sigma-Tau. Other income and revenues also includes royalties recognized under license agreements with Crinos S.p.A., which expired in December 2006, and gains on fixed asset disposal.

Cost of goods sold.

Our cost of goods sold was €3.09 million for 2006 compared to €2.91 million in 2005. Cost of goods sold as percent of product sales was 75.9% in 2006 and 86.6% in 2005. The decrease in costs as a percentage of sales was due to the revised estimate on manufacturing facilities and equipment useful life which resulted in lower depreciation expenses allocated to cost of goods sold. In addition, we wrote off certain inventory in 2006.

Research and development expenses.

We incurred research and development expenses of €8.93 million for 2006 compared to €4.56 million in 2005. The expenses were primarily for the development of defibrotide to treat and prevent VOD and increased headcount. The difference between the periods is primarily due to 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. Also contributing to the increase was an increase in stock based compensation of €288 thousand compared to stock based compensation of €117 thousand in 2005.

General and administrative expenses.

Our general and administrative expenses were €5.42 million in 2006 compared to €2.28 million in 2005. The increase in 2006 was primarily due to increased headcount and facilities related expenses, general corporate expenses of being a public company, legal and other professionals fees and increased administrative costs resulting from performing administrative functions internally as opposed to through affiliated administrative service agreements and stock based compensation expense of €619 thousand compared to stock based compensation of €329 thousand in 2005.

Depreciation and amortization expense.

Depreciation and amortization expense was €261 thousand in 2006 compared to €118 thousand 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 are included in cost of goods sold.

Interest income (expense), net.

Interest income (expense) on a net basis was income of €490 thousand in 2006 compared to expense of €4.148 million in 2005. The components of interest income (expense) on a net basis changed during the periods 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 private placement offering in June 2006. In 2005, interest expense on the Series A notes was €4.095 million, including non-cash interest expense of €3.837 million from amortization of the issue discount and issue cost. These notes were converted or redeemed in June 2005. Additionally, interest income increased to €708 thousand as the result of a higher amount of invested funds.

Income taxes.

Income tax expense was nil and €646 thousand for the year ended December 31, 2006 and 2005, respectively. In 2005 our income tax expense included an update of our assumptions underlying the recovery of a pre-paid tax asset that we inherited from the original spin-off from Sirton. We believe that the tax benefits related to the prepayment will no longer be available, therefore in 2005 we wrote off the entire pre-paid tax asset.

Net loss.

Our net loss was €14.4 million in 2006 compared to €12.3 million in 2005. The difference was primarily due to increases in research and development expenses, general and administrative expenses and stock based compensation partially offset by a decrease in interest expense in 2006 compared to 2005 and an increase in revenue.

LIQUIDITY AND CAPITAL RESOURCES

During 2005, we used approximately €8.5 million of cash to fund operations, and working capital requirements and approximately €1.4 million for capital expenditures and the acquisition of intangible assets. We funded these amounts from the following sources:

· €3.6 million in gross revenues;

· €1.912 million in gross proceeds from the sales of Series A notes;

· €3.9 million in capital contributions from our then-majority shareholder, FinSirton;

· $24.3 million in gross proceeds from our initial public offering of 2.7 million of our ordinary shares;

· $10.9 million in gross proceeds from a private placement of 1,551,125 of our ordinary shares together with warrants to purchase 620,450 ordinary shares; and

· €2.5 million in cash available at December 31, 2004.

During 2006, we used approximately €12.2 million of cash to fund operations and working capital requirements, approximately €1.9 million for capital expenditures and the acquisition of intangible assets, paid €4 million to Crinos and €4 million into escrow for the benefit of Crinos. We funded these amounts from the following sources:

· €4.3 million in gross revenues;

· $22.1 million in gross proceeds from a private placement of 1,943,525 of our ordinary shares together with warrants to purchase 388,705 ordinary shares;

· $2.2 million in gross proceeds from exercise of warrants and stock options;

· €5.5 million in loans; and

· €12.8 million from cash available at December 31, 2005.

During 2007, we used approximately €10.2 million of cash to fund operations and working capital requirements, approximately €11.1 million for capital expenditures and acquisition of intangible assets, including €8 million paid to Crinos. We funded these amounts from the following sources:

· €7.6 million in gross revenues;

· $47.5 million in gross proceeds from a private placement of 2,354,000 ordinary shares;

· $8.4 million in gross proceeds from the exercise of warrants and stock options;

· €279 thousand in short term borrowing; and

· €10.2 million from cash available at December 31, 2006.

At December 31, 2007, we had an aggregate of €5.68 million in debt outstanding. Additional information about the maturity and repayment obligations for this debt and interest rate structure and our material commitments for capital expenditures is provided below under “Contractual Obligations and Commitments.”

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

· the scope and results of our clinical trials;

· whether we are able to commercialize and sell defibrotide for the uses for which we are developing it;

· advancement of other product candidates in development;

· the timing of, and the costs involved in, obtaining regulatory approvals;

· the cost of manufacturing activities;

· the costs associated with building a future commercial infrastructure;

· the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and results of such litigation; and

· our ability to establish and maintain additional collaborative arrangements.

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

· our ability to obtain FDA and European regulatory marketing approval for and to commercially launch defibrotide to treat severe VOD;

· the success of our other clinical and pre-clinical development programs, including development of defibrotide to prevent VOD and to treat multiple myeloma;

· the receptivity of the capital markets to financings of biotechnology companies; and

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

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

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

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

RESEARCH AND DEVELOPMENT

We discover, research and conduct initial development of our product candidates at our facilities in Italy, and also hire consultants to do so in various countries in Europe and the United States. We typically conduct preclinical laboratory and animal studies of product candidates either ourselves or through other research facilities. We typically engage medical centers to conduct clinical trials of our product candidates. In certain cases, where we believe the development costs will be substantial, we may enter into collaborative arrangements to help us develop those product candidates. We expense research and development costs as incurred.

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 services and clinical trials for our product candidates. During the years ended December 31, 2005, 2006 and 2007, we had four major categories of research projects relating to our product candidates: defibrotide to treat VOD, defibrotide to prevent VOD, defibrotide to treat multiple myeloma and assorted other projects. The table below presents our research and development expenses by project for each of the years ended December 31, 2005, 2006 and 2007.

	For The Years Ended December 31,		
(in thousands)	**2005**	**2006**	**2007**
Defibrotide to treat VOD	€ 4,123	€ 7,067	€ 11,636
Defibrotide to prevent VOD	175	590	869
Multiple myeloma	50	59	17
Others	209	1,211	2,576
Total	€ 4,557	€ 8,927	€ 15,098

In December 2005, the Dana-Farber Cancer Institute at Harvard University completed a Phase II clinical trial in the United States of defibrotide to treat severe VOD. We started enrollment of patients in a Phase III clinical trial of this product candidate in the United States in the second quarter of 2006. We do not anticipate obtaining FDA or European regulatory approval of this product candidate before 2009. The table above also includes research and development expenses that we incurred in connection with a Phase II/III clinical trial of defibrotide to treat VOD in Europe and Israel that was sponsored by a committee of clinical investigators and conducted by Consorzio Mario Negri Sud. The committee of clinical investigators terminated this trial in October 2005.

Defibrotide to prevent VOD is also currently in a Phase II/III clinical trial of children in Europe sponsored by our company and the European Group for Blood and Marrow Transplantation. We do not anticipate obtaining European regulatory approval of this product candidate before 2009.

An independent Phase I/II clinical trial in Italy of defibrotide, in combination with melphalan, prednisone and thalidomide, to treat patients with advanced and refractory multiple myeloma started in December 2005. The Phase I portion included 24 patients in four cancer centers in Italy and concluded in 2007. The Phase II portion is scheduled to include 50 patients in 10 cancer centers in Italy. The principal investigator is Dr. Antonio Palumbo, M.D., at the Division of Hematology, University of Turin, Italy.

The table above includes research and development expenses that we incurred in connection with a Phase I clinical trial of defibrotide to mobilize and increase the number of stem cells available in patients' and donors' blood for subsequent stem cell transplantation sponsored by the National Institute of Tumors of Milan. The National Institute of Tumors of Milan terminated this trial in December 2005.

We expect to continue to increase our research and development expenses for the research and development of defibrotide to treat and prevent VOD and the treatment of multiple myeloma and possibly for other indications for defibrotide. This will involve sponsoring or funding, or both, clinical trials in both the United States and Europe. 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. We expect that we will need additional funds before we have completed the development of our product candidates. We may seek to raise these funds through licensing and other collaboration agreements or through the sale of debt or equity securities. There can be no assurance that we will be successful in raising additional funds or that if we are, it will be on favorable terms.

A further discussion of the risks and uncertainties associated with developing our product candidates and certain consequences of failing to do so are set forth in the risk factors under the heading "Risks Relating to Our Business" as well as other risk factors.

Intellectual Property Rights And Patents

As of December 31, 2007, we had eight issued U.S. patents, seven pending U.S. patent applications, 31 issued foreign patents, 103 pending foreign patent applications and one international patent application (not nationalized yet). These include the following. The United States Patent & Trademark Office issued a patent covering our manufacturing process of defibrotide in 1991, which expired on January 15, 2008. In April 2001, we filed a patent application with the United States Patent & Trademark Office and corresponding patent applications in certain foreign countries regarding the use of defibrotide in stem cell transplants, which expires in 2021.

Patent rights and other proprietary rights are important in our business. We have sought, and intend to continue to seek, patent protection for our inventions and rely upon patents, trademarks, trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain a competitive advantage.

However, the patent positions of companies like ours involve complex legal and factual questions and, therefore, their enforceability cannot be predicted with any certainty. Our patents, those licensed to us, and those that may be issued to us in the future may be challenged, invalidated or circumvented, and the rights granted under them may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be approved for sale and commercialized, our relevant patent rights may expire or remain in force for only a short period following commercialization.

TREND INFORMATION

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

In connection with our purchase of the Italian marketing rights to defibrotide and related trademarks from Crinos, we paid Crinos €4 million in 2006, placed another €4 million in escrow, which was released to Crinos in April 2007, paid Crinos an additional installment of €4 million in December 2007 and agreed to pay Crinos a final installment of €4 million by December 31, 2008.

We expect our costs for the following current clinical trials and related studies to increase substantially in 2008 compared to 2007 as we enroll patients and pay the related clinical trial centers and clinical research organizations:

§ The expanded access program of defibrotide to treat VOD in the United States;

§ Toxicology studies related to our Phase III clinical study of defibrotide to treat VOD in the United States; and

§ Phase II/III clinical trial of defibrotide to prevent VOD in children in Europe.

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

OFF-BALANCE SHEET ARRANGEMENTS

We do not have any off-balance sheet arrangements.

TABULAR DISCLOSURE OF CONTRACTUAL OBLIGATIONS

Contractual Obligations and Commitments

Our major contractual obligations and commitments relate to our real estate mortgages, other financing from banks and financial institutions, obligations to pay Crinos for the Italian defibrotide marketing rights and related trademarks and various service agreements (including those related to our clinical trials).

The following table summarizes our long-term commitments as of December 31, 2007.

Amounts in thousands except for share and per share data	**Total**	**1 Year**	**2 Years**	**3 Years**	**4 Years**	**5 Years**	**More than 5 Years**
Long-Term Debt Obligations:							
Mortgage loans	€ 2,600	€ 400	€ 400	€ 400	€ 400	€ 400	€ 600
Finance loans	1,056	348	362	231	115	-	-
Equipment loans	1,517	401	410	415	291	-	-
Research loan	510	113	117	121	125	34	-
	€ 5,683	€ 1,262	€ 1,289	€ 1,167	€ 931	€ 434	€ 600
Purchase Obligations	€ 4,000	€ 4,000	€ -	€ -	€ -	€ -	€ -
Operating leases	849	199	199	199	191	31	30
Clinical research organizations	1,265	1,106	142	9	8	-	-
Research and development programs	733	513	143	77	-	-	-
Consultants	909	580	327	1	1	-	-
	7,756	6,398	811	286	200	31	30
Total	€ 13,439	€ 7,660	€ 2,100	€ 1,453	€ 1,131	€ 465	€ 630

We received a loan commitment from the Minister for University and Research granted through San Paolo-IMI Bank in September 2000. The loan is for financing research and development of defibrotide to treat and prevent VOD, and it bears interest at 1.0% per annum. We will need to repay this loan in installments every six months beginning six months after the completion of the related research and development, but no later than January 2012. At December 31, 2007, the amount outstanding under this loan was €318 thousand.

On July 9, 2004, we obtained a loan in the approximate amount of €487 thousand from Cassa di Risparmio di Parma e Piacenza. The loan was obtained pursuant to Law No. 1329 of 28 November 1965 (Legge Sabatini), a law that facilitates the purchase and the lease of new production equipment. The loan is secured by a lien on our equipment and machinery. On August 4, 2004, we obtained an additional loan in the amount of €388 thousand from Cassa di

Risparmio di Parma e Piacenza under the same terms and conditions. At December 31, 2007, the aggregate amount outstanding under these two loans was €306 thousand.

On April 20, 2006, we obtained a five year financing facility from Banca Intesa Medicredito S.p.A. of up to €1 million to finance our purchase and installation of two reactors in our manufacturing facility. The facility has a five-year term and bears interest at the three-month Euribor rate plus 1.7%. It is secured by Banca Intesa debt securities in the aggregate amount of €525 thousand that we purchased and which expire on May 10, 2011. We make installment payments on the facility of €131 thousand every six months until its final maturity in April 2011. At December 31, 2007, the aggregate amount outstanding under this facility was €919 thousand.

On June 28, 2006, we obtained a loan in the amount of €2.8 million from Banca Nazionale Del Lavoro S.p.A. The loan is secured by a mortgage on certain of our land and buildings. It bears interest at the six month Euribor rate plus 1.00%, the principal of which will be repaid in 14 installments, every six months, starting from December 27, 2007 until final maturity in 2014 and the interest on which will be paid every six months starting from June 27, 2006. At December 31, 2007, the amount outstanding under this loan was €2.6 million.

On June 30, 2006, we obtained a loan in the amount of €750 thousand from San Paolo IMI 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% over the Euribor rate. The loan is payable in thirteen quarterly installments of approximately €58 beginning on June 15, 2008 through June 15, 2011. Interest is due quarterly beginning on September 15, 2006. The agreement requires us to maintain a minimum level of net shareholders' equity determined in accordance with Italian generally accepted accounting principles. At December 31, 2007, the amount outstanding under this loan was €750 thousand.

On December 20, 2006 we obtained three loans from Banca Intesa S.p.A. The first of these loans is in the amount of €230 thousand for a term of 60 months, maturing on December 31, 2006. Principal and interest are due in 20 quarterly installments beginning on March 31, 2007. It bears interested at the three month Euribor rate plus 1%. At December 31, 2007, the amount outstanding under this loan was €188 thousand.

The second loan is in the amount of €500 thousand for a term of 60 months, maturing on December 31, 2011. Principal and interest are due in 60 monthly installments beginning on January 31, 2006. It bears interest at the three month Euribor rate plus 1%. At December 31, 2007, the amount outstanding under this loan was €409 thousand.

The third loan is in the amount of €225 thousand for a term of 57 months (after a technical preamortization period from December 20, 2006 to March 15, 2007) maturing on December 15, 2011. It must be used within six months for investments in the innovation of products and/or production processes or to buy manufacturing equipment. Principal and interest payments are due in quarterly installments starting on June 15, 2007. It bears interest at the three month Euribor rate plus 0.8%. At December 31, 2007, the amount outstanding under this loan was €193 thousand.

Our commitments for clinical research consist of fixed price contracts with third-party research organizations related to clinical trials for the development of defibrotide and related consulting services for advice regarding FDA issues.

In connection with our purchase of the Italian marketing rights to defibrotide and related trademarks from Crinos, we paid Crinos €4 million in 2006, placed another €4 million in escrow, which was released to Crinos in April 2007, paid Crinos an additional installment of €4 million in December 2007 and agreed to pay Crinos a final installment of €4 million by December 31, 2008.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

DIRECTORS AND SENIOR MANAGEMENT

Set forth below is the name, birth date, position and a brief account of the business experience of each of our executive officers, significant employees and directors as of March 31, 2008.

Name	Date of Birth (mm/dd/yyyy)	Position
Dr. Laura Ferro	08/03/1951	President and Chief Executive Officer, Director
Gary Gemignani	05/26/1965	Executive Vice-President and Chief Financial Officer
Dr. Massimo Iacobelli	04/28/1959	Senior Vice-President, Scientific Director

Armando Cedro	07/16/1955	Chief of Manufacturing
Salvatore Calabrese	01/04/1970	Vice-President, Finance and Secretary
Dr. Kenneth Anderson (1)	10/03/1951	Director
Gigliola Bertoglio (2)	08/22/1934	Director
Luca Breveglieri (3)	01/23/1952	Director
Marco Codella	09/17/1959	Director
David Kroin	08/24/1975	Director
Dr. Lee M. Nadler (4)	03/22/1947	Director
Malcolm Sweeney (5)	01/21/1949	Director
Dr. Andrea Zambon (6)	01/14/1958	Director

(1) Member of the compensation committee and clinical committee.

(2) Member of the audit committee (chairperson) and nominating and corporate governance committee.

(3) Member of the nominating and corporate governance committee (chairperson).

(4) Member of the compensation committee, nominating and corporate governance committee and clinical committee.

(5) Member of the audit committee.

(6) Member of the audit committee, clinical committee and compensation committee (chairperson).

Dr. Laura Ferro has served as our President and Chief Executive Officer and one of our directors since 1991. Her current term as a director expires on the date of the ordinary shareholders' meeting approving our 2007 Italian GAAP financial statements, which would normally be held in April 2008. Dr. Ferro is also the President and Chief Executive Officer of our largest shareholder, FinSirton. She also serves as Vice President of Sirton, a subsidiary of FinSirton that specializes in manufacturing pharmaceutical products. Dr. Ferro is also a member of the board of directors of each of FinSirton, Sirton and Foltene Laboratories S.p.A., a former subsidiary of FinSirton that is in the hair care products business. From 1991 to 1997, Dr. Ferro held various executive positions at Sirton, including Chief Executive Officer and Chairperson of the research and development unit. Prior to that, Dr. Ferro was a practicing physician for 15 years. Dr. Ferro is the chairperson of the research committee of Europharm, the European Association of Small and Medium-Sized Pharmaceutical Companies, and is a member of the executive committee of Farmindustria, an Italian pharmaceutical industry group. She is also the President of the Gianfranco Ferro Foundation, a not-for-profit Italian organization with the mission of stimulating research, education and dissemination of information on the correct use of medications and adverse events of medicines. Dr. Ferro received her M.D. and Ph.D. degrees from the University of Milan, and a MBA from Bocconi University in Milan in 1994. Dr. Ferro is a licensed physician. She was certified in psychiatry at the University of Milan in 1981 and in Clinical Pharmacology at the University of Milan in 1994.

Gary G. Gemignani has served as our Executive Vice-President and Chief Financial Officer since June 2006. From 2004 to 2005, Mr. Gemignani was the Vice President and Controller of Financial Reporting and Accounting, US Pharmaceuticals Division, of Novartis AG, a pharmaceutical and consumer health company. From 1998 to 2004, he held a variety of vice-president level positions for Prudential Financial Inc., a financial products and services provider. From 1993 to 1998, Mr. Gemignani held a variety of senior financial positions at Wyeth (formerly American Home Products), a pharmaceutical, consumer healthcare and animal health company. From 1986 to 1993, he was an employee of Arthur Andersen & Co. Mr. Gemignani received a bachelor of science in accounting from St. Peter's College.

Dr. Massimo Iacobelli has served as our Senior Vice-President, Scientific Director since 2002 and as our Vice President, Clinical Development and Chief Medical Office from 1995 to 2002. From 1990 to 1994, he was the Senior Vice-President, Medical Marketing, at Sirton. From 1988 to 1989, Dr. Iacobelli directed the Drug Safety Department at Bayer S.p.A. He received a medical degree from Università degli Studi, Napoli, Italy.

Armando Cedro has served as our Chief of Manufacturing since 2003. From 1997 to 2003, he served as our Active Pharmaceutical Ingredient Production Manager. From 1987 to 1997, he served as the Chemical Research and Development Laboratories and Pilot Plant Manager at Sirton. From 1982 to 1987, he served as the Chemical Development Laboratory Manager at Societa Prodotti Antibiotici, a manufacturer of antibiotic pharmaceutical products. Mr. Cedro received a degree in Industrial Chemistry from the Universita degli Studi di Milano, Italy.

Salvatore Calabrese has served as our Vice-President, Finance and Secretary since February 2005. From December 2003 until February 2005, he was an Accounting and Finance Manager for Novuspharma, S.p.A., a development stage biopharmaceutical company focused on the discovery and development of cancer drugs and a subsidiary of Cell Therapeutics, Inc., a public reporting company, which then merged into Cell Therapeutics, Inc. He reported to the Chief Financial Officer of Cell Therapeutics, Inc. and was responsible for cost containment, budgeting, financial reporting and the implementation of Sarbanes-Oxley compliance. From September 1996 until

November 2003, Mr. Calabrese was employed by PricewaterhouseCoopers as an accountant and was a Manager in Assurance Business Advisory Services at the time of departure. From October 2000 to June 2003, Mr. Calabrese worked in the Boston, MA office of PricewaterhouseCoopers. He earned a Bachelors' Degree in Economics at the University of Messina and a Masters' Degree in Accounting, Audit and Financial Control at the University of Pavia. He is also a chartered accountant in the Republic of Italy.

Dr. Kenneth Anderson has served as one of our directors since June 2005. His current term expires on the date of the ordinary shareholders' meeting approving our 2007 Italian GAAP financial statements, which would normally be held in April 2008. Dr. Anderson has been a professor at the Dana-Farber Cancer Institute, Cancer Research and Clinical Care, since 1980, a professor of medicine at Harvard Medical School since 2000 and a Kraft Family professor of medicine at Harvard Medical School since 2002. He has been the Chief of the Division of Hematologic Neoplasia at the Dana-Farber Cancer Institute since 2002, the Vice Chair of the Joint Program in Transfusion Medicine at Harvard Medical School since 2000, the Director of the Jerome Lipper Multiple Myeloma Center at the Dana-Farber Cancer Institute since 2000, the Associate Medical Director of Brigham and Women's Hospital Blood Bank since 1998 and an attending physician at the Bone Marrow Transplantation Service at Brigham and Women's Hospital since 1997. Dr. Anderson is a member of 11 medical and scientific societies and on the editorial boards of 11 medical and scientific journals. He received a Bachelors' degree, summa cum laude, from Boston University in 1973, a M.D. from Johns Hopkins University School of Medicine in 1977 and a Masters' Degree in Art from Harvard University in 2000.

Gigliola Bertoglio has served as one of our directors since December 2004. Her current term as a director expires on the date of the ordinary shareholders' meeting approving our 2007 Italian GAAP financial statements, which would normally be held in April 2008. Ms. Bertoglio has been a self-employed consultant since January 2003. From 1970 through 2003 she was employed by Reconta Ernst & Young (the Italian affiliate of Ernst & Young LLP) and its predecessors and was an audit partner beginning in 1977. From 1998 until leaving the firm, she was responsible for the firm's Capital Market Group in Italy. From 1989 to 1998, she was responsible for directing the firm's Professional Standards Group and member of the Accounting and Auditing Standards Group of Ernst & Young International and as a coordinating audit partner on clients with international operations. From 1977 to 1989, Ms. Bertoglio was a partner of the Italian firm of Arthur Young & Co. (the predecessor to Ernst & Young) where she was responsible for directing the firm's Professional Standards Group and serving in an advisory role to the Accounting and Auditing Standards Group of Arthur Young International and as a coordinating audit partner on clients with international operations. From 1970 to 1977, she was an Audit Manager (1970 to 1974) and an Audit Principal (1975 to 1977) with the Italian firm of Arthur Young & Co. in its Rome and Milan offices. Prior to 1970, Ms. Bertoglio was employed in the New York offices of Horwath & Horwath and LKH&H, both of which were public accounting firms. She earned a degree in Public Accounting from New York University and a Diploma in Accounting from Economics Institution in Biella, Italy. She was a Certified Public Accountant (active license to August 31, 2002, inactive after that) in the United States and included in the Register of Authorized Auditors of Consob, the Italian Stock Exchanges regulatory agency of public companies.

Luca Breveglieri has served as one of our directors since April 2006. His current term expires on the date of the ordinary shareholders' meeting approving our 2007 Italian GAAP financial statements, which would normally be held in April 2008. Mr. Breveglieri is an Italian-qualified attorney and has been a partner of Breveglieri Verzini e Soci, an Italian law firm, since 2000. From 1982 to 2000, Mr. Breveglieri was the founding partner of Breveglieri e Associati. Mr. Breveglieri is an Italian certified public accountant. Mr. Breveglieri received a degree in law from Universita degli Studi, Pisa, Italy, in 1977.

Marco Codella has served as one of our directors since June 2005. His current term expires on the date of the ordinary shareholders' meeting approving our 2007 Italian GAAP financial statements, which would normally be held in April 2008. Mr. Codella has been the Chief Financial Officer of Sigma Tau Industrie Farmaceutiche Riunite S.p.A., an international family of pharmaceutical companies, since May 1999. Mr. Codella has been a professor of Economics and Management Accounting at University of Rome, La Sapienza since 2001. From 1997 to 1999, Mr. Codella was the Finance, IT and Logistics Director of Crown Cork & Seal Italy S.p.A., an Italian subsidiary of Crown Holdings, Inc., a manufacturer of packaging products to consumer marketing companies. From 1994 to 1997, Mr. Codella was the Finance and IT Director of Crown Cork & Seal Italy S.p.A. From 1990 to 1994, Mr. Codella held various finance positions at Digital Equipment Italia S.p.A., an Italian subsidiary of Digital Equipment Corporation, a computer company. From 1987 to 1990, Mr. Codella was the Finance Manager of an Italian subsidiary of Ampex Corporation, a provider of technology for acquisition, storage and processing of visual information. From 1984 to 1987, Mr. Codella was an auditor at Deloitte, Haskins & Sells, an accounting firm. Mr. Codella is a director of Sigma Tau Farmaceutiche Riunite S.p.A., Eubiotina Research S.p.A., Biosint S.p.A., Avantgarde S.p.A., SigmaTau Health Science S.p.A., Techogen S.p.A. and Kenton S.r.l., each of which is a subsidiary of Sigma Tau Finanziaria S.p.A., and Fonchim, a pension fund for chemical industry workers. Mr. Codella is an Italian certified public accountant. Mr. Codella graduated summa cum laude from Rome University in 1984 with a degree in economics.

David Kroin has served as a member of our board of directors since November 2005. His current term as a director expires on the date of the ordinary shareholders' meeting approving our 2007 Italian GAAP financial statements, which would normally be held in April 2008. Mr. Kroin has notified us that he does not plan to stand for re-election for the 2008-2009 term. Mr. Kroin has been the Managing Director of Great Point Partners, LLC, an asset management firm focusing in the healthcare industry, with an emphasis on life sciences, since September 2003. Mr. Kroin has also been a director of Biodel Inc., a biopharmaceutical company, since July 2006. From December 1998 to September 2003, Mr. Kroin was a senior member of the healthcare group at J.H. Whitney & Co., an alternative asset

management firm. From June 1997 to December 1998, Mr. Kroin worked as an analyst in the corporate finance and mergers and acquisitions group at Merrill Lynch& Co., Inc. Mr. Kroin graduated from the University of Michigan with a B.S. in actuarial mathematics in May 1997. Mr. Kroin was nominated for election by Biomedical Value Fund, L.P. and Biomedical Offshore Value Fund, Ltd., two of the investors in our October 2005 private placement, pursuant to a voting agreement among the participants in the private placement and FinSirton.

Dr. Lee M. Nadler has served as one of our directors since June 2005. His current term expires on the date of the ordinary shareholders' meeting approving our 2007 Italian GAAP financial statements, which would normally be held in April 2008. Dr. Nadler is the Senior Vice President of Experimental Medicine at Harvard University's Dana-Farber Cancer Institute and a Professor of Medicine at Harvard University. He joined the staff of the Dana-Farber Cancer Institute in 1977, and was promoted to the faculty in 1980. He served as chief and chair of several departments, including serving as the First Chairperson of the Dana-Farber Cancer Institute's Department of Adult Oncology. Dr. Nadler received a medical degree from Harvard Medical School in 1973.

Malcolm Sweeney has served as one of our directors since April 2007. His current term expires on the date of the ordinary shareholders' meeting approving our 2007 Italian GAAP financial statements, which would normally be held in April 2008. From 2001 to 2005, Mr. Sweeney was the Head of Financial Reporting and Accounting of the Pharma Division at Novartis AG, a major international pharmaceutical company. From 1990 to 2000, Mr. Sweeney worked for IMS Health Inc., (formerly IMS International), a provider of market intelligence to the pharmaceutical and healthcare industries, and associated companies. He held the positions of Corporate Controller and Senior Director of Finance for IMS Health Inc., as well as that of Leader of European Shared Services for Dun and Bradstreet in 1994 and 1995 when Dun and Bradstreet used to own IMS Health Inc. and several other major information service providers. From 1974 to 1990, he held a variety of finance positions for divisions of General Electric. Mr. Sweeney resides in the U.K., is a chartered accountant, admitted to the Institute of England & Wales in 1974 when working for KPMG (formerly Peat, Marwick, Mitchell and Co.). He received a Bachelor of Science in Physics, Economics and Philosophy from the University of Exeter in 1970.

Dr. Andrea Zambon has served as one of our directors since June 2005. His current term expires on the date of the ordinary shareholders' meeting approving our 2007 Italian GAAP financial statements, which would normally be held in April 2008. Dr. Zambon is the president and chief executive officer of Kjos, a holding company that focuses its investments in technology driven companies. Dr. Zambon was a co-founder and President of a web-based company, OKSalute S.p.A. serving the medical community from 2000 until 2002. From 2000 until 2004 he was President of Zambon, S.p.A, the holding company of Zambon Group, S.p.A., an Italian pharmaceutical and chemical company that operates in 19 countries in Europe, North and South America and Asia. From 1989 until 1999, he served in various capacities at Zambon Group S.p.A., including President and Chief Executive Officer from 1991 to 1999, Managing Director from 1991 to 1993, Managing Director of Zambon Research, S.p.A. in 1990, a research subsidiary of Zambon Research S.p.A., and manager of the international regulatory affairs unit in 1989. From 1988 to 1989, Dr. Zambon was employed by Smith Kline & Beckman in various departments, including clinical development, regulatory affairs, and market research, for three new chemical businesses. From 1986 to 1987 he was employed by Zambon Group, S.p.A. where he helped establish its research and development division. He has served on numerous corporate and industry association boards. Dr. Zambon earned a Medical Degree from the University of Milan Medical School.

