Gentium S.p.A.
Form 20-F
March 31, 2010
As filed with the Securities and Exchange Commission on March 31, 2010

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, 2009

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.

Title of each class	Name of each exchange on which registered
American Depositary Shares	The Nasdaq Global Market
Ordinary shares, no par value*	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.

14,956,317 ordinary shares

- 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 o Non-accelerated filer x

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 development and manufacture of our primary product candidate, defibrotide, an investigational drug based on single-stranded DNA extracted from pig intestines. Our development of defibrotide has been focused on the treatment and prevention of 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 or radiation treatments, that are given prior to stem cell transplantation. Severe VOD is the most extreme form of VOD and is associated with multiple-organ failure and high rates of morbidity and mortality. We have completed two clinical trials, a Phase III trial of defibrotide for the treatment of severe VOD in the U.S., Canada and Israel and a Phase II/III pediatric trial in Europe for the prevention of VOD. Defibrotide has been given "orphan" status by the U.S. Food and Drug Agency, or FDA, and the European Medicines Agency, or EMEA, which means that we will have limited market exclusivity upon regulatory approval. Defibrotide has also been granted "fast-track product" designation by the FDA for the treatment of VOD. While we have not yet obtained regulatory approval to market defibrotide, we are authorized to distribute defibrotide on a pre-approved basis under a treatment IND protocol in the U.S. and through a named-patient program throughout the rest of the world. We do not know of any FDA or EMEA approved treatments for VOD.

We are currently completing certain preclinical and clinical studies requested by regulatory authorities. As part of our overall strategy, we anticipate filing for regulatory approval for defibrotide in the U.S. and Europe by the end of our second quarter in 2011. We are also working closely on our U.S. regulatory strategy with our commercial partner, Sigma-Tau Finanziaria S.p.A. and its affiliate Sigma-Tau Pharmaceuticals, Inc., to which we have licensed our commercial rights to defibrotide for both the treatment and prevention of VOD in the Americas.

We have a manufacturing plant in Italy where we produce active pharmaceutical ingredients, which are subsequently used to make the finished forms of various drugs. We believe that we are the sole worldwide producer of defibrotide. In addition to defibrotide, we manufacture urokinase and sulglicotide, both of which are sold to third parties. All of the Company's operating assets are located in Italy.

We have accumulated a deficit of approximately €100 million since our inception and expect to continue to incur net operating losses for the foreseeable future. However, absent the need to fund any additional clinical trials, we believe that our cash and cash equivalents, including the upfront payment received from Sigma-Tau Pharmaceuticals, Inc. in connection with the expansion of the license for defibrotide in the Americas, together with revenues generated from our named-patient and cost recovery programs, will be sufficient to meet our obligations for at least the next twelve months.

We are subject to a number of risks, including our ability to successfully obtain regulatory approval for defibrotide, the uncertainty that defibrotide will become a successful commercial product, our ability to generate projected revenue through our named-patient and cost recovery programs, our dependence on corporate partners, our ability to obtain

financing, if necessary, and potential changes in the health care industry.

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, 2008 and December 31, 2009 and for the three years ended December 31, 2009 are derived from our audited financial statements, which are included in this annual report. The selected financial data as of December 31, 2005, December 31, 2006 and December 31, 2007 and for the years ended December 31, 2005 and December 31, 2006 have 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.

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,					
	2005	2006	2007	2008	2009	2009(1)
Revenues:						
Product sales to related party	€ 3,260	€ 3,754	€ 2,704	€ 651	€ 195	$ 279
Product sales to third parties	101	321	2,390	4,792	9,507	13,625
Total product sales	3,361	4,075	5,094	5,443	9,702	13,904
Other revenues	280	109	15	25	129	185
Other revenues from related party	-	140	2,500	1,970	337	483
Total revenues	3,641	4,324	7,609	7,438	10,168	14,572
Operating costs and expenses:						
Cost of goods sold	2,911	3,092	4,584	5,596	4,002	5,736
Charges from related parties	1,047	854	748	537	279	400
Research and development	4,557	8,927	14,497	9,569	3,512	5,033
General and administrative	2,284	5,421	6,279	7,668	6,036	8,651
Depreciation and amortization	118	261	725	998	916	1,313
Write-down of assets	-	-	13,740	3,403	-	-
	10,917	18,555	40,573	27, 771	14,745	21,133
Operating loss	(7,276)	(14,231)	(32,964)	(20,333)	(4,577)	(6,561)
Foreign currency exchange gain (loss), net	(249)	(627)	(4,001)	173	162	232
Interest income (expense), net	(4,148)	490	1,357	256	(110)	(158)
Pre-tax income loss	(11,673)	(14,368)	(35,608)	(19,904)	(4,525)	(6,487)
Income tax expense (benefit):						
Current	-	-	-	-	-	-
Deferred	646	-	-	-	-	-
	646	-	-	-	-	-
Net loss	€ (12,319)	€ (14,368)	€ (35,608)	€ (19,904)	€ (4,525)	$ (6,487)

Net loss per share:						
Basic and Diluted	€ (1.41)	€ (1.78)	€ (1.33)	€ (1.33)	€ (0.30)	$ (0.43)

(1) Euro amounts are translated into U.S. dollars using the Noon Buying Rate for the Euro on December 31, 2009, of U.S. $1.4332 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.

(000s omitted except per share data	2005	2006	2007	2008	2009	2009(1)
Balance Sheet Data:						
Cash and cash equivalent...	€ 12,785	€ 10,205	€ 25,964	€ 11,491	€ 1,392	$ 1,995
Working capital	11,758	13,543	19,002	3,152	1,041	1,492
Property, net	8,631	9,424	11,544	10,751	9,717	13,926
Total assets	26,113	35,393	51,959	26,901	18,167	26,037
Long-term debt, net of current maturities	2,485	5,683	4,421	3,268	3,098	4,440
Shareholders' equity	17,474	21,687	28,359	10,451	7,330	10,505
Capital stock	€ 9,611	€ 11,774	€ 14,946	€ 14,956	€ 106,962	$ 153,298
Number of shares	9,610,630	11,773,613	14,946,317	14,956,317	14,956,317	14,956,317

(1) Euro amounts are translated into U.S. dollars using the Noon Buying Rate for the Euro on December 31, 2009, of U.S. $1.4332 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
2005	1.2400	1.1842
2006	1.2661	1.3197
2007	1.3797	1.4603
2008	1.4695	1.3919
2009	1.3935	1.4332

Source: Federal Reserve Statistical Releases H.10 and G.5

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 2009	1.4795	1.4235
October 2009	1.5029	1.4532
November 2009	1.5085	1.4828
December 2009	1.5100	1.4243
January 2010	1.4536	1.3870
February 2010	1.3995	1.3476
March 2010 (through March 26, 2010)	1.3758	1.3344

Source: Federal Reserve Statistical Release H.10

On March 26, 2010, the noon buying rate was €1.00 to $1.3398.

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 may not be able to meet our future cash requirements without obtaining additional capital from external sources.

As of December 31, 2009, we had €1,392 million in cash and cash equivalents. We have generated net losses since our inception. Our net losses for the year ended December 31, 2009 and for the year ended December 31, 2008 were €4.53 million and €19.90 million, respectively. We expect to incur significant losses over the next several years as we pursue regulatory approval for defibrotide, which may require additional clinical trials, testing and regulatory compliance activities, and commercialization efforts and related activities. In addition, our long-term ability to generate cash from operations is dependent in part on the success of our current strategic partner, Sigma-Tau Pharmaceuticals, Inc., as well as the likelihood and timing of new strategic licensing and partnering relationships and/or the successful commercialization of defibrotide. If we incur operating losses for longer than we expect and/or we are unable to raise additional capital, we may become insolvent and unable to continue our operations.

Since our inception, we have financed our operations primarily through the sale of equity and convertible notes, interest income earned on cash and cash equivalents, and debt provided through secured lines of credit. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly-issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations.

Absent the need to fund any additional clinical trials, we believe that our cash and cash equivalents, including the upfront payment received from Sigma-Tau Pharmaceuticals, Inc. in connection with the expansion of the license for defibrotide in the Americas, together with revenues generated from our named-patient and cost recovery programs, will be sufficient to meet our obligations for at least the next twelve months. However, if we elect to increase our spending above current plans or perform additional clinical trials, we may need to obtain additional capital through equity or debt financings, loans and collaborative agreements with corporate partners, which may not be available to us on favorable terms, if at all.

Our failure to raise additional funds in the future may delay the development of defibrotide.

The development of defibrotide will require a commitment of substantial funds in order to obtain regulatory approval. For the year ended December 31, 2009, our cash used in operating activities was €5.16 million. Capital expenditures for year ended December 31, 2009 was €0.25 million. You should review the additional information about our liquidity and capital resources in the Operating and Financial Review and Prospects section of this annual report.

Our future capital requirements are dependent upon many factors, some of which are beyond our control, including:

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the successful and continued development of defibrotide in preclinical and clinical testing in our existing and any future clinical trials;

- 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 United States Food and Drug Administration, or FDA, European Medicines Agency, or EMEA, or other regulators;
- the timing of regulatory approvals needed to market defibrotide;
- success of our named-patient and cost recovery programs; and
- market acceptance of defibrotide.

We may need additional funds before we have obtained regulatory approval for defibrotide. 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 defibrotide. We may also be forced to curtail, cease or restructure our operations, obtain funds by entering into arrangements with collaborators on unattractive terms or relinquish rights to defibrotide that we would not otherwise relinquish in order to continue independent operations.