Our Scientific Advisory Board

Our scientific advisory board advises us with respect to our product development strategy as well as the scientific and business merits of licensing opportunities or acquisition of compounds and the availability of opportunities for collaborations with other pharmaceutical companies. We have in the past compensated and in the future intend to compensate scientific advisory board members with cash fees for attending meetings. In addition to Dr. Lee Nadler and Dr. Kenneth Anderson, who are also directors, the current scientific advisory board members are:

Ralph B. D'Agostino, Sr. Ph.D. has been a Professor of Mathematics/Statistics at Boston University since 1977 and a Professor of Public Health at Boston University, School of Public Health, Department of Epidemiology and Biostatistics since 1982. He has been the editor of Statistics in Medicine since 1998. Dr. D'Agostino is also an Associate Editor of American Journal of Epidemiology, and on the editorial board of Current Therapeutic Research and the Journal of Hypertension. He has been the director of the Statistics and Consulting Unit at Boston University and Director of Data Management and Statistics at the Framingham Study. Dr. D'Agostino has served as an expert consultant to the FDA since 1974. He is a Fellow of the American Statistical Association and the Cardiovascular Epidemiology section of the American Heart Association. He has twice, in 1981 and 1995, received the FDA Commissioner's Special Citation. He received an A.B. in Mathematics, summa cum laude, from Boston University in 1962, an A.M. in Mathematics from Boston University in 1964 and a Ph.D. in Mathematical Statistics from Harvard University in 1968.

Dr. Stephen Fredd M.D. has been a consultant to the pharmaceutical industry since 2002. From 1980 to 2002, Dr. Fredd was the Deputy Director of the Division of Cardi-Renal Drugs of the Center for Drug Evaluation and Research at the FDA. From 1987 to 1997, he was the Director and Founder of the Division of Gastrointestinal and Coagulation Drugs of the Center for Drug Evaluation and Research at the FDA. From 1982 to 1987, Dr. Fredd was a Medical Officer and the Acting Director of the Officer of Orphan Products Development of the Office of the Commissioner at the FDA. From 1980 to 1982, he was a Medical Officer at the Division of Antinflammatory, Oncological and Radiopharmaceutical Drugs of the Center for Drug Evaluation and Research at the FDA. From 1965 to 1980, Dr. Fredd was a privately practicing doctor of internal medicine. From 1977 to 1980, he was an Assistant Professor of Medicine at George Washington University Medical Center, and from 1965 to 1977, he was an Instructor in Medicine at New York University Medical Center. Dr. Fredd received FDA Awards of Merit in 1989 and 1997, FDA Commendable Service Awards in 1987 and 1998 and the FDA Commissioner's Special Citation in 1989. Dr. Fredd received an A.B., magna cum laude, from Princeton University in 1955 and a M.D. from New York University Medical Center in 1959.

Richard Champlin, M.D. has been a Professor of Medicine and Chairman of the Department of Blood and Marrow Transplantation at the University of Texas M. D. Anderson Cancer Center since 1990. From 1981 to 1990, Dr. Champlin was an Assistant and Associate Professor of Medicine and directed the Transplantation Biology Program at the UCLA Center for the Health Sciences. Dr. Champlin chaired the Working Committee on Alternative Donors and Cell Sources of the International Bone Marrow Transplant Registry from 1995 to 2000. He was the founding president of the American Society of Blood and Marrow Transplantation from 1992 to 1994 and president of the Council for Donor, Transplant and Collection Centers for the National Marrow Donor Program from 1990 to 1993. He has been a vice president of the Foundation for Accreditation of Hematocellular Therapy since 1996, was a member of the Biologic Response Modifiers Advisory Board for the FDA from 1999 to 2002 and was a member of the Hematology Board, American Board of Internal Medicine from 1996 to 2002. Dr. Champlin is a member of several scientific societies and serves on the Editorial Boards of Blood, Bone Marrow Transplantation and Journal of Hematotherapy. He has been the President of the Center for International Blood and Marrow Transplantation since 2003. Dr. Champlin received a M.D. from the University of Chicago's Pritzker School of Medicine in 1975.

COMPENSATION

Compensation of Directors and Executive Officers

For the year ended December 31, 2005, the aggregate cash compensation to our executive officers and directors as a group was approximately €918 thousand. For the year ended December 31, 2006, the aggregate cash compensation to our executive officers and directors as a group was approximately €1.092 million. For the year ended December 31, 2007, the aggregate cash compensation to our executive officers and directors as a group was approximately €1.291 million. During the year ended December 31, 2005, we granted options to purchase an aggregate of 690,000 ordinary shares to our executive officers and directors at exercise prices ranging from $8.00 to $10.00 per share that, as amended, terminate in dates ranging from March 15, 2010 to November 29, 2015. During the year ended December 31, 2006, we granted options to purchase an aggregate of 130,000 ordinary shares to our executive officers and directors at exercise prices ranging from $12.60 to $17.35 that, as amended, terminate on dates ranging from April 28, 2016 to June 1, 2016. During the year ended December 31, 2007, we granted options to purchase an aggregate amount of 429,000 ordinary shares to executive officers and directors at exercise prices ranging from $16.52 to $18.95 that terminate on dates ranging from March 26, 2017 to November 9, 2017.

Share-Based Compensation Plans

2004 Equity Incentive Plan

Our board of directors proposed a capital increase for our 2004 Equity Incentive Plan to our shareholders on September 2, 2004. Our shareholders approved that capital increase on September 30, 2004. Our board of directors approved the specific terms of our 2004 Equity Incentive Plan effective as of September 30, 2004. Our shareholders approved the specific terms of our 2004 Equity Incentive plan on April 28, 2005. On July 31, 2006, our board of directors approved an amended and restated version of our 2004 Equity Incentive Plan to reflect minor revisions, including an Italian law requirement that all shares issued under the plan be paid for in cash in at least an amount equal to €4.50 per share, which was the net worth of our company at the time of the capital increase relating to the plan. On March 26, 2007, our board of directors approved an amendment to the Amended and Restated 2004 Equity Incentive Plan, extending the term of the plan to 2019. Our shareholders approved this amendment on April 27, 2007.

The incentive plan authorizes 1,500,000 ordinary shares for issuance. The maximum number of shares that may be issued under the incentive plan subject to incentive share options is 1,500,000. At December 31, 2007, there were 1,500,000 shares underlying outstanding options, with a weighted average exercise price of $12.64. Shares subject to share awards that have expired or otherwise terminated without having been exercised in full again become available for the grant of awards under the incentive plan. In the event of a share split or other alteration in our capital structure,

without the receipt of consideration, appropriate adjustments will be made to outstanding awards to prevent dilution or enlargement of participant's rights. The plan is governed by Italian law.

Our incentive plan provides for the grant of incentive share options (as defined in Section 422 of the U.S. Internal Revenue Code) to employees, including officers and employee-directors, and nonstatutory share options, restricted share purchase rights, restricted share unit awards, share appreciation rights and share bonuses to employees, including our officers, directors and consultants who are subject to tax in the United States. The incentive plan also provides for the periodic automatic grant of nonstatutory share options to our non-employee directors.

The incentive plan is administered by our board of directors or a committee appointed by our board of directors. The board or the committee determines recipients and types of awards to be granted, including the number of shares subject to an award, the vesting schedule of awards, the exercisability of awards, and subject to applicable restrictions, other terms of awards. The board of directors has delegated administration of the incentive plan to the compensation committee.

The term of share options granted under the incentive plan generally may not exceed ten years, although the capital increase relating to the ordinary shares issuable upon exercise of such options expires on September 30, 2019. Our compensation committee determines the price of share options granted under the incentive plan, provided that the exercise price for an incentive share option cannot be less than 100% of the fair market value of our ordinary shares on the date of grant. No incentive share option may be granted to any person who, at the time of the grant, owns (or is deemed to own) ordinary shares possessing more than 10% of our total voting ordinary shares, unless the option exercise price is at least 110% of the fair market value of the ordinary shares on the date of grant and the term of the incentive share option does not exceed five years from the date of grant. The exercise price for a nonstatutory share option can vary in accordance with a predetermined formula while the option is outstanding. In addition, the aggregate fair market value, determined at the time of grant, of the ordinary shares with respect to which an incentive share option first becomes exercisable during any calendar year (under the incentive plan and all of our other equity compensation plans) may not exceed $100 thousand.

Options granted under the incentive plan vest at the rate determined by our compensation committee. Typically, options granted under the incentive plan vest over three years, with one-third of the shares covered by the option vesting on the first anniversary of the grant date and the remainder vesting monthly over the next two years.

Generally, the optionee may not transfer a share option other than by will or the laws of descent and distribution unless the optionee holds a nonstatutory share option that provides otherwise. However, an optionee may designate a beneficiary who may exercise the option following the optionee's death. An optionee whose service relationship with us ceases for any reason may exercise the option to the extent it was vested for the term provided in the share option agreement. Options generally expire three months after the termination of an optionee's service. However, if an optionee is permanently disabled or dies during his or her service, that person's options generally may be exercised up to 12 months following disability or death.

Share appreciation rights granted under our incentive plan may be paid in our ordinary shares, cash or a combination of the two, as determined by our board of directors. The grant of a share appreciation right may be granted subject to a vesting schedule determined by our board of directors.

Restricted share purchase rights granted under the incentive plan may be granted pursuant to a repurchase option in our favor that will lapse in accordance with a vesting schedule and at a price determined by the board of directors (or a committee appointed by the board of directors). Restricted share unit awards may be granted subject to a vesting schedule determined by the board of directors (or a duly appointed committee). Rights under a share bonus or a restricted share purchase award are transferable only upon such terms and conditions as are set forth in the relevant agreement, as determined by the board of directors (or the committee appointed by the board of directors) in its sole discretion.

When we become subject to Section 162(m) of the Internal Revenue Code which denies a deduction to publicly held companies for certain compensation paid to specified employees in a taxable year to the extent the compensation exceeds $1.0 million, no person may be granted share options and/or share appreciation rights under the incentive plan covering more than 500,000 ordinary shares in any fiscal year. In addition, no person may be granted restricted share purchase rights, share units and/or share bonuses under the incentive plan covering more than 250,000 ordinary shares in any fiscal year. However, in connection with a participant's first year of employment, such participant may be granted options and/or share appreciation rights covering up to 600,000 ordinary shares and restricted share purchase rights, share units and/or share bonuses covering up to 500,000 ordinary shares.

In the event of certain corporate transactions (including, but not limited to, a sale or other disposition of all or substantially all of our assets, a merger or a consolidation), all outstanding awards under the incentive plan will be subject to the terms and conditions of the agreement memorializing the transaction. The agreement may provide for the assumption or substitution of awards by any surviving entity, the acceleration of vesting (and exercisability, if applicable) or the cancellation of awards with or without consideration. In addition, at the time of grant, our board of directors may provide for acceleration of vesting in the event of a change in control. In the event of a change in control, non-employee director options outstanding under the incentive plan will automatically become vested and will terminate if not exercised prior to such a change in control.

The board of directors may amend the incentive plan at any time. Amendments will be submitted for shareholder approval to the extent required by applicable laws, rules and regulations. The incentive plan will terminate on September 30, 2019 unless sooner terminated by the board of directors or a committee appointed by the board of directors.

2004 Italy Stock Award Sub-Plan

Our Amended and Restated 2004 Italy Stock Award Sub-Plan is a part of our Amended and Restated 2004 Equity Incentive Plan and provides for the grant of share options and the issuance of share grants to certain of our employees who reside in the Republic of Italy and who are liable for income tax in the Republic of Italy. Generally, the exercise price for a share option under the Italy sub-plan cannot be less than the average of the closing price of our ordinary shares listed on the American Stock Exchange or The Nasdaq Global Market System, as applicable, over the 30 days preceding the date of grant. No share option granted under our Italy sub-plan may cover more than 10% of the voting rights in our annual meeting of shareholders or 10% of our capital or equity. Share grants will be made in consideration for past services.

Generally, a participant under the Italy sub-plan may not transfer a share award other than by applicable law. However, a participant under the Italy sub-plan may designate a beneficiary who may exercise the award following the participant's death.

In the event of certain corporate transactions (including, but not limited to, a sale or other disposition of all or substantially all of our assets, a merger or a consolidation), all outstanding awards under the Italy sub-plan will be subject to the terms and conditions of the agreement memorializing the transaction. The agreement may provide for the assumption or substitution of awards by any surviving entity, the acceleration of vesting (and exercisability, if applicable) or the cancellation of awards with or without consideration. In addition, at the time of grant, our board of directors may provide for acceleration of vesting in the event of a change in control.

The Italy sub-plan will terminate on September 30, 2019 unless sooner terminated by our board of directors.

2004 Nonstatutory Share Option Plan and Agreement

Our board of directors proposed a capital increase for our 2004 Nonstatutory Share Option Plan and Agreement to our shareholders on September 2, 2004 and our shareholders approved that capital increase on September 30, 2004. Our board adopted the specific terms of our 2004 Nonstatutory Share Option Plan and Agreement on October 1, 2004. Our shareholders approved the specific terms of our 2004 Nonstatutory Share Option Plan and Agreement on April 28, 2005. The sole person eligible to receive an option under the plan was Cary Grossman, our former Executive Vice President and Chief Financial Officer. On October 1, 2004, Mr. Grossman received an option to purchase all 60,000 shares authorized for issuance under the plan. The exercise price of the option issued under the plan is $4.50. The option became fully vested on December 15, 2004. On March 23, 2006, we and Mr. Grossman amended and restated this option to have an exercise price of $5.58 to comply with a requirement under Italian law. We entered into an agreement with Mr. Grossman whereby we agreed to pay him $64,800 (the amount of the aggregate increase in the exercise price), subject to certain conditions, in return for amending the exercise price. Mr. Grossman has exercised this option in full.

2007 Stock Option Plan

Our board of directors proposed a capital increase for our 2007 Stock Option Plan and the specific terms of such plan on March 26, 2007. Our shareholders approved the capital increase and the terms of the plan on April 27, 2007.

The 2007 Stock Option Plan authorizes 1,000,000 ordinary shares for issuance. At December 31, 2007, there were 116,500 shares underlying outstanding options, with a weighted average exercise price of $16.16. Shares subject to options that have expired or otherwise terminated without being exercised in full again become available for issuance under the plan. In the event of a share split or other alteration in our capital structure, without the receipt of consideration, appropriate adjustments will be made to the outstanding awards to prevent dilution or enlargement of a participant’s rights. The plan is governed by Italian law.

The 2007 Stock Option Plan provides for the grant of incentive stock options (as defined in Section 422 of the U.S. Internal Revenue Code) to employees, including officers and employee-directors, and nonstatutory stock options. The plan also provides for the periodic automatic grant of nonstatutory stock options to our non-employee directors.

The 2007 Stock Option Plan is administered by our board of directors or a committee appointed by our board of directors. The board or the committee determines recipients and types of options to be granted, including the number of shares subject to an option, the vesting schedule of options, the exercisability of options, and subject to applicable restrictions, other terms of options. The board of directors has delegated administration of the 2007 Stock Option Plan to the compensation committee.

The term of share options granted under the 2007 Stock Option Plan generally may not exceed the earlier of ten years and March 26, 2022. Our compensation committee determines the price of share options granted under the 2007 Stock Option Plan, provided that the exercise price for an incentive share option cannot be less than the higher of:

· 100% of the fair market value (110% for 10-percent shareholders) of our shares on the date of grant,

· an amount corresponding, as of the date of exercise, to €3.02 per share and

· an amount corresponding, as of the date of exercise, to the nominal value of each share.

No incentive share option may be granted to any person who, at the time of the grant, owns (or is deemed to own) ordinary shares possessing more than 10% of our total voting ordinary shares, unless the option exercise price is at least 110% of the fair market value of the ordinary shares on the date of grant and the term of the incentive share option does not exceed five years from the date of grant. The exercise price for a nonstatutory share option can vary in accordance with a predetermined formula while the option is outstanding. In addition, the aggregate fair market value, determined at the time of grant, of the ordinary shares with respect to which an incentive share option first becomes exercisable during any calendar year (under the 2007 Stock Option Plan and all of our other equity compensation plans) may not exceed $100 thousand.

Options granted under the 2007 Stock Option Plan vest at the rate determined by our compensation committee. Typically, options granted under the 2007 Stock Option Plan vest over three years, at the rate of one-third of the shares covered by the option vesting on the first anniversary of the grant date and the remainder vesting monthly over the next two years.

Generally, the optionee may not transfer a share option other than by will or the laws of descent and distribution unless the optionee holds a nonstatutory share option that provides otherwise. However, an optionee may designate a beneficiary who may exercise the option following the optionee's death. An optionee whose service relationship with us ceases for any reason may exercise the option to the extent it was vested for the term provided in the share option agreement. Options generally expire three months after the termination of an optionee's service. However, if an optionee is permanently disabled or dies during his or her service, that person's options generally may be exercised up to 12 months following disability or death.

Each director who is not otherwise one of our employees or consultants automatically is granted a nonstatutory share option for 10,000 ordinary shares upon his or her initial election or appointment to our board of directors. These grants vest one-third one year after the date of grant and the remainder in twenty-four equal monthly installments beginning one year and one month from the date of grant, provided that the person is still serving as a non-employee director on each such vesting date. Upon the conclusion of each ordinary annual meeting of our shareholders, each non-employee director receives a nonstatutory share option for 5,000 ordinary shares. These grants vest in twelve equal monthly installments beginning one month from the date of grant, provided that the person is still serving as a non-employee director on each such vesting date. The exercise price of the options granted to non-employee directors is equal to the fair market value of our ordinary shares on the date of grant and the term ends on the earlier of ten years after the date of the grant and March 26, 2022.

In the event of certain corporate transactions (including, but not limited to, a sale or other disposition of all or substantially all of our assets, a merger or a consolidation), all outstanding options under the 2007 Stock Option Plan will be subject to the terms and conditions of the agreement memorializing the transaction. The agreement may provide for the assumption or substitution of options by any surviving entity, the acceleration of vesting (and exercisability, if applicable) or the cancellation of options with or without consideration. In addition, at the time of grant, our board of directors may provide for acceleration of vesting in the event of a change in control. In the event of a change in control, non-employee director options outstanding under the 2007 Stock Option Plan will automatically become vested and will terminate if not exercised prior to such a change in control.

The board of directors may amend the 2007 Stock Option Plan at any time. Amendments will be submitted for shareholder approval to the extent required by applicable laws, rules and regulations. The 2007 Stock Option Plan will terminate on March 26, 2022 unless sooner terminated by the board of directors or a committee appointed by the board of directors.

Other pension and retirement plans

We do not have any other pension or retirement plans, other than a 401(k) plan for our U.S. employees.

BOARD PRACTICES

Board Composition

Our board of directors currently consists of nine members: Dr. Anderson, Ms. Bertoglio, Mr. Breveglieri, Mr. Codella, Dr. Ferro, Mr. Kroin, Dr. Nadler, Mr. Sweeney and Dr. Zambon. Dr. Anderson, Ms. Bertolglio, Mr. Breveglieri, Dr. Nadler, Mr. Sweeney and Dr. Zambon have never been employed by us or any of our subsidiaries and are independent directors. FinSirton agreed to vote its shares in favor of electing one person designated by Biomedical Value Fund, L.P. and Biomedical Offshore Value Fund, Ltd. for so long as such entities collectively own ADSs representing at least 5% of our outstanding ordinary shares. Mr. Kroin is the designee of those two shareholders. Mr. Kroin has notified us that he does not plan to stand for re-election for the 2008-2009 term. FinSirton also agreed to vote its shares in favor of electing one person designated by Sigma Tau Finanziaria S.p.A. Mr. Codella is the designee of Sigma Tau. We do not have any agreements with any of our directors that provide for benefits upon termination of employment, although under Italian law, if directors are removed by the vote of shareholders at an ordinary

shareholders' meeting prior to the end of their term without cause, they may have a claim for damages against us. These damages may include, but are not limited to, compensation that would otherwise have been paid to the director for the remainder of his or her term and damage to his or her reputation.

Our Compensation Committee recommends the compensation of our directors to our shareholders and our board of directors. Under Italian law, our shareholders determine the compensation of our directors relating to basic board service, such as annual fees for serving on the board and fees for attending board meetings. Our directors then determine "additional" compensation for our directors for serving on the various board committees and attending committee meetings. Our Compensation Committee, board of directors and shareholders have approved the following director compensation for the term from our April 2007 ordinary shareholder meeting to our April 2008 shareholder meeting. Each director (other than Dr. Ferro) would receive, as applicable:

- €20 thousand per year for being a member of the board;
- €1 thousand for each board meeting attended;
- an additional €3 thousand for each board meeting attended in person that is held outside of the continent in which the director resides or that requires travel for more than 5 hours from his or her residence;

- an additional €18 thousand per year for being the chairperson of the audit committee;
- €2 thousand per committee meeting attended for the chairperson of the nominating and corporate governance committee and the chairperson of the compensation committee;
- €1 thousand per committee meeting attended for the other members of the nominating and corporate governance committee and the compensation committee;
- €4 thousand per committee meeting attended for all members of the audit committee, including the chairperson;
- options to purchase 5,000 ordinary shares per year to the chairperson of the clinical committee and options to purchase 3,000 shares per year to the other members of the clinical committee; and
- €4 thousand per committee meeting attended for all members of the clinical committee, including the chairperson.

Each of our non-employee directors (other than Dr. Nadler) receives an option to purchase 10,000 ordinary shares upon initial election to the board of directors. We granted Dr. Nadler additional cash compensation instead of options to purchase ordinary shares upon his initial election to the board of directors. Each of our non-employee directors also receive an option to purchase an additional 5,000 ordinary shares upon reelection at each annual shareholder's meeting.

Board Committees and Code of Ethics

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee.

Audit Committee. Our audit committee consists of Ms. Bertoglio, Mr. Sweeney and Dr. Zambon, each of whom is an independent director. Ms. Bertoglio and Mr. Sweeney are both audit committee financial experts. The audit committee is a standing committee of, and operates under a written charter adopted by, our board of directors. The audit committee:

- establishes procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters and the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- has the authority to engage independent counsel and other advisors, as it determines necessary to carry out its duties, and determine the compensation of such counsel and advisors, as well as its ordinary administrative expenses; and
- approves related party transactions.

Our audit committee directly oversees our independent accountants, including the resolution of disagreements between management and the independent accountants. As discussed below, under Italian law, our board of statutory auditors also oversees our independent accountants with respect to our Italian GAAP financial statements. Under Italian law, our shareholders must be the party that appoints, terminates and determines the compensation for our independent accountants, although our audit committee does make recommendations on such matters to our board of directors, which in turn makes recommendations to our shareholders.

Our board adopted an "Organizational and Operational Model" permitted by Italian Legislative Decree of June 8, 2001 No. 231 (relating to the administrative responsibility of companies). This document consists of:

- operating procedures and reporting system;

- internal supervisory and monitoring body; and
- a disciplinary system.

Compensation Committee. Our compensation committee consists of Dr. Anderson, Dr. Nadler and Dr. Zambon, each of whom is independent director. Under Nasdaq rules, the compensation of a U.S. domestic company's chief executive officer and all other officers must be determined, or recommended to the board of directors, either by a compensation committee comprised of independent directors or a majority of the independent directors of its board of directors. Disclosure of individual management compensation information is mandated by the Exchange Act proxy rules, but foreign private issuers are generally exempt from that requirement. Our compensation committee performs the duties required by the rules of Nasdaq including making decisions and recommendations regarding salaries, benefits, and incentive compensation for our executive officers. Part of the compensation of our directors is fixed periodically by our shareholders at their annual ordinary shareholder meetings. We disclose the aggregate compensation of our executive officers and directors in our Exchange Act reports, but not individual compensation of those officers or directors.

Nominating and Corporate Governance Committee. Our nominating and corporate governance committee consists of Ms. Bertoglio, Mr. Breveglieri and Dr. Nadler, each of whom is an independent director. Under Nasdaq rules, the directors of a U.S. domestic company must be either selected or recommended for the board of directors' selection by either a nominating committee comprised solely of independent directors or by a majority of the independent directors. Under Italian law, directors may also be nominated by our shareholders. Our nominating and corporate governance committee performs the duties required by Nasdaq, including assisting the board of directors in fulfilling its responsibilities by:

- identifying and approving individuals qualified to serve as members of our board of directors;
- selecting director nominees for our annual meetings of shareholders;
- evaluating our board's performance; and
- developing and recommending to our board corporate governance guidelines and oversight with respect to corporate governance and ethical conduct.

Our shareholders are able to nominate directors other than those nominated by the nominating committee.

Clinical Committee. Our clinical committee consists of Dr. Nadler, Dr. Anderson and Dr. Zambon. Our clinical committee assists the board of directors in fulfilling its oversight responsibilities with respect to clinical and regulatory matters. The clinical committee's primary purposes are to:

- review management's design and execution of clinical trials;
- provide input and advice to management regarding the same; and
- periodically update the rest of the board of directors regarding the company's performance of the clinical trials and the committee's advice regarding the same.

Other Committees. Our board of directors may establish other committees as it deems necessary or appropriate from time to time, including, but not limited to, an executive committee.

Board of Statutory Auditors

Under Italian law, in addition to electing our board of directors, our shareholders also elect a board of statutory auditors. The statutory auditors are elected for a term of three years, may be reelected for successive terms and may be removed only for cause and with the approval of a competent court. Each member of the board of statutory auditors must provide certain evidence that he or she is qualified to act in that capacity under Italian law, and that he or she meets certain professional standards. The board of statutory auditors is required to verify that we comply with applicable law and our by-laws, respect the principles of correct administration and maintain adequate organizational structure, internal controls and administrative and accounting system, and oversees our independent accountants with respect to our Italian GAAP financial statements.

The following table sets forth the names of the three members of our board of statutory auditors and the two alternate statutory auditors and their respective positions, as of the date of this annual report. The current board of statutory auditors was elected on April 28, 2006 for a term that ends at the date of the ordinary shareholders' meeting to approve our 2008 annual financial statements, which would normally be held in April 2009.

Name	Position

Giorgio Iacobone	Chairman
Carlo Ciardiello	Member
Augusto Belloni	Member
Domenico Ferrari	Alternate
Romano Chiapponi	Alternate

Mr. Iacobone and Mr. Belloni also serve as members of the board of statutory auditors of Sirton.

In 2005, our board of statutory auditors met five times and attended four board of directors meetings and two shareholders meetings. In 2006, they met five times and attended nine board of director meetings and six shareholder meetings. In 2007, they met six times and attended six board of director meetings and one shareholder meeting. In 2007, we accrued €90 thousand as compensation for their service as our statutory auditors.

Indemnification of Directors and Executive Officers and Limitation of Liability

We have entered into indemnification agreements with each of our directors and executive officers which may, in some cases, be broader than the specific indemnification provisions contained in Italian law.

At present, there is no pending litigation or proceeding involving any of our directors, officers, employees, or agents where indemnification by us will be required or permitted and we are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

We have purchased directors' and officers' liability insurance, including liabilities arising under the Securities Act, and intend to maintain this insurance in the future.

EMPLOYEES

The table below shows the number, activity and geographic location of our permanent employees as of December 31, 2005, 2006 and 2007. All of our employees are in Italy, except for four individuals, including Gary Gemignani, our Executive Vice President and Chief Financial Officer, who are based in the United States. Prior to June 2005, most of our administrative, accounting, finance and business development services were performed by employees of FinSirton and Sirton. In 2005 we established our administrative, finance and accounting department.

	As of December 31,		
	2005	**2006**	**2007**
Administration, accounting, finance, business development	6	12	18
R&D, clinical, regulatory	17	20	23
Production, quality assurance control	26	33	39
Total	49	65	80

Italian law imposes certain confidentiality obligations on our employees and provides that either any intellectual property created by them while in our employ belong to us or we have a right of option on it, although we must compensate them for such intellectual property creation. Our employees in Italy are subject to national collective bargaining agreements. National agreements are negotiated collectively between the national associations of companies within a given industry and the respective national unions. National agreements provide a basic framework on working conditions, including, among other things, pay, security and other provisions. Our employees other than executive officers in Italy were subject to a collective bargaining agreement that was renewed on May 10, 2005 and expires on December 31, 2009. Our executive officers in Italy are subject to a collective bargaining agreement that was renewed on November 20, 2004 and expires on December 31, 2008. We believe that we maintain satisfactory relations with our employees.

Under Italian law, employees are entitled to amounts based on salary and years of service upon leaving their employment, even if we terminate them for cause or they resign. We had a liability for these termination indemnities of €685 thousand at December 31, 2007. Under Italian law, we make social security and national healthcare contributions for our employees to the Italian government, which provides pension and healthcare insurance benefits.

SHARE OWNERSHIP

Dr. Laura Ferro and members of her family control FinSirton. As a result, Dr. Ferro may be deemed to beneficially own FinSirton's shares of our company. Dr. Ferro disclaims such beneficial ownership. Dr. Ferro also holds options that, within 60 days of March 31, 2008, are vested as to 315,788 shares.

To our knowledge, none of our other directors and officers listed herein owned one percent or more of our ordinary shares at March 31, 2008. See "Item 7, Major Shareholders and Related Party Transactions."

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

MAJOR SHAREHOLDERS

The following table shows information with respect to the beneficial ownership of our ordinary shares as of March 31, 2008 by:

- each person, or group of affiliated persons, who we know owns beneficially 5% or more of our ordinary shares, and
- all of our directors and executive officers as a group.

At March 31, 2008, we had 14,956,317 ordinary shares outstanding. Except as indicated in the footnotes to this table and subject to community property laws where applicable, the persons named in the table have sole voting and investment power with respect to all ordinary shares shown as beneficially owned by them. Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC. Ordinary shares underlying our convertible securities that are exercisable within 60 days from March 31, 2008 are deemed outstanding for computing the amount and percentage owned by the person or group holding such convertible securities, but are not deemed outstanding for computing the percentage owned by any other person or group.

	Number of Shares Beneficially Owned	Percent
Principal Shareholders		
FinSirton S.p.A.(1)	3,750,000	25.1%
Paolo Cavazza (2)	2,685,329	17.9%
Claudio Cavazza (3)	2,472,002	16.5%
Sigma Tau Finanziaria S.p.A. (4)	2,384,335	15.9%
Defiante Farmaceutica, L.D.A. (5)	1,084,335	7.2%
All directors and executive officers as a group (13 persons) (6)	4,607,869	29.1%

(1) Address is Piazza XX Settembre 2, 22079 Villa Guardia (Como), Italy. The board of directors of FinSirton, including Dr. Laura Ferro, who is our Chief Executive Officer, President and one of our directors, may be deemed to share voting or dispositive control with FinSirton over the ordinary shares in Gentium that FinSirton beneficially owns. The members of the board of directors of FinSirton, including Dr. Ferro, disclaim beneficial ownership of such shares. FinSirton entered into a loan agreement with Intesa San Paolo S.p.A. on June 12, 2007, and in connection therewith, pledged 700,000 ordinary shares in our company to Intesa San Paolo S.p.A. to secure repayment of such loan.

(2) Based upon information obtained from a Schedule 13D filed with the SEC, as amended. Address is Via Tesserte, 10, Lugano, Switzerland. Consists of (i) 1,300,000 outstanding ADSs held by Sigma Tau Finanziaria S.p.A., (ii) 1,011,001 outstanding ADSs held by Defiante Farmaceutica L.d.A., (iii) 73,334 ordinary shares issuable upon exercise of warrants currently exercisable held by Defiante; and (iv) 300,994 outstanding ADSs held by Chaumiere Consultadoria e Servicos S.A. Mr. Paolo Cavazza owns, directly and indirectly, 40% of the outstanding equity of Sigma Tau Finanziaria S.p.A. and so may be deemed to beneficially own the shares beneficially owned by Sigma Tau Finanziaria S.p.A. In connection with a purchase by Sigma Tau Finanziaria S.p.A. of 800,000 ordinary shares from FinSirton in April 2005, FinSirton agreed that, if the per share price in a sale by our shareholders of all of our ordinary shares is less than $5.00 per share, FinSirton will transfer to Sigma Tau Finanziaria S.p.A. an additional number of ordinary shares equal to (x) $3.2 million divided by the product determined by multiplying (i) 0.8 by (ii) the per share sale price less (y) 800,000 ordinary shares. Sigma Tau Finanziaria S.p.A. owns, directly and indirectly, 100% of the outstanding equity of Defiante and so may be deemed to be the beneficial owner of the outstanding ordinary shares and ADSs held by Defiante and issuable upon exercise of Defiante's warrants. Mr. Paolo Cavazza and members of his family indirectly own Chaumiere and so may be deemed to beneficially own the ADSs beneficially owned by Chaumiere.

(3) Based upon information obtained from a Schedule 13G filed with the SEC, as amended. Address is Via Sudafrica, 20, Rome, Italy 00144. Consists of (i) 1,300,000 outstanding ADSs held by Sigma Tau Finanziaria S.p.A., (ii) 1,011,001 outstanding ADSs held by Defiante Farmaceutica L.d.A., (iii) 73,334 ordinary shares issuable upon exercise of warrants currently exercisable held by Defiante and (iv) 87,667 ADSs held by Inverlochy Consultadoria e Servicos LdA. Mr. Claudio Cavazza owns, directly and indirectly, 60% of the outstanding equity of Sigma Tau Finanziaria S.p.A. and so may be deemed to beneficially own the shares beneficially owned by Sigma Tau Finanziaria S.p.A. In connection with a purchase by Sigma Tau Finanziaria S.p.A. of 800,000 ordinary shares from FinSirton in April 2005, FinSirton agreed that, if the per share price in a sale by our shareholders of all of our

ordinary shares is less than $5.00 per share, FinSirton will transfer to Sigma Tau Finanziaria S.p.A. an additional number of ordinary shares equal to (x) $3.2 million divided by the product determined by multiplying (i) 0.8 by (ii) the per share sale price less (y) 800,000 ordinary shares. Sigma Tau Finanziaria S.p.A. owns, directly and indirectly, 100% of the outstanding equity of Defiante and so may be deemed to be the beneficial owner of the outstanding ordinary shares and ADSs held by Defiante and issuable upon exercise of Defiante's warrants. Inverlochy Consultadoria e Servicos, LdA is indirectly wholly-owned by Mr. Claudio Cavazza. By reason of such relationship, Mr. Cavazza may be deemed to beneficially own the ADSs held by Inverlochy Consultadoria e Servicos, LdA.

(4) Based upon information obtained from a Schedule 13D filed with the SEC, as amended. Address is Via Sudafrica 20, 00144 Roma, Italy. Consists of (i) 1,300,000 outstanding ADSs held by Sigma Tau Finanziaria S.p.A., (ii) 1,011,001 outstanding ADSs held by Defiante and (iii) 73,334 ordinary shares issuable upon exercise of warrants currently exercisable held by Defiante. Sigma Tau Finanziaria S.p.A. owns, directly and indirectly, 100% of the outstanding equity of Defiante and so may be deemed to be the beneficial owner of the outstanding ordinary shares and ADSs held by Defiante and issuable upon exercise of Defiante's warrants. The board of directors of Sigma Tau Finanziaria S.p.A. may be deemed to share voting or dispositive power with Sigma Tau Finanziaria S.p.A. over the ordinary shares in our company that Sigma Tau Finanziaria S.p.A. beneficially owns, and so may be deemed to beneficially own the ordinary shares that Sigma Tau Finanziaria S.p.A. beneficially owns. In connection with a purchase by Sigma Tau Finanziaria S.p.A. of 800,000 ordinary shares from FinSirton in April 2005, FinSirton agreed that, if the per share price in a sale by our shareholders of all of our ordinary shares is less than approximately $5.00 per share, FinSirton will transfer to Sigma Tau Finanziaria S.p.A. an additional number of ordinary shares equal to (x) $3.2 million divided by the product determined by multiplying (i) 0.8 by (ii) the per share sale price less (y) 800,000 ordinary shares.

(5) Based upon information obtained from a Schedule 13G filed with the SEC, as amended. Address is Rua dos Ferreios, 260, Funchal-Madeira (Portugal) 9000-082. Includes 73,334 ordinary shares issuable upon exercise of warrants currently exercisable.

(6) Includes 857,869 ordinary shares issuable upon exercise of options currently exercisable and exercisable with 60 days of March 31, 2008.

As of March 31, 2008, there were no record holders of our ordinary shares located in the United States. There were no changes in percentage ownership by the holders listed above since January 1, 2005 except for the following.

· FinSirton sold 450,000 of our ordinary shares that it owned to third parties in January 2005 and an additional 800,000 shares in April 2005 to Sigma Tau Finanziaria S.p.A. Mr. Paolo Cavazza and Mr. Claudio Cavazza may be deemed to have acquired the ordinary shares acquired by Sigma Tau Finanziaria S.p.A.

· In connection with our initial public offering in June 2005, Defiante acquired 359,505 ordinary shares upon the exercise of our Series A notes, and Mr. Paolo Cavazza, Mr. Claudio Cavazza and Sigma Tau Finanziaria S.p.A. may be deemed to have acquired such shares.

· All shareholders of our company prior to our initial public offering were substantially diluted by the shares issued in that public offering.

· All shareholders of our company prior to our October 2005 private placement were substantially diluted by the shares issued in that private placement.

· In our October 2005 private placement, Chaumiere Consultadoria e Servicos S.A. acquired 152,376 ordinary shares. Mr. Paolo Cavazza may be deemed to have acquired the ordinary shares acquired by Chaumiere Consultadoria e Servicos S.A.

· All shareholders of our company prior to our June 2006 private placement substantially diluted by the shares issued in that private placement.

· All shareholders of our company prior to our February 2007 private placement were substantially diluted by the shares issued in that private placement.

· In our February 2007 private placement, Chaumiere acquired 87,667 ordinary shares, Defiante acquired 87,666 ordinary shares and Inverlochy acquired 87,667 ordinary shares. Paolo Cavazza maybe deemed to have acquired the ordinary shares acquired by Chaumiere. Paolo Cavazza, Claudio Cavazza and Sigma Tau Finanziaria S.p.A. may be deemed to have acquired the ordinary shares acquired by Defiante. Claudio Cavazza may be deemed to have acquired the ordinary shares acquired by Inverlochy.

· In June 2007, Biomedical Value Fund, L.P. sold 227,447 ordinary shares to Sigma-Tau Finanziaria S.p.A. and 304,468 ordinary shares to Defiante, and Biomedical Offshore Value Fund, Ltd. sold 272,553 ordinary shares to Sigma-Tau Finanziaria S.p.A. and 259,362 ordinary shares to Defiante.

The holders of 5% or more of our outstanding ordinary shares do not have different voting rights than other holders of our ordinary shares. Dr. Ferro and her family, through their ownership of 100% of the outstanding ordinary shares of FinSirton, may effectively control all decisions and actions that must be made or taken by holders of our ordinary shares by virtue of the fact that FinSirton beneficially owned approximately 25% of our outstanding ordinary shares at March 31, 2008.

Change of control arrangements

There are no arrangements of which we are aware that could result in a change of control over us other than those described above and the following.

· We and certain parties are subject to certain registration rights, as described below.

· FinSirton has agreed to vote its ordinary shares in our company in favor of electing a nominee to our board of directors, as described below.

Registration Rights

Holders of shares issued upon conversion of Series A notes and warrants

We have registered the resale of 502,334 ordinary shares pursuant to an investor rights agreement with the purchasers of our Series A notes and related warrants with respect to the ordinary shares issued upon conversion of the Series A notes and issuable upon exercise of the warrants. The agreement provides that, beginning 270 days after the effective date of the registration statement relating to our initial public offering, the holders of a majority of the ordinary shares that were issued upon conversion of our Series A notes or exercise of our warrants would be entitled to demand that we register their shares for resale under the Securities Act of 1933, as amended. We are not required to effect more than three registrations for these holders under these demand registration rights. These demand rights terminate on June 21, 2008. No more than two of the demand registrations may be effected using a Form F-1 registration statement. The securities registered pursuant to F-1 registrations must have an aggregate offering price of $2.5 million and any short-form or Form F-3 registrations must have an aggregate offering price of $1.0 million.

The investor rights agreement also provides that if we propose to register any of our securities under the Securities Act, either for our own account or for the account of other shareholders exercising registration rights, the holders of warrants or ordinary shares received upon conversion of the Series A notes or warrants are entitled to notice of the registration and are entitled to include such ordinary shares in any such registration. These "piggyback rights" are subject to conditions and limitations, among them a minimum aggregate offering price of $1.0 million each and the right of the underwriters of an offering to limit the number of ordinary shares included in the registration. These piggyback rights terminate on June 21, 2008.

We have registered ADSs representing such ordinary shares, in addition to the ordinary shares themselves. We are generally required to bear all of the expenses of these registrations, except underwriting discounts and selling commissions. Registration of these ADSs results in those ADSs becoming freely tradable without restriction under the Securities Act.

Alexandra Global Master Fund Ltd., Generation Capital Associates and Sigma Tau Finanziaria S.p.A.

We have registered the resale of 1,250,000 ordinary shares pursuant to an investor rights agreement with Alexandra Global Master Fund Ltd. and Generation Capital Associates with respect to an aggregate of 450,000 ADSs held by those parties and with Sigma Tau Finanziaria S.p.A. with respect to 800,000 ordinary shares held by Sigma Tau Finanziaria S.p.A. Each investor rights agreement provides that beginning six months after the effective date of the registration statement relating to our initial public offering, the holders of the majority of the ordinary shares covered by that agreement would be entitled to demand that we register their shares for resale under the Securities Act. These "demand rights" are subject to limitations described in the agreements. We are not required to effect more than two registrations under these demand registration rights pursuant to each agreement. These demand rights terminate on June 21, 2008. The securities registered pursuant to F-1 registrations must have an aggregate offering price of $2.0 million and any short-form or Form F-3 registrations must have an aggregate offering price of $1.0 million.

Each investor rights agreement also provides that if we propose to register any of our securities under the Securities Act, either for our own account or for the account of other shareholders exercising registration rights, the holders are entitled to notice of the registration and are entitled to include ordinary shares in any such registration. These "piggyback rights" are subject to conditions and limitations, among them a minimum aggregate offering price of $1.0 million each and the right of the underwriters of an offering to limit the number of shares included in the registration. These piggyback rights terminate on June 21, 2008.

We have registered ADSs representing such ordinary shares in addition to the ordinary shares themselves. We are generally required to bear all of the expenses of these registrations, except underwriting discounts and selling

commissions. Registration of these ADSs results in those ADSs becoming freely tradable without restriction under the Securities Act.

Underwriters of our initial public offering

We have registered the resale of 151,200 ordinary shares pursuant to warrants issued to the underwriters of our initial public offering. Each purchase option provides that, beginning one year after the effective date of the registration statement relating to our initial public offering and ending four years after the effective date of the registration statement relating to our initial public offering, the holders of a majority of all of the ordinary shares issuable upon exercise of the purchase options may, on one occasion, demand that we register for resale all or any portion of the purchase options and all of the ordinary shares issuable upon exercise of the purchase options and kept the registration statement effective for at least six consecutive months.

Each purchase option also provides that if we propose to register any of our securities under the Securities Act, either for our own account or for the account of other shareholders exercising registration rights, the holders are entitled to notice of the registration and are entitled to include ordinary shares in any such registration, which we must keep effective for at least six consecutive months. These “piggyback rights” commence one year after the effective date of the registration statement relating to our initial public offering and terminate on seven years after the effective date of the registration statement relating to our initial public offering.

We have registered ADSs representing such ordinary shares in addition to the ordinary shares themselves. We are generally required to bear all of the expenses of these registrations, except underwriting discounts and selling commissions. Registration of these ADSs results in those ADSs becoming freely tradable without restriction under the Securities Act.

October 2005 private placement participants

We have registered the resale of 2,264,643 ordinary shares pursuant to a registration rights agreement between us and the purchasers of our ordinary shares and warrants in our October 2005 private placement. We must keep the registration statement effective until all of the securities registered have been sold or may be sold without volume restrictions pursuant to Rule 144(k).

We have registered ADSs representing such ordinary shares in addition to the ordinary shares themselves. We are generally required to bear all of the expenses of these registrations, except underwriting discounts and selling commissions. Registration of these ADSs results in those ADSs becoming freely tradable without restriction under the Securities Act.

June 2006 private placement participants

We have registered the resale of 2,409,971 ordinary shares pursuant to a registration rights agreement between us and the purchasers of our ordinary shares and warrants in our June 2006 private placement. We must keep the registration statement effective until all of the securities registered have been sold or may be sold without volume restrictions pursuant to Rule 144.

We have registered ADSs representing such ordinary shares in addition to the ordinary shares themselves. We are generally required to bear all the expenses of these registrations, except underwriting discounts and selling commissions. Registration of these ADSs results in those ADSs being freely tradable without registration under the Security Act.

February 2007 private placement participants

We have registered the resale of 2,354,000 ordinary shares pursuant to a registration agreement between us and the purchasers of our ordinary shares in our February 2007 private placement. We must keep the registration statement effective until all of the securities registered have been sold or may be sold without volume restrictions pursuant to Rule 144.

We have registered ADSs representing such ordinary shares in addition to the ordinary shares themselves. We are generally required to bear all the expenses of these registrations, except underwriting discounts and selling commissions. Registration of these ADSs results in those ADSs being freely tradable without registration under the Security Act.

RELATED PARTY TRANSACTIONS

Other than described below, since January 1, 2008, we have not entered into or proposed to enter into any transaction or loan with any affiliate of ours, any of our directors, executive officers, holders of 10% or more of our ordinary shares, any member of their immediate family or any enterprise over which any such person is able to exercise a significant influence other than our employment agreements with our executive officers.

Control by Dr. Ferro's Family

Dr. Laura Ferro, who is our Chief Executive Officer and President and one of our directors, and members of her family control FinSirton. As a result, Dr. Ferro and her family indirectly control approximately 25% of our outstanding ordinary shares at March 31, 2008.

Agreements with various entities

On January 2, 2006, we entered into a Service Agreement with FinSirton pursuant to which FinSirton supplies us with general management and personnel administration services. This agreement was amended in 2007 and is renewable automatically each year barring cancellation of the agreement, which requires notice one month prior to expiration. Starting from January 2007, we pay FinSirton €975 per employee per year for personnel services and €54 thousand per year for general management services. This agreement allows us to revise the payroll service at €195 per employee per year if we manage internally some of the payroll activities.

On January 2, 2006, we entered into a Service Agreement with Sirton pursuant to which Sirton supplies us with a number of business services including quality control, analytical assistance for research and development, engineering services, general and car rental services, utilities services, and maintenance services. This agreement amended in 2007 and is renewable automatically each year barring cancellation of the agreement, which requires notice one month prior to expiration.

On January 1, 2005, we entered into a Commercial Lease Contract with FinSirton to lease space for offices, laboratories and storage facilities. The contract expires on December 31, 2010. The area leased is approximately 1,750 square meters in size. The contract provides for an annual fee of €156 thousand which is updated each year on the basis of the variation of the cost of living index.

On January 1, 2007, we entered into a Commercial Lease Contract with FinSirton to lease additional space for offices, manufacturing space, laboratories and storage facilities. This contract expires on December 31, 2013. The area leased is approximately 600 square meters in size. The contract provides for an annual fee of €30 thousand which is updated each year on the basis of variation of the cost of living index.

On January 1, 2005, we entered into a Commercial Lease Contract with Sirton to lease space for laboratories and manufacturing of urokinase. This contract expires on December 31, 2013. The area leased is 100 square meters in size. The contract provides for an annual fee of €8 thousand which is updated each year on the basis of variation of the cost of living index.

On January 2, 2006, we entered into a Contract to Supply Active Ingredients with Sirton, pursuant to which we sell urokinase, calcium heparin, defibrotide, sulglicotide and glucidamine to Sirton, which Sirton uses to produce specialty pharmaceutical products. The agreement automatically renews each year unless one party gives written notice of its intent to terminate the agreement at least one month prior to the annual termination date. In 2007, we earned revenues of an aggregate of €2.704 million under this agreement. On December 1, 2007, we amended this agreement to delete references to defibrotide.

On November 30, 2007, we entered into a Manufacturing Agreement with Sirton, pursuant to which Sirton will manufacture finished ampoules and capsules of defibrotide from the raw ingredient. The agreement may be terminated by either party upon 60 days notice. In 2007, we incurred costs of an aggregate of €248 thousand under this agreement.

FinSirton guaranteed Sirton's payment of its trade payable to us outstanding at December 31, 2007, net of our account payable to Sirton.

Three of the participants in our February 2007 private placement are affiliated with other shareholders, one of our commercial partners and one of our directors:

· Defiante Farmaceutica, L.d.A. purchased 87,666 ordinary shares in the February 2007 private placement. Defiante also converted its Series A notes into 359,505 ordinary shares at the consummation of our initial public offering and holds warrants issued in connection with the Series A notes to purchase 73,334 ordinary shares;

· Chaumiere Consultadoria e Servicos SDC Unipessoal LdA purchased 87,667 ordinary shares in the February 2007 private placement. Chaumiere also purchased which purchased 152,376 ordinary shares and warrants to purchase 60,951 ADSs in our October 2005 private placement; and

· Inverlochy Consultadoria & Servicos LdA purchased 87,667 ordinary shares in the February 2007 private placement.

Each of these investors is an affiliate of Sigma Tau Finanziaria S.p.A., which owns 1,300,000 ordinary shares. Pursuant to a voting agreement between Sigma-Tau Finanziaria S.p.A. and FinSirton, a designee of Sigma-Tau Finanziaria S.p.A., Marco Codella, was elected to be a member of our board of directors upon consummation of our initial public offering in June 2005. Mr. Codella is the Chief Financial Officer of Sigma Tau Industrie Farmaceutice Reunite S.p.A., which is a wholly-owned subsidiary of Sigma-Tau Finanziaria S.p.A. Each of these three investors is also an affiliate of Sigma-Tau Pharmaceuticals, Inc., which is a party to a License and Supply Agreement with us pursuant to which we have licensed the right to market defibrotide to treat VOD in North America, Central America and South America to Sigma-Tau Pharmaceuticals, Inc. and pursuant to which Sigma-Tau Pharmaceuticals, Inc has agreed to purchase defibrotide for this use from us. This agreement is described in more detail in "Business—Our Strategic Alliances—License and Distribution Agreements." Sigma-Tau Pharmaceuticals, Inc. also has a right of first refusal to market defibrotide for certain other uses in North America, Central America and South America.

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and officers containing provisions that may require us to indemnify them against liabilities that may arise by reason of their status or service as directors or officers and to advance their expenses incurred as a result of any proceeding against them. However, we will not indemnify directors or officers with respect to liabilities arising from willful misconduct of a culpable nature.

INTERESTS OF EXPERTS AND COUNSEL

Not applicable.

ITEM 8. FINANCIAL INFORMATION

CONSOLIDATED STATEMENTS

Please refer to Item 18, “Financial Statements” of this annual report.

OTHER FINANCIAL INFORMATION

Export Sales

Not applicable.

Legal Proceedings

We are not a party to any legal or governmental proceeding that is pending or, to our knowledge, threatened or contemplated against our company that, if determined adversely to us, would have a materially adverse effect, either individually or in the aggregate, on the business, financial condition or results of operations.

Dividend Policy

We have never declared or paid any cash dividends on our ordinary shares. We currently intend to retain all available funds to support our operations and to finance the growth and development of our business. We are not subject to any contractual restrictions on paying dividends. Under Italian law and our bylaws, our payment of any annual dividend must be proposed by our board of directors and is subject to the approval of our shareholders at the annual ordinary shareholders' meeting. Before dividends may be paid out of our net income in any year, we must allocate an amount equal to 5% of the net income to our legal reserve until such reserve is at least equal to 20% of the aggregate par value of our issued shares, which we call our "capital." If a loss in our capital occurs, we may not pay dividends until the capital is reconstituted or reduced by the amount of such losses. We may pay dividends out of available retained earnings from prior years, provided that after such payment, we will have a legal reserve at least equal to the legally required minimum of 20% of the capital. We may not approve or pay dividends until this minimum is met. If the minimum is met, the board of directors proposes the issuance of a dividend and the shareholders approve that issuance, the shareholders' resolution will specify the manner and the date for their payment.

Any dividend we declare will be paid to the holders of ADSs, subject to the terms of the deposit agreement, to the same extent as holders of our ordinary shares, less the fees and expenses payable under the deposit agreement. Any dividend we declare will be distributed by the depositary to the holders of the ADSs. Cash dividends on our ordinary shares, if any, will be paid in U.S. dollars.

If we issue debt securities in the future, until those debt securities are repaid in full, we may not declare dividends if it results in the aggregate of the capital and reserves being less than half of the outstanding amount of the debt.

The board of directors may not approve interim dividends at times between our annual ordinary shareholders' meetings. Any future determination relating to dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including our future earnings, capital requirements, financial condition, future prospects and other factors as the board of directors may deem relevant.

Under Italian law, Italian companies are required to supply to the Italian tax authorities certain information regarding the identity of non-resident shareholders in connection with the payment of dividends. Shareholders are required to provide their Italian tax identification number, if any, or alternatively, in the case of legal entities, their name, country of establishment and address, or in the case of individuals, their name, address and place and date of birth, or in the case of partnerships, the information required for individuals with respect to one of their representatives. In the case of ADSs owned by non-residents of Italy, we understand that the provision of information concerning the depositary, in its capacity as holder of record of the ordinary shares underlying the ADSs, will satisfy this requirement. However, beneficial U.S. ADS holders are entitled to a reduction of the withholding taxes applicable to dividends paid to them under the income tax convention currently in effect between the United States and Italy. In order for you to benefit from that reduction, we are required to furnish certain information concerning you to the Italian tax authorities, and therefor any claim by you for those benefits would need to be accompanied by the required information.

SIGNIFICANT CHANGES

No significant changes have occurred since the date of the most recent annual financial statements.

ITEM 9. THE OFFER AND LISTING
OFFER AND LISTING DETAILS

Our ADSs are listed on Nasdaq under the symbol “GENT.” Neither our ordinary shares nor our ADSs are listed on a securities exchange outside the United States. The Bank of New York is our depositary for purposes of issuing the ADRs representing the ADSs. Each ADS represents one ordinary share.

Trading in our ADSs on the Nasdaq Global Market System commenced on May 16, 2006. Prior to this date, our ADSs were traded on the American Stock Exchange, beginning June 16, 2005 and ending on May 15, 2006, the date we de-listed. The following table sets forth, for each of the periods indicated, the high and low closing prices per ADS as reported by the American Stock Exchange and Nasdaq, as applicable.

	Price Range of ADSs	
	High	Low
2005		
Second Quarter (beginning June 16, 2005)	$ 9.10	$ 8.77
Third Quarter	$ 8.99	$ 6.92
Fourth Quarter	$ 8.68	$ 7.05
2006		
First Quarter	$ 13.25	$ 7.85
Second Quarter	$ 19.76	$ 12.17
Third Quarter	$ 15.49	$ 12.95
Fourth Quarter	$ 22.74	$ 17.01
Full Year	$ 22.74	$ 7.85
2007		
First Quarter	$ 22.44	$ 17.00
Second Quarter	$ 20.25	$ 15.98
Third Quarter	$ 24.40	$ 15.78
Fourth Quarter	$ 23.06	$ 13.51
Full Year	$ 24.40	$ 13.51
2008		
Month Ended		
September 30, 2007	$ 24.40	$ 22.97
October 31, 2007	$ 23.06	$ 21.30
November 30, 2007	$ 20.60	$ 14.16
December 31, 2007	$ 16.00	$ 13.51
January 31, 2008	$ 13.98	$ 8.99
February 28, 2008	$ 10.4368	$ 7.52
March 31, 2008 (through March 28, 2008)	$ 8.68	$ 6.35

The closing price of the ADSs on Nasdaq on March 28, 2008 was $6.35.

Sources: American Stock Exchange and the Nasdaq Stock Market

PLAN OF DISTRIBUTION

Not applicable.

MARKETS

Our ADSs are listed on The Nasdaq Global Market under the symbol “GENT.” Neither our ordinary shares nor our ADSs are listed on a securities exchange outside the United States.

SELLING SHAREHOLDERS

Not applicable.

DILUTION

Not applicable.

EXPENSES OF THE ISSUE

Not applicable.

ITEM 10. ADDITIONAL INFORMATION.

SHARE CAPITAL

Not applicable.

MEMORANDUM AND ARTICLES OF ASSOCIATION

Bylaws

The following is a summary of certain information concerning our ordinary shares and by-laws (Statuto) and of the Italian law provisions applicable to companies whose shares are not listed in a regulated market in the European Union, as in effect at the date of this annual report. The summary contains all the information that we consider to be material regarding the shares but does not purport to be complete and is qualified in its entirety by reference to our by-laws or Italian law, as the case may be.

Under Italian law, most of the procedures regulating our company other than those provided for under, including certain rights of shareholders, are contained in our bylaws as opposed to our articles of association. Amendments to our bylaws requires approval at an extraordinary meeting of shareholders, as described below.

In January 2003, the Italian government approved a wide-ranging reform of the corporate law provisions of the Italian Civil Code, which came into force on January 1, 2004. On September 30, 2004, our shareholders approved a number of amendments to our by-laws dictated or made possible by the 2003 corporate law reform. Our bylaws were also amended on April 28, 2005, November 29, 2005, April 28, 2006 and April 27, 2007. The following summary takes into account the 2003 corporate law reform and the consequent amendments to our by-laws.

General

As of March 31, 2008, our issued and outstanding share capital consisted of 14,956,317 ordinary shares, par value €1 per share. The Euro currency was adopted in Italy on January 1, 1999. The redenomination of the ordinary shares from Italian Lira into Euro was approved by our shareholders on December 27, 2000. All the issued and outstanding shares are fully paid, non-assessable and in registered form.

We are registered with the Companies' Registry of Como. Our registered offices are located in Piazza XX Settembre n. 2, Comune di Villa Guardia, frazione Civello, Como, Italy, registration number 02098100130.

Our corporate purpose is the manufacturing, on behalf of our company and third parties, and marketing in both Italy and other countries, of pharmaceutical preparations, pharmaceutical products, raw materials for pharmaceutical and parapharmaceutical use and in general all and any products sold by pharmacies or for hospital use, excluding in all cases the retail sale in Italy of pharmaceutical preparations and products, medical articles and clinical apparatuses in general and organic and inorganic products that may be used in agrotechnical and/or zootechnical fields. We may also prepare and organize for our own account or on behalf of third parties the documentation required for obtaining authorizations for marketing pharmaceutical products in compliance with the regulations in force in the countries of destination and be the holders of those authorizations. We may grant and/or transfer licenses to Italian and foreign enterprises or corporate bodies or acquire licenses for ourselves or third parties. For each product contemplated by our corporate purposes, we may carry out research programs in general and in particular technological, chemical, pharmacotoxicological and clinical research programs in the hospital and pharmaceutical field. We are generally authorized to take any commercial transactions necessary or useful to achieve our corporate purpose, with the exclusion of investment services and other financial or professional activities reserved by Italian law to authorized entities.

Authorization of shares

Our shareholders may authorize the issuance of additional shares at any time at an extraordinary shareholders' meeting. However, the newly issued shares may not be purchased before all the outstanding shares are entirely paid for. On September 30, 2004, after a recommendation by our board of directors, our shareholders approved a capital increase to allow for the issuance of:

· up to 1,560,000 ordinary shares available for grant under our share option plans;

· up to 1,335,000 ordinary shares upon the conversion of the Series A senior convertible promissory notes;

· up to 881,100 ordinary shares upon the exercise of the warrants; and

· 4,554,000 ordinary shares, including the shares underlying the ADSs in our initial public offering (including ordinary shares underlying the underwriters' purchase option and the over-allotment option).

The authorization for the ordinary shares authorized at this meeting is valid until September 30, 2009, other than the 1,560,000 shares available for grant under our Amended and Restated and 2004 Equity Incentive Plan and our Amended and Restated Nonstatutory Plan and Agreement, whose authorization is valid until September 30, 2019, and except that 1,353,297 of these ordinary shares were authorized for issuance in connection with our issuance of the Series A notes and related warrants, but were not actually issued, and so become unauthorized and unissuable under Italian law.