We have started to generate limited revenues from sales of defibrotide and have had significant losses to date, and we do not know whether we will ever generate significant revenues or achieve profitability.

We have generated limited revenues through commercial sales of our active pharmaceutical ingredients and, recently, pre-approval sales of defibrotide through our named-patient and cost recovery programs. We had total net product sales of €5.09 million, €5.44 million and €9.70 million in 2007, 2008 and 2009, respectively. Even if we are successful in obtaining regulatory approval to market defibrotide, we may have very limited markets and may not generate enough revenues from defibrotide to fund our business. In addition, the FDA and EMEA have designated defibrotide to treat severe 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.

Our ability to continue as a going concern is largely dependent on the revenues being generated from the distribution of defibrotide on a pre-approved compassionate use basis through our named-patient and cost recovery programs. If we fail to generate projected revenues from such compassionate use programs, we may need to obtain additional capital through equity or debt financings, loans and collaborative agreements with corporate partners, which may not be available to us on favorable terms, if at all, in order to fund our operations over the next twelve months.

We expect to continue to incur significant expenses as we develop and seek regulatory approval for defibrotide. We incurred a net loss of €35.61 million, €19.90 million and €4.53 million in 2007, 2008 and 2009, 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 American Depositary Shares, or ADSs, may decline.

We currently do not have any regulatory approvals to sell defibrotide to treat or prevent VOD, and we cannot guarantee that we will ever be able to sell defibrotide to treat or prevent VOD anywhere in the world.

We must demonstrate that defibrotide satisfies rigorous standards of safety and effectiveness before the FDA, EMEA and other regulatory authorities will approve defibrotide for commercial marketing. While we have completed two clinical trials for defibrotide to treat and prevent VOD, the data obtained from these trials may not be sufficient to obtain regulatory approval and we may be required to conduct additional clinical trials. We do not currently have the funds to run an additional clinical trial and we would likely need to obtain additional capital through equity or debt financings, loans and collaborative agreements with corporate partners, which may not be available to us on favorable terms, if at all. As a result, we may not be able to commercialize defibrotide for sale anywhere in the world.

The FDA and other regulatory authorities may require us to conduct other clinical trials of defibrotide to treat severe VOD or prevent VOD, which may delay or prevent approval and commercialization of our product candidate.

On December 7, 2009, we announced final clinical trial results for our current Phase III clinical trial of defibrotide to treat severe VOD and our Phase II/III pediatric prevention trial in Europe to prevent VOD, both of which were presented at the American Society of Hematology Conference in New Orleans. While data from these two trials are encouraging, we may have to conduct a new clinical trial of defibrotide to treat VOD using a concurrent control group of untreated patients before obtaining regulatory approval in the U.S. or Europe for either the treatment or prevention indications. We currently do not, and we may never, have enough capital to commence and complete a new clinical trial of defibrotide to treat VOD. In addition, even if we are able to commence a new clinical trial, one or more

clinical centers where the clinical trial is to be conducted may not be willing to conduct such a clinical trial 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. Therefore, we may never be able to obtain regulatory approval of defibrotide to treat VOD.

We may be required to suspend or discontinue any future clinical trials, if necessary, due to adverse events or other safety issues that could preclude approval of defibrotide and negatively affect our business model and stock price.

If we are required to conduct any future clinical trials for defibrotide, such trials may be suspended at any time for a number of safety-related reasons. For example, we may voluntarily suspend or terminate such clinical trials if at any time we believe that defibrotide prevents 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 and prevent VOD, to prevent deep vein thrombosis, or any other indication for which approval is sought.

It is possible that additional adverse events or safety issues could emerge from future data, which could impact conclusions relating to the safety of defibrotide. Any problems that arise from the use of defibrotide would severely harm our business operations.

We expect to rely upon our affiliate, Sirton Pharmaceuticals S.p.A., for various services, and we may not be able to quickly replace these services if it becomes bankrupt or otherwise unavailable.

We depend on a number of services from Sirton Pharmaceuticals S.p.A., including steam related to our manufacturing plant, lab space, and filling and packaging services for defibrotide for use in our compassionate use programs and any future clinical trials. If Sirton were to become bankrupt or otherwise cease providing these services, we may not be able to replace these services in a timely manner. Such a delay would impact our compassionate use programs and any future clinical trials.

Sirton, who is our affiliate, owes us a receivable that we may not be able to collect.

At December 31, 2009, Sirton owed us a receivable of €1.38 million and we owed Sirton a payable of €0.28 million. Sirton has been unable to make timely payments on the outstanding receivables. Currently, Sirton is evaluating its strategic options in order to avoid bankruptcy, which raises additional concerns on our ability to collect the outstanding receivables. In 2009, the Company and Sirton formally offset €0.74 million of payables due to Sirton against the same amount of receivables due from Sirton. We may never be able to collect the net receivable due to us from Sirton.

Defibrotide 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 defibrotide is 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 defibrotide or its manufacture, or failure to comply with regulatory requirements, may result in:

- restrictions on defibrotide or manufacturing processes;
- withdrawal of defibrotide 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 defibrotide when and if defibrotide is approved.

Our manufacturing facility and the manufacturing facility of Patheon S.p.A., who we have contracted to fill and finish defibrotide, are subject to continuing regulation by Italian authorities and are subject to inspection and regulation by the FDA and EMEA. These authorities could force us to stop manufacturing our products if they determine that we or Patheon are not complying with applicable regulations or require us to complete further costly alterations to our facilities.

We manufacture active pharmaceutical ingredients at our manufacturing facility in Italy. We have hired Patheon S.p.A. to process our lead active pharmaceutical ingredient, defibrotide, into the finished drug at Patheon's manufacturing facility. These facilities are subject to continuing regulation by the Italian Health Authority and other Italian regulatory authorities with respect to manufacturing defibrotide. The facilities are also subject to inspection and regulation by the FDA and EMEA with respect to manufacturing our product candidates for investigational use. Also, part of the process for obtaining approval from the FDA and EMEA for defibrotide is approval by those authorities of these manufacturing facilities in compliance with current good manufacturing practices. After receiving initial approval, if any, the FDA or EMEA will continue to inspect our manufacturing facilities, including inspecting them unannounced, to confirm whether we and Patheon are complying with 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 Patheon are not complying with applicable regulations. In addition, these regulators may require us to complete costly alterations to our facilities.

We expect to rely upon a sole processor, Patheon Italia, to fill and finish defibrotide into marketable formulations, and we may not be able to quickly replace Patheon if it fails in its duties.

If Patheon does not or is not able to perform these services for any reason, it may take us time to find a replacement processor. Such a delay could potentially put us in breach of our contractual obligations into which we may enter, violate local laws requiring us to deliver the product to those in need, and impact our revenues.

We may have difficulty obtaining raw material for defibrotide.

Defibrotide is based on pig intestines. If our current sources of pig intestines develop safety problems or other issues that impact our supply of pig intestines, 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 defibrotide.

If our third-party clinical trial vendors fail to comply with strict regulations, the clinical trials for defibrotide 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 defibrotide. 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 throughout the world in order to continue the development of defibrotide. In addition, we have entered into an agreement with MDS Pharma Services (U.S.) Inc. (now INC Research Inc.) to perform clinical research services in connection with clinical trials conducted in the United States and agreements with KKS-UKT, GmbH (now CenTrial, GmbH) and MDS Pharma Services S.p.A. (now Inc Research S.r.l.) 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 defibrotide 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.

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

Our internal ability to handle the marketing and distribution functions for defibrotide is limited and we do not expect to develop the capability to provide marketing and distribution for defibrotide. 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 and prevent 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 defibrotide to prevent VOD outside the Americas. 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 qualified personnel and key relationships, we may be unable to successfully develop and commercialize defibrotide or otherwise manage our business effectively.

We are highly dependent on our senior management, whose services are critical to the successful implementation of research and development, manufacturing and regulatory strategies and develop and maintain relationships with qualified researchers. If we lose their services or the services of one or more of the other members of our senior management or other key researcher, our ability to successfully commercialize defibrotide 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 defibrotide 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 cannot incentivize such key employees with certain forms of equity grants, such as restricted stock awards, or grant stock options with an exercise price at or near the recent trading prices of our ADSs, both of which could further limit our ability to retain and hire key personnel.

On March 1, 2010, we announced our decision to close our New York office and began transitioning the New York activities to our headquarters in Como, Italy. If we are unsuccessful in transitioning these activities, our business and results of operations could be negatively impacted. In addition, we may 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 have sold Prociclide and Noravid (two formulations of defibrotide) in Italy to treat vascular disease with risk of thrombosis, which may affect the pricing of defibrotide in Europe for the prevention or treatment of VOD.

Until December 31, 2008, through our distribution agreement with Crinos S.p.A., we sold Prociclide and Noravid (both forms of defibrotide) in Italy to treat vascular disease with risk of thrombosis. While we have stopped selling Prociclide and Noravid for this treatment in Italy, if defibrotide is approved for sale in Europe or Italy to treat and prevent VOD, or both, we may need to also obtain approval from regulators as to what price we can charge for these uses of defibrotide. The regulators may impose an artificially low cap on defibrotide based on the relatively low price-point of Prociclide and Noravid previously sold in Italy for the treatment of vascular disease with risk of thrombosis.

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. Incidence of VOD may decrease with new technologies and conditioning regimens, which will negatively impact our sales opportunities. 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 defibrotide is designed to treat. These companies include Genzyme Corp., Millennium Pharmaceuticals, Inc., Otsuka Pharmaceutical Co., Ltd., Eisai Co., Ltd., and Celgene Corp.