On November 29, 2005, after a recommendation by our board of directors, our shareholders approved a capital increase of 713,518 ordinary shares to be reserved for issuance upon exercise of the warrants we issued to the participants in our October 2005 private placement and the placement agent for that private placement.

On April 28, 2006, after a recommendation by our board of directors, our shareholders approved an amendment to our bylaws that provides that our board of directors be granted, pursuant to articles 2443 and 2420-*ter* of the Italian Civil Code, with the power to (i) increase the capital of our company in cash, up to €90 million of par value, in one or more transactions, and to reserve all or part of such amount for the exercise of warrants issued by means of the same resolution of our board of directors providing for the relevant capital increase; (ii) issue convertible bonds (including subordinated) and increase the capital of our company, in one or more transactions, up to €10 million of par value, through the issuance of ordinary shares reserved for the conversion of such convertible bonds, and to reserve all or part of such convertible bonds for issuance upon the exercise of warrants issued by means of the same resolution of our board of directors providing for issuance of the convertible bonds; and (iii) in each case, exclude or limit the option right of our shareholders if our board of directors determines that exclusion or limitation to be in the interest of our company.

On May 31, 2006, pursuant to the powers granted by the shareholders' meeting dated April 28, 2006, our board of directors resolved upon a capital increase of 466,446 ordinary shares to be reserved for issuance upon exercise of warrants. On December 15, 2006, pursuant to the powers granted by the shareholders' meeting dated April 28, 2006, our board of directors resolved upon a capital increase of 151,200 ordinary shares to be reserved for issuance upon exercise of warrants.

On February 6, 2007, pursuant to the powers granted by the shareholders' meeting dated April 28, 2006, our board of directors resolved upon a capital increase of 2,354,000 ordinary shares to be subscribed within March 9, 2007, by "strategic investors."

On April 27, 2007, after a recommendation by our board of directors, our shareholders approved a capital increase relating to 1,000,000 ordinary shares to be reserved for issuance pursuant to exercise of options available for grant under our 2007 Stock Option Plan.

Form and transfer of shares

Our ordinary shares are not represented by share certificates; rather, they are registered in book-entry form. All of our ordinary shares are issued through Monte Titoli, an Italian clearinghouse and depositary, and held through various participants, primarily financial institutions, on Monte Titoli's system. Transfers in our ordinary shares are processed on Monte Titoli's system. We update our shareholder book (*libro soci*) that we keep at our corporate offices for Italian law purposes from time to time with the names of the record shareholders based on information that will be provided to us by Monte Titoli participants.

This shareholder book is the controlling register of our record shareholders for Italian law purposes, including for establishing the record shareholders for shareholder meetings, declaration of dividends and stock splits or combinations. A shareholders' name must be entered on this shareholder book in order for the shareholder to establish its rights against us.

There are no limitations on the right to own or vote our ordinary shares, including by non-Italian residents or foreign residents. However, owners of our ordinary shares must establish an account with a Monte Titoli participant. Owners of ADSs representing our ordinary shares are subject to certain limitations as to their rights as explained in our risk factors entitled, *"Risks Relating to Being an Italian Corporation - You may not have the same voting rights as the holders of our ordinary shares and may not receive voting materials in time to be able to exercise your right to vote," "- You may not be able to participate in rights offerings and may experience dilution of your holdings as a result" and "- You may be subject to limitations on transfer of your ADSs."* There are no provisions in our articles of association or bylaws that would have an effect of delaying, deferring or preventing a change of control of our company and that would operate only with respect to a merger, acquisition or corporate restructuring involving our company. There are no provisions in our bylaws governing the ownership threshold above which shareholder ownership must be

disclosed. There are no provisions discriminating against any existing or prospective holder of our ordinary shares as a result of such shareholder owning a substantial number of our shares. There are no sinking fund provisions or provisions providing for liability for further capital calls by our company.

Dividend rights

Our payment of any annual dividend must be proposed by our board of directors and is subject to the approval of our shareholders at the annual ordinary shareholders' meeting. Before dividends may be paid out of our unconsolidated net income in any year, we must allocate an amount equal to 5% of the Italian GAAP net income to our legal reserve until such reserve is at least equal to 20% of the aggregate par value of our issued shares, which we call our "capital." If a loss in our capital occurs, we may not pay dividends until the capital is reconstituted or reduced by the amount of such losses. We may pay dividends out of available retained earnings from prior years, provided that after such payment, we will have a legal reserve at least equal to the legally required minimum of 20% of the capital. We may not approve or pay dividends until this minimum is met. If the minimum is met, the board of directors proposes the issuance of a dividend and the shareholders' resolution approves that issuance, the shareholders' resolution will specify the manner and the date for their payment. Any dividends which shareholders do not collect within five years of the date on which they become payable will be forfeited by those shareholders and we will keep the money. The board of directors may not approve interim dividends at times between our annual ordinary shareholders' meetings.

Board of directors

Pursuant to our by-laws, our board of directors must consist of between three and eleven individuals. Our board of directors is elected at an ordinary shareholders' meeting and the members stay in their office for no longer than one year. Our directors, who may but are not required to be shareholders, may be re-elected. Directors do not stand for reelection at staggered intervals. Cumulative voting rights are not permitted or required. There are no provisions in our articles of association or bylaws regarding retirement or non-retirement of our directors under an age limit requirement.

Our board of directors has complete power of our ordinary and extraordinary administration and in particular may perform all acts it deems advisable for the achievement of our corporate purposes, except for the actions reserved by applicable law or the by-laws to a vote of the shareholders at an ordinary or extraordinary shareholders' meeting. See also, "Item 10, Additional Information, Memorandum and Articles of Association, Meetings of Shareholders."

If we cannot repay our creditors, and a court determines that our directors did not perform their duties regarding the preservation of our assets, the court may find our directors liable to our creditors.

Our board of directors must appoint a chairman (*presidente*) and may appoint a vice-chairman and a secretary. The chairman of the board of directors is our legal representative. Our board of directors may delegate certain powers to one or more managing directors (*amministratori delegati*) or to an executive committee (*comitato esecutivo*), determine the nature and scope of the delegated powers of each director and of the executive committee and revoke such delegation at any time. Italian law provides that the board or, if it delegates such duties, the managing directors or executive committee, must ensure that our organizational and accounting structure is appropriate to our business. If the board delegates these duties to managing directors or an executive committee, then the managing directors or the executive committee, as the case may be, must report to our board of directors at least every six months on our business and the main transactions carried out by us or by our subsidiaries, if any. The board, the managing directors or the executive committee, as the case may be, must report to our board of statutory auditors at least every six months on our business and the main transactions carried out by us or our subsidiaries, if any.

Our board of directors may also appoint one or more senior managers (*direttori generali*) who report directly to the board. These senior managers may be employees, and the board may delegate any powers to them that the board has not already delegated to managing directors or an executive committee, and subject to the limitations discussed below.

Under Italian law, our board of directors may not delegate certain responsibilities, including the preparation and approval of draft financial statements, the approval of merger and de-merger plans to be presented to shareholders' meetings, increases in the amount of our share capital or the issuance of convertible debentures (if any such power has been delegated to our board of directors by our shareholders at an extraordinary shareholders' meeting) and the fulfillment of the formalities required when our capital is required to be reduced as a result of accumulated losses that affect our stated capital by more than one third. See also, "Item 10, Additional Information, Memorandum and Articles of Association, Meetings of Shareholders."

Meetings of our board of directors are called three days in advance or, in case of necessity, one day in advance to each director and each statutory auditor. Statutory auditors are normally required to attend our board meetings, but if a meeting has been duly called, the board can validly take action at the meeting even if the board of statutory auditors do not attend. If the meeting has not been duly called, the meeting is nevertheless validly constituted if all of the directors in office and all of the statutory auditors are present. The chairman may call meetings on his own initiative and meetings must be called upon the request of two directors.

Meetings of our board of directors may be held in person, or by audio-conference or tele-conference, in any member state of the European Union or in the United States. The quorum for meetings of our board of directors is a majority of the directors in office. Resolutions are adopted by the vote of a majority of the directors present at a meeting at which a quorum is present.

Under Italian law, directors having any interest in a proposed transaction must disclose their interest to the board and to the statutory auditors, even if such interest is not in conflict with our interest in the same transaction. The interested director is not required to abstain from voting on the resolution approving the transaction, but the resolution must state explicitly the reasons for, and the benefit to us of, the approved transaction. If these provisions are not complied with, or if the transaction would not have been approved without the vote of the interested director, the resolution may be challenged by a director or by our board of statutory auditors if the approved transaction may be prejudicial to us. A

managing director, a member of the executive committee or any senior manager having any interest in a proposed transaction that he or she has authority to approve must solicit prior board approval of such transaction. The interested director or senior manager may be held liable for damages to us resulting from a resolution adopted in breach of the above rules. Finally, directors may be held liable for damages to us if they illicitly profit from insider information or corporate opportunities.

Under Italian law, directors may be removed from office at any time by the vote of shareholders at an ordinary shareholders' meeting although, if removed in circumstances where there was no just cause, such directors may have a claim for damages against us. These damages may include, but are not limited to, compensation that would otherwise have been paid to the director for the remainder of their term and damage to their reputation. Directors may resign at any time by written notice to our board of directors and to the chairman of our board of statutory auditors. Our board of directors must appoint substitute directors to fill vacancies arising from removals or resignations, subject to the approval of the board of statutory auditors, to serve until the next ordinary shareholders' meeting. If at any time more than half of the members of our board of directors resign or otherwise cease to be directors, the board of directors in its entirety ceases to be in office and our board of statutory auditors must promptly call an ordinary shareholders' meeting to appoint new directors.

Our Compensation Committee recommends the compensation of our directors to our shareholders and our board of directors. Under Italian law, our shareholders determine the compensation of our directors relating to basic board service, such as annual fees for serving on the board and fees for attending board meetings. Our board of directors, after consultation with our board of statutory auditors, may determine the remuneration of directors that serve on the various board committees and/or perform management or other special services for us, such as managing directors. Our directors are entitled to reimbursement for expenses reasonably incurred in connection with their service as directors, such as expenses incurred in travel to attend board meetings. Our articles of association and bylaws do not contain any provisions with respect to borrowing powers exercisable by our directors.

Effective January 1, 2004, an Italian share corporation may adopt one of three different models of corporate governance structure. The three models are:

· a board of directors and a board of statutory auditors, which is the historical model that all companies had prior to January 1, 2004;

· a one-tier model with a single board of directors, including an audit committee composed of independent non-executive directors; or

· a two-tier model, including a management board, which is entrusted with management responsibilities, and a supervisory board which is entrusted mainly with control and supervisory responsibilities and, among other functions, appoints and removes the members of the management board and approves our annual financial statements.

Replacing the historical model with the new one-tier model or two-tier model requires an extraordinary shareholders meeting resolution. The amended by-laws approved by our shareholders on September 30, 2004 do not provide for a change in our governance structure. As a result, we continue to have a board of directors and a board of statutory auditors.

Statutory auditors

In addition to electing our board of directors, our shareholders elect a board of statutory auditors (*Collegio Sindacale*) from individuals qualified to act in such capacity under Italian law. At our ordinary shareholders' meetings, the statutory auditors are elected for a term of three fiscal years, may be re-elected for successive terms and may be removed only for cause and with the approval of a competent court. Each member of our board of statutory auditors must provide certain evidence that he is qualified to act in such capacity under Italian law and meets certain professional standards.

Our by-laws currently provide that the board of statutory auditors shall consist of three statutory auditors and two alternate statutory auditors (who are automatically substituted for a statutory auditor who resigns or is otherwise unable to serve).

Our board of statutory auditors is required, among other things, to verify that we:

· comply with applicable laws and our by-laws;

· respect principles of good governance; and

· maintain adequate organizational structure, internal controls and administrative and accounting system.

Our board of statutory auditors is required to meet at least once each ninety days. In addition, our statutory auditors are supposed to attend meetings of our board of directors and shareholders' meetings. If they do not attend two

consecutive meetings of the board of directors or shareholders, they may be terminated for cause by the shareholders. Our statutory auditors may decide to call a meeting of our shareholders, ask for information about our management from our directors, carry out inspections and verifications at our offices and exchange information with our external auditors. Any shareholder may submit a complaint to our board of statutory auditors regarding facts that the shareholder believes should be subject to scrutiny by our board of statutory auditors, which must take any complaint into account in its report to the shareholders' meeting. If shareholders collectively representing 5% of our share capital submit such a complaint, our board of statutory auditors must promptly undertake an investigation and present its findings and any recommendations to a shareholders' meeting (which must be convened immediately if the complaint appears to have a reasonable basis and there is an urgent need to take action). Our board of statutory auditors may report to a competent court serious breaches of directors' duties. The court may take such actions as it feels appropriate, including inspecting our company's operations, removing directors, appointing temporary administrators to manage our company and any other actions that the court feels is necessary to preserve the value of our company for our creditors and shareholders.

As mentioned in the preceding section, effective January 1, 2004, Italian share corporations may depart from the traditional Italian model of corporate governance structure and opt for two alternative models, neither of which includes a board of statutory auditors. Our amended by-laws do not provide for a change in our governance structure, although we do have an audit committee simply as an internal body of our board of directors.

External auditor

The 2003 corporate law reform requires us to appoint an external auditor or a firm of external auditors, each of them qualified to act in such capacity under Italian law, that shall verify during the fiscal year that our accounting records are correctly kept and accurately reflect our activities, and that our financial statements correspond to the accounting records and the verifications conducted by the external auditors and comply with applicable rules. The external auditor or the firm of external auditors express their opinion on the financial statements in a report that may be reviewed by the shareholders at our offices prior to the annual shareholders' meeting. The report remains on file at our offices and may be reviewed after the annual shareholders' meeting as well; it is also published for review by the general public.

The external auditor or the firm of external auditors are appointed for a three-year term by the vote of our shareholders at an ordinary shareholders' meeting. At the ordinary shareholders' meeting, the shareholders may ask questions of the board of statutory auditors about their view of the auditors prior to voting on whether to appoint the auditors. Once appointed, the shareholders may remove the auditors only for cause and with the approval of the board of statutory auditors and of a competent court.

On April 27, 2007, our shareholders appointed Reconta Ernst & Young S.p.A., with offices in Italy, as our external U.S. GAAP auditors for fiscal year 2007, and as our external Italian GAAP auditors for fiscal years 2007 through 2009.

Meetings of shareholders

Shareholders are entitled to attend and vote at ordinary and extraordinary shareholder's meetings. Votes may be cast personally or by proxy. Shareholders' meeting may be called by our board of directors (or our board of statutory auditors) and must be called if requested by holders of at least 10% of the issued shares. Shareholders are not entitled to request that a meeting of shareholders be convened to vote on issues which as a matter of law shall be resolved upon the basis of a proposal, plan or report by our board of directors. If the shareholders' meeting is not called despite the request by shareholders and such refusal is unjustified, a competent court may call the meeting.

We may hold meetings of shareholders at our registered office in Villa Guardia, or elsewhere within Italy, any other member of the European Union or in the United States following publication of notice of the meeting in the *"Gazzetta Ufficiale della Repubblica Italiana"* or in the newspaper *"Il Sole 24 Ore"* at least 15 days before the date fixed for the meeting. Our bylaws provide that we must mail written notice of meetings to our shareholders at least 10 days before the date fixed for the meeting. The depositary will mail to all record holders of ADSs a notice containing a summary of all information included in any notice of a shareholders' meeting received by the depositary. The notice of a shareholders' meeting must specify two meeting dates for an ordinary or extraordinary shareholders' meeting (first and second "calls"). The notice of the shareholders' meeting also specifies the dates for further calls. The notice must contain a list of the items to be dealt with and state the day, hour and place for the meeting for both the first and second calls. However, if the above procedures are not complied with, the shareholders' meeting will still be deemed to be validly held if all outstanding shares are represented, all other holders having the right to vote are present and the meeting is attended by a majority of the board of directors and the board of statutory auditors.

We must convene an ordinary shareholders' meeting at least once a year within 120 days after the end of the fiscal year. Our annual financial statements must be approved by vote of our shareholders at this annual ordinary shareholders' meeting. We may delay holding the shareholders' meeting to up to 180 days after the end of the fiscal

year if we must prepare consolidated financial statements or if particular circumstances concerning our structure or our purposes so require. At ordinary shareholders' meetings, our shareholders also appoint the external auditors, approve any distribution of dividends that have been proposed by our board of directors, elect our board of directors and statutory auditors, determine their remuneration and vote on any business matter the resolution or authorization of which is entrusted to the shareholders by law.

We may call extraordinary shareholders' meetings to vote upon split-ups, dissolutions, appointment of receivers and similar extraordinary actions. We may also call extraordinary shareholders' meetings to vote upon proposed amendments to our by-laws, issuance of convertible debentures, mergers and de-mergers and capital increases and reductions, if the actions may not be authorized by the board of directors. The board of directors has the authority to transfer our registered office within Italy, authorize, on a non-exclusive basis, amendments to our by-laws that are required by law, authorize mergers by absorption into us of our subsidiaries in which we hold all or at least 90% of the issued share capital, authorize reductions of our share capital in case of withdrawal of a shareholder and indicate who among the directors is our legal representative. If the shareholders authorize the issuance of shares or other securities at an extraordinary meeting, they may delegate the power to make specific issuances to the board of directors.

Once our shareholders have authorized the issuance of securities, those securities must be fully paid for before the shareholders may authorize the issuance of additional securities, unless the shareholders meet and vote to cancel those authorized but not purchased securities.

The quorum for an ordinary meeting of our shareholders on the first call is 50% of the outstanding ordinary shares, while on second call there is no quorum requirement. In either case, resolutions are carried by the majority of ordinary shares present or represented at the meeting. The quorum for an extraordinary meeting of shareholders is a majority of the outstanding ordinary shares on the first call and more than one-third of the outstanding shares on second call. Resolutions are carried by a majority of the outstanding ordinary shares on first call and at least two-thirds of the holders of shares present or represented at the meeting on second call. In addition, certain matters (such as, for example, a change in our purpose, the transfer of our registered office outside Italy or our liquidation prior to the date set forth in our by-laws) must be carried by the holders of more than one-third of the outstanding ordinary shares (not just the ordinary shares present or represented at the meeting).

Shareholders are entitled to one vote per ordinary share. Neither Italian law nor our by-laws limit the right of non-resident or foreign owners to hold or vote their shares. Shareholders do not need to "lodge" their share certificates (if any) or any communication from their broker in order to take part in the meeting. As a registered shareholder, the depositary (or its nominee) will be entitled to vote the ordinary shares underlying the ADSs. The deposit agreement requires the depositary (or its nominee) to accept voting instructions from owners of ADSs and to execute such instructions to the extent permitted by law.

Shareholders may appoint proxies by delivering in writing an appropriate instrument of appointment to us. Our directors, auditors and employees may not be proxies. Italian law provides that any one proxy cannot represent more than 20 shareholders prior to the company "making recourse to the risk capital market." Italian scholars are undecided as to whether listing shares on an exchange outside of Italy constitutes "making recourse to the risk capital market." If we are deemed to make recourse to the risk capital market by means of listing ADSs representing our ordinary shares on the Nasdaq Global Market System, any one proxy cannot represent more than 50 shareholders if the aggregate par value of our ordinary shares is €5 million or less or more than 100 shareholders if the aggregate par value of our ordinary shares is more than €5 million but less than or equal to €25 million. If the aggregate par value of our ordinary shares is more than €25 million, any one proxy cannot represent more than 200 shareholders. At December 31, 2007, we had 14,946,317 shares outstanding, the aggregate par value of which is €14,946,317, and so if we are deemed to make recourse to the risk capital market, each proxy may not represent more than 100 shareholders.

Preemptive rights

Pursuant to Italian law, holders of outstanding ordinary shares and convertible debentures are entitled to subscribe for issuance of ordinary shares or convertible debentures in proportion to their holdings at the time that the shareholders authorize the capital increase for those issuances, unless those issuances are for non-cash considerations. The preemptive rights may be waived or limited by shareholders' resolution adopted by the affirmative vote of holders of more than 50 percent of the ordinary shares at an extraordinary meeting of shareholders, or by a board of directors if the bylaws delegate such power to the board of directors, and such waiver or limitation is in the interest of the company. There can be no assurance that the holders of ADSs may be able to exercise fully any preemptive rights to which our holders of ordinary shares may be entitled. If ADS holders are not able to exercise their preemptive rights, the depositary will, to the extent possible, dispose of such rights for their account.

FinSirton waived its preemptive right in connection with the authorization of our private placement of the Series A notes and warrants, the issuance of options under our Amended and Restated 2004 Equity Incentive Plan and Amended and Restated Nonstatutory Share Option Plan and Agreement and the issuance of 4,554,000 additional ordinary shares, which includes the shares underlying the ADSs offered in our initial public offering and the shares issued in our October 2005 private placement. Our shareholders waived their preemptive rights in connection with the

authorization of 713,518 ordinary shares to be reserved for issuance upon exercise of the warrants we issued to the participants in our October 2005 private placement and the placement agent for that private placement.

Our board of directors excluded the shareholders' pre-emptive rights in connection with the authorization of 1,943,525 ordinary shares and 466,446 ordinary shares to be reserved for issuance of the warrants we issued to the participants in our June 2006 private placement. Our board of directors also excluded the shareholders' pre-emptive rights in connection with the authorization of 2,354,000 ordinary shares we issued to the participants in our February 2007 private placement. Our shareholders waived their pre-emptive rights in connection with the authorization of 1,000,000 ordinary shares to be reserved for issuance upon exercise of options available for grant under our 2007 Stock Option Plan.

Preference shares; other securities

Italian law permits us to issue preference shares with limited voting rights, other classes of equity securities with different economic and voting rights, "participation certificates" with limited economic and voting rights, as well as "tracking shares," if our by-laws permit such issuances. Our by-laws currently do allow us to issue these securities. We may also issue convertible and non-convertible debt securities. In order to issue these securities, our board of directors would need to recommend to our shareholders that they approve the issuance of particular securities in connection with a capital increase, and the shareholders would need to vote to approve such an issuance and capital increase at an extraordinary meeting. The board would also need to recommend, and the shareholders would need to approve by vote at the extraordinary meeting, specific terms of the securities. The shareholders may vote at the extraordinary meeting to delegate to the board of directors the power to issue those securities from time to time, but not more than five years from the date of the extraordinary meeting.

Debt-equity ratio

Italian law provides that we may issue debt securities for an amount not exceeding twice the amount of the sum of the aggregate par value of our ordinary shares (which we call our capital), our legal reserve and any other disposable reserves appearing on our latest Italian balance sheet approved by our shareholders. The legal reserve is a reserve to which we allocate 5% of our Italian GAAP net income each year until it equals at least 20% of our Italian GAAP capital. One of the other reserves that we maintain on our balance sheet is a "share premium reserve", meaning amounts paid for our ordinary shares in excess of the capital. Until our outstanding debt securities are repaid in full, we may not voluntarily reduce our capital or distribute our reserves (such as by declaring dividends) in the event the aggregate of the capital and reserves, following such reduction of capital and/or distribution of reserves, is less than half of the outstanding amount of the debt securities. If our equity is reduced by losses or otherwise such that the amount of the outstanding debt securities is more than twice the amount of our equity, we cannot distribute profits to our shareholders until the ratio between the amount of our debt securities and our capital and reserves is restored. Moreover, some legal scholars are of the opinion that in such a case the ratio must be restored by a recapitalization of our company. If our equity is reduced, we could recapitalize by means of issuing new shares or having our current shareholders contribute additional capital to our company, although there can be no assurance that we would be able to find purchasers for new shares or that any of our current shareholders would be willing to contribute additional capital. These laws regarding the ratio of debt securities to capital and reserves do not apply to issuances of debt securities to professional investors (as defined by Italian law). However, in such a case, should the professional investors transfer such debt securities to third parties not qualified as professional investors, the former remain liable to us for the payment of such securities.

Reduction of equity by losses

Italian law requires us to reduce our shareholders' equity in certain situations. Our shareholders' equity has three main components: capital, legal reserves and other shareholders' equity (such as any premium paid for the shares over the par value and any retained earnings). We apply our losses from operations against our shareholders' equity other than legal reserves and capital first. If additional losses remain, or if we have no shareholders' equity other than legal reserves and capital, and the additional losses are more than one-third of the amount of our legal reserves and capital, our board of directors must call a shareholder's meeting as soon as possible. The shareholders must vote to elect to either reduce the legal reserves and capital by the amount of the remaining losses, or to carry the losses forward for up to one year. If the shareholders vote to elect to carry the losses forward up to one year, and at the end of the year, the losses are still more than one-third of the amount of the legal reserves and capital, then we must reduce our legal reserves and capital by the amount of the losses. However, as an S.p.A., we must maintain capital of at least €120 thousand. If the amount of the losses would reduce our capital to less than €120 thousand, then:

· we would need to increase our capital, which we could do by issuing new shares or having our shareholders contribute additional capital to our company, although there can be no assurance that we would be able to find purchasers for new shares or that any of our current shareholders would be willing to contribute additional capital; or

· our shareholders would need to convert our company to an "S.r.l", which has a lower capital requirement of €10 thousand; or

· if neither of these options were taken, our shareholders or, if they do not so resolve, a court of competent jurisdiction, could appoint a receivor to liquidate our company.

Segregation of assets and proceeds

Pursuant to the 2003 corporate law reform, effective January 1, 2004, our board of directors may resolve to segregate our assets into one or more separate pools. Such pools of assets may have an aggregate value not exceeding 10% of our shareholders' equity. Each pool of assets must be used exclusively for the carrying out of a specific business and may not be attached by our general creditors Similarly, creditors with respect to such specific business may only attach those assets that are included in the corresponding pool. Tort creditors, on the other hand, may always attach any of our assets. Our board of directors may authorize us to issue securities carrying economic and administrative rights relating to a pool. In addition, financing agreements relating to the funding of a specific business may provide that the proceeds of such business be used exclusively to repay the financing. Such proceeds may be attached only by the financing party and such financing party would have no recourse against other assets of ours.

We have no present intention to enter into any such transaction and none is currently in effect.

Liquidation rights

Pursuant to Italian law and subject to the satisfaction of the claims of all creditors, our shareholders are entitled to a distribution in liquidation that is equal to the par value of their shares (to the extent available out of our net assets). Preferred shareholders and holders of "participating certificates" typically do not participate in the distribution of assets of a dissolved corporation beyond their established contractual preferences. Once the rights of preferred shareholders and holders of participating certificates and the claims of all creditors have been fully satisfied, holders of ordinary shares are entitled to the distribution of any remaining assets.

Purchase of shares by us

We are permitted to purchase our outstanding shares, subject to certain conditions and limitations provided for by Italian law. We may only purchase the shares out of profits available for dividends or out of distributable reserves, in each case as appearing on the latest shareholder-approved financial statements. Further, we may only repurchase fully paid-in shares. Such purchases must be authorized by our shareholders by vote at an ordinary shareholders' meeting. The number of shares to be acquired, together with any shares previously acquired by us or any of our subsidiaries may not (except in limited circumstances) exceed in aggregate 10% of the total number of shares then issued and the aggregate purchase price of such shares may not exceed the earnings reserve specifically approved by shareholders. Shares held in excess of such 10% limit must be sold within one year of the date of purchase. Similar limitations will apply with respect to purchases of our ordinary shares by any subsidiaries we may create in the future.

A corresponding reserve equal to the purchase price of such shares must be created in the balance sheet, and such reserve is not available for distribution, unless such shares are sold or cancelled. Shares purchased and held by us may be resold only pursuant to a resolution of our shareholders adopted at an ordinary shareholders' meeting. The voting rights attaching to the shares held by us or our subsidiaries cannot be exercised, but the shares can be counted for quorum purposes in shareholders' meetings. Dividends and other rights, including pre-emptive rights, attaching to such shares will accrue to the benefit of other shareholders.

Notification of the acquisition of shares

In accordance with Italian antitrust laws, the Italian Antitrust Authority is required to prohibit the acquisition of control in a company which would thereby create or strengthen a dominant position in the domestic market or a significant part thereof and which would result in the elimination or substantial reduction, on a lasting basis, of competition, provided that certain turnover thresholds are exceeded. However, if the turnover of the acquiring party and the company to be acquired exceed certain other monetary thresholds, the antitrust review of the acquisition falls within the exclusive jurisdiction of the European Commission.

Minority shareholders' rights; withdrawal rights

Shareholders' resolutions which are not adopted in conformity with applicable law or our by-laws may be challenged (with certain limitations and exceptions) within ninety days by absent, dissenting or abstaining shareholders representing individually or in the aggregate at least 5% of our share capital (as well as by our board of directors or our board of statutory auditors). Shareholders not reaching this threshold or shareholders not entitled to vote at our meetings may only claim damages deriving from the resolution.

Dissenting or absent shareholders may withdraw from the company as a result of shareholders' resolutions approving, among others things, material modifications of our purpose or of the voting rights of our ordinary shares, our transformation from a share corporation into a different legal entity or the transfer of our registered seat outside Italy. In such a case, our other shareholders would have a pre-emptive right to purchase the shares of the withdrawing shareholder. Should no shareholder exercise that pre-emptive right, the shares must be offered to third parties or, in

the absence of any third party wishing to buy them, they will be purchased by us by using the available reserves. In the event no reserve is available, our capital must be reduced accordingly. According to the 2003 corporate law reform, any repurchase of such shares by us must be on terms authorized by our board of directors, upon consultation with our board of statutory auditors and our external auditor, having regard to our net assets value, our prospective earnings and the market value of our ordinary shares, if any. Under the 2003 corporate law reform, we may set forth different criteria in our bylaws for the consideration to be paid to withdrawing shareholders. We have not done so as of the date of this annual report.

Each shareholder may bring to the attention of the board of statutory auditors facts or acts which such shareholder deems wrongful. If such shareholders represent more than 5% of our share capital, our board of statutory auditors must investigate without delay and report its findings and recommendations to our shareholders' meeting. Shareholders representing more than 10% of our share capital have the right to report to the competent court serious breaches of the duties of the directors which may be prejudicial to us or to our subsidiaries. In addition, shareholders representing at least 20% of our share capital may commence derivative suits before the competent court against our directors, statutory auditors and general managers. We may waive or settle the suit unless shareholders holding at least 20% of the shares vote against such waiver or settlement. We will reimburse the legal costs of such action in the event that the claim of such shareholders is successful and the court does not award such costs against the relevant directors, statutory auditors or general managers.