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 or develop a generic form of defibrotide. Their products may also prove to be more effective, safer or less costly than defibrotide, which could hurt our ability to recognize any significant revenues.

In May 2003, the FDA designated defibrotide as an orphan drug to treat severe 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, EMEA 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 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 defibrotide can be approved for sale and commercialized, our relevant patent rights may expire or remain in force for only a short period following commercialization. We have been issued a patent in the U.S. and several other countries which covers the method for determining the biological activity of defibrotide. This patent expires in 2022 in most countries. We believe this to be an important patent because the analytical release of a biological product like defibrotide is a key step in confirming the purity and biological activity of the final product. There may be no opportunities to extend this patent and thereby extend exclusivity related to FDA and EMEA, in which case we could face increased competition for defibrotide. Patent expiration could adversely affect our ability to protect future product development and, consequently, our operating results and financial position. In addition, generic innovators may be able to circumvent this patent and design a novel analytical method for determining the biological activity of defibrotide. In this case, a generic defibrotide could potentially be on the market once the relevant protections offered by our orphan designations end.

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 that 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 American Depositary Shares

Our ADSs have generally had low trading volume, and its public trading price has been volatile.

Between our initial public offering on June 21, 2005 and December 31, 2009, the closing price of our American Depositary Shares, or ADSs, have fluctuated between $.33 and $24.40 per share, with an average daily trading volume for the twelve months ended December 31, 2009 of approximately 54,736 ADSs. The market may experience significant price and volume fluctuations that are often unrelated to the operating performance of individual companies.

In addition to general market volatility, many factors may have a significant adverse effect on the market price of our ADSs, including:

- continuing operating losses, which we expect over the next several years as we continue our development activities;
- announcements of decisions made by regulators;
- results of our preclinical studies and clinical trials;
- announcements of improvements, new commercial products, failures of products, or progress toward commercialization by our competitors or peers;
- influence and control by our commercial partner and significant shareholder, Sigma-Tau Finanziaria S.p.A.;
- developments concerning proprietary rights, including patent and litigation matters;
- publicity regarding actual or potential results with respect to product candidates under development by us or by our competitors;
- regulatory developments; and
- quarterly fluctuations in our financial results.

We may not remain listed on the Nasdaq Global Market.

Between our public offering and May 2006, our ADSs were listed on the American Stock Exchange. Since May 2006, our ADSs have been listed on the Nasdaq Global Market. The Nasdaq Global Market sets forth various requirements that we must meet in order for our ADSs to continue to be listed on the Nasdaq Global Market. Violations of the continued listing requirements include:

- if the closing bid price of our ADSs drops below $1.00 for a period of 30 consecutive trading days;
- if our stockholders' equity falls below $10 million; or
- if we fail to maintain a market value of publicly held securities of at least $5 million for 30 consecutive trading days.

If we violate any of these continued listing requirements, our ADSs could be delisted from the Nasdaq Global Market. The delisting of our ADSs could have negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest, and fewer business development opportunities.

As of December 31, 2009, our stockholders' equity was $10.5 million (€7.33 million). If we fail to meet the stockholders' equity or fail to meet the minimum bid price and minimum market value requirements, we may be delisted from the Nasdaq Global Market.

Our largest shareholders exercise 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, including obtaining potential financing.

Our largest shareholder, FinSirton S.p.A., will own approximately 25% of our outstanding ordinary shares at March 31, 2010. Dr. Laura Ferro, who is our former Chief Executive Officer and President and a current member on our board of directors, together with members of her family controls FinSirton. In addition, Sigma-Tau Finanziaria S.p.A., along with its affiliates, will own approximately 18% of our outstanding ordinary shares at March 31, 2010. Marco Codella, who is the chief financial officer of Sigma-Tau Finanziaria, serves as a member of our board of directors. Moreover, we have licensed our rights in defibrotide to treat and prevent VOD to Sigma-Tau Pharmaceuticals, Inc., a wholly owned subsidiary of Sigma-Tau Finanziaria.

Both FinSirton and Sigma-Tau Finanziaria 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. 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.

As discussed in our risk factor entitled "Our shareholders can prevent us from executing a financing by alleging that our board of directors acted with serious irregularities when approving such financing, because the terms of such financing could harm our company," both FinSirton and Sigma-Tau Finanziaria own enough of our ordinary shares to bring legal action against our board of directors and may be able to prevent us from completing an important corporate event, such as a financing. In addition, under Italian law, directors are not required to recuse themselves from any discussion even if a conflict of interest exists. Accordingly, directors that are affiliated with our shareholders may be present for certain discussions that involve or impact the shareholders to which such directors are affiliated.

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 in compliance with our bylaws and applicable law, and may require prior approval of our shareholders at an extraordinary shareholders' meeting.

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 of directors 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 an extraordinary 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 second 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, in general, under Italian law, our existing shareholders and any holders of convertible securities (except in specific cases) have preemptive rights to acquire any such shares pro rated on their percentage interest in our company and on the same terms as approved for such capital increase. 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 by the board 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.

Italian law provides, with respect to shareholders' resolutions approving capital increase, that, in the event of absence of the minutes of the meeting, impossibility or illegality of the resolution, any interested person may, for a period of 180 days following the filing of the shareholders' resolution with the Register of Companies, challenge such resolution. If a shareholders' meeting was not called to approve the capital increase, the relevant resolution should be considered invalid and, any interested person may challenge the capital increase for a period of 90 days following the approval of the financial statements referring to the year during which the shareholders' resolution has been, also partially, executed. In addition, once our shareholders authorize a capital increase, all those authorized shares that have been subscribed need to be entirely paid-up before the shareholders may authorize a new capital increase. These restrictions could limit our ability to issue new equity or convertible debt securities on a timely basis.

Our shareholders can prevent us from executing a financing by alleging that our board of directors acted with serious irregularities when approving such financing, because the terms of such financing could harm our company.

On August 12, 2008, Sigma-Tau Finanziaria S.p.A., together with one of its affiliates, filed a claim in the Court of Como claiming that our board of directors acted with serious irregularities in violation of their duties as directors when approving a potential financing, because such financing could harm the company. On August 18, 2008, the Court of Como issued a temporary order preventing us from moving forward with a potential financing. While this claim was later dismissed for lack of damages, it did, nonetheless, prevent the directors from implementing the potential financing. Any group of shareholders constituting at least 10% of our outstanding ordinary shares could bring a similar action on a future board resolution regarding a financing or other important corporate action, and an Italian court could prevent the transaction from moving forward by issuing an order to that effect.

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 our capital, of our legal reserve and of 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 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 amount of such ordinary shares that

is allocated to the capital. At December 31, 2009, the sum of our capital, legal reserves and other reserves on our unaudited Italian GAAP balance sheet was €28.6 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 allocate 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 to reflect on-going losses, in certain cases of losses exceeding 1/3 of the capital of the Company. We are also required to maintain a minimum capital of €120 thousand. At December 31, 2009, 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, our company could be liquidated.

We apply our losses from operations against our legal reserves and capital. If our capital is reduced for more than one-third as a result of losses, our board of directors must call a shareholders' meeting as soon as possible. The shareholders should take appropriate measures, which may include, inter alia, either the reduction of the legal reserves and capital by the amount of the remaining losses, or the carrying out of 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 capital, then we must reduce our capital by the amount of the losses.

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. In particular, the following laws are worth mentioning: (i) Law no. 604/1966, regulating the individual dismissals; (ii) Law no. 223/1991, concerning the collective dismissal procedure; (iii) Law no. 428/1990, providing for the information and consultation procedure in case of transfer of the undertaking or part thereof and (iv) Legislative decree no. 25/2007, introducing a general right to information and consultation for employees. 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 or ADSs, 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 Prociclide and Noravid (both forms of defibrotide) in Italy to treat deep vein thrombosis, and, in 1993, our founding company received approval to manufacture and sell a form of defibrotide in Italy to both treat and prevent all vascular disease with risk of thrombosis. We are currently focused on the development of defibrotide to treat and prevent VOD in the United States and Europe.

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." 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, 2009.

	For the Year Ended December 31,		
(in thousands)	2007	2008	2009
Land and buildings	€ 162	€ 4	€ -
Plant and machinery	1,839	544	206
Industrial equipment	582	179	5
Other	90	13	23
Leasehold improvements	249	27	3
Computer Software	69	224	12
Construction in progress	250	172	28
Total	€ 3,241	€ 1,163	€ 277

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, an investigational drug based on DNA derived from pig intestines, which our founding company discovered over 20 years ago. We are focused on development and manufacture of defibrotide 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 or radiation treatments that are given prior to stem cell transplantation. Severe VOD is the most extreme form of VOD and is associated with multiple-organ failure and results in high morbidity and mortality. Defibrotide has been studied in a number of clinical trials and more recently we have concluded a Phase III clinical trial of defibrotide to treat severe VOD in the United States, Canada and Israel. In addition, we have concluded a Phase II/III clinical trial of defibrotide in Europe to prevent VOD in children. While we have not yet obtained regulatory approval to market defibrotide, we are authorized to distribute defibrotide on a pre-approved basis under a treatment IND protocol in the U.S. and through a named-patient program throughout the rest of the world.

Due to the historically low complete response and survival rates and lack of treatments for VOD, we believe there is an immediate need for a drug to treat and prevent 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 as a fast track product. The FDA approval process for defibrotide for this use remains dependent upon sufficient data in connection with a clinical trial to treat severe VOD.