Liability for mismanagement of subsidiaries

Pursuant to the 2003 corporate law reform, if we, acting in our own interest or the interest of third parties, mismanage a company that we control, we are liable to that company's shareholders and creditors for ensuing damages. That liability is excluded if the ensuing damage is fully eliminated, including through subsequent transactions, or the damage is effectively offset by the global benefits deriving in general to the company from the continuing exercise of such direction and coordination powers. We are presumed to have control over, among other companies, any subsidiary whose financial statements are consolidated into ours. Since we currently have no subsidiaries, this law does not apply to us at this time.

LIMITATION OF LIABILITY AND INDEMNIFICATION MATTERS

Insofar as indemnification for liabilities arising under Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or persons controlling our company under the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

THE NASDAQ GLOBAL MARKET

Our ADSs are listed on The Nasdaq Global Market under the trading symbol "GENT."

COMPARISON OF ITALIAN AND DELAWARE CORPORATE LAWS

WE ARE GOVERNED BY THE CORPORATE LAWS IN ITALY, WHICH ARE IN SOME CASES LESS FAVORABLE TO SHAREHOLDERS THEN THE CORPORATE LAWS IN DELAWARE, UNITED STATES.

The following is a summary of material differences between the Delaware General Corporate Law and the laws of Italy.

Mergers and other extraordinary corporate transactions

Under Delaware law, a merger or consolidation requires the approval of a majority of the votes cast by the holders of shares entitled to vote in person or by proxy and if any class or series is entitled to vote thereon as a class, the affirmative vote of a majority of the shares within each class or series entitled to vote as a class in person or by proxy, unless the certificate of incorporation requires a greater vote. The sale, lease, exchange or other disposition of all, or substantially all, the property and assets, of a Delaware corporation requires a majority vote unless the certificate of incorporation requires a greater vote. Under Delaware law, the dissolution of a corporation requires a majority vote unless the certificate of incorporation requires a greater vote.

Under Italian law, a merger or consolidation requires the approval of a majority of the votes cast by the shareholders entitled to vote in person or by proxy at an extraordinary shareholders' meeting. Our bylaws designate power to approve mergers of wholly-owned subsidiaries and subsidiaries of which we own at least 90% to our board of directors, although our shareholders may overrule our board of directors.

Amendments to charter documents

Under Delaware law, charter documents are composed of two documents: a certificate of incorporation and bylaws. An amendment to the certificate of incorporation ordinarily requires a majority vote (unless the certificate of incorporation requires a greater vote). If a class or series is entitled separately to vote on an amendment, its majority vote (unless the certificate of incorporation requires a greater vote), separately calculated, is necessary to approve the

amendment. In addition, under Delaware law, the holders of outstanding shares of a class or series are entitled to vote as a class upon a proposed amendment by a majority vote (unless the certificate of incorporation requires a greater vote), whether or not entitled to vote thereon by the provisions of a company's certificate of incorporation, if the amendment would have certain effects identified in Delaware law.

Under Delaware law, directors of a corporation may adopt, amend or repeal the corporation's bylaws, unless the certificate of incorporation reserves the power exclusively to the shareholders, or the shareholders, in amending, repealing or adopting a particular bylaw, expressly provide that the board of directors may not amend or repeal that bylaw. Unless the certificate of incorporation or a bylaw adopted by the shareholders provides otherwise, a corporation's shareholders may amend, repeal or adopt the corporation's bylaws even though the bylaws may also be amended, repealed or adopted by its directors.

Under Italian law, the charter documents are composed of articles of association and bylaws. An amendment to these documents requires the approval of a majority of the votes cast by the shareholders entitled to vote in person or by proxy at an extraordinary shareholders' meeting, except that certain extraordinary actions, such as change in our purpose, liquidation or issuance of preferred shares and others, only require the approval of more than one-third of our outstanding shares for both first and second call.

Naming of companies

Under Delaware law a company shall use one of these same endings or others, including “association”, “company”, “corporation”, “club”, “foundation”, “fund”, “incorporated,” “institute”, “society”, “union”, “syndicate” or “limited” (or thereof, with or without punctuation), or words (or abbreviations thereof, with or without punctuation) of like import of foreign countries or jurisdictions (provided they are written in roman characters or letters).

Under Italian law, the name of a corporation must end in “S.p.A.” or “Societá per Azioni.”

Capital

Delaware law permits companies to be incorporated with par value shares, no par value shares or a combination of such. If a Delaware company issues par value shares and receives an amount in excess of the par value, the directors may attribute a portion of the excess as “capital.” If a Delaware company issues no par value shares, the directors may attribute a portion of the amount paid as “capital.”

Italian law permits companies to be incorporated with par value shares, no par value shares or a combination of such. If an Italian company issues par value shares and receives an amount in excess of the par value, the par value is attributed as “capital” and the excess is attributed to a “premium reserve,” which is part of shareholders’ equity. If an Italian company issues no par value shares, the entire amount is attributed as “capital.”

Franchise tax

Delaware levies a franchise tax based on authorized capital. Italian law has no such tax.

Liability of shareholders

The liability of shareholders of a Delaware company is limited to the amount paid for their shares. The liability of shareholders of a Italian company is also limited to the amount paid for their shares.

Quorum of shareholders

Under Delaware law, with respect to any matter, a quorum shall be present at a meeting of shareholders if the holders of a majority of the shares entitled to vote are represented at the meeting in person or by proxy, unless otherwise provided in the certificate of incorporation. Where a separate vote by a class or series or classes or series is required, a quorum shall be present at a meeting of shareholders if the holders of a majority of the shares entitled to vote are represented at the meeting in person or by proxy, unless otherwise provided in the certificate of incorporation.

Under Italian law, a quorum shall be present at an ordinary meeting of shareholders on first call if the holders of 50% of the outstanding ordinary shares are represented at the meeting in person or by proxy, but there is no quorum requirement on second call. A quorum shall be present at an extraordinary meeting of shareholders on first call if the holders of a majority of the outstanding ordinary shares are represented at the meeting in person or by proxy and if the holders of more than one-third of the outstanding shares are represented at the meeting in person or proxy on second call.

Actions without a meeting-shareholders

Under Delaware law, shareholders may take action without a meeting if a consent in writing is signed by the shareholders having the minimum number of votes that would be necessary to take such action at a meeting, unless the certificate of incorporation provides otherwise.

Under Italian law, shareholders may not act without a meeting.

Special/extraordinary meetings

Under Delaware law, special meetings of shareholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or the bylaws.

Under Italian law, an extraordinary shareholders' meeting may be called by our board of directors and must be called if requested by holders of at least 10% of the issued shares. Shareholders are not entitled to request that a meeting of shareholders be convened to vote on issues which as a matter of law shall be resolved upon the basis of a proposal, plan or report by our board of directors. If the shareholders' meeting is not called despite the request by shareholders and such refusal is unjustified, a competent court may call the meeting.

Director qualifications

Under Delaware law, directors need not be residents of Delaware or shareholders of the corporation unless the certificate of incorporation or bylaws so require. The certificate of incorporation or bylaws may prescribe other qualifications for directors.

Under Italian law, the only requirement for directors is that they have not been deemed "legally incompetent" to be a director under Italian law. "Legal incompetence" is determined by a competent court and can be determined for reasons such as lack of mental capacity, physical incapability, emotional instability, bankruptcy, certain criminal convictions or drug or alcohol addiction.

Election of directors

Under Delaware law, unless otherwise provided in the certificate of incorporation, shareholders are not entitled to cumulative voting in the election of directors. Absent such provision, the directors of a corporation are elected by a plurality of the votes cast by the holders of shares entitled to vote in person or by proxy at a meeting of shareholders at which a quorum is present.

Under Italian law, shareholders are not entitled to cumulative voting in the election of directors. The directors of a corporation are elected by a majority of the votes cast by the holders of shares entitled to vote in person or by proxy at an ordinary meeting of shareholders at which a quorum is present.

Actions without a meeting - directors

Under Delaware law, any action required or permitted to be taken at any meeting of the board of directors may be taken without a meeting if all members of the board consent to it in writing or by electronic transmission, and the writing or electronic transmission is filed with the minutes of proceedings of the board unless otherwise restricted by the certificate of incorporation or bylaws.

Under Italian law, directors may not act without a meeting.

Removal of directors

Under Delaware law, one or more or all the directors of a corporation may be removed for cause or, unless provided in the certificate of incorporation, removed without cause by the shareholders by the affirmative vote of the majority of votes cast by the holders of shares entitled to vote thereon, subject to certain exceptions.

Under Italian law, directors may be removed from office at any time by the vote of shareholders at an ordinary shareholders' meeting although, if removed in circumstances where there was no just cause, such directors may have a claim for damages against us. These damages may include, but are not limited to, compensation that would otherwise have been paid to the director for the remainder of their term and damage to their reputation. Our board of directors must appoint substitute directors to fill vacancies arising from removals, subject to the approval of the board of statutory auditors, to serve until the next ordinary shareholders' meeting. If at any time more than half of the members of our board of directors are removed or otherwise cease to be directors, the board of directors in its entirety ceases to be in office and our board of statutory auditors must promptly call an ordinary shareholders' meeting to appoint new directors.

Location of directors meetings

Delaware law provides that, unless otherwise restricted by the certificate of incorporation or bylaws, the board may hold its meetings outside of the State of Delaware. Under Italian law and our bylaws, meetings of our board of directors may be held in person, or by audio-conference or tele-conference, in any member state of the European Union or in the United States.

Limitation of liability and indemnification

Delaware law requires directors and members of any committee designated by the board of directors to discharge their duties in good faith and with that degree of diligence, care and skill which ordinary prudent people would exercise under similar circumstances and positions. Delaware law permits a corporation to set limits on the extent of a director's liability. Italian law requires directors and members of any committee designated by the board of directors to discharge their duties in good faith and with that degree of diligence required by the nature of their office and their specific competence. If we cannot repay our creditors, and a court determines that our directors did not perform their duties regarding the preservation of our assets, the court may find our directors liable to our creditors. Italian law permits a corporation to set limits on the extent of a director's liability. We intend to enter into indemnification agreements with our directors. We have already agreed to indemnify our directors for any tax penalties inflicted upon, among other people, our directors who, when acting on our behalf and in our interest, breach or cause breaches of tax laws unintentionally, except in the case of fraud, and to consider, on a case by case basis, waiving our right of recourse against directors who breach tax laws that result in monetary penalties inflicted on us.

Dividends

Delaware law provides that the board of directors of a corporation may authorize and the corporation may make distributions subject to any restrictions in its certificate of incorporation. However, Delaware law provides that distributions may not be made if, after giving effect to the distribution, the corporation would not be able to pay its debts as they become due in the usual course of its business or total assets would be less than total liabilities.

Under Italian law, our payment of any annual dividend must be proposed by our board of directors and is subject to the approval of our shareholders at the annual ordinary shareholders' meeting. Before dividends may be paid out of our unconsolidated net income in any year, we must allocate an amount equal to 5% of the net income to our legal reserve until such reserve is at least equal to 20% of the aggregate par value of our issued shares, which we call our "capital." If our capital is reduced as a result of accumulated losses, we may not pay dividends until the capital is reconstituted or reduced by the amount of such losses. We may pay dividends out of available retained earnings from prior years, provided that after such payment, we will have a legal reserve at least equal to the legally required minimum of 20% of the capital. We may not approve or pay dividends until this minimum is met. If the minimum is met, the board of directors proposes the issuance of a dividend and the shareholders' resolution approves that issuance, the shareholders' resolution will specify the manner and the date for their payment. Any dividends which shareholders do not collect within five years of the date on which they become payable will be forfeited by those shareholders and we will keep the money. The board of directors may not approve interim dividends at times between our annual ordinary shareholders' meetings.

Return of capital

Delaware law provides that corporations may return capital by dividend, redemption or repurchase subject to certain solvency tests. Shareholder approval is not required for these transactions so long as the corporation meets the solvency tests.

Under Italian law, we are permitted to purchase our outstanding shares, subject to certain conditions and limitations provided for by Italian law. We may only purchase the shares out of profits available for dividends or out of distributable reserves, in each case as appearing on the latest shareholder-approved financial statements. Further, we may only repurchase fully paid-in shares. Such purchases must be authorized by our shareholders by vote at an ordinary shareholders' meeting. The number of shares to be acquired, together with any shares previously acquired by us or any of our subsidiaries may not (except in limited circumstances) exceed in aggregate 10% of the total number of shares then issued and the aggregate purchase price of such shares may not exceed the earnings reserve specifically approved by shareholders. Shares held in excess of such 10% limit must be sold within one year of the date of purchase. Similar limitations will apply with respect to purchases of our ordinary shares by any subsidiaries we may create in the future.

A corresponding reserve equal to the purchase price of such shares must be created in the balance sheet, and such reserve is not available for distribution, unless such shares are sold or cancelled. Shares purchased and held by us may be resold only pursuant to a resolution of our shareholders adopted at an ordinary shareholders' meeting. The voting rights attaching to the shares held by us or our subsidiaries cannot be exercised, but the shares can be counted for quorum purposes in shareholders' meetings. Dividends and other rights, including pre-emptive rights, attaching to such shares will accrue to the benefit of other shareholders.

Officers

Under Delaware law, a corporation is required to have such officers as are required to sign instruments to be filed with the Secretary of State and stock certificates. It is necessary that the corporation have at least two officers to comply with this requirement. The corporation has complete freedom to designate its executives by whatever names it wishes

and to allocate the managerial power delegated to executives as the corporation may wish. Any number of offices may be held by the same person unless otherwise provided by the certificate of incorporation or the by-laws. Officers may be chosen in any way and by any person or body if the by-laws or a resolution of the governing body so specifies.

Under Italian law, there are no requirements for any specific numbers or titles of officers.

Share certificates

Under Delaware law, the shares of a corporation shall be represented by certificates, provided that the board of directors of the corporation may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertified stock. However, existing shareholders and future shareholders are able to obtain a stock certificate signed by or in the name of the corporation by the chairman or vice-chairman of the board of directors or the president or vice-president, and by the treasurer or an assistant treasurer, or the secretary or an assistant secretary of such corporation if they desire. The terms governing preferred stock must be expressed “in clear language” in the certificate of incorporation (or by a separate resolution authorized by the charter).

Under Italian law, the shares of a corporation may be issued in either registered or certificated form. Our bylaws provide that our ordinary shares are not certificated. Rather, they are held through various participants, primarily institutions, on Monte Titoli's system and registered by book-entry form on our shareholders book.

Preemptive rights

Under Delaware law, shareholders do not possess preemptive rights as to the issuance of additional securities by the corporation, unless the certificate of incorporation provide otherwise.

Under Italian law, holders of outstanding ordinary shares and convertible debentures are entitled to subscribe for issuance of ordinary shares or convertible debentures in proportion to their holdings at the time that the shareholders authorize the capital increase for those issuances, unless those issuances are for non-cash considerations. The preemptive rights may be waived or limited by shareholders' resolution adopted by the affirmative vote of holders of more than 50 percent of the ordinary shares at an extraordinary meeting of shareholders and such waiver or limitation is in the interest of our company.

Liquidation rights generally

Under Delaware law, shareholders are entitled to share ratably in the distribution of assets upon the dissolution of their corporation. Preferred shareholders typically do not participate in the distribution of assets of a dissolved corporation beyond their established contractual preferences. Once the rights of preferred shareholders have been fully satisfied, holders of common stock are entitled to the distribution of any remaining assets.

Under Italian law, and subject to the satisfaction of the claims of all creditors, our shareholders are entitled to a distribution in liquidation that is equal to the par value of their shares (to the extent available out of our net assets). Preferred shareholders and holders of "participating certificates" typically do not participate in the distribution of assets of a dissolved corporation beyond their established contractual preferences. Once the rights of preferred shareholders and holders of participating certificates have been fully satisfied, holders of ordinary shares are entitled to the distribution of any remaining assets.

Shareholder derivative suits

Under Delaware law, a derivative suit may be brought only if the plaintiff was a record or beneficial owner of shares at the time of the transaction of which he or she complains, and the initial pleading in the suit states that the ownership requirement is satisfied, and with particularity, the efforts of the plaintiff to have the suit brought for the corporation by the board of directors, or the reasons for not making such efforts. The court may require the plaintiff to give security for the expenses incurred or expected to be incurred by the defendants. The court may also require the plaintiff to pay expenses to the defendants if the court finds, upon final judgment for the defendants, that the suit was brought without reasonable cause.

Under Italian law, a shareholder's name must be entered in the shareholder's register in order to establish his rights as a shareholder against us. Each shareholder may bring to the attention of the board of statutory auditors facts or acts which such shareholder deems wrongful. If such shareholders represent more than 5% of our share capital, our board of statutory auditors must investigate without delay and report its findings and recommendations to our shareholders' meeting. Shareholders representing more than 10% of our share capital have the right to report to the competent court serious breaches of the duties of the directors which may be prejudicial to us or to our subsidiaries. In addition, shareholders representing at least 20% of our share capital may commence derivative suits before the competent court against our directors, statutory auditors and general managers. We may waive or settle the suit unless shareholders holding at least 20% of the shares vote against such waiver or settlement. We will reimburse the legal costs of such action in the event that the claim of such shareholders is successful and the court does not award such costs against the

relevant directors, statutory auditors or general managers.

Dissenters' rights

Any shareholder of a Delaware corporation has the right to dissent from any plan of merger or consolidation to which the corporation is a party, provided that unless the certificate of incorporation otherwise provides, a shareholder shall not have the right to dissent from any plan of merger or consolidation with respect to shares of a class or series which is listed on a national securities exchange or is held of record by not less than 2,000 holders on the record date fixed to determine the shareholders entitled to vote upon the plan of merger or consolidation. A dissenting shareholder has a right of appraisal of its shares.

Under Italian law, shareholders' resolutions which are not adopted in conformity with applicable law or our by-laws may be challenged (with certain limitations and exceptions) within ninety days by absent, dissenting or abstaining shareholders representing individually or in the aggregate at least 5% of our share capital (as well as by our board of directors or our board of statutory auditors). Shareholders not reaching this threshold or shareholders not entitled to vote at our meetings may only claim damages deriving from the resolution.

Dissenting or absent shareholders may withdraw from the company as a result of shareholders' resolutions approving, among others things, material modifications of our purpose or of the voting rights of our ordinary shares, our transformation from a share corporation into a different legal entity or the transfer of our registered office outside Italy. In such a case, our other shareholders would have a pre-emptive right to purchase the shares of the withdrawing shareholder. Should no shareholder exercise that pre-emptive right, the shares must be offered to third parties or, in the absence of any third party wishing to buy them, they will be purchased by us by using the available reserves. In the event no reserve is available, our capital must be reduced accordingly. According to the 2003 corporate law reform, any repurchase of such shares by us must be on terms authorized by our board of directors, upon consultation with our board of statutory auditors and our external auditor, having regard to our net assets value, our prospective earnings and the market value of our ordinary shares, if any. Under 2003 corporate law reform, we may set forth different criteria in our bylaws for the consideration to be paid to withdrawing shareholders in such withdrawal. We have not done so as of the date of this annual report.

Interested shareholder transactions

Delaware corporations are subject to the State of Delaware's "business combination" statute. In general, that statute prohibits a publicly-traded corporation from engaging in various "business combination" transactions with any "interested stockholder" for a period of three years after the time that the shareholder became an interested stockholder, unless the business combination is approved by the board prior to the time the shareholder became an interested stockholder, the interested stockholder acquired 85% or more of the outstanding shares in a transaction in which it became an interested stockholder, or the business combination is approved by the board and by holders of two-thirds of the shares not held by the interested stockholder. A "business combination" includes mergers, assets sales and other transactions resulting in financial benefit to a shareholder. An "interested stockholder" is a person who, together with affiliates and associates, owns 15% or more of a corporation's voting stock.

Under Italian law, directors having any interest in a proposed transaction must disclose their interest to the board and to the statutory auditors, even if such interest is not in conflict with our interest in the same transaction. The interested director is not required to abstain from voting on the resolution approving the transaction, but the resolution must state explicitly the reasons for, and the benefit to us of, the approved transaction. If these provisions are not complied with, or if the transaction would not have been approved without the vote of the interested director, the resolution may be challenged by a director or by our board of statutory auditors if the approved transaction may be prejudicial to us. A legal representative of our company having any interest in a proposed transaction that he or she has authority to approve must solicit prior board approval of such transaction. The interested director may be held liable for damages to us resulting from a resolution adopted in breach of the above rules. Finally, directors may be held liable if they illicitly profit from insider information or corporate opportunities.

Inspection of books and records

Under Delaware law, upon the written request of any shareholder, the corporation shall mail to such shareholder its balance sheet as at the end of the preceding fiscal year, and its profits and loss and surplus statements for such fiscal year. Inspection rights are extended to any person who beneficially owns stock through either a voting trustee or nominee who holds the stock of record on behalf of such person. Where the shareholder is other than a record holder, such person must state under oath the person's status as a shareholder and produce documentary evidence of beneficial ownership. Any shareholder is entitled to examine a corporation's relevant books and records for any proper purpose, namely, a purpose reasonably related to such person's interest as a shareholder, upon written demand stating the purpose thereof.

Under Italian law, our shareholders may review the report of the board of directors on the management of our company and the report of our statutory auditors and our accounting firm on our financial statements during the fifteen days prior to the ordinary shareholders' meeting to approve those financial statements. The report remains on file at our

offices and may be reviewed after the annual shareholders' meeting as well; it is filed with the Companies' Registry of Como for review by the general public. Moreover, any shareholder is entitled to examine the shareholders' ledger and the ledger of the minutes of the shareholders' meeting, at any time.

Registered office

Delaware law requires a "registered office" in Delaware. Italian law requires a registered office in Italy.

Issuance of shares

Under Delaware law, directors have the authority to issue shares of common stock. If the certificate of incorporation so provides, they may also designate the terms of preferred stock and issue shares of preferred stock.

Under Italian law, issuances of any shares, ordinary or otherwise, require an amendment to our bylaws to increase our capital, which must be recommended to our shareholders by our board of directors and approved by a vote of our shareholders at an extraordinary meeting of shareholders. Our shareholders may not authorize the issuance of shares for a period of more than five years from the date of the extraordinary shareholders' meeting. Once our shareholders have authorized the issuance of securities, those securities must be paid for before the newly issued shares may be purchased. The board would also need to recommend, and the shareholders would need to approve by vote at the extraordinary meeting, specific terms of the securities. Also, our shareholders can authorize the board of directors to increase our capital, one or more times, for a certain amount, 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.

Debt-equity ratio

Under Delaware law, a corporation is not restricted as to the amount of debt securities that it may issue.

Under Italian law, we may issue debt securities for an amount not exceeding twice the amount of the sum of the aggregate par value of our ordinary shares (which we call our capital), our legal reserve and any other disposable reserves appearing on our latest Italian balance sheet approved by our shareholders. The legal reserve is a reserve to which we allocate 5% of our net income each year until it equals at least 20% of our capital. One of the other reserves that we maintain on our balance sheet is a "share premium reserve", meaning amounts paid for our ordinary shares in excess of the capital. Until our outstanding debt securities are repaid in full, we may not voluntarily reduce our capital or distribute our reserves (such as by declaring dividends) in the event the aggregate of the capital and reserves, following such reduction of capital and/or distribution of reserves, is less than half of the outstanding amount of the debt securities. If our equity is reduced by losses or otherwise such that the amount of the outstanding debt securities is more than twice the amount of our equity, we cannot distribute profits to our shareholders until the ratio between the amount of our debt securities and our capital and reserves is restored. Moreover, some legal scholars are of the opinion that in such a case the ratio must be restored by a recapitalization of our company. If our equity is reduced, we could recapitalize by means of issuing new shares or having our current shareholders contribute additional capital to our company, although there can be no assurance that we would be able to find purchasers for new shares or that any of our current shareholders would be willing to contribute additional capital. These laws regarding the ratio of debt securities to capital and reserves do not apply to issuances of debt securities to professional investors (as defined by Italian law). However, in such a case, should the professional investors transfer such debt securities to third parties not qualified as professional investors, the former remain liable to us for the payment of such securities.

Reduction of equity by losses

Under Delaware law, a corporation's shareholders' equity is reduced by losses, and may become negative.

Italian law requires us to reduce our shareholders' equity in certain situations. Our shareholders' equity has three main components: capital, legal reserves and other shareholders' equity (such as any premium paid for the shares over the

par value and any retained earnings). We apply our losses from operations against our shareholders' equity other than legal reserves and capital first. If additional losses remain, or if we have no shareholders' equity other than legal reserves and capital, and the additional losses are more than one-third of the amount of our legal reserves and capital, our board of directors must call a shareholder's meeting as soon as possible. The shareholders must vote to elect to either reduce the legal reserves and capital by the amount of the remaining losses, or to carry the losses forward for up to one year. If the shareholders vote to elect to carry the losses forward up to one year, and at the end of the year, the losses are still more than one-third of the amount of the legal reserves and capital, then we must reduce our legal reserves and capital by the amount of the losses. However, as an S.p.A., we must maintain capital of at least €120 thousand. If the amount of the losses would reduce our capital to less than €120 thousand, then:

· we would need to increase our capital, which we could do by issuing new shares or having our shareholders contribute additional capital to our company, although there can be no assurance that we would be able to find purchasers for new shares or that any of our current shareholders would be willing to contribute additional capital; or

· our shareholders would need to convert our company to an "S.r.l", a private limited liability company, which has a lower capital requirement of €10 thousand; or

· if neither of these options were taken, our shareholders or, if they do not so resolve, a court of competent jurisdiction, could appoint a receivor to liquidate our company.

Comparison of our Corporate Governance Procedures with Nasdaq's Corporate Governance Requirements

The Nasdaq Marketplace Rules set forth the corporate governance requirements of companies listed on The Nasdaq Stock Market. Subsection (a)(1) of Marketplace Rule 4350 provides that a foreign private issuer may follow its home country practices in lieu of the corporate governance requirements of The Nasdaq Stock Market, under certain circumstances. Pursuant to this Marketplace Rule 4350(a)(1), we follow Italian practices in lieu of four of The Nasdaq Stock Market's corporate governance requirements pertaining to: (1) quorum requirements, (2) our audit committee, (3) distribution of an annual report and (4) solicitation of proxies and provision of proxy statements for shareholder's meetings.

Quorum requirements.

The Nasdaq Stock Market: Marketplace Rule 4350(f) sets forth The Nasdaq Stock Market's quorum requirement for shareholder meetings, stating that "in no case shall such quorum be less than 33 1/3% of the outstanding shares of the company's common voting stock."

Italian practices: In accordance with Italian law, our shareholders are entitled to attend and vote at an ordinary and extraordinary shareholders' meetings. Shareholders are notified of two meeting dates for an ordinary and extraordinary shareholders' meeting (first and second "calls"). The quorum for an ordinary meeting of shareholders on the first call is 50% of the outstanding ordinary shares, while on a second call there is no quorum requirement. The quorum for an extraordinary meeting of shareholders is a majority of the outstanding ordinary shares on the first call and more than one-third of the outstanding shares on a second call.

Audit committee.

The Nasdaq Stock Market: Rule 4350(d)(3) of The Nasdaq Marketplace Rules requires compliance with Rule 10A-3 of the Securities Exchange Act of 1934, as amended, which requires that:

- a company's audit committee be directly responsible for the appointment, compensation, retention and oversight of the work of any registered public accounting firm engaged (including resolution of disagreements between management and the auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the company;
- each such registered public accounting firm must report directly to the audit committee;
- that the audit committee establish procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters;
- that the audit committee have authority to engage independent counsel and other advisors;
- that the audit committee determine compensation for the independent accountants; and
- that the audit committee determine compensation for any advisors to the audit committee, as well as its ordinary administrative expenses.

Italian practices: Under Italian law, our shareholders, not the audit committee, must be the party that appoints, terminates and determines the compensation for our independent accountants, although our audit committee does make recommendations on such matters to our board of directors, which in turn makes recommendations to our shareholders. As a result, our audit committee is not able to perform all of the duties required by Rule 10A-3 of the Securities Exchange Act of 1934, as amended. Our audit committee directly oversees our independent accountants, including the resolution of disagreements between management and the independent accountants. Under Italian law, our board of statutory auditors also oversees our independent accountants with respect to our Italian GAAP financial statements. Rule 10A-3 provides that foreign private issuers with a board of statutory auditors established in accordance with local law or listing requirements and meeting specified requirements with regard to independence and responsibilities (including the performance of most of the specific tasks assigned to audit committees by the rule, to the extent prohibited by local law) ("Statutory Auditor Requirements") are exempt from the audit committee requirements established by the rule. Our board of directors has determined that, because of the existence and nature of our board of statutory auditors, together with the performance of other duties under Rule 10A-3 by our shareholders and the performance of the remaining duties by our audit committee, we either satisfy Rule 10A-3 or qualify for an

exemption provided by Rule 10A-3 from the audit committee requirements of Rule 10A-3.

Annual Reports

The Nasdaq Stock Market: Marketplace Rule 4350(b)(1)(A) requires issuers to distribute to shareholders and Nasdaq an annual report containing audited financial statements a reasonable period time prior to the issuer's annual meeting of shareholders.

Italian practices: Italian practice is to file the issuer's Italian GAAP financial statements with its registered office (similar to a state secretary of state in the United States) at least 15 days prior to the shareholder's meeting. We also intend to post such financial statements on our website at such time.

Proxy Solicitation and Proxy Statements

The Nasdaq Stock Market: Marketplace Rule 4350(g) requires issuers to solicit proxy statements for all meetings of shareholders and to provide copies of such proxy solicitation to Nasdaq.

Italian Practice: As a foreign private issuer, we are exempt from the proxy rules of the Securities Exchange Act of 1934, as amended. We do not solicit proxies from holders of our ordinary shares, nor are we required to do so under Italian law. Our depositary, the Bank of New York, does solicit proxies from ADS holders for instructions on how to vote its ordinary shares at our shareholder meetings. The Bank of New York also delivers reports from our board of directors regarding the agenda items for the shareholder meetings to the ADS holders. We file these board reports, the Bank of New York's proxy card and any related items with the SEC on Form 6-K.

MATERIAL CONTRACTS

The contracts described below have been entered into by our company since January 1, 2005 and, as of the date of this report, contain provisions under which we have an obligation or right which is or may be material to us. This discussion is not complete and should be read in conjunction with the agreements described below, each of which has been filed with the SEC as an exhibit to this annual report.