On December 7, 2009, we announced final clinical trial results for our current Phase III clinical trial of defibrotide to treat severe VOD and our Phase II/III pediatric prevention trial in Europe to prevent VOD. We are currently completing certain preclinical and clinical studies requested by regulatory authorities. As part of our overall strategy, we anticipate filing for regulatory approval for defibrotide in the U.S. and Europe by the end of second quarter 2011. We expect to utilize the data from the two studies, together with data obtained from our compassionate use programs, whereby we have been authorized to distribute defibrotide on a pre-approval basis, to support our regulatory submissions and any future clinical trials that may be necessary. We are also working closely on our U.S. regulatory strategy with our commercial partner, Sigma-Tau Finanziaria S.p.A. and its affiliate Sigma-Tau Pharmaceuticals, Inc., to which we have licensed our commercial rights to defibrotide for both the treatment and prevention of VOD in the Americas.

We also manufacture defibrotide and sulglicotide at our manufacturing facility near Como, Italy, and we lease a facility from one of our affiliates, Sirton, to manufacture urokinase. These products are active pharmaceutical ingredients used to make other drugs. Our revenues from the sales of these products to date have amounted to €5.1 million, €5.4 million and €9.7 million in 2007, 2008 and 2009, respectively. In 2009, we launched a named-patient program and cost recovery program, which have generated approximately €4.9 million in net sales for the year ended December 31, 2009.

Our strategy is to obtain regulatory approval for defibrotide to treat and prevent veno-occlusive disease. 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 defibrotide and enable our future production. We plan to work with our existing license partner, Sigma-Tau Pharmaceuticals, Inc., and are seeking additional license partners to help with the development and commercialization of defibrotide. We also are attempting to grow our active pharmaceutical ingredient, or API, business through volume and price increases of sulglicotide and urokinase.

Market Overview

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.

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 "Hepatic 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 12% of patients who undergo stem cell transplants develop VOD. According to an article in the November 15, 1998 edition of Blood, the Journal of the American Society of Hematology, 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 EMEA approved treatments at this time for VOD.

Strategy

Our strategic objective is to obtain regulatory approval for defibrotide to treat and prevent VOD. We plan to continue to work with our existing license partner, Sigma-Tau Pharmaceuticals, Inc., for the development of defibrotide and commercialization of defibrotide in the Americas. Outside of the Americas, we are seeking additional license partners to help with the development and commercialization of defibrotide. We also are attempting to grow our active pharmaceutical ingredient, or API, business through volume and price increases of sulglicotide and urokinase.

- Obtain regulatory approval to use defibrotide to treat and prevent VOD. Gentium, as well as independent investigators, have run several studies showing the potential efficacy and safety of defibrotide in the treatment and prevention of VOD (see detail under "Product Candidate" section below). We have received orphan status from both the FDA and EMEA for defibrotide. In addition, we have received fast track designation for the use of defibrotide for the treatment of severe VOD prior to stem cell transplantation. The approval of defibrotide for either the treatment or prevention of VOD may be dependent on one or more future clinical trials. It is possible that both the FDA and EMEA will view the results of treatment and prevention trials as supportive of one another, although the exact regulatory approval may include only an indication of prevention, treatment, or both.

- Increase our marketing capacity, including the use of strategic partnerships. We have a strategic license agreement with Sigma-Tau Pharmaceuticals, Inc. to market defibrotide to treat and prevent 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. We intend to develop the capacity to market defibrotide in other jurisdictions and/or pursue similar marketing agreements with other strategic partners for Europe and Asia Pacific.

- Compassionate use programs to maximize pre-approval data. We distribute defibrotide on a pre-approved compassionate use basis through our named-patient and treatment IND programs. We obtain data on the efficacy and safety of defibrotide through these programs. We expect to utilize this data to supplement the data obtained from our completed clinical trials and any future clinical trials that may be necessary. As of February 28, 2010, over 475 patients have received defibrotide through this program.

- Growth of API Business. We currently sell sulglicotide to Samil for use in the South Korean market, and to Crinos for use in the Italian market and urokinase to Crinos, for the Italian market, and UCB for the Spanish market, and, to a small extent, sodium heparin for use in the Italian market. Our goal is to maximize the utilization of our manufacturing facility and we are exploring ways to increase capacity of urokinase and sulglicotide. We are also looking at re-negotiating our existing supply agreements to achieve greater profitability and longer-term commitments.

Product Candidate

Defibrotide is an investigational drug based on single-stranded DNA extracted from pig intestines which is under development for the treatment and prevention of VOD, a consequence of cancer treatments, such as chemotherapy or radiation treatments, that are given prior to stem cell transplantation. Currently, and to the best of our knowledge, there are no FDA or EMEA approved treatments for this life-threatening disease. Defibrotide was granted orphan status in 2003 for the treatment of severe VOD and in 2007 for the prevention of VOD, and similar status by EMEA in 2004 for both the treatment and prevention of VOD. Orphan status provides us with limited market exclusivity upon regulatory approval. Defibrotide has also been granted fast-track product designation by the FDA for the treatment of VOD. While we have not yet obtained regulatory approval to market defibrotide, we are authorized to distribute defibrotide on a pre-approved basis under a treatment IND protocol in the U.S. and through a named-patient program throughout the rest of the world.

Defibrotide to treat severe VOD

The December 2000 edition of 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 study found 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. The study found that defibrotide was generally safely administered with no significant side-effects.

The December 15, 2002 edition of Blood published results from 88 patients with severe VOD following stem cell transplants who were treated with defibrotide from March 1995 to May 2001. This study 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 held 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 study found 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 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.

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 partially funded by a $525 thousand grant 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.

The January 2004 edition of Bone Marrow Transplantation published results from 45 children and adolescents with VOD following stem cell transplants who were treated with defibrotide. 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 study found 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.

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 the secondary endpoint is survival after 100 days.

On December 7, 2009, we announced final clinical trial results for our current Phase III clinical trial of defibrotide to treat severe VOD at the American Society of Hematology Conference in New Orleans. On an intent to treat basis (ITT), 24% of patients in the Defibrotide arm compared to 9% of patients in the historical control arm achieved complete response at 100 days (p=0.0148). For the secondary efficacy analysis on an ITT basis, the mortality rate at day 100 was 75% for patients in the historical control arm compared to 62% for patients in the Defibrotide arm (p=0.0508). The ITT analysis included 123 patients with symptoms consistent with VOD that were identified and then reviewed for eligibility in the historical control arm by an independent medical review committee. 32 cases were selected as having an unequivocal diagnosis of severe VOD and multi-organ failure (graft versus host disease was ruled out) and met all protocol-required entry criteria. 102 patients were enrolled in the defibrotide treatment group and baseline characteristics were balanced between the two arms.

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. The European Group for Blood and Marrow Transplantation, a not-for-profit scientific society, conducted a Phase II/III clinical trial in Europe and Israel of defibrotide to prevent VOD in children. Unlike our Phase III treatment trial in the United States, we had a randomized control group of patients who received no treatment unless they developed VOD, at which time they received defibrotide treatment.

The results of a study on defibrotide in patients at high risk of VOD were presented at the 2002 annual meeting of the American Society of Hematology. One of 57 patients who received defibrotide as a preventative agent developed VOD. No patients experienced significant bleeding.

At the 2005 annual meeting of the European Group for Blood and Marrow Transplantation, the results of a study on defibrotide in patients who received chemotherapy and stem cell transplants were announced. 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.

At the 2006 annual meeting of the American Society of Hematology conference, 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 were announced. The results suggested that defibrotide may provide effective and safe prevention against VOD. The study tested patients who received stem cell transplants. None of the 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.

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

The results of a study on defibrotide in patients who received stem cell transplants and had elevated risks for VOD were reported in the November 16, 2007 edition of Blood. One of 41 evaluable patients who received defibrotide as a preventative agent developed VOD. No serious adverse events were reported.

On December 7, 2009, we announced final clinical trial results from our Phase II/III pediatric prevention study to prevent VOD at the American Society of Hematology conference. Defibrotide demonstrated a 40% reduction in the incidence of VOD within 30 days after stem cell transplantation. The analysis included 356 patients; 180 patients in the prophylaxis arm and 176 patients in the control arm. Although the study was not powered to assess mortality, a composite score was measured as a secondary endpoint, incorporating VOD-associated morbidity (including respiratory failure, renal failure, encephalopathy) and mortality; this score significantly favored defibrotide prophylaxis ($p=0.0340$). The study confirmed that the mortality in patients with VOD, independent of severity, is four times higher than in patients without VOD. Additionally, the incidence and severity of acute graft versus host disease (GvHD) by day 100 in the allogeneic SCT recipients (246 patients) was significantly reduced from 63% for the

control arm to 45% for the prophylaxis arm (p=0.0044 for incidence of GvHD and p=0.0032 for severity). Defibrotide was well tolerated and no difference in adverse events was observed between the two study arms.

Defibrotide Pre-Approval

Historically, we sold defibrotide as an active pharmaceutical ingredient to our affiliate, Sirton, who then used the active pharmaceutical ingredient for defibrotide to fill and finish the product into ampoule and capsule forms. Sirton then sold these forms of defibrotide to Crinos S.p.A., a subsidiary of Stada Arzneimittel AG. Crinos, pursuant to a distribution agreement entered into with us, sold these products throughout Italy, under the trademarks Prociclide and Noravid, to treat and prevent vascular disease with risk of thrombosis.