License and Distribution Agreements

On June 14, 2005, we entered into a letter agreement amending the terms of our December 7, 2001 License and Supply Agreement with Sigma Tau Pharmaceuticals, Inc., which expanded the territory in which we licensed to Sigma Tau Pharmaceuticals, Inc. the right to market defibrotide to treat VOD from the United States to North America, Central America and South America and revised certain of the provisions relating to Sigma Tau's right of first refusal to market certain additional products.

On October 12, 2007, we entered into another letter agreement with Sigma Tau Pharmaceuticals, Inc., pursuant to which Sigma Tau Pharmaceuticals, Inc. agree to reimburse us for 50% of certain costs relating to our Phase III clinical trial of defibrotide to treat severe VOD.

On January 2, 2006, we entered into a Contract to Supply Active Ingredients with Sirton, pursuant to which we sell urokinase, calcium heparin, defibrotide, sulglicotide and glucidamine to Sirton, which Sirton uses to produce specialty pharmaceutical products. The agreement automatically renews each year unless one party gives written notice of its intent to terminate the agreement at least one month prior to the annual termination date. In 2007, we earned revenues of an aggregate of €2.704 million under this agreement. On December 1, 2007, we amended this agreement to delete references to defibrotide.

On December 28, 2006, we entered into a Master Agreement with Crinos S.p.A. whereby we agreed to acquire the Italian marketing authorizations for defibrotide, as well as certain other related assets, including trademarks, for €16 million and other consideration. We paid €4 million of the purchase price to Crinos on December 28, 2006 and paid €4 million into escrow at the same time. The escrowed sums will be released to Crinos after the official publication of the transfer of the marketing authorizations by Italian regulators, which happened in April 2007. We agreed to pay another €4 million to Crinos no later than December 31, 2007 (which we paid), and the final €4 million to Crinos no later than December 31, 2008. Crinos agreed to transfer the trademarks to us at the time of the final payment. Crinos granted us licenses to use the trademarks until such time. If the Italian regulators do not publicize the transfer of the marketing authorizations by December 31, 2007, the escrowed funds will be released to us, we will have no obligation to pay the second or third installments and the transfer of the marketing authorizations and the trademarks will not be effected. Crinos also agreed to stop distributing the injectable formulation of defibrotide starting on December 28, 2008, and the oral formulation of defibrotide starting on December 31, 2008. Crinos agreed to irrevocably waive and

terminate its right of first refusal to market future therapeutic indications for defibrotide in the European market that was set forth in our License Agreement dated May 17, 2002 with Crinos. In return, we agreed to pay Crinos a 1.5% royalty on net sales of defibrotide for the treatment and prevention of VOD in Europe for seven years, starting with the official launch date of treatment or prevention (whichever is first) of VOD in Germany, France, Italy, the United Kingdom or Spain (whichever country such product is first launched).

We also entered into a Distribution and Promotion dated December 28, 2006 with Crinos as part of the same transaction, whereby we agreed to sell the oral formulation of defibrotide to Crinos, and allow Crinos to distribute such oral formulation, until December 31, 2008, with certain exceptions for sales to hospitals and otherwise as required by Italian law. In 2007, we earned revenues of an aggregate of €1.7 million under this agreement.

Clinical Trial Agreements

On March 14, 2007, we entered into a Master Services Agreement with MDS Pharma Services (US), Inc. Under this agreement, MDS Pharma provides us with clinical and regulatory consulting services, including with respect to our current Phase III clinical trial of defibrotide to treat VOD with multiple organ failure in the United States and the related historical arm control trial. In 2007, we incurred cost for an aggregate of $6.151 million under this agreement.

Loan Agreements

On April 20, 2006, we entered into a Financing Contract with Banca Intesa Medicredito S.p.A. providing for a five year financing facility of up to €1 million to finance our purchase and installation of two reactors in our manufacturing facility. The facility has a five-year term and bears interest at the three-month Euribor rate plus 1.7%. It is secured by Banca Intesa debt securities in the aggregate amount of €525 thousand that we purchased and which expire on May 10, 2011. We make installment payments on the facility of €131 thousand every six months until its final maturity in April 2011. At December 31, 2007, the aggregate amount outstanding under this facility was €900 thousand.

On June 14, 2006, we entered into a Loan Agreement with Banca Nazionale Del Lavoro S.p.A. for a loan in the amount of €2.8 million. The loan is secured by a mortgage on certain of our land and buildings. It bears interest at the six month Euribor rate plus 1.00%, the principal of which will be repaid in 14 installments, every six months, starting from December 27, 2007 until final maturity in 2014 and the interest on which will be paid every six months starting from June 27, 2006. At December 31, 2007, the amount outstanding under this loan was €2.6 million.

On June 30, 2006, we obtained a loan in the amount of €750 thousand from San Paolo IMI 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% over the Euribor rate. The loan is payable in thirteen quarterly installments of approximately €58 beginning on June 15, 2008 through June 15, 2011. Interest is due quarterly beginning on September 15, 2006. The agreement requires us to maintain a minimum level of net shareholders' equity determined in accordance with Italian generally accepted accounting principles. At December 31, the amount outstanding under this loan was €750 thousand.

On December 20, 2006, we entered into three Loan Agreements with Banca Intesa S.p.A. The first of these was for a loan in the amount of €230 thousand for a term of 60 months, maturing on December 31, 2006. Principal and interest are due in 20 quarterly installments beginning on March 31, 2007. It bears interested at the three month Euribor rate plus 1%. At December 31, 2007, the amount outstanding under this loan was €188 thousand.

The second Loan Agreement was for a loan in the amount of €500 thousand for a term of 60 months, maturing on December 31, 2011. Principal and interest are due in 60 monthly installments beginning on January 31, 2006. It bears interest at the three month Euribor rate plus 1%. At December 31, 2007, the amount outstanding under this loan was €409 thousand.

The third Loan Agreement was for a loan in the amount of €225 thousand for a term of 57 months (after a technical preamortization period from December 20, 2006 to March 15, 2007) maturing on December 15, 2011. It must be used with six months for investments in the innovation of products and/or production processes or to buy manufacturing equipment. Principal and interest payments are due in quarterly installments starting on June 15, 2007. It bears interest at the three month Euribor rate plus 0.8%. At December 31, 2007, the amount outstanding under this loan was €193 thousand.

EXCHANGE CONTROLS

No exchange control consent is required in Italy for the transfer to persons outside of Italy of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of an Italian company.

TAXATION

Tax Consequences Applicable to US Holders

The following contains a description of the principal United States federal and Italian tax consequences of the purchase, ownership and disposition of ADSs or ordinary shares by a US holder, as defined below. This summary does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a decision to purchase ADSs representing our ordinary shares and each potential purchaser is therefore urged to consult its own tax advisor.

In particular, this summary deals only with US holders who will hold their ADSs as a capital asset and does *not* address the tax treatment of a US holder (i) who owns ADSs representing 10% or more of our voting shares (either directly or through attribution); (ii) who holds ADSs in connection with a permanent establishment or fixed base of business located in Italy; (iii) who holds ADSs in the ordinary course or as an integral part of the holder's trade or business or as part of a hedging, straddle, integrated or conversion transaction; (iv) who is subject to special treatment under the US income tax laws (such as securities dealers, brokers, traders that elect to mark to market, insurance companies, banks, tax-exempt organizations, partnerships and other pass-through entities); (v) whose functional currency is not the US dollar; or (vi) who is a resident of Italy for purposes of Italian domestic law or the Income Tax Convention, as defined below, or acts through an Italian permanent establishment or fixed base to which the ADSs are connected. In addition, the following discussion does not address any aspect of state, local or non-US tax laws (other than certain Italian tax laws) or any alternative minimum tax consequences.

The summary is based upon tax laws of the United States and the Republic of Italy and on the provisions of the income tax convention between the United States and Italy (the "Income Tax Convention") in each case as in effect on the date hereof, all of which are subject to change (possibly with retroactive effect). We will not update this summary to reflect changes in laws and if such a change occurs, this summary could become inaccurate. In this regard, a new tax treaty to replace the current income tax convention was signed on August 25, 1999, but has not yet been ratified. This new treaty, if ratified, would not change significantly the provisions of the Income Tax Convention that are discussed below. For purposes of these laws and income tax conventions, beneficial owners of ADRs representing ADSs should be treated as the beneficial owners of the ordinary shares represented by the ADSs. Prospective purchasers of the ADSs are advised to consult their own tax advisors as to the tax consequences of the purchase, ownership and disposition of the ADSs including, in particular, state and local tax consequences.

For purposes of this section, a US holder means (i) an individual citizen or resident of the United States; (ii) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) organized in or under the laws of the US or any political subdivision thereof; (iii) an estate the income of which is includible in gross income for US federal income tax purposes regardless of its source; (iv) a trust if a US court is able to exercise primary jurisdiction over the administration of the trust and one or more US persons have the authority to control all substantial decisions of the trust; and (v) any other person that is subject to US federal income taxation on a net income basis in respect of income attributable to its ownership of the ADSs. A US owner means a US holder that is considered a resident of the United States for purposes of the Income Tax Convention and who is not subject to an anti-treaty shopping provision.

It is expected that the Italian Government may in the future be authorized by the Italian Parliament to implement a general reform of the tax regime applicable to financial income.

Italian Taxation of US Holders

General. Under Italian law, financial instruments issued by an Italian company are subject to the same tax regime as shares, provided that their remuneration is entirely represented by a participation in the economic results of the issuer. Pursuant to Article 10(3) of the Income Tax Convention, the tax regime of dividends set forth therein applies to income from corporate rights of an Italian company, which is subject to the same taxation treatment as income from shares under the laws of Italy. One interpretation of these laws would be that a beneficial owner of an ADS should be subject to the same tax regime as a beneficial owner of a share for purposes of both Italian law and the Income Tax Convention. However, no official interpretation has been issued by the Italian tax authorities on this subject matter to date.

Income Tax Withholding on Dividends. We do not anticipate making any distributions with respect to our ordinary shares in the foreseeable future. However, if we were to make distributions with respect to our ordinary shares, we would generally be required under Italian law, except as otherwise discussed below, to apply a 27% final withholding tax on payments made to holders of ADSs who are not residents of Italy for tax purposes. Under Italian law, US owners can claim a refund of up to four-ninths of the Italian withholding tax withheld on dividends (thereby effectively reducing the rate of withholding to 15%) by presenting evidence to the Italian tax authorities that income taxes have been fully paid on the dividends in the country of residence of the US owners in an amount at least equal to the total refund claimed. US holders should consult their own tax advisers concerning the possible availability of this refund, which traditionally has been payable only after extensive delays.

Under the Income Tax Convention, dividends paid to US owners will be subject to Italian withholding tax at a reduced rate of 15%. However, the amount that we will initially make available to the depositary for payment to US owners will reflect withholding at the 27% rate. US owners who comply with the certification procedures described below may claim a refund of the difference between the 27% rate and the 15% rate (referred to herein as a "treaty refund"). The certification procedure will require the US owner (i) to obtain from the US Internal Revenue Service

(generally, by filing Form 8802) a form of certification required by the Italian tax authorities with respect to each dividend payment (Form 6166, printed on U.S. Department of Treasury stationary), unless a previously filed certification is effective with respect to the payment, (ii) to produce a statement whereby the US owner represents that it is a US owner that does not maintain a permanent establishment in Italy, and (iii) to set forth certain other required information. The time for processing requests for certification by the Internal Revenue Service can be lengthy. Accordingly, US owners should begin the process of obtaining a certification from the Internal Revenue Service as soon as possible after receiving instructions from the depositary.

The depositary's instructions will specify certain deadlines for delivering the documentation required to obtain a treaty refund, including the certification that the US owners must obtain from the US Internal Revenue Service. In the case of ADSs held by US owners through a broker or other financial intermediary, the required documentation should be delivered to such financial intermediary for transmission to the depositary. In all other cases, US owners should deliver the required documentation directly to the depositary. We have agreed with the depositary that if the required documentation is received by the depositary on or within 30 days after the dividend payment date and, in our reasonable judgment, such documentation satisfies the requirements for a refund of Italian withholding taxes under the income tax convention then in effect between the United States and Italy, we will (within 45 days after that) pay an amount equal to the treaty refund to the depositary for the benefit of the US owners entitled thereto.

If the depositary does not receive a US owner's required documentation within 30 days after the dividend payment date, the US owner may for a short grace period (specified in the depositary's instructions) continue to claim an amount equal to the treaty refund by delivering the required documentation (either through the US owner's financial intermediary or directly, as the case may be) to the depositary. However, after this grace period, the treaty refund must be claimed directly from the Italian tax authorities rather than through the depositary. Expenses and extensive delays have been encountered by US owners seeking refunds from the Italian tax authorities.

Income Tax on Capital Gains. Under Italian law, capital gains realized by a person who is not a resident of Italy (not having a permanent establishment or fixed base in Italy to which the ADSs are connected) on the disposal of a "qualified" shareholding contribute to determine the overall taxable income for income tax purposes, to the extent of forty percent (40%) of the overall gain. Losses can be offset against taxable gains for a corresponding amount and, if in excess, can be carried forward up to four years. A "qualified" shareholding is defined as ordinary shares and/or rights (including ADSs) that represent more than 20% of share capital voting in the ordinary shareholders' meeting or 25% of a company's total share capital. A "disposal" of a qualified shareholding occurs if, in any 12-month period following the date when a shareholding meets one of the thresholds illustrated above, a shareholder disposes of shares or ADSs that, individually or in the aggregate, constitute a "qualified" shareholding. The taxable gain realized by (i) an individual shareholder who is not a resident of Italy would be subject to progressive personal income tax rates presently ranging from 23% 43%; (ii) a corporate shareholder who is not a resident of Italy would be subject to corporate income tax, currently levied at a rate of 27.5%.

Generally, Italian capital gain tax, levied at a rate of 12.5%, is imposed on gains realized upon the transfer or sale of "non-qualified" shareholdings whether held within or outside Italy. A "non-qualified" shareholding is defined as an interest in ordinary shares and/or rights (including ADSs) which does not reach the thresholds described above for a qualified shareholding.

Furthermore, pursuant to the Income Tax Convention, a US owner will not be subject to Italian capital gain tax or to Italian individual or corporate income tax unless such US owner has a permanent establishment or fixed base in Italy to which the owner's ADSs is effectively connected. To this end, US owners selling ADSs and claiming benefits under the Income Tax Convention may be required to produce appropriate documentation establishing that the above-mentioned conditions have been met.

Estate and Gift Tax. Inheritance and gift taxes, abolished in 2001, have been re-introduced in the Italian system by Law Decree No. 262 of 3 October 2006 (converted into law, with amendments, by Law No. 286 of 24 November 2006), as amended. Such taxes will apply on the overall net value of the relevant assets, at the following rates, depending on the relationship between the testate (or donor) and the beneficiary (or donee): (a) 4%, if the beneficiary (or donee) is the spouse or a direct ascendant or descendant (such rate only applying on the net asset value exceeding, for each person, €1 million); (b) 6%, if the beneficiary (or donee) is a brother or sister (such rate only applying on the net asset value exceeding, for each person, €100,000); (c) 6% if the beneficiary (or donee) is another relative within the fourth degree or a direct relative-in-law as well an indirect relative-in-law within the third degree; and (d) 8% if the beneficiary is a person, other those mentioned other (a), (b) and (c), above. In case the beneficiary has a serious disability recognized pursuant to applicable law, inheritance and gift taxes will apply on its portion of the net asset value exceeding €1.5 million.

Transfer tax. In connection with the Italian stamp duty tax on transfer of shares and ADSs, according to article 37 of Law Decree no. 248 of December 31, 2007, converted with amendments into Law no. 31 of February 28, 2008, the stamp duty has been abolished with regards to contracts having as their object the transfer of shares. In certain cases the relevant transfer acts would be subject to the registration tax at a flat amount equal to €168.

United States Taxation of US Holders

Taxation of Distributions Made on ADSs. As previously indicated, we do not anticipate making any distributions with respect to our ordinary shares in the foreseeable future. However, if we were to make distributions with respect to our ordinary shares, the amount of such distribution (including the amount of any Italian taxes withheld therefrom) would generally be includible in the gross income of a US holder of an ADS (on the date of receipt by the depositary) as foreign source dividend income to the extent that such distributions are paid out of our current or accumulated earnings and profits, as determined for United States federal income tax purposes. If the amount of any distribution paid on our ordinary shares exceeds our current and accumulated earnings and profits, that excess will first reduce a holder's basis in its ADSs and, to the extent the distribution is in excess of the holder's basis, the excess will be treated as capital gain. Dividends paid to US holders that are corporations will not be eligible for the dividends-received deduction (which is generally applicable only to dividends paid by US corporations).

Legislation enacted in 2003 reduces the maximum tax rate for certain dividends received by individuals to 15 percent for taxable years beginning on or before December 31, 2008, subject to exceptions for certain short-term and hedged stock positions. Dividends received from a "qualified foreign corporation" generally qualify for the reduced rate. In this regard, a foreign corporation that is not a passive foreign investment company (PFIC) in the year that the dividends are paid or in the preceding taxable year will generally constitute a qualified foreign corporation with respect to any dividends paid by it on its stock if the stock is readily tradable on an established securities market in the United States. Because the ADSs are readily tradable on an established securities market in the United States, we should constitute a qualified foreign corporation and dividends paid by us prior to 2009 on our ordinary shares and received by US holders of ADSs that are individuals should qualify for the reduced rate, subject to above-mentioned exception for certain short-term and hedged stock positions, so long as we are not a PFIC in the year the dividends are paid or in the preceding taxable year (and so long as the ADSs continue to be readily tradeable on an established securities market). While we do not believe that we are currently a PFIC, no assurances can be provided that we will not constitute a PFIC in any year during which we make a distribution on our ordinary shares (or in the taxable year preceding the year of distribution).

The amount of any cash distribution received in Euro with respect to the ADSs will equal the US dollar value of the distribution, including the amount of any Italian taxes withheld therefrom, determined at the spot exchange rate in effect on the date that the distribution is received by the depositary (regardless of whether or not the distribution is in fact converted into US dollars), and a US holder will have a tax basis in the Euro equal to that same value. Upon a subsequent sale or other disposition of the Euro, any gain or loss recognized by the US holder will be ordinary income or loss for US federal income tax purposes.

Subject to general foreign tax credit limitations, a US holder may elect to credit any Italian income taxes withheld on dividends paid with respect to the ADSs against the holder's US federal income tax liability (provided, *inter alia*, that the US holder satisfies certain holding requirements with respect to the ADSs). Amounts withheld in excess of the applicable rate under the income tax convention in effect between the United States and Italy in respect of a US holder who qualifies for the benefits of the convention will not be eligible for this credit, but the US holder may claim a refund for this excess from the Italian tax authorities. See "Item 10, Additional Information, Taxation, Italian Taxation of US Holders, Income Tax Withholding on Dividends." As an alternative to claiming a foreign tax credit, a US holder may claim a deduction for any withheld Italian income taxes, but only with respect to a year for which the US holder elects to do so with respect to all of its foreign income taxes. There are complex rules that limit the amount of foreign income taxes that may be credited against a US holder's federal income tax liability, and US holders are strongly urged to consult their own tax advisors as to the applicability and effect of these limitations.

Sales or other Disposition of the ADSs. Subject to the discussion set forth below regarding PFICs, a US holder will recognize capital gain or loss for US federal income tax purposes on the sale or other disposition of the ADSs equal to the difference between the amount realized on the disposition and the holder's basis in the ADSs. Such gain or loss will generally be long-term capital gain or loss if the US holder has owned the ADSs for more than one year at the time of the sale or other disposition.

Back-up Withholding. A US holder may be subject to back-up withholding at the applicable rate with respect to dividends paid on or proceeds from the sale or other disposition of the ADSs unless the US holder (a) is an exempt recipient or (b) provides a taxpayer identification number, certifies as to no loss of exemption from back-up withholding and otherwise complies with all applicable back-up withholding requirements.

Special Rules Applicable to PFICs. Special federal income tax rules apply to US holders who own stock in a PFIC. In this regard, a foreign corporation is generally considered a PFIC for any taxable year in which 75% or more of its gross income is passive income or in which 50% or more of the average value of its assets are considered "passive assets" (generally assets that generate passive income or assets held for the production of passive income). We believe that we currently are not a PFIC and do not anticipate that we will become a PFIC in the future.

However, if we were to be classified as a PFIC, a US holder would generally be subject to a special tax at ordinary income tax rates on so-called "excess distributions"—which include both certain distributions received on the ADSs and gain recognized on any sale or other disposition of the ADSs. The amount of income tax on these excess distributions will be increased by an interest charge to compensate for any tax deferral, calculated as if the excess distributions were earned ratably over the period the US holder held the ADSs. In addition, the tax on excess distributions treated as earned in prior years will be subject to tax at the maximum rate applicable in the year in which such income is deemed to have been earned. The harshness of the foregoing rules may be avoided if the US holder properly elects to include in its ordinary income each year such holder's pro rata share of our ordinary earnings and to include in its long-term capital gain income each year such holder's pro rata share of our net capital gain, whether or not distributed. However, we do not intend to provide US holders with the information that they would need in order to make this election. Alternatively, a holder of ADSs may avoid the tax consequences detailed above by making a mark-to-market election, but only if the ADSs are "regularly traded" for purposes of Section 1296 of the Code. No assurances can be made that the ADSs will be regularly traded and, in any event, a US holder should consult its own tax advisor before making any election under Section 1296 of the Code.

In addition, if we were to be classified as a PFIC, US holders would not qualify for the benefit of the reduced US federal tax rate applicable to certain dividends received by individuals through the end of 2008, as described above in "United States Taxation of US Holders—Taxation of Distributions Made on the ADSs."

DIVIDENDS AND PAYING AGENTS

Not applicable.

STATEMENTS BY EXPERTS

Not applicable.

DOCUMENTS ON DISPLAY

We are subject to the periodic reporting and other informational requirements of the Exchange Act applicable to a foreign private issuer. Under the Exchange Act, we file annual reports on Form 20-F within six months of our fiscal year end, and we submit other reports and information under cover of Form 6-K with the SEC. Copies of the registration statements, their accompanying exhibits, as well as such reports and other information, when so filed, may be inspected without charge and may be obtained at prescribed rates at the SEC's Public Reference Room located at 450 Fifth Street, N.W., Room 1200, Washington, D.C. 20549. You may obtain information regarding the Washington, D.C. Public Reference Room by calling the SEC at 1-800-SEC-0330 or by contacting the SEC at its website at www.sec.gov.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act.

SUBSIDIARY INFORMATION

Currently, we do not have any subsidiaries.

ITEM 11.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 December 31, 2007, substantially all of our cash and cash equivalents were held in accounts at financial institutions located in the Republic of Italy and the United States, that we believe are of acceptable credit quality. We invest our cash in liquid instruments that meet high credit quality standards and generally have maturity at the date of purchase of less than three months. We are exposed to exchange rate risk with respect to certain of our cash balances that are denominated in U.S. dollar. As of December 31, 2007, we held a cash balance of $34.6 million that was denominated in U.S. dollar. This dollar-based cash balance is available to be used for future acquisitions and other liquidity requirements that may be denominated in such currency. We are exposed to unfavorable and potentially volatile fluctuations of the U.S. dollar against the Euro (our functional currency).

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

appreciation of the Euro against the United States dollar could result in a charge to our operating results and a reduction in the value of our United States dollar denominated assets upon remeasurement.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES.

Not applicable.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARRANGEMENTS AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

None.

ITEM 15. CONTROLS AND PROCEDURES

Management's Report on Internal Control Over Financial Reporting

(a) We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) of the Exchange Act, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act) as of the end of the period covered by this annual report was carried out under the supervision and with the participation of our management, including our chief executive officer and chief financial officer. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

(b) Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on our assessment, we believe that, as of December 31, 2007, our internal control over financial reporting is effective based on those criteria.

(c) There has not been any change in our internal control over financial reporting identified in the evaluation required by Rule 13a-15 or Rule 15d-15 of the Exchange Act that occurred during the period covered by this annual report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

(d) The report of Reconta Ernst and Young S.p.A., independent registered public accounting firm, on our internal control over financials reporting as of December 31, 2007 is included below.

Gentium S.p.A.
March 28, 2008

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Gentium S.p.A.

We have audited Gentium's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Gentium's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Gentium maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Gentium S.p.A. as of December 31, 2007 and 2006, and the related statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2007 and our report dated March 28, 2008 expressed an unqualified opinion thereon.

Reconta Ernst & Young S.p.A.
Milan, Italy
March 28, 2008

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

We have both a Board of Statutory Auditors and an Audit Committee. Our board of directors has determined that Gigliola Bertoglio and Malcolm Sweeney each qualifies as an "audit committee financial expert" within the meaning of this Item 16A.

Ms. Bertoglio has served as one of our directors since December 2004. Her current term as a director expires on the date of the ordinary shareholders' meeting approving our 2007 Italian GAAP financial statements, which would normally be held in April 2008. Ms. Bertoglio has been a self-employed consultant since January 2003. From 1970 through 2002 she was employed by Reconta Ernst & Young (the Italian affiliate of Ernst & Young LLP) and its predecessors and was an audit partner beginning in 1977. From 1998 until leaving the firm, she was responsible for the firm's Capital Market Group in Italy. From 1989 to 1998, she was responsible for directing the firm's Professional Standards Group and member of the Accounting and Auditing Standards Group of Ernst & Young International and as a coordinating audit partner on clients with international operations. From 1977 to 1989, Ms. Bertoglio was a partner of the Italian firm of Arthur Young & Co. (the predecessor to Ernst & Young) where she was responsible for directing the firm's Professional Standards Group and serving in an advisory role to the Accounting and Auditing Standards Group of Arthur Young International and as a coordinating audit partner on clients with international operations. From 1970 to 1977, she was an Audit Manager (1970 to 1974) and an Audit Principal (1975 to 1977) with the Italian firm of Arthur Young & Co. in its Rome and Milan offices. Prior to 1970, Ms. Bertoglio was employed in the New York offices of Horwath & Horwath and LKH&H, both of which were public accounting firms. She earned a degree in Public Accounting from New York University and a Diploma in Accounting from Economics Institution in Biella, Italy. She was a Certified Public Accountant (active license to August 31, 2002, inactive after that) in the United States and included in the Register of Authorized Auditors of Consob, the Italian Stock Exchanges regulatory agency of public companies.

Mr. Sweeney has served as one of our directors since April 2007. His current term expires on the date of the ordinary shareholders' meeting approving our 2007 Italian GAAP financial statements, which would normally be held in April 2008. From 2001 to 2005, Mr. Sweeney was the Head of Financial Reporting and Accounting of the Pharma Division at Novartis AG, a major international pharmaceutical company. From 1990 to 2000, Mr. Sweeney worked for IMS Health Inc., (formerly IMS International), a provider of market intelligence to the pharmaceutical and healthcare industries, and associated companies. He held the positions of Corporate Controller and Senior Director of Finance for IMS Health Inc., as well as that of Leader of European Shared Services for Dun and Bradstreet in 1994 and 1995 when Dun and Bradstreet used to own IMS Health Inc. and several other major information service providers. From

1974 to 1990, he held a variety of finance positions for divisions of General Electric. Mr. Sweeney resides in the U.K., is a chartered accountant, admitted to the Institute of England & Wales in 1974 when working for KPMG (formerly Peat, Marwick, Mitchell and Co.). He received a Bachelor of Science in Physics, Economics and Philosophy from the University of Exeter in 1970.

ITEM 16B. CODE OF ETHICS

We have adopted a code of ethics, as defined in Item 16B of Form 20-F under the Securities Exchange Act of 1934, as amended, that is applicable to, among others, our Chief Executive Officer and Chief Financial Officer. Copies of this code of ethics are available upon request by writing to us at the address on the cover page of this annual report; we have also posted the code of ethics on our website at www.gentium.it. Material appearing on this website is not incorporated by reference into this annual report. If we amend the provisions of this code of ethics, or if we grant any waiver of such provisions, we will disclose such amendment or waiver on our website at the same address.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the fees contractually agreed to with our independent auditors, Reconta Ernst & Young S.p.A. for the fiscal years ended December 31, 2006 and 2007:

(in thousands of Euros)	**Year ended December 31,**	
	2006	**2007**
Audit Fees	€ 180	€ 120
Audit-Related Fees	30	5
Tax Fees	—	35
All Other Fees	—	—
Total fees	€ 210	€ 160

In the above table, in accordance with the SEC's definitions and rules, "audit fees" are fees for professional services for the audit of a company's financial statements, and for services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements. Reconta Ernst & Young S.p.A. did not provide any tax compliance services or advice on specific changes in tax regulations for the years ended December 31, 2006 and 2007.

To help ensure the independence of our independent registered public accounting firm, the Audit Committee is required to pre-approve all audit and non-audit services to be performed for us by our independent registered public accounting firm. All audit and permitted non-audit services, including the fees and terms thereof, to be performed by our independent registered public accounting firm must be approved in advance by the Audit Committee.

None of the hours expended upon Reconta Ernst & Young S.p.A.'s engagement to audit our financial statements for the year ended December 31, 2007 were attributed to work performed by persons other than Reconta Ernst & Young S.p.A.'s full-time, permanent employees.