In 2007, we changed our relationship with Sirton, from customer to a contract manufacturer, and sold the finished forms of Prociclide and Noravid to Crinos directly. On December 31, 2008, the distribution agreement with Crinos expired and, consistent with our overall strategy, we chose not to renew this agreement and discontinued the manufacture of defibrotide to be finished into Prociclide and Noravid. We have not pursued any sales of Prociclide and Noravid in the Italian market in 2009. On August 19, 2009, the Italian Health Agency accepted the Company's request to withdraw the marketing authorization for Prociclide and Noravid; however, these products will be sold in Italy through May 2010. The Company had made the request to withdraw the marketing authorization of these forms of defibrotide as part of the Company's overall strategy regarding the development of defibrotide to treat and prevent VOD.

On March 6, 2009, we entered into a supply and distribution agreement with IDIS Limited, whereby IDIS was contracted to be the exclusive supplier of defibrotide on a named-patient supply basis in all countries other than countries in Europe and the Americas. This agreement was amended on April 15, 2009 to include all countries other than Italy and countries in the Americas, and further amended on May 22, 2009 to include all countries other than Italy and the United States of America. Gentium supplies the finished and labeled product to IDIS who in turn provides the product directly to hospitals in all countries except Italy and the United States.

We have also instituted an expanded access program, which gives patients diagnosed with VOD in the United States access to defibrotide under a treatment IND. Under an expanded access program, the FDA allows early access to investigational drugs that are being developed to treat serious or life-threatening 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 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. On September 29, 2009, we entered into an agreement with US Oncology Clinical Development, whereby US Oncology was contracted as a clinical research organization to administer and recover costs on behalf of us in connection with this program. We expect to collect additional usage tolerability and safety data from patients of this program to support our planned New Drug Application for the treatment of Severe VOD and/or the prevention of VOD.

Our revenues from sales of defibrotide, including Prociclide and Noravid, were €2.76 million, €1.73 million, and €4.90 for 2007, 2008 and 2009, respectively.

Other Products

Sulglicotide

Sulglicotide is developed from swine duodenum and appears to have ulcer healing and gastrointestinal protective properties. We sell sulglicotide primarily to Samil, a South Korean company, for use in manufacturing a product of Samil's in South Korea, and to Crinos S.p.A. to be sold in the Italian market.

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 a number of companies, including Crinos and UCB.

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 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 under the FDA's good clinical practices regulations;
- 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 Investigational New Drug Application, each clinical institution that desires to participate in a proposed clinical trial must have the clinical protocol reviewed and approved by an Institutional Review Board. The 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. 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 a 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 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 safety and effectiveness information while the drug is marketed. 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. 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 for the treatment of severe VOD and the prevention of 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. 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 Privacy 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. In addition, the American Recovery and Reinvestment Act of 2009, or ARRA, imposed additional requirements for covered entities to protect individually identifiable health information. While we do not believe we are directly regulated as a covered entity under HIPAA, the HIPAA standards and requirements under ARRA 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 and ARRA 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 (a 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.

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.

Pediatric Investigation Plan

The pediatric investigation plan, or PIP, is a key element in the European pediatric regulations and came into effect in January 2007. The PIP is a plan for defining the use of a medicinal product across all age groups of the pediatric population and across all indications. The pediatric committee, or PDCO, is a body within EMEA responsible for overseeing the requirements of the pediatric regulation. The PDCO may grant a waiver from using a medicinal product in certain (or all) indications and/or certain (or all) pediatric age groups, and/or a deferral of the start or completion of all or some of the studies in the PIP. If a sponsor complies with a PIP agreed by PDCO, the sponsor may receive a six-month extension on patents covering the product described in the plan, or if the product has been designated an orphan drug by EMEA, an additional two years of market exclusivity, even if a pediatric indication is not approved.

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 the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and, without incentives, it is unlikely that the marketing of the medicinal product within the European Union would generate sufficient income to justify the necessary investments in the relevant medicinal product. 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 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 and sulglicotide.

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.

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.

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 this 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, such as Genzyme Corp., Millennium Pharmaceuticals, Inc., Otsuka Pharmaceutical Co., Ltd., Eisai Co., Ltd., and Celgene Corp, 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, 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, our former Chief Executive Officer and President and a current member of our board of 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, 2009, is subject to a mortgage securing repayment of an aggregate of €2.0 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 GMPs, 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 produce defibrotide and sulglicotide at this facility and have capability to produce sodium and calcium heparin. 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 or calcium and sodium heparin 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 for the fiscal year 2010 are set forth below:

Product	Estimated Current Production Levels (kilograms/year)	Maximum Production Capacity With Two Eight Hour Shifts (kilograms/year)	Percentage of Utilization
Defibrotide	180	4,400	4%

Until December 31, 2008, we manufactured defibrotide to be filled and finished and sold under the trademarks Prociclide and Noravid to treat and prevent vascular disease with risk of thrombosis in Italy. We have discontinued the manufacture of defibrotide for this use; however, we will continue to manufacture defibrotide to meet future demands and for clinical trials and compassionate use purposes.

Our estimated current production, production capacity, and percentage of utilization for sulglicotide for the fiscal year 2010 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	7,015	7,015	100%

Our estimated current production, production capacity, and percentage of utilization for urokinase for the fiscal year 2010 are set forth below:

Product	Estimated Current	Percentage of

	Production Level (millions of units/year)	Maximum Production Capacity With One Eight Hour Shift (millions of units/year)	Utilization
Urokinase	37,800	37,800	100%

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.

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. In addition, we 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 are a biopharmaceutical company focused on the development and manufacture of our primary product candidate, defibrotide, an investigational drug based on single-stranded DNA extracted from pig intestines. Our development of defibrotide has been focused on the treatment and prevention of a disease VOD, a condition in which some of the veins in the liver are blocked as a result of cancer treatments, such as chemotherapy or radiation treatments, that are given prior to stem cell transplantation. Severe VOD is the most extreme form of VOD and is associated with multiple-organ failure and high rates of morbidity and mortality. We have completed two clinical trials, a Phase III trial of defibrotide for the treatment of severe VOD in the U.S., Canada and Israel and a Phase II/III pediatric trial in Europe for the prevention of VOD. Defibrotide has been given orphan status by the FDA and EMEA, which means that we will have limited market exclusivity upon regulatory approval. Defibrotide has also been granted fast-track product designation by the FDA for the treatment of VOD. While we have not yet obtained regulatory approval to market defibrotide, we are authorized to distribute defibrotide on a pre-approved basis under a treatment IND protocol in the U.S. and through a named-patient program throughout the rest of the world. We do not know of any FDA or EMEA approved treatments for VOD.

We are currently completing certain preclinical and clinical studies requested by regulatory authorities. As part of our overall strategy, we anticipate filing for regulatory approval for defibrotide in the U.S. and Europe by the end of our second quarter in 2011. We are also working closely on our U.S. regulatory strategy with our commercial partner, Sigma-Tau Finanziaria S.p.A. and its affiliate Sigma-Tau Pharmaceuticals, Inc., to which we have licensed our commercial rights to defibrotide for both the treatment and prevention of VOD in the Americas.

We have a manufacturing plant in Italy where we produce active pharmaceutical ingredients, which are subsequently used to make the finished forms of various drugs. We believe that we are the sole worldwide producer of defibrotide. In addition to defibrotide, we manufacture urokinase and sulglicotide, both of which are sold to third parties. All of the Company's operating assets are located in Italy.

Historically, we sold defibrotide as an active pharmaceutical ingredient to our affiliate, Sirton, who then filled and finished the defibrotide active pharmaceutical ingredient into ampoule and capsule forms. Sirton then sold these ampoules and capsules to Crinos S.p.A., a subsidiary of Stada Arzneimittel AG. Crinos, pursuant to a distribution agreement entered into with us, sold these products throughout Italy, under the trademarks Prociclide and Noravid, to treat and prevent vascular disease with risk of thrombosis in Italy.

In 2007, we changed our relationship with Sirton, from customer to a contract manufacturer, and sold the finished forms of Prociclide and Noravid to Crinos directly. On December 31, 2008, the distribution agreement with Crinos expired and, consistent with our overall strategy, we chose not to renew this agreement and discontinued the manufacture of defibrotide to be finished into Prociclide and Noravid. In August, 2009, the Italian Health Agency accepted the Company's request to withdraw the marketing authorization for Prociclide and Noravid but granted an extension of the marketing authorization through May 2010 in order to sell the products that were previously distributed.

In 2009 we launched a named-patient program, administered by IDIS Limited, and a cost recovery program, administered by US Oncology Clinical Development. Both of these programs are designed to provide defibrotide to patients on a pre-approval compassionate use basis. For the year ended December 31, 2009, sales of defibrotide through these programs amounted to approximately 51% of our total product sales.

In January 2010, we amended and expanded our existing license agreement with Sigma-Tau Pharmaceuticals, Inc. to include the prevention indication of defibrotide for the Americas. Following this amendment, we decided to close our New York office and consolidate our corporate activities within our headquarters in Italy.

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

	For The Years Ended December 31,		
(in thousands)	2007	2008	2009
Product sales:			
Prociclide and Noravid	€ 2,756	€ 1,728	€ -
Urokinase	1,461	844	1,974
Sulglicotide	764	2,672	2,789
Other	113	199	35
Named-patient/cost recovery program sales	-	-	4,904
Total product sales	5,094	5,443	9,702
Other revenues	2,515	1,995	466
Total revenue	€ 7,609	€ 7,438	€ 10,168

Of our product sales in the periods shown in the table above, all were sales in Italy except for 13.5% during the year ended December 31, 2007 and 49.1% during the year ended December 31, 2008, which were primarily sales of sulglicotide in South Korea, and 85.9% for the year ended December 31, 2009, which were sales of sulglicotide in South Korea, sales of urokinase in Spain and sales of defibrotide through the named-patient and cost recovery programs. Substantially all of our other revenues is the result of a cost sharing arrangement with Sigma-Tau Pharmaceuticals, Inc., entered into in 2007, under which Sigma-Tau Pharmaceuticals, Inc. agreed to reimburse us for 50% of certain costs incurred in our Phase III clinical trial of defibrotide to treat severe VOD and milestone payments under our 2001 License and Supply Agreement entered into with Sigma-Tau Pharmaceuticals, Inc.

We expect to continue to incur net losses as we continue the development of defibrotide, apply for regulatory approvals and expand our operations. However, absent the need to fund any additional clinical trials, we believe that our cash and cash equivalents, including the upfront payment received from Sigma-Tau Pharmaceuticals, Inc. in connection with the expansion of the license for defibrotide in the Americas, together with revenues generated from our named-patient and cost recovery programs, will be sufficient to meet our obligations for at least the next twelve months. However, if we elect to increase our spending above current plans or perform additional clinical trials, we may need to obtain additional capital through equity or debt financings, loans and collaborative agreements with corporate partners, which may not be available to us on favorable terms, if at all.

As of December 31, 2009, 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 mature within three months of purchase. We are exposed to exchange rate risk with respect to certain of our cash balances and accounts receivables that are denominated in U.S. dollars. As of December 31, 2009, we held a cash balance of $0.50 million, receivables of $0.96 million and payables of $1.99 million that were denominated in U.S. dollars. This dollar-based balances are 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 remeasurement 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 affect 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 was from the sale of products, named-patient and cost recovery programs and from collaborative arrangements. We recognize revenue from product sales when ownership of the product is transferred to and accepted by the customer, the sales price is fixed or determinable, and collectability 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. Revenues are recorded net of applicable allowance for contractual adjustments entered into with customers.

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. 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. Revenue associated with substantive at-risk milestones is recognized based upon the achievement of the milestones as defined in the respective agreements. We defer and recognize as revenue non-refundable payments received in advance that are related to the future performance over the life of the related research project. We recognize reimbursements to fund research and development efforts as the qualified expenditures are made. Finally, royalty revenues are recognized when earned when the applicable sales are made.

Inventories

Inventories consist of raw materials, semi-finished and finished active pharmaceutical ingredients and defibrotide distributed through the named-patient and treatment IND programs. 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.

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. We also review our inventory for quality assurance and quality control issues identified in the manufacturing process and determine if a write-down is necessary. 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.

Prior to commencement of selling defibrotide through the named-patient and cost recovery programs, we had expensed all costs associated with the production of defibrotide as research and development expense. Subsequent to signing the agreements associated with the named-patient and cost recovery programs, we capitalized the subsequent costs of manufacturing defibrotide as inventory, including costs to convert existing raw materials to active pharmaceutical ingredient and costs to package and label previously manufactured inventory whose costs had already been expensed as research and development expense. Until we sell the inventory for which a portion of the costs were previously expensed, the carrying value of our inventories and our cost of sales will reflect only incremental costs incurred subsequent to the signing of these agreements.

We expense costs relating to the production of clinical products as research and development expense in the period incurred, which are not expected to be sold through the named-patient and cost recovery programs and will continue to do so until we receive an approval letter from the United States Food and Drug Administration, or FDA, or European Medicines Agency, or EMEA, for a new product or product configuration. Upon receipt of an approval letter from FDA or EMEA for a new product or product configuration, we will begin to capitalize the subsequent inventory costs relating to that product configuration.

Impairment of Long-lived Assets

Our long-lived assets consist primarily of property and equipment. We evaluate our ability to recover the carrying value of long-lived assets used in our business, considering changes in the business environment or other facts and circumstances that suggest their value may be impaired.

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

Research and Development Expenses

We have several activities, and their related costs, that are included in research and development expenses. These activities include primarily salaries and benefits of our direct employees, employee stock based compensation expense, facility costs, overhead costs, clinical trial costs and related trial product manufacturing costs, contracted services and subcontractor costs. Clinical trial costs include costs associated with contract research organizations. The billings that we receive from contract research organizations for services rendered may not be received for several months following the service. We accrue the estimated costs of the contract research organizations related services based on our estimate of management fees, site management and monitoring costs and data management costs. Our research and development department is in continuous communication with our contract research organizations to assess both their progress on the underlying study and the reasonableness of their cost estimates. Differences between estimated trial costs and actual have not been material to date, and any changes have been made when they become known. Under this policy, research and development expense can vary due to accrual adjustments related to the underlying clinical trials and the expenses incurred by the contract research organizations. At December 31, 2009, we had €0.32 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.

Stock-Based Compensation

Employee stock-based compensation is estimated at the date of grant based on the employee stock award's fair value using the Black-Scholes option-pricing model and is recognized as expense ratably over the requisite service period, which is generally the vesting period, in a manner similar to other forms of compensation paid to employees. The Black-Scholes option-pricing model requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock, the expected term of the award and the expected forfeiture rate. When establishing an estimate of the expected term of an award, we consider the vesting period of the award, our recent historical experience of employee stock option exercise, the expected volatility and a comparison to relevant peer group data.

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

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

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

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

Recent Accounting Pronouncements

Please see Note 2 of our financial statements, “Summary of Significant Accounting Policies to our Financial Statements,” for a discussion of new accounting standards.

Results of Operations

The following tables set forth our results of operations:

	For The Years Ended December 31,		
	2007	2008	2009
Amounts in thousands except share and per share data			
Revenues:			
Product sales to related party	€ 2,704	€ 651	€ 195
Product sales to third parties	2,390	4,792	9,507
Total product sales	5,094	5,443	9,702
Other revenues	15	25	129
Other revenues from related party	2,500	1,970	337
Total Revenues	7,609	7,438	10,168
Operating costs and expenses:			
Cost of goods sold	4,584	5,596	4,002
Research and development	14,497	9,569	3,512
General and administrative	6,279	7,668	6,036
Depreciation and amortization	725	998	916
Charges from related parties	748	537	279
Write-down of assets	13,740	3,403	-
Total operating costs and expenses:	40,573	27,771	14,745
Operating loss	(32,964)	(20,333)	(4,577)
Foreign currency exchange gain/(loss), net	(4,001)	173	162
Interest income/(expense), net	1,357	256	(110)
Loss before income tax expense	(35,608)	(19,904)	(4,525)
Net loss	€ (35,608)	€ (19,904)	€ (4,525)
Net loss per share:			
Basic and diluted net loss per share	(2.52)	(1.33)	(0.30)
Weighted average shares used to compute basic and diluted net loss per share	14,105,128	14,956,263	14,956,317

Year Ended December 31, 2009 Compared to Year Ended December 31, 2008

Product sales.

Our product sales were €9.70 million for 2009 compared to €5.44 million for 2008, an increase of €4.26 million or 78.3%. The increase was primarily due to the launch in April 2009 of the named-patient program and the launch in September 2009 of the cost recovery program in the U.S. Named-patient program and cost recover program sales, for the year ended December 31, 2009 amounted to €4.90 million.

Sales to a related party, Sirton, for the year ended December 31, 2009 and 2008 represented 2% and 12% of the total product sales, respectively. The decrease in sales to a related party is primarily due to the fact that in the second quarter of 2009 we terminated our supply agreement with Sirton and entered into direct sales agreements with Sirton's customers in order to mitigate the risk associated with Sirton's poor financial condition. Additionally, after March

2008, we did not recognize product sales to a related party, unless paid in advance, amounting to €1.08 million, because one of the criteria stated by SAB 104 ("collectability is reasonably assured") was not met.

Sales to third parties increased to €9.51 million for 2009 compared to €4.79 million for 2008, an increase of €4.72 million or 98.5%. The increase was primarily due to the launch in 2009 of the named-patient and cost recovery programs, which amounted to €4.90 million in sales. Excluding such sales, sales to third parties related to the API business would have been €4.61 million and €4.79 million in 2009 and 2008, respectively, with a decrease of €0.18 million or 3.8%, primarily due to slight decrease on unit sold of sulglicotide, offset by price increase and higher volume of urokinase sold in 2009 compared to prior year.

Other revenues

Our other revenues were €0.47 million for 2009 compared to €1.99 million for 2008. The decrease versus the prior-year is primarily attributable to a decrease in activities that were reimbursed from Sigma-Tau under our cost sharing agreement, offset by a milestone payment from Sigma-Tau of €0.23 million ($0.35 million) for completion of the phase III clinical trial.

Cost of goods sold.

Our cost of goods sold was €4.00 million for 2009 compared to €5.60 million for 2008. Cost of goods sold as a percentage of product sales, was 41% in 2009 compared to 103% in 2008. The percentage decrease is primarily due to higher margin on defibrotide sold through the named-patient program and price increases in the API business. The Company fully expensed the cost of inventory in the prior year. Additionally, the higher percentage of cost of goods sold in 2008 was primarily due to the fact that product sales to a related party, Sirton, were not recognized in the amount of €1.08 million due to Sirton's poor financial condition and concerns over the ability to collect such receivables.

Research and development expenses.

We incurred research and development expenses of €3.51 million in 2009 compared to €9.57 million for 2008. Research and development expenses in 2009 and 2008 are net of €0.85 and €0.79 million, respectively, of government grants in the form of a tax credit. The reduction from the prior year is a result of a decrease in the activities related to the treatment and prevention studies.

General and administrative expenses.