ITEM 16D. EXEMPTION FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Under Italian law, our shareholders, not the audit committee, must be the party that appoints, terminates and determines the compensation for our independent accountants, although our audit committee does make recommendations on such matters to our board of directors, which in turn makes recommendations to our shareholders. As a result, our audit committee is not able to perform all of the duties required by Rule 10A-3 of the Securities Exchange Act of 1934, as amended. Our audit committee has established procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls and auditing matters, has authority to engage independent counsel and other advisors and determine the compensation of such advisors, as well as its ordinary administrative expenses, and also oversees, with the board of statutory auditors, our independent accountants (including resolution of disagreements between management and the independent accountants regarding financial reporting). Rule 10A-3 provides that foreign private issuers with a board of statutory auditors established in accordance with local law or listing requirements and meeting specified requirements with regard to independence and responsibilities (including the performance of most of the specific tasks assigned to audit committees by the rule, to the extent prohibited by local law) ("Statutory Auditor Requirements") are exempt from the audit committee requirements established by the rule. Our board of directors has determined that, because of the existence and nature of our board of statutory auditors, together with the performance of other duties under Rule 10A-3 by our shareholders and the performance of the remaining duties by our audit committee, we either satisfy Rule 10A-3 or qualify for an exemption provided by Rule 10A-3 from the audit committee requirements of Rule 10A-3.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

ITEM 18. FINANCIAL STATEMENTS

GENTIUM S.p.A.
INDEX TO FINANCIAL STATEMENTS

ITEM 19. EXHIBITS

Exhibit	Description
Charter documents	
1(i)	Articles of Association of Gentium S.p.A., formerly known as Pharma Research S.r.l. dated November 11, 1993, incorporated by reference to Exhibit 3(i) to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
1(ii)	Amended and Restated Bylaws of Gentium S.p.A. dated April 27, 2007, incorporated by reference to Exhibit 1(ii) to the Annual Report on Form 20-F previously filed with the SEC on April 30, 2007.
American Depositary Share Documents	
2.1	Form of Deposit Agreement among Gentium S.p.A., The Bank of New York and the owners and beneficial owners from time to time of American Depositary Receipts (including as an exhibit the form of American Depositary Receipt), incorporated by reference to Exhibit 4.6 to Amendment No. 5 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on June 9, 2005.
2.2	Form of American Depositary Receipt (see Exhibit 2.1).
Security Subscription Agreements	
2.3	Securities Subscription Agreement among Gentium S.p.A. and the other parties thereto dated as of May 31, 2006, incorporated by reference to Exhibit 4.9.1 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.
2.4	Securities Subscription Agreement among Gentium S.p.A. and the other parties thereto, dated as of February 6, 2007, incorporated by reference to Exhibit 2 to the report on Form 6-K, previously filed with the SEC on February 7, 2007.
Warrants	
2.5	Form of warrant (regarding Series A financing), incorporated by reference to Exhibit 4.2.2 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
2.6	

	Form of Representatives' Purchase Option between Gentium S.p.A. and Maxim Group LLC and I-Bankers Securities Inc., incorporated by reference to Exhibit 1.2 to Amendment No. 5 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on June 9, 2005.
2.7	Form of American Depositary Shares Purchase Warrant by Gentium S.p.A. dated October 14, 2005, incorporated by reference to Exhibit 4.8.2 to the Registration Statement on Form F-1, Registration No. 333-130796, previously filed with the SEC on December 30, 2005.
2.8.1	Form of American Depositary Shares Purchase Warrant by Gentium S.p.A. dated June 6, 2006, incorporated by reference to Exhibit 4.9.2 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.
2.8.2	Form of Ordinary Share Warrant by Gentium S.p.A. dated June 6, 2006, incorporated by reference to Exhibit 4.9.3 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.

Investor Rights and Registration Rights Agreements

2.9.1	Form of Investors' Rights Agreement between Gentium S.p.A. and holders of the Series A senior convertible promissory notes and warrants dated October 15, 2004, incorporated by reference to Exhibit 4.2.4 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.

Exhibit	Description
2.9.2	Amendment No. 1 to Gentium S.p.A. Series A Senior Convertible Promissory Notes, Warrants, Subscription Agreements and Investor Rights Agreements among Gentium S.p.A. and the other parties thereto dated May 27, 2005, incorporated by reference to Exhibit 4.2.6 to Amendment No. 4 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on May 31, 2005.
2.10	Investors' Rights Agreement by and among Gentium S.p.A., Alexandra Global Master Fund Ltd. and Generation Capital Associates made as of January 10, 2005, incorporated by reference to Exhibit 4.3 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
2.11	Investors' Rights Agreement by and among Gentium S.p.A. and Sigma Tau Finanziaria S.p.A. made as of April 4, 2005, incorporated by reference to Exhibit 4.5 to Amendment No. 1 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on April 7, 2005.
2.12	Registration Rights Agreement among Gentium S.p.A. and the other parties thereto made and entered into as of October 14, 2005, incorporated by reference to Exhibit 4.8.3 to the Registration Statement on Form F-1, Registration No. 333-130796, previously filed with the SEC on December 30, 2005.
2.13	Registration Rights Agreement among Gentium S.p.A. and the other parties thereto made and entered into as of June 6, 2006, incorporated by reference to Exhibit 4.9.4 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.
2.14	Registration Rights Agreement among Gentium S.p.A. and the other parties thereto made and entered into as of February 9, 2007, incorporated by reference to Exhibit 4.10.3 to the Registration Statement on Form F-3, Registration No. 333-141198, previously filed with the SEC on March 9, 2007.
Equity Incentive and Stock Option Plans	
4.1.1	Amended and Restated 2004 Equity Incentive Plan, incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-8, Registration No. 333-137534, previously filed with the SEC on September 22, 2006.
4.1.2	Amendment No. 1 to Amended and Restated 2004 Equity Incentive Plan, made as of March 26, 2007, incorporated by reference to

	Exhibit 4.1.2 to the Annual Report on Form 20-F for the year ended December 31, 2007, previously filed with the SEC on April 30, 2007.
4.2.1	Amended and Restated Nonstatutory Share Option Plan and Agreement dated March 23, 2006, incorporated by reference to Exhibit 4.2 to the Annual Report on Form 20-F for the year ended December 31, 2005, previously filed with the SEC on May 30, 2006.
4.2.2	Amendment No. 1 to Amended and Restated Nonstatutory Share Option Plan and Agreement, made as of March 26, 2007, incorporated by reference to Exhibit 4.2.2 to the Annual Report on Form 20-F for the year ended December 31, 2007, previously filed with the SEC on April 30, 2007.
4.3	2007 Stock Option Plan, dated March 26, 2007, incorporated by reference to Exhibit 4.42 to the Annual Report on Form 20-F for the year ended December 31, 2007, previously filed with the SEC on April 30, 2007.
Loan Agreements	
4.4	Ministry for Universities, Scientific and Technological Research Loan granted to Gentium S.p.A., successor in interest to Crinos Industria Farmacobiologica S.p.A., by Sanpaolo Imi S.p.A., dated September 27, 2000, incorporated by reference to Exhibit 10.6 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.

Exhibit	Description
4.5	Loan Agreement between Banca Nazionale del Lavoro S.p.A. and Gentium S.p.A. dated June 14, 2006 incorporated by reference to Exhibit 10.7.3 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.
4.6	Loan Agreement for €230,000 with Banca Intesa S.p.A., dated December 20, 2006, incorporated by reference to Exhibit 2 to the report on Form 6-K, previously filed with the SEC on February 2, 2007.
4.7	Loan Agreement for €500,000 with Banca Intesa S.p.A., dated December 20, 2006, incorporated by reference to Exhibit 3 to the report on Form 6-K, previously filed with the SEC on February 2, 2007.
4.8	Loan Agreement for €225,000 with Banca Intesa S.p.A., dated December 20, 2006, incorporated by reference to Exhibit 4 to the report on Form 6-K, previously filed with the SEC on February 2, 2007.
4.9	Financing Contract between Banca Intesa Mediocredito S.p.A. and Gentium S.p.A. dated April 20, 2006, incorporated by reference to Exhibit 4.36.2 to the Annual Report on Form 20-F for the year ended December 31, 2005, previously filed with the SEC on May 30, 2006.
4.10	Loan Agreement, dated June 30, 2006, between San Paolo IMI S.p.A. and Gentium S.p.A. , incorporated by reference to Exhibit 4.43 to the Annual Report on Form 20-F for the year ended December 31, 2006, previously filed with the SEC on April 30, 2007.
Clinical Trial Agreements	
4.11.1	Master Services Agreement, dated March 14, 2007, between MDS Pharma Services (US), Inc. and Gentium S.p.A., incorporated by reference to Exhibit 1 to the report on Form 6-K, previously filed with the SEC on March 20, 2007.
4.11.2	Statement of Work, effective August 8, 2007, between Gentium S.p.A. and MDS Pharma Services, Inc. (prospective arm), incorporated by reference to Exhibit 3 to the report on Form 6-K, previously filed with the SEC on August 22, 2007.
4.11.3	Statement of Work, effective August 8, 2007, between Gentium S.p.A. and MDS Pharma Services, Inc. (historical arm), incorporated by reference to Exhibit 4 to the report on Form 6-K,

	previously filed with the SEC on August 22, 2007.

License and Distribution Agreements

4.12.1	License and Supply Agreement by and between Gentium S.p.A. and Sigma-Tau Pharmaceuticals, Inc. (assignee of Sigma Tau Industrie Farmaceutiche Riunite S.p.A.) dated December 7, 2001, incorporated by reference to Exhibit 10.15 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
4.12.2	Letter Agreement, dated October 12, 2007, between Gentium S.p.A. and Sigma-Tau Pharmaceuticals, Inc., incorporated by reference to Exhibit 99.4 to the report on Form 6-K, previously filed with the SEC on December 12, 2007.
4.13.1	Contract to Supply Active Ingredients between Sirton Pharmaceuticals S.p.A. and Gentium S.p.A. dated January 2, 2006, incorporated by reference to Exhibit 4.24.2 to the Annual Report on Form 20-F for the year ended December 31, 2005, previously filed with the SEC on May 30, 2006.
4.13.2	Amendment No. 1 to Contract to Supply Active Ingredients, effective as of December 7, 2007, by and between Gentium S.p.A. and Sirton Pharmaceuticals S.p.A.
4.14.1	Master Agreement, dated December 28, 2006, among Gentium S.p.A., Crinos S.p.A., SFI Stada Financial Investments Ltd. and SFS Stada Financial Services International Ltd., incorporated by reference to Exhibit 2 to the report on Form 6-K, previously filed with the SEC on January 3, 2007.
4.14.2	Distribution Agreement, dated December 28, 2006, between Gentium S.p.A. and Crinos S.p.A., incorporated by reference to Exhibit 6 to the report on Form 6-K, previously filed with the SEC on January 3, 2007.

Exhibit	Description
Management Services Agreements	
4.15	Service Agreement between FinSirton S.p.A. and Gentium S.p.A. dated January 2, 2006, incorporated by reference to Exhibit 10.25.2 to the Annual Report on Form 20-F for the year ended December 31, 2005, previously filed with the SEC on May 30, 2006.
4.16	Service Agreement between Sirton Pharmaceuticals S.p.A. and Gentium S.p.A. dated January 2, 2006, incorporated by reference to Exhibit 10.26.2 to the Annual Report on Form 20-F for the year ended December 31, 2005, previously filed with the SEC on May 30, 2006.
Leases	
4.17	Commercial Lease Contract between Gentium S.p.A. and Sirton Pharmaceuticals S.p.A. dated January 1, 2005, incorporated by reference to Exhibit 10.33 to Amendment No. 2 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on May 10, 2005.
4.18	Commercial Lease Contract between Gentium S.p.A. and FinSirton S.p.A. dated January 1, 2005, incorporated by reference to Exhibit 10.32 to Amendment No. 2 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on May 10, 2005.
4.19	Commercial Lease Contract between Gentium S.p.A. and FinSirton S.p.A. dated January 1, 2007, incorporated by reference to Exhibit 4.32.2 (improperly coded as Exhibit 4.43(2)) to the Annual Report on Form 20-F for the year ending December 31, 2006, previously filed with the SEC on April 30, 2007.
Miscellaneous	
4.20	Form of indemnification agreement between Gentium S.p.A. and each officer and director, incorporated by reference to Exhibit 10.34 to Amendment No. 2 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on May 10, 2005.
Certifications and Consents	
12.1	Chief Executive Officer Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2	Chief Financial Officer Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

13.1	Chief Executive Officer Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
13.2	Chief Financial Officer Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15(a)	Consent of Reconta Ernst & Young S.p.A. dated March 28, 2008.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Gentium S.p.A.

We have audited the accompanying balance sheets of Gentium S.p.A. as of December 31, 2007 and 2006, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Gentium S.p.A. as of December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Gentium's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 28, 2007 expressed an unqualified opinion thereon.

Reconta Ernst & Young S.p.A.
Milan, Italy

March 28, 2008

GENTIUM S.p.A.
BALANCE SHEETS

Amounts in thousands except share and per share data	As of December 31, 2006	2007
ASSETS		
Cash and cash equivalents	€ 10,205	€ 25,964
Restricted cash	4,000	-
Accounts receivable	227	805
Accounts receivable from related parties	3,478	4,149
Inventories, net	1,499	1,510
Prepaid expenses and other current assets	1,427	4,844
Total Current Assets	20,836	37,272
Property, manufacturing facility and equipment, at cost	18,974	20,590
Less: Accumulated depreciation	9,550	9,046
Property, manufacturing facility and equipment, net	9,424	11,544
Intangible assets, net of amortization	556	2,592
Available for sales securities	560	525
Other non-current assets	4,017	26
Total Assets	**€ 35,393**	**€ 51,959**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable	€ 4,734	€ 9,583
Accounts payable to Crinos	-	4,000
Accounts payable to related parties	454	2,095
Accrued expenses and other current liabilities	1,198	1,223
Deferred revenue	140	-
Current portion of capital lease obligations	43	107
Current maturities of long-term debt	724	1,262
Total Current Liabilities	7,293	18,270
Long-term debt, net of current maturities	5,683	4,421
Capital lease obligations	48	223
Termination indemnities	682	686
Total Liabilities	13,706	23,600
Share capital (par value: €1.00; 15,111,292 and 18,454,292 shares authorized, 11,773,613 and 14,946,317 shares issued and outstanding at December 31, 2006 and 2007, respectively)	11,774	14,946
Additional paid in capital	49,476	88,618
Accumulated other comprehensive income/(loss)	32	(2)
Accumulated deficit	(39,595)	(75,203)
Total Shareholders' Equity	21,687	28,359
Total Liabilities and Shareholders' Equity	**€ 35,393**	**€ 51,959**

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

GENTIUM S.p.A.
STATEMENTS OF OPERATIONS

Amounts in thousands except share and per share data	For the Year Ended December 31, 2005	2006	2007
Revenues:			
Product sales to related party	€ 3,260	€ 3,754	€ 2,704
Product sales to third parties	101	321	2,390
Total product sales	3,361	4,075	5,094
Other revenues	280	249	2,515
Total Revenues	3,641	4,324	7,609
Operating costs and expenses:			
Cost of goods sold	2,911	3,092	3,983
Research and development	4,557	8,927	15,098
General and administrative	2,284	5,421	6,279
Depreciation and amortization	118	261	725
Charges from related parties	1,047	854	748
Write-down of acquired assets	-	-	13,740
	10,917	18,555	40,573
Operating loss	(7,276)	(14,231)	(32,964)
Interest income	156	708	1,674
Foreign currency exchange (loss), net	(249)	(627)	(4,001)
Interest expense	(4,304)	(218)	(317)
Loss before income tax expense	(11,673)	(14,368)	(35,608)
Income tax expense	646	-	-
Net loss	€ (12,319)	€ (14,368)	€ (35,608)
Net loss per share:			
Basic and diluted net loss per share	€ (1.78)	€ (1.33)	€ (2.52)
Weighted average shares used to compute basic and diluted net loss per share	6,933,104	10,808,890	14,105,128

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

GENTIUM S.p.A.
STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
FOR THE YEARS ENDED DECEMBER 31, 2005, 2006 AND 2007

Amounts in thousands except share and per share data	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income/(loss)	Total Shareholders' Equity
Balance at December 31, 2004	5,000	€ 5,000	€ 5,834	€ (12,908)	- €	€ (2,074)
Capital contribution			3,900			3,900
Warrants issued in connection with Series A convertible Notes			138			138
Beneficial conversion feature on Warrants issued in conjunction with the Series A convertible Notes			138			138
Accretion of Warrant			(388)			(388)
Beneficial conversion feature on Series A convertible Notes			1,111			1,111
Issuance of ordinary shares in initial public offering, net	2,700	2,700	13,501			16,201
Stock based compensation			474			474
Conversion of Series A Notes into ordinary shares, net	360	360	1,886			2,246
Issuance of ordinary shares in private placement, net	1,551	1,551	6,496			8,047
Net loss for 2005				(12,319)		(12,319)
Balance at December 31, 2005	9,611	€ 9,611	€ 33,090	€ (25,227)	- €	17,474
Unrealized gains on marketable securities					32	32
Issuance of ordinary shares in private placement, net	1,943	1,943	13,953			15,896
Issuance of ordinary shares upon exercise of options	22	22	75			97
Issuance of ordinary shares upon exercise of warrants	198	198	1,442			1,640
Stock based compensation			916			916
Net loss for 2006				(14,368)		(14,368)
Balance at December 31, 2006	11,774	€ 11,774	€ 49,476	€ (39,595)	32	€ 21,687
Unrealized loss on marketable securities					(34)	(34)
Issuance of ordinary shares in private placement, net	2,354	2,354	32,129			34,483
Issuance of ordinary shares upon exercise of options	28	28	90			118
Issuance of ordinary shares upon exercise of warrants, net	790	790	5,119			5,909
Stock based compensation			1,804			1,804
Net loss for 2007				(35,608)		(35,608)
Balance at December 31, 2007	14,946	€ 14,946	€ 88,618	€ (75,203)	(2)	€ 28,359

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

GENTIUM S.p.A.
STATEMENTS OF CASH FLOWS

Amounts in thousands except share and per share data	For the Year Ended December 31,		
	2005	**2006**	**2007**
Cash Flows From Operating Activities:			
Net loss	€ (12,319)	€ (14,368)	€ (35,608)
Adjustments to reconcile net loss to net cash used in operating activities:			
Write-down of acquired assets	-	-	13,740
Unrealized foreign exchange loss	750	509	2,951
Depreciation and amortization	1,315	1,008	1,538
Stock based compensation	474	908	1,804
Deferred revenue	(281)	(143)	(140)
Gain on fixed asset disposal	-	(23)	(15)
Adjustment of inventory to net realizable value	291	-	206
Non cash interest expense	3,837	4	-
Deferred income tax	646	-	-
Changes in operating assets and liabilities:			
Accounts receivable	(376)	(1,830)	(1,249)
Inventories	(1,033)	129	(217)
Prepaid expenses and other current and noncurrent assets	(150)	(482)	(3,426)
Accounts payable and accrued expenses	(1,794)	2,165	10,243
Termination indemnities	158	(24)	4
Net cash used in operating activities	(8,482)	(12,147)	(10,169)
Cash Flows From Investing Activities:			
Capital expenditures	(1,263)	(1,445)	(2,890)
Intangible assets expenditures	(124)	(503)	(215)
Proceeds on disposal of fixed assets	-	23	15
Purchases of marketable securities	-	(530)	-
Restricted cash	-	(4,000)	4,000
Acquisition of Crinos Assets	-	(4,000)	(12,000)
Net cash used in investing activities	(1,387)	(10,455)	(3,089)
Cash Flows From Financing Activities:			
Proceeds from initial public offering and private placements, net of offering expenses	24,801	15,896	34,483
Proceeds from warrant and stock option exercises, net	-	1,736	6,027
Repayments of long-term debt	(581)	(681)	(724)
Proceeds (repayment) of/from short term borrowings	(2,790)	-	279
Principal payment of capital lease obligation	-	(42)	(89)
Proceeds from Series A convertible Notes	1,459	-	-
Repayment of Series A convertible Notes	(4,221)	-	-
Proceeds (repayment) of affiliate's loan	(2,200)	-	-
Early extinguishment of long term debt	-	(1,868)	-
Proceeds from long-term debt	-	5,518	-
Capital contributions	3,900	-	-
Net cash provided by financing activities	20,368	20,559	39,976

Increase/(decrease) in cash and cash equivalents	10,499	(2,043)	18,717
Effect of exchange rate on cash and cash equivalents	(175)	(537)	(2,958)
Cash and cash equivalents, beginning of period	2,461	12,785	10,205
Cash and cash equivalents, end of period	€ 12,785	€ 10,205	€ 25,964

Amounts in thousands	For The Years Ended December 31,		
	2005	**2006**	**2007**
Supplemental disclosure of cash flow information:			
Cash paid for interest	€ 504	€ 219	€ 320
Supplemental disclosure of non cash investing and financing activities:			
Assets acquired under lease obligations	€ 127	€ 132	€ 328
Computer equipment acquired under a facility loan	40	-	-
Conversion of notes payable into ordinary shares	2,408	-	-
Fair value of warrants issued with convertible notes	597	-	-
Fair value of options issued to underwriters	190	-	-
Fair value of warrants issued with shares		715	-
Value of beneficial conversion feature of convertible notes and warrants	5,369	-	-

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

GENTIUM S.p.A.

NOTES TO FINANCIAL STATEMENTS

For the Three Years Ended December 31, 2007

(All amounts in thousands of Euro or U.S. dollars unless specified otherwise)

1. BUSINESS AND BASIS OF PRESENTATION

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

We have a plant in Italy where we manufacture active pharmaceutical ingredients, which are used to make the finished forms of various drugs. One of those active pharmaceutical ingredients is defibrotide. We have an affiliated company, Sirton Pharmaceuticals S.p.A. (Sirton), process defibrotide into the finished drug, and then we sell that finished drug in Italy to treat and prevent vascular disease with risk of thrombosis. The other active pharmaceutical ingredients that we manufacture are urokinanse, calcium heparin, sodium heparin and sulglicotide. We sell these other active pharmaceutical ingredients to other companies to be made into various drugs. All of the Company's operating assets are located in Italy, and more than 53% of product revenue in 2007 was to Sirton.

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 or US$, except share and per share data.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

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 and manage the operations of the Company on an aggregate basis. Accordingly, the Company operates in one segment, which is the biopharmaceutical industry.

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

Concentration of Credit Risk: Financial Instruments that potentially subject the Company to concentrations of credit risks consist principally of cash, cash equivalents, marketable securities and trade receivables. The Company has cash investments policies that limit investments to short-term low risk instruments. To mitigate the credit risks associated with our largest customer, Sirton, we obtained a guarantee from its parent company, FinSirton and we monitor the credit worthiness of FinSirton. The Company performs ongoing credit evaluations of other customers and maintains allowances for potential credit losses. Collateral is generally not required. Trade receivables from one foreign customer are guaranteed by a letter of credit from a primary bank institution.

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

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

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

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

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

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

Marketable Securities: The Company's marketable securities are classified as securities available for sale in non-current assets and are carried at fair value based on market prices. Unrealized gains and losses (which are deemed

to be temporary), if any, are reported in other comprehensive income or loss as a separate component of shareholders' equity.

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

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

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

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

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

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

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

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

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

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

product manufacturing costs, contract and other outside service fees, employee stock based compensation expenses and allocated facilities and overhead costs.

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

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

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

Share Based Compensation: The Company has always accounted for share based compensation on the basis of fair value, previously under SFAS 123 and as of July 1, 2005, under SFAS 123(R), *"Share Based Payments"*. The adoption of SFAS 123R did not have a significant impact on the Company as the fair valuations previously used to estimate the fair value of share based compensation were unchanged. Compensation expense for awards that are ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period of the equity compensation award, which is generally the vesting period.

From time to time, the Company grants options to persons other than officers, employees and directors, such as consultants. Grants of equity instruments to such persons are also accounted for under EITF 96-18, *"Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*". Under the EITF, equity instruments granted to such persons requires the measuring of the fair value of that instrument at the earlier of either i) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached (a "performance commitment"); or ii) the date at which the counterparty's performance is complete. Fair value of the option grant is estimated on the grant date using the Black-Scholes option-pricing model. The Black-Scholes model takes into account volatility in the price of the Company's stock, the risk-free interest rate, the estimated life of the option, the closing market price of the Company's stock and the exercise price.

Fair Value of Financial Instruments: The carrying amounts of cash and cash equivalents, accounts receivables, prepaid expenses, other current assets, accounts payable and accrued expenses approximate fair values due to the short-term maturities of these instruments. Marketable securities are carried at the market price. The carrying value of the Company's debt obligation approximates fair value.

Comprehensive Income: Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income, or SFAS130, requires us to display comprehensive income (loss) and its components as part of our financial statements. Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income or (loss) (or "OCI"). OCI includes certain changes in stockholders' equity that are excluded from net loss. Specifically, we include only unrealized gains or losses on our available for sale securities in OCI. Other comprehensive income (loss), net of tax, for the years ended December 31, 2005, 2006 and 2007, was €(12,319), €(14,336) and €(35,642), respectively.

Recently Issued Accounting Standards:

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

In June 2007, the FASB ratified EITF Issue No. 07-3, "*Accounting for Nonrefundable Advance Payments of Goods or Services Received for Use in Future Research and Development Activities*" (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for goods and services that will be used or rendered in future R&D activities pursuant to executory contractual arrangements be deferred and recognized as an expense in the period that the related goods are delivered or services are performed. EITF 07-3 is effective for us beginning on January 1, 2008. We do not expect this pronouncement to have a material effect on our financial statements.

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

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities-Including an Amendment of FASB Statement No. 115* ("SFAS No. 159"). SFAS No. 159 permits entities to chose to measure many financial instruments and certain other items at fair value. The objective of SFAS No. 159 is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. SFAS No. 159 is effective for us beginning January 1, 2008. We do not believe that SFAS No. 159 will have a material impact on our financial statements.

Effective January 1, 2007, the Company adopted FASB Interpretation No. 48 (FIN 48), "*Accounting for Uncertainty in Income Taxes*". FIN 48 prescribes a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company had no material unrecognized tax benefits before or after the adoption of FIN 48.

3. RELATED PARTIES

The Company has significant relationships with two privately owned Italian companies, FinSirton and its wholly owned subsidiary, Sirton. FinSirton, the parent company of several businesses, is the Company's largest shareholder (approximately 25% ownership at December 31, 2007) and originally the sole shareholder. The Company's Chief Executive Officer serves in the same capacity for FinSirton and is a member of the Board of Directors.

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

The Company has historically sold the active pharmaceutical ingredient form of defibrotide and other active pharmaceutical ingredients to Sirton, who then manufactured and sold the finished products primarily to one customer, Crinos. As a result, approximately 97%, 92% and 53% of the Company's product sales for the years ended December 31, 2005, 2006 and 2007, respectively, have been to Sirton. In connection with the Company's 2006 distribution agreement with Crinos regarding defibrotide (see Note 5), the Company entered into an agreement with Sirton, which expires on November 30, 2009, pursuant to which Sirton manufactures the finished defibrotide ampoules and capsules that the Company then sells to Crinos. Accordingly, the Company expects that product sales to Sirton will continue to decrease.

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

Finally, the Company leases space for manufacturing, offices, laboratories and storage facilities from Sirton and FinSirton. These agreements expire on December 31, 2010 and 2013. Total expense under these operating leases for the years ended December 31, 2005, 2006 and 2007 amounted to €164, €167 and €199 respectively. See Note 17 for such operating lease commitments.

For the years ended December 31, 2005, 2006 and 2007, the Company had the following transactions with FinSirton and Sirton:

	For the Year Ended December 31,		
	2005	2006	2007
Revenues			
Product sales	€ 3,260	€ 3,754	€ 2,704
Expenses			
Cost of goods sold	-	-	248
Research and development	-	-	185
Charges from related parties	1,047	854	748
Total	1,047	854	1,181

As of December 31, 2006 and 2007 the Company had the following balances with FinSirton and Sirton:

	December 31,	
	2006	2007
Accounts Receivable - Sirton	€ 3,477	€ 4,147
Account Receivable FinSirton	1	2
	3,478	4,149
Accounts Payable Sirton	405	2,077
Account Payable FinSirton	49	18
	454	2,095

Sirton has been unable to make timely payments on outstanding receivables. As a result, FinSirton, our largest shareholder and Sirton's parent, has guaranteed Sirton's payment of its outstanding trade payable to us as of December 31, 2007, net of our account payable to Sirton, recognizing itself as joint debtor.

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

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

4. COLLABORATIVE ARRANGEMENTS

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

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

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

On October 12, 2007, the Company and Sigma-Tau entered into a cost sharing agreement to address the need for additional funding not included in the original license and supply agreement. Under this agreement Sigma-Tau will reimburse the Company for 50% of certain costs incurred in the Company's ongoing Phase III clinical trial of defibrotide to treat severe VOD. We recognize the reimbursement of research and development expenses as revenue when we incur the costs subject to reimbursement. For the year ended December 31, 2007, the Company recorded €2.36 million of payments received from Sigma-Tau as other revenue. The Company anticipates additional reimbursements in 2008.

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

	For the Year Ended December 31,		
	2005	2006	2007
Research and development cost reimbursement	-	-	€ 2,360
Upfront payments recognized ratably	€ 280	€ 140	€ 140
	-	-	-
	€ 280	€ 140	€ 2,500

5. ACQUISTION OF MARKETING AUTHORIZATION AND TRADEMARKS

On December 28, 2006, the Company entered into a Master Agreement with Crinos S.p.A. to acquire the Italian marketing authorizations and related trademarks regarding defibrotide known as Prociclide and Noravid for €16,000. Prociclide and Noravid are sold in Italy to treat vascular disease with risk of thrombosis. As part of the transaction, Crinos waived its right of first refusal to market future therapeutic indications for defibrotide in the European market, and the Company agreed to pay Crinos a 1.5% royalty on net sales of defibrotide for the treatment and/or prevention of VOD in Europe for seven years. The transfer of the market authorizations was subject to approval by the Italian regulators, which occurred on April 26, 2007.

The Company entered into this transaction for long term strategic purposes. Specifically, the Company will now be able to manage defibrotide globally with control over the distribution of defibrotide and the flexibility to market defibrotide itself or seek marketing partners for the European market. As a result, the Company wrote off all but €2,260 of the €16,000 purchase price (€13,740 charge) based primarily on an analysis of the net present value of the estimated future cash flows from the sales of only the oral formulation of defibrotide through December 31, 2008, as well as other cash flows through 2012. These remaining assets, marketing authorizations and trademarks, are included in

other intangible assets.

As part of the same transaction, the Company also entered into a Distribution and Promotion Agreement with Crinos, whereby Crinos agreed to purchase Prociclide and Noravid from the Company and to continue to promote and distribute it in Italy to treat vascular disease with risk of thrombosis. Crinos agreed to immediately cease sales of the injectible formulation of such products to the retail market. Crinos may only purchase and distribute such products in injectible formulation for sales to hospitals and other public health organizations. Crinos may sell the oral formulations of such products to both the retail and hospital markets until December 31, 2008, and thereafter only to the hospital market.

As of December 31, 2007, the Company had paid €12,000 of the purchase price and is obligated to pay the balance of €4,000 by no later than December 31, 2008.