Our general and administrative expenses were €6.04 million in 2009 compared to €7.67 million in 2008. In 2008, we established a reserve for doubtful accounts in the ammount of €1.78 million, of which €0.68 was releasedin 2009. Additionally, the Company had lower payroll costs due to the temporary layoffs under a special public fund used in Italy under the “Cassa Integrazione Guadagni” program.

Depreciation and amortization expense.

Depreciation and amortization expense was €0.92 million in 2009 compared to €1.00 million in 2008. Depreciation expense excludes depreciation of our manufacturing facilities included in our cost of goods sold.

Foreign currency exchange gain (loss), net

Our foreign currency exchange gain (loss) is primarily due to remeasurement at December 31, 2009 of U.S. dollar cash balances. The positive result between 2008 and 2009 is due to a more favorable exchange rate in 2009 and a lower cash balance.

Interest income/(expense), net.

Interest income /(expense), net amounted to €(0.11) million and €0.26 million in 2009 and 2008, respectively. The decrease in interest income /(expense), net is a result of a lower amounts of invested funds in 2009 compared to the prior period as well as a decrease in interest rates.

Net loss.

Our net loss was €4.53 million in 2009 compared to €19.90 million in 2008. The difference was primarily due to net sales generated with the launch of the named-patient program, decrease in general and administrative expense, research and development expense, and higher margin on products sold through the named-patient program.

Year Ended December 31, 2008 Compared to Year Ended December 31, 2007

Product sale.

Our product sales were €5.44 million for 2008 compared to €5.09 million for 2007, an increase of €0.35 million or 7%. The increase was primarily due to an increase in demand for our products from our customers. Sales to a related party, Sirton, for the year ended December 31, 2007 and 2008 represented 53% and 12% of the total product sales, respectively. The decrease in sales to a related party is primarily due to the fact that we did not recognize product sales to a related party for sale transactions consummated after March 2008, amounting to €1.08 million, because one of the criteria stated by SAB 104 ("collectability is reasonably assured") was not met. In addition, in contemplation of the expiration of our distribution agreement with Crinos, we stopped selling Prociclide and Noravid as a finished product to Crinos during the three month period ended December 31, 2008. Sales to third parties increased to €4.79 million for the year ended December 31, 2008 due to higher sales volume of sulglicotide. Sulglicotide is used by a South Korean manufacturer to produce a finished product.

Other revenues

Our other revenues were €1.99 million for 2008 compared to €2.51 million for 2007. Fluctuation versus the prior-year period is primarily due to timing on the recognition of reimbursement from Sigma Tau, under a cost sharing arrangement entered into during the third quarter of 2007, of certain costs incurred in our ongoing phase III clinical trial of defibrotide to treat severe VOD.

Cost of goods sold.

Our cost of goods sold was €5.60 million for 2008 compared to €4.58 million in 2007. Cost of goods sold as a percentage of product sales was 103% in 2008 compared to 90% in 2007. The decrease in gross margin was primarily due to the non-recognition of product sales to a related party, Sirton, for sale transactions consummated after March 2008. The Company did not recognize product sales due to Sirton's poor financial condition, which caused concerns over the collectability of such receivables.

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

Research and development expenses.

We incurred research and development expenses of €9.57 million in 2008 compared to €14.50 million for 2007. Research and development expenses are net of €0.79 million government grants accrued as a reduction of expense. Excluding such grants, research and development expense would have been €10.36 million and €14.50 million in 2008 and 2007, respectively. Research and development expenses were primarily for the development of Defibrotide to treat and prevent VOD. The decrease from the comparable period in 2007 is the timing of performance of clinical research organizations and regulatory activities. Also contributing to the research and development expenses was stock based compensation of €0.38 million in 2008 compared to €0.44 million in 2007.

General and administrative expenses.

Our general and administrative expenses were €7.67 million in 2008 compared to €6.28 million in 2007. The 2008 general and administrative expenses reflect the establishment of an allowance for doubtful accounts of €1.78 million. General and administrative expenses include general corporate expenses, legal and other professional fees and stock based compensation expense of €1.50 million in 2008 compared to €1.36 million in 2007.

Depreciation and amortization expense.

Depreciation and amortization expense was €1.00 million in 2008 compared to €0.73 million in 2007. Depreciation expense excludes depreciation of our manufacturing facilities included in our cost of goods sold.

Write-down of assets

We recorded an impairment of €3.40 million in 2008 compared to €13.74 million in 2007. Write-down of assets include the write-down of acquired trademarks for Prociclide and Noravid (both forms of defibrotide), the Italian marketing authorizations for Prociclide and Noravid, inventory, and the Company's patents. The trademarks and marketing authorizations for Prociclide and Noravid have been written-down due to the expiration and non-renewal by the Company of the distribution agreement with Crinos S.p.A., which distributed Prociclide and Noravid in Italy to treat and prevent vascular disease with risk of thrombosis. Because the Company has decided to discontinue the distribution of Prociclide and Noravid, doubt has been raised concerning the recoverability of future cash flows expected to be derived from these assets. Therefore, the Company has impaired €1.70 million of the remaining net book value of the trademarks and Italian marketing authorizations for Prociclide and Noravid. In addition, the Company wrote down €1.23 million of the remaining book value of semi-finished and finished Prociclide and Noravid in our inventory, including such products expected to be returned by Crinos, as these products are no longer saleable. At December 31, 2008, we wrote down the remaining carrying value of the Company's patents amounting to €0.48 million, because there was no expected future cash flows to support the amounts to be derived over the remaining useful life of the patents.

Foreign currency exchange gain (loss), net

Our foreign currency exchange gain (loss) is primarily due to remeasurement at December 31, 2008 of U.S. dollar cash balances. The positive result between 2007 and 2008 is due to a more favorable exchange rate in 2008 and a lower cash balance in 2008 versus 2007.

Interest income, net.

Interest income, net amounted to €0.26 million and €1.36 million in 2008 and 2007, respectively. Gross interest income amounted to €0.59 million and €1.67 million in 2008 and 2007, respectively, a decrease of €1.08 million. The decrease is a result of a lower amount of invested funds in the 2008 period and decrease in interest rates. Interest expense totaled €0.33 million and €0.32 million in 2008 and 2007, respectively, an increase of €0.01 million attributable to an fluctuation in interest rate.

Net loss.

Our net loss was €19.90 million in 2008 compared to €35.61 million in 2007. The difference was primarily due to the write-down of assets acquired from Crinos amounting to €13.74 million, foreign exchange gain and lower research and development expenses, offset by an increase in general and administrative expenses due to the allowance for doubtful accounts of €1.78 million.

LIQUIDITY AND CAPITAL RESOURCES

During 2007, we used approximately €14.2 million of cash to fund operations and working capital requirements, €0.81 to reimburse current portions of long term debts and capital lease obligations, and approximately €7.1 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.

During 2008, we used approximately €12.78 million of cash to fund operations and working capital requirements, €1.60 to reimburse current portion of long term debts, short term borrowings and capital lease obligations, and approximately €0.59 million for capital expenditures. We funded these amounts from the following sources:

- €7.44 million in gross revenues;
- €147 proceeds from long term debt, and
- €25.96 million from cash available at December 31, 2007.

During 2009, we used approximately €5.16 million of cash to fund operations and working capital requirements, €1.17 to reimburse current portion of long term debts and capital lease obligations, and approximately €4.25 million for

capital expenditures, including €4 million paid to Crinos. We funded these amounts from the following sources:

- €9.70 million in gross revenues;
- €0.26 million in sales of marketable securities; and
- €11.49 million from cash available at December 31, 2008.

At December 31, 2009, we had an aggregate of €3.51 million in debt outstanding and had €1.39 million in cash and cash equivalents. In connection with the closure of our New York office, we will be using approximately €1.51 ($1.71) million of cash, which will be funded by cash available and approximately €5.11 ($7.00) million from the upfront payment received in connection with the amendment and expansion of the license agreement with Sigma-Tau Pharmaceuticals, Inc. 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 and prevent 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 receptivity of the capital markets to financings, generally, and of biotechnology companies, specifically; and
- our ability to enter into additional collaborative arrangements with corporate and academic collaborators and the success of such relationships.

Through December 31, 2009, the Company had accumulated losses of approximately €100 million. However, absent the need to fund any additional clinical trials, management believes that the Company's cash and cash equivalents, including the upfront payment received from Sigma-Tau Pharmaceuticals, Inc. in connection with the expansion of the license agreement for defibrotide in the Americas, together with revenues generated from the Company's named-patient and cost recovery programs, will be sufficient to meet the Company's obligations for at least the next twelve months. If the Company elects to increase its spending above current plans or perform additional clinical trials, it may need to obtain additional capital through equity or debt financings, loans and collaborative agreements with corporate partners, which may not be available to the Company on favorable terms, if at all.

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."

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, 2007, 2008 and 2009, we had three major categories of research projects relating to defibrotide to treat VOD, defibrotide to prevent VOD and assorted other projects. The table below presents our research and development expenses by project for each of the years ended December 31, 2007, 2008 and 2009.

	For The Years Ended December 31,		
(in thousands)	2007	2008	2009
Defibrotide to treat VOD	€ 11,035	€ 7,131	€ 641
Defibrotide to prevent VOD	869	1,055	2,102
Others	2,593	1,383	769
Total	€ 14,497	€ 9,569	€ 3,512

We expect to continue to incur expenses for the development of defibrotide to treat and prevent VOD. We will need additional funds before we have completed the development of defibrotide to treat and prevent VOD. A further discussion of the risks and uncertainties associated with developing defibrotide 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, 2009, we had nine issued U.S. patents, eight pending U.S. patent applications, 26 issued foreign patents, 46 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.