6. INVENTORIES

The Company's inventories consisted of:

	December 31, 2006	December 31, 2007
Raw materials	€ 293	€ 385
Semi-finished goods	689	845
Finished goods	517	280
Total	€ 1,499	€ 1,510

For the years ended December 31, 2006 and 2007, respectively, the Company reserved €341 and €547 to adjust a by-product cost to its net realizable value and to account for excess inventory compared with forecast sales.

7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	December 31, 2006	December 31, 2007
VAT receivables	€ 876	€ 3,776
Other prepaid expenses and current assets	551	1,068
Total prepaid expenses and current assets	€ 1,427	€ 4,844

The value added tax (or "**VAT**") amounts represent a tax on the value of consumption. VAT has no effect on the Company's operating results, as payments and receipts are allowed to be netted against each other in periodic filings with the tax authorities. The VAT payment system is a "custodial" relationship. VAT liabilities are generated when the Company invoices customers, including the VAT amount, and VAT receivables are created when the Company purchases goods and services subject to VAT. In 2007, the Company submitted to the Italian Tax Authorities a request for reimbursement of the 2007 quarterly VAT credits in a total amount of €1,280, of which it has received €391 in reimbursement.

The increase in the VAT receivable is mainly due to the Company's purchase of the Italian marketing authorization and related trademarks for defibrotide from Crinos, as explained in footnote 3. The VAT receivable on such

transaction amounted to €2,100, and a corresponding offset is included in accounts payable. The Company agreed to submit a VAT credit reimbursement request to the tax authorities and assign such VAT credit to Crinos.

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

8. PROPERTY, MANUFACTURING FACILITY AND EQUIPMENT

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

	December 31,					
	2006			2007		
	Cost	Accumulated Depreciation	Net book value	Cost	Accumulated Depreciation	Net book value
Land and building	€ 2,624	1,179	1,445	€ 2,683	1,185	1,498
Plant and machinery	14,075	7,402	6,673	14,434	6,700	7,734
Industrial equipment	832	598	234	1,085	635	450
Other	670	335	335	1,047	380	667
Leasehold improvements	46	9	37	295	78	217
Internally Developed Software	389	27	362	458	68	390
Construction in progress	338	-	338	588	-	588
	€ 18,974	9,550	9,424	€ 20,590	9,046	11,544

As of December 31, 2007, we performed a physical count of the Company's manufacturing facility and equipments and reconciled them with the Company's fixed asset register and general ledger. We wrote off those assets not in use and fully amortized or that had no physical presence in the Company's facilities. The total of such assets had a historical cost of €1,596 and accumulated depreciation of €1,538, resulting in a net write-off of €58 which has been included in statements of operations as depreciation expense.

Property, manufacturing facility and equipment include €132 and €460 at December 31, 2006 and December 31, 2007, respectively, of lab instruments acquired under capital lease agreements. The related accumulated depreciation at December 31, 2006 and December 31, 2007 was €9 and €38, respectively.

9. INTANGIBLE ASSETS

The Company's intangible assets consisted of:

	December 31,					
	2006			2007		
	Cost	Accumulated amortization	Net book value	Cost	Accumulated amortization	Net book value
Patent rights	€ 855	401	454	€ 1,093	595	498
Licenses and trademarks	134	32	102	1,280	184	1,096
Marketing authorizations	-	-	-	1,131	133	998
Total	€ 989	433	556	€ 3,504	912	2,592

The amount of amortization expense for the years ended December 31, 2006 and 2007 was €184 and €479, respectively. We estimate that we will incur amortization for the years ended December 31, 2008, 2009, 2010, 2011, 2012 and 2013 of €637, €637, €479, €418, €285 and €136, respectively.

10. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of:

	December 31, 2006	2007
Due to employees	€ 680	€ 802
Due to social security	152	220
Withholding tax due	157	160
Other payables	209	41
Total	€ 1,198	€ 1,223

11. CREDIT FACILITY, LONG-TERM DEBT AND LEASES

Long term debt, net of current maturities consists of:

		December 31, 2006	2007
a)	Mortgage loan bearing interest at the Euribor 6 month rate plus 1.0% due June 2014 (4.8% and 5.71% at December 31, 2006 and 2007 respectively)	2,800	2,600
b)	Equipment loan secured by marketable securities, bearing interest at the Euribor 3 months rate plus 1.70% due April 2011 (5.36% and 6.38% at December 31, 2006 and 2007 respectively)	1,050	919
c)	Equipment loan bearing interest at the Euribor 3 months rate plus 1.20% due June 2011 (4.86% and 5.88% at December 31, 2006 and 2007 respectively)	750	750
d)	Financing loan bearing interest at the Euribor 1 months rate plus 1.00% due December 2011 (4.60% and 5.29% at December 31, 2006 and 2007 respectively)	500	409
e)	Equipment loans secured by the underlying equipment pursuant to the Sabatini Law, interest at 2.1%	481	306
f)	Research loan from the Italian Ministry for University and Research, interest at 1% per annum, due January 2012	351	318
g)	Financing loan bearing interest at the Euribor 3 months rate plus 1.00% due December 2011 (4.66% and 4.68% at December 31, 2006 and 2007 respectively)	225	193
h)		230	188

	Equipment loan bearing interest at the Euribor 3 months rate plus 0.80% due December 2011 (4.46% and 5.48% at December 31, 2006 and 2007 respectively)				
i)	Other		20		-
			6,407		5,683
	Less current maturities		724		1,262
	Total	€	5,683	€	4,421

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

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

The maturities of long-term debt are as follows:

	December 31, 2007
2008	1,262
2009	1,289
2010	1,167
2011	491
2012	434
Thereafter	600
Total	€ 5,683

12. INTEREST RATE CAP AGREEMENTS

On June 28, 2006, 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 commitment. 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. The fair market value of the interest cap agreement as of December 31, 2007 is €6.

On July 4, 2006 the Company entered into an interest rate cap agreement with San Paolo IMI S.p.A. providing protection against fluctuations in interest rates with respect to 50% of the total loan commitment. 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. The fair market value of the interest cap agreement as of December 31, 2007 is €10.

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 commitment. 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. The fair market value of the interest cap agreement as of December 31, 2007 is €4.

13. INCOME TAXES

The Company's income tax expense consisted of the following:

	For the Year Ended December 31,		
	2005	2006	2007
Income tax expense:			
Current	€ -	€ -	-
Deferred	646	-	-
Total income tax expense	€ 646	€ -	-

The components of the Company's deferred tax assets and liabilities are as follows:

	As of December 31,	
	2006	2007
Deferred tax assets:		
Net operating losses	€ 7,823	€ 12,067
Capitalization of research & development costs	2,897	4,698
Write down of intangible assets		3,190
Other	3	106
Deferred tax assets	10,723	20,061
Deferred tax liabilities:		
Other	—	—
Deferred tax liabilities	—	—
Net deferred tax assets	10,723	20,061
Valuation Allowance	(10,723)	
Net deferred taxes	€ -	€ (20,061)

Under the Italian tax system, operating losses cannot be carried back to claim refunds. Instead, losses are carried forward five years, and any overpayments that may have been made can be credited against future amounts due for income tax or employee social security payments. The Company has reviewed its deferred tax assets in light of the cumulative loss that has been incurred in the periods presented. Although the Company has paid some income taxes in the past, the Company believes that with its expected future research and development costs, it is more likely than not that the Company will not be able to generate sufficient taxable income to utilize the deferred tax assets prior to their expiration. Accordingly, a valuation allowance has been established against these deferred tax assets.

As of December 31, 2007, the Company's tax position and relative carry-forward is as follows:

Year	Tax loss	Tax benefit	Expiring date
2004	3,128	1,032	2009
2005	7,580	2,502	2010
2006	12,997	4,289	2011
2007	20,172	6,334	2012

The Company provided no benefit for its operating losses due to the accumulated losses noted above.

14. SHAREHOLDERS' EQUITY

The Company had 11,773,613 and 14,946,317 ordinary shares of €1.00 par value per share issued and outstanding as of December 31, 2006 and December 31, 2007, respectively. On December 31, 2007, the authorized shares were 18,454,292. Authorized capital is as follows:

	December 31	
	2006	2007
Issued and outstanding	11,773,613	14,946,317
Reserved for share option plans	1,538,000	2,510,000
Reserved for exercise of warrants	1,648,004	846,300
Reserved for future offerings	151,675	151,675
	15,111,292	18,454,292

From October 2004 to January 2005, the Company sold convertible promissory notes in a private placement. As part of the private placement, the Company issued warrants for the purchase of an aggregate of 503,298 ordinary shares at a purchase price (as adjusted) of $9.52 per share. The warrants have a term of exercise of five years. Through December 31, 2007, the Company issued 22,734 ordinary shares upon exercise of these warrants for proceeds of $216 (€170).

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

On June 21, 2005, the Company completed an IPO of 2,400,000 ordinary shares at a price of $9.00 per share, generating gross proceeds of $21,600 (€17,863), and on July 27, 2005, the underwriters exercised part of their over-allotment option by purchasing an additional 300,000 ordinary shares generating additional gross proceeds of $2,700 (€2,252). The IPO underwriting discount and other offering costs amounted to €3,919 and were charged against additional paid-in capital. In connection with the IPO the Company granted warrants to purchase 151,200 ordinary shares to the underwriters for services rendered during the IPO. The fair value of the instruments was estimated to be €190, and was included within other offering costs. Through December 31, 2007, we had issued 107,990 ordinary shares upon exercise of these warrants at a price per share of $11.25, for proceeds of $1,215 (€914).

On October 14, 2005, the Company completed a private placement of 1,551,125 ordinary shares at $7.05 per ordinary share. Gross proceeds from the offering were $10,900 (€9,100). The private placement offering cost amounted to €1,066 and was charged against additional paid in capital. As part of the private placement, the Company issued warrants for the purchase of an aggregate of 620,450 ordinary shares at an exercise price of $9.69 per ordinary share. The warrants have a term of exercise of five years. In addition, the Company issued to one of the placement agents a five year warrant for the purchase of 93,068 ordinary shares at an exercise price of $9.69 per ordinary share. As of December 31, 2007, all of the warrants had been exercised and the Company had issued 713,518 ordinary shares underlying these warrants for aggregate proceeds of $6,914 (€5,000).

On June 6, 2006, the Company completed a private placement of 1,943,525 ordinary shares at $11.39 per ordinary share. Gross proceeds from the offering were $22,100 (€17,200). The private placement offering costs amounted to €1,333 and were charged against additional paid-in capital. As part of the private placement, the Company issued warrants for the purchase of an aggregate of 388,705 ordinary shares at an exercise price of $14.50 per ordinary share. The warrants have a term of five years. Through December 31, 2007, we had issued 143,920 ordinary shares upon exercise of these warrants for proceeds of $2,087 (€1,490). In addition, the Company issued to one of the placement agents a five year warrant for the purchase of 77,741 ordinary shares at an exercise price of $17.40 per ordinary share.

On February 9, 2007, the Company completed a private placement of 2,354,000 ordinary shares at $20.17 per ordinary share. Gross proceeds from the offering were $47,500 (€36,504). The private placement offering costs amounted to €2,021 and were charged against additional paid-in capital.

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

Warrants

A summary of the warrant activity for the three years ended December 31, is presented below.

	Warrants		Weighted Average Exercise Price	
Balance, December 31, 2004	503,298	€	7.15	$9.52
Granted	713,518	€	8.21	$9.69
Exercised	-		-	-
Cancelled	-		-	-
Balance, December 31, 2005	1,216,816	€	8.14	$9.61
Granted	617,646	€	12.13	$14.07
Exercised	(197,458)	€	8.29	$10.52
Cancelled	-			
Balance, December 31, 2006	1,637,004	€	9.63	$11.18
Granted	—		—	—
Exercised	(790,704)	€	7.51	$10.57
Cancelled	—		—	—
Balance, December 31, 2007	846,300	€	6.29	$11.75

15. EQUITY INCENTIVE PLANS.

Amended and Restated 2004 Equity Incentive Plan

Certain of the Company's employees and directors participate in the Amended and Restated 2004 Equity Incentive Plan and Italy Stock Award Plan. The Plans were initially adopted on September 30, 2004 and amended on April 27, 2007. The Plans provide for the issue of incentives awards for up to 1,500,000 ordinary shares to employees, consultants, directors, and non-employee directors. Awards may be in the form of either incentive and non-qualified options, restricted share grants, share appreciate rights and share bonuses. Our compensation committee determines the price of share options granted under the incentive plan, provided that the exercise price for an incentive share option cannot be less than 100% of the fair market value of our ordinary shares on the date of grant. The term of share options granted under the incentive plan generally may not exceed ten years, although the capital increase relating to the ordinary shares issuable upon exercise of such options expires on September 30, 2019.

Options granted under the incentive plan vest at the rate determined by our compensation committee. Typically, options granted under the incentive plan to officers and employees vest over three years, with one-third of the shares covered by the option vesting on the first anniversary of the grant date and the remainder vesting monthly over the next two years.

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

2004 Italy Stock Award Sub-Plan

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

Amended and Restated Nonstatutory Stock Option Plan and Agreement

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

2007 Stock Option Plan

On April 27, 2007, the Company's shareholders approved the 2007 Stock Option Plan providing for options that may be granted to the Company's directors, employees and consultants to purchase up to 1,000,000 ordinary shares, and a related capital increase of the Company in cash for a maximum amount of €1.00 of par value for such shares.

In accordance with the provision of SFAS No. 123R, stock-based compensation cost is measured at the grant date based on the fair value of the award ultimately expected to vest and is recognized as expense over the service period, which is generally the vesting period. The Company recorded non-cash compensation expense of €474, €908 and €1,805 for the years ended December 31, 2005, 2006 and 2007, respectively. The Company expects to incur significant non-cash compensation expense for option grants in the future. As of December 31, 2007 total compensation cost not yet recognized was €3,427, which is expected to be expensed over a remaining weighted average vesting period of 36 months.

The weighted average grant-date fair market value of options granted to officers, employees, directors and consultants for the years ended December 31, 2005, 2006 and 2007, as of the date of the grants, was $2.74, $4.42 and $10.03, respectively. The fair value of each option grant is estimated on the grant date using the Black-Scholes option-pricing model. The valuation of options granted was based on the following weighted average assumptions:

	Year ended December 31, 2005	**Year ended December 31, 2006**	**Year ended December 31, 2007**
Risk free interest rate	3.94%	4.96%	4.47%
Expected dividend yield	0%	0%	0%
Expected stock price volatility	40%	40%	60%
Expected term	3 years	3 years	4.9 years

All of the Company's stock options vest ratably through continued employment over the vesting period. The number of options expected to vest is based on estimated forfeitures of options that were outstanding at December 31, 2007. Once vested, options become exercisable immediately.

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

As share-based compensation expense recognized in the statement of operations for the year ended December 31, 2007 is based on awards ultimately expected to vest, reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeiture percentage was estimated to be approximately zero in the year ended December 31, 2007. If pre-vesting forfeitures occur in the future, the Company will record the effect of such forfeitures as the forfeitures occur.

The Company applies EITF 96-18 in accounting for options granted to consultants. For the years ended December 31, 2005, 2006 and 2007, the Company issued 50,000, 15,000 and 5,000 options, respectively, to consultants and recorded non-cash compensation expense of approximately €148, €94 and €44, respectively.

A summary of the Company's stock option activity based on the exchange rate in effect on the grant date, is as follows:

	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	€ 10.12	$13.45
Exercised	-	(22,000)	€ 4.23	$5.58
Cancellations	-	-	-	-
Options outstanding at December 31, 2006	423,000	1,115,000	€ 7.15	$9.45
Options available under the 2007 Plan	1,000,000	-		
Granted	(533,500)	529,500	€ 13.56	$18.34
Exercised	-	(28,000)	€ 4.21	$5.58
Cancellations	-	-	-	-
Options outstanding at December 31, 2007	889,500	1,616,500	€ 9.31	$12.43

Cash received on stock options exercised amounted to $123 and $156 in the years ended December 31, 2006 and 2007, respectively. The intrinsic value of options exercised in 2006 and 2007 was $145 and $423, respectively. The estimated fair value of shares vested during 2005, 2006 and 2007 was $821, $1,813 and $3,981, respectively.

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

	Options Outstanding			Options Exercisable	
Exercise Price	Number Outstanding	Weighted- Average Years Remaining on Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
€3.79 ($5.58)	10,000	1.75	€3.79 ($5.58)	10,000	€3.79 ($5.58)
€4.81 ($7.08)	15,000	7.82	€4.81 ($7.08)	10,833	€4.81 ($7.08)
€5.37 ($7.90)	10,000	7.91	€5.37 ($7.90)	6,947	€5.37 ($7.90)
€5.43 ($8.00)	50,000	2.82	€5.43 ($8.00)	50,000	€5.43 ($8.00)
€6.11 ($9.00)	832,000	7.51	€6.11 (€9.00)	670,249	€6.11 (€9.00)
€6.79 ($10.00)	25,000	1.96	€6.79 ($10.00)	25,000	€6.79 ($10.00)
€8.15 ($12.00)	15,000	1.72	€8.15 ($12.00)	15,000	€8.15 ($12.00)
€8.56 ($12.60)	90,000	8.42	€8.56 ($12.60)	45,000	€8.56 ($12.60)
€10.05 ($14.80)	22,500	9.96	€10.05 ($14.80)	-	€10.05 ($14.80)
€11.22 ($16.52)	89,000	9.64	€11.22 ($16.52)	5,000	€11.22 ($16.52)
€11.79($17.35)	40,000	8.32	€11.79($17.35)	35,557	€11.79($17.35)
€12.87 ($18.95)	373,000	9.23	€12.87 ($18.95)	-	€12.87 ($18.95)

€12.71 ($18.71)	45,000	9.32	€12.71 ($18.71)	23,352	€12.71 ($18.71)
	1,616,500			896,938	

At December 31, 2007 the aggregate intrinsic value of the outstanding options was $4,881 and the aggregate intrinsic value of the exercisable options was $4,096.

16. NET LOSS PER SHARE

Net loss per share is computed using the weighted average number of ordinary shares outstanding during the applicable period. Because the effect is antidilutive, the Company has excluded from the calculation of diluted net loss per share the impact of 896,486 ordinary equivalent shares resulting from the assumed exercise of stock options and warrants under the treasury stock method. There is no difference between basic and diluted net loss per share for all periods presented.

17. COMMITMENTS AND CONTINGENCIES

In April 2007, the Company entered into a five year term capital lease agreement to finance €218 in lab equipment purchases. The borrowing is payable in equal monthly installments of €4 over a period of 60 months. The agreement is classified as a capital lease and expires in March 2012.

In April 2007, the Company entered into a five year term capital lease agreement to finance €110 in lab equipment purchases. The borrowing is payable in equal monthly installments of €2 over a period of 60 months. The agreement is classified as a capital lease and expires in March 2012.

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

		Operating Leases	Capital Leases
2008	€	199	124
2009		199	73
2010		199	73
2011		191	73
2012		31	21
Thereafter		30	
Total minimum lease payments	€	849	364
Less: imputed interest			(34)
Present value of net minimum lease payment			330
Less: Current portion of capital lease payment			(107)
Long term portion of capital lease payment			223

As of December 31, 2007, we had €3.934 million of future payables under outstanding contracts with various contract research organizations that are not revocable. Most of these contracts are on a cost plus or actual cost basis.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

GENTIUM S.P.A.
(*Registrant)*

By: /s/ Laura Ferro, M.D.

Dr. Laura Ferro
President and Chief Executive Officer

Date: March 31, 2008

INDEX OF EXHIBITS

Exhibit	Description
Charter documents	
1(i)	Articles of Association of Gentium S.p.A., formerly known as Pharma Research S.r.l. dated November 11, 1993, incorporated by reference to Exhibit 3(i) to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
1(ii)	Amended and Restated Bylaws of Gentium S.p.A. dated April 27, 2007, incorporated by reference to Exhibit 1(ii) to the Annual Report on Form 20-F previously filed with the SEC on April 30, 2007.
American Depositary Share Documents	
2.1	Form of Deposit Agreement among Gentium S.p.A., The Bank of New York and the owners and beneficial owners from time to time of American Depositary Receipts (including as an exhibit the form of American Depositary Receipt), incorporated by reference to Exhibit 4.6 to Amendment No. 5 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on June 9, 2005.
2.2	Form of American Depositary Receipt (see Exhibit 2.1).
Security Subscription Agreements	
2.3	Securities Subscription Agreement among Gentium S.p.A. and the other parties thereto dated as of May 31, 2006, incorporated by reference to Exhibit 4.9.1 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.
2.4	Securities Subscription Agreement among Gentium S.p.A. and the other parties thereto, dated as of February 6, 2007, incorporated by reference to Exhibit 2 to the report on Form 6-K, previously filed with the SEC on February 7, 2007.
Warrants	
2.5	Form of warrant (regarding Series A financing), incorporated by reference to Exhibit 4.2.2 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
2.6	

	Form of Representatives' Purchase Option between Gentium S.p.A. and Maxim Group LLC and I-Bankers Securities Inc., incorporated by reference to Exhibit 1.2 to Amendment No. 5 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on June 9, 2005.
2.7	Form of American Depositary Shares Purchase Warrant by Gentium S.p.A. dated October 14, 2005, incorporated by reference to Exhibit 4.8.2 to the Registration Statement on Form F-1, Registration No. 333-130796, previously filed with the SEC on December 30, 2005.
2.8.1	Form of American Depositary Shares Purchase Warrant by Gentium S.p.A. dated June 6, 2006, incorporated by reference to Exhibit 4.9.2 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.

Exhibit	Description
2.8.2	Form of Ordinary Share Warrant by Gentium S.p.A. dated June 6, 2006, incorporated by reference to Exhibit 4.9.3 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.
Investor Rights and Registration Rights Agreements	
2.9.1	Form of Investors' Rights Agreement between Gentium S.p.A. and holders of the Series A senior convertible promissory notes and warrants dated October 15, 2004, incorporated by reference to Exhibit 4.2.4 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
2.9.2	Amendment No. 1 to Gentium S.p.A. Series A Senior Convertible Promissory Notes, Warrants, Subscription Agreements and Investor Rights Agreements among Gentium S.p.A. and the other parties thereto dated May 27, 2005, incorporated by reference to Exhibit 4.2.6 to Amendment No. 4 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on May 31, 2005.
2.10	Investors' Rights Agreement by and among Gentium S.p.A., Alexandra Global Master Fund Ltd. and Generation Capital Associates made as of January 10, 2005, incorporated by reference to Exhibit 4.3 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
2.11	Investors' Rights Agreement by and among Gentium S.p.A. and Sigma Tau Finanziaria S.p.A. made as of April 4, 2005, incorporated by reference to Exhibit 4.5 to Amendment No. 1 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on April 7, 2005.
2.12	Registration Rights Agreement among Gentium S.p.A. and the other parties thereto made and entered into as of October 14, 2005, incorporated by reference to Exhibit 4.8.3 to the Registration Statement on Form F-1, Registration No. 333-130796, previously filed with the SEC on December 30, 2005.
2.13	Registration Rights Agreement among Gentium S.p.A. and the other parties thereto made and entered into as of June 6, 2006, incorporated by reference to Exhibit 4.9.4 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.
2.14	

	Registration Rights Agreement among Gentium S.p.A. and the other parties thereto made and entered into as of February 9, 2007, incorporated by reference to Exhibit 4.10.3 to the Registration Statement on Form F-3, Registration No. 333-141198, previously filed with the SEC on March 9, 2007.

Equity Incentive and Stock Option Plans

4.1.1	Amended and Restated 2004 Equity Incentive Plan, incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-8, Registration No. 333-137534, previously filed with the SEC on September 22, 2006.
4.1.2	Amendment No. 1 to Amended and Restated 2004 Equity Incentive Plan, made as of March 26, 2007, incorporated by reference to Exhibit 4.1.2 to the Annual Report on Form 20-F for the year ended December 31, 2007, previously filed with the SEC on April 30, 2007.
4.2.1	Amended and Restated Nonstatutory Share Option Plan and Agreement dated March 23, 2006, incorporated by reference to Exhibit 4.2 to the Annual Report on Form 20-F for the year ended December 31, 2005, previously filed with the SEC on May 30, 2006.

Exhibit	Description
4.2.2	Amendment No. 1 to Amended and Restated Nonstatutory Share Option Plan and Agreement, made as of March 26, 2007, incorporated by reference to Exhibit 4.2.2 to the Annual Report on Form 20-F for the year ended December 31, 2007, previously filed with the SEC on April 30, 2007.
4.3	2007 Stock Option Plan, dated March 26, 2007, incorporated by reference to Exhibit 4.42 to the Annual Report on Form 20-F for the year ended December 31, 2007, previously filed with the SEC on April 30, 2007.
Loan Agreements	
4.4	Ministry for Universities, Scientific and Technological Research Loan granted to Gentium S.p.A., successor in interest to Crinos Industria Farmacobiologica S.p.A., by Sanpaolo Imi S.p.A., dated September 27, 2000, incorporated by reference to Exhibit 10.6 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
4.5	Loan Agreement between Banca Nazionale del Lavoro S.p.A. and Gentium S.p.A. dated June 14, 2006 incorporated by reference to Exhibit 10.7.3 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.
4.6	Loan Agreement for €230,000 with Banca Intesa S.p.A., dated December 20, 2006, incorporated by reference to Exhibit 2 to the report on Form 6-K, previously filed with the SEC on February 2, 2007.
4.7	Loan Agreement for €500,000 with Banca Intesa S.p.A., dated December 20, 2006, incorporated by reference to Exhibit 3 to the report on Form 6-K, previously filed with the SEC on February 2, 2007.
4.8	Loan Agreement for €225,000 with Banca Intesa S.p.A., dated December 20, 2006, incorporated by reference to Exhibit 4 to the report on Form 6-K, previously filed with the SEC on February 2, 2007.
4.9	Financing Contract between Banca Intesa Mediocredito S.p.A. and Gentium S.p.A. dated April 20, 2006, incorporated by reference to Exhibit 4.36.2 to the Annual Report on Form 20-F for the year ended December 31, 2005, previously filed with the SEC on May 30, 2006.
4.10	

	Loan Agreement, dated June 30, 2006, between San Paolo IMI S.p.A. and Gentium S.p.A. , incorporated by reference to Exhibit 4.43 to the Annual Report on Form 20-F for the year ended December 31, 2006, previously filed with the SEC on April 30, 2007.

Clinical Trial Agreements

4.11.1	Master Services Agreement, dated March 14, 2007, between MDS Pharma Services (US), Inc. and Gentium S.p.A., incorporated by reference to Exhibit 1 to the report on Form 6-K, previously filed with the SEC on March 20, 2007.
4.11.2	Statement of Work, effective August 8, 2007, between Gentium S.p.A. and MDS Pharma Services, Inc. (prospective arm), incorporated by reference to Exhibit 3 to the report on Form 6-K previously filed with the SEC on August 22, 2007.
4.11.3	Statement of Work, effective August 8, 2007, between Gentium S.p.A. and MDS Pharma Services, Inc. (historical arm), incorporated by reference to Exhibit 4 to the report on Form 6-K previously filed with the SEC on August 22, 2007.

Exhibit	Description
License and Distribution Agreements	
4.12.1	License and Supply Agreement by and between Gentium S.p.A. and Sigma-Tau Pharmaceuticals, Inc. (assignee of Sigma Tau Industrie Farmaceutiche Riunite S.p.A.) dated December 7, 2001, incorporated by reference to Exhibit 10.15 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
4.12.2	Letter Agreement, dated October 12, 2007, between Gentium S.p.A. and Sigma-Tau Pharmaceuticals, Inc., incorporated by reference to Exhibit 99.4 to the report on Form 6-K, previously filed with the SEC on December 12, 2007.
4.13.1	Contract to Supply Active Ingredients between Sirton Pharmaceuticals S.p.A. and Gentium S.p.A. dated January 2, 2006, incorporated by reference to Exhibit 4.24.2 to the Annual Report on Form 20-F for the year ended December 31, 2005, previously filed with the SEC on May 30, 2006.
4.13.2	Amendment No. 1 to Contract to Supply Active Ingredients, effective as of December 7, 2007, by and between Gentium S.p.A. and Sirton Pharmaceuticals S.p.A.
4.14.1	Master Agreement, dated December 28, 2006, among Gentium S.p.A., Crinos S.p.A., SFI Stada Financial Investments Ltd. and SFS Stada Financial Services International Ltd., incorporated by reference to Exhibit 2 to the report on Form 6-K, previously filed with the SEC on January 3, 2007.
4.14.2	Distribution Agreement, dated December 28, 2006, between Gentium S.p.A. and Crinos S.p.A., incorporated by reference to Exhibit 6 to the report on Form 6-K, previously filed with the SEC on January 3, 2007.
Management Services Agreements	
4.15	Service Agreement between FinSirton S.p.A. and Gentium S.p.A. dated January 2, 2006, incorporated by reference to Exhibit 10.25.2 to the Annual Report on Form 20-F for the year ended December 31, 2005, previously filed with the SEC on May 30, 2006.
4.16	Service Agreement between Sirton Pharmaceuticals S.p.A. and Gentium S.p.A. dated January 2, 2006, incorporated by reference to Exhibit 10.26.2 to the Annual Report on Form 20-F for the year ended December 31, 2005, previously filed with the SEC on May 30, 2006.

Leases

4.17	Commercial Lease Contract between Gentium S.p.A. and Sirton Pharmaceuticals S.p.A. dated January 1, 2005, incorporated by reference to Exhibit 10.33 to Amendment No. 2 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on May 10, 2005.
4.18	Commercial Lease Contract between Gentium S.p.A. and FinSirton S.p.A. dated January 1, 2005, incorporated by reference to Exhibit 10.32 to Amendment No. 2 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on May 10, 2005.
4.19	Commercial Lease Contract between Gentium S.p.A. and FinSirton S.p.A. dated January 1, 2007, incorporated by reference to Exhibit 4.32.2 (improperly coded as Exhibit 4.43(2)) to the Annual Report on Form 20-F for the year ending December 31, 2006, previously filed with the SEC on April 30, 2007.

Exhibit	Description
Miscellaneous	
4.20	Form of indemnification agreement between Gentium S.p.A. and each officer and director, incorporated by reference to Exhibit 10.34 to Amendment No. 2 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on May 10, 2005.
Certifications and Consents	
12.1	Chief Executive Officer Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2	Chief Financial Officer Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
13.1	Chief Executive Officer Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
13.2	Chief Financial Officer Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15(a)	Consent of Reconta Ernst & Young S.p.A. dated March 28, 2008.