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, and various service agreements (including those related to our clinical trials).

The following table summarizes our long-term commitments as of December 31, 2009.

(in thousands)	Total	1 Year	2 Years	3 Years	4 Years	5 Years	More than 5 Years
Long-Term Debt Obligations:							
Mortgage loans	€ 1,800	€ 400	€ 400	€ 400	€ 400	€ 200	€ -
Finance loans	375	250	125	-	-	-	-
Equipment loans	706	415	291	-	-	-	-
Research loan	217	166	51	-	-	-	-
	€ 3,098	€ 1,231	€ 867	€ 400	€ 400	€ 200	€ -
Operating leases	47	16	16	15	-	-	-
Capital lease obligation	91	70	21	-	-	-	-
Research and Development Programs	323	323	-	-	-		
Total	€ 3,559	€ 1,640	€ 904	€ 415	€ 400	€ 200	€ -

We received various loans from the Minister for University and Research granted through San Paolo-IMI Bank (now Intesa SanPaolo) in September 2000 and December 2008. The loans are for financing research and development of defibrotide to treat and prevent VOD and bears interest at 1.0% per annum. We will need to repay the first 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, 2009, the amount outstanding under this loan was €145 thousand. We will need to repay the second loan in seven installments due every six months, beginning January 2009. At December 31, 2009, the amount outstanding under this loan was €85 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, 2009, these loans were fully reimbursed.

On April 20, 2006, we obtained a five year financing facility from Banca Intesa Mediocredito S.p.A. of up to €1 million to finance our purchase and installation of two reactors in our manufacturing facility. The financing 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 €263 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. In December 2009, Banca Intesa Mediocredito S.p.A agreed to defer payment of principal due for 12 months, extending the original term of the loan to 2012. At December 31, 2009, the aggregate amount outstanding under this facility was €394 thousand.

On June 14, 2006, we obtained a loan in the amount of €2,800 thousand 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. In December 2009, Banca Nazionale Del Lavoro S.p.A. agreed to defer payment of principal due for 12 months, extending the original term of the loan to 2015. At December 31, 2009, the principal amount outstanding under this loan was €2,000 thousand.

On June 30, 2006, we obtained a loan in the amount of €750 thousand from San Paolo IMI S.p.A (now Banca Intesasanpaolo 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. The Company was in compliance with this provision of the agreement at December 31, 2009. In December 2009, San Paolo IMI S.p.A agreed to defer payment of principal due for 12 months, extending the original term of the loan to 2012. At December 31, 2009, the amount outstanding under this loan was €437 thousand.

On December 20, 2006 we obtained three loans from Banca Intesa S.p.A (now Banca Intesasanpaolo 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, 2011. Principal and interest are due in 20 quarterly installments beginning on March 31, 2007. It bears interest at the three-month Euribor rate plus 1%. In December 2009, Banca Intesa S.p.A agreed to defer payment of principal due for 12 months, extending the original term of the loan to 2012. At December 31, 2009, the amount outstanding under this loan was €110 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%. In December 2009, Banca Intesa S.p.A agreed to defer payment of principal due for 12 months, extending the original term of the loan to 2012. At December 31, 2009, the amount outstanding under this loan was €222 thousand.

The third loan is in the amount of €225 thousand for a term of 57 months (after a technical pre-amortization 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%. In December 2009, Banca Intesa S.p.A agreed to defer payment of principal due for 12 months, extending the original term of the loan to 2012. At December 31, 2009, the amount outstanding under this loan was €113 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 paid Crinos a final installment of €4 million in January 2009.

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, 2010.

Name	Age	Position
Dr. Khalid Islam (1)	54	President and Chief Executive Officer
Gary Gemignani (2)	44	Executive Vice-President and Chief Financial Officer
Dr. Massimo Iacobelli	50	Senior Vice-President, Scientific Director
Salvatore Calabrese	40	Senior Vice-President, Finance
Gigliola Bertoglio (3)	75	Director
Marco Codella	50	Director
Dr. Glenn Cooper (4)	57	Director
Dr. Laura Ferro (1)	59	Director
Dr. Bobby W. Sandage, Jr. (5)	56	Director

(1) Member of the scientific oversight committee.

(2) Will be leaving as of March 31, 2010 in connection with our previously disclosed closure of our New York office.

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

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

(5) Member of the scientific oversight committee (chairperson) and audit committee.

Dr. Khalid Islam has served as our Chairman of our Board of Directors since December 2009 and our Chief Executive Officer since November 2009. Dr. Islam is the founder and current Chairman of Ki Consulting AG, a consulting firm specializing in the development of pharmaceutical drugs. Dr. Islam is also the co-founder of Sirius Healthcare Partners, an advisory firm for mid-cap and small-cap life science companies. From July 1999 until May 2008, Dr. Islam was the President and Chief Executive Officer for Arpida AG, a Swiss biopharmaceutical company that focuses on novel products for the treatment of microbial infections. Prior to that, Dr. Islam worked as an Alliance Manager for Hoechts Marion Roussel, a global pharmaceutical company, where he assisted with drug discovery and development. Dr. Islam has extensive experience working on behalf of pharmaceutical companies with both the United States Food and Drug Administration (FDA) and European Medicines Agency (EMEA) and has been involved with the development and marketing of several pharmaceutical products. Dr. Islam has previously served as a member of the Board of Directors for Arpida AG, Rheoscience A/S, and Arpida Inc. Dr. Islam received a B.S. in Biochemistry from Chelsea College, University of London, in 1977 and his Ph.D. from Imperial College, University of London, in 1983.

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 for the 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, 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.

Salvatore Calabrese has served as our Senior Vice-President of Finance since February 2010 and our Vice-President of Finance 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.

Gigliola Bertoglio has served as one of our directors from December 2004. Following the termination of our board of directors in August 2009, Ms. Bertoglio was re-elected to our board of directors on October 15, 2009. Ms. Bertoglio has been a partner of Audirevi S.r.l., an Italian registered public accounting firm, since January 2005 and was a self-employed consultant during 2004. 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, a member of the Accounting and Auditing Standards Group of Ernst & Young International and a coordinating audit partner for 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, served in an advisory role to the Accounting and Auditing Standards Group of Arthur Young International and was a coordinating audit partner for 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 is 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 Exchange's regulatory agency for public companies.

Marco Codella has served as one of our directors from June 2005. Following the termination of our board of directors in August 2009, Mr. Codella was re-elected to our board of directors on October 15, 2009. 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 and he has been Chief Financial Officer of Sigma-Tau Finanziaria S.p.A. since July 2008. Mr. Codella was a professor of Economics and Management Accounting at University of Rome, La Sapienza from 2001 to 2007. 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 Finanziaria S.p.A. He is also a Director of Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., Biosint S.p.A., Tecnogen S.p.A., Sigma-Tau Healthscience LLC, Sigma-Tau India, Sigma-Tau BV, and Sigma-Tau Healthscience International BV, each of which is a subsidiary of Sigma-Tau Finanziaria S.p.A. Mr. Codella is an Italian certified public accountant. Mr. Codella graduated summa cum laude from Rome University in 1984 with a degree in economics.

Dr. Glenn Cooper has served as one of our directors since October 2009. Dr. Cooper served as Chairman and Chief Executive Officer of Nasdaq-listed Indevus Pharmaceutical, a specialty pharmaceutical company focused on urology and endocrinology, from 1993 until 2009 when Indevus Pharmaceutical was acquired by Endo Pharmaceuticals. Prior to joining Indevus in 1993, Dr. Cooper held numerous executive level positions, including President and Chief Executive Officer of Progenitor, Inc., Executive Vice President and Chief Operating Officer of Sphinx Pharmaceuticals Corporation, and various clinical and regulatory positions with NYSE-listed Eli Lilly and Company. Dr. Cooper has participated in the development and commercialization of numerous drugs, including Prozac®, Axid®, Lorabid®, Ceclor®, SANCTURA®, SANCTURA XR®, Supprelin-LA®, and Vantas®. Dr. Cooper is currently a member of the Board of Directors of Repligen Corporation, listed on Nasdaq. Dr. Cooper received an M.D. from Tufts University School of Medicine, performed his postdoctoral training in Internal Medicine and Infectious Diseases at the New England Deaconess Hospital and the Massachusetts General Hospital and received a B.A. from Harvard University.

Dr. Laura Ferro is our former President and Chief Executive Officer and has served as one of our directors from 1991. Following the termination of our board of directors in August 2009, Dr. Ferro was re-elected to our board of directors on October 15, 2009. Dr. Ferro is the former President and Chief Executive Officer of our largest shareholder, FinSirton. From 1991 to 2010, Dr. Ferro also held various positions at Sirton Pharmaceuticals S.p.A., a subsidiary of FinSirton that specializes in manufacturing pharmaceutical products. Prior to that, Dr. Ferro was a practicing physician for 15 years. Dr. Ferro 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 effects 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.

Dr. Bobby W. Sandage, Jr. has served as one of our directors since October 2009. From 1991, and until Indevus Pharmaceuticals was acquired by Endo Pharmaceuticals in 2009, Dr. Sandage held various positions at Indevus Pharmaceuticals, including as Executive Vice President of Research and Development and Chief Scientific Officer. Following the acquisition of Indevus Pharmaceuticals, Dr. Sandage served as the Executive Vice President for Endo Pharmaceuticals, a pharmaceutical company listed on Nasdaq that is engaged in the research, development, sale and marketing analgesic products and products to treat various urological and endocrinological conditions. Prior to joining Indevus Pharmaceuticals, Dr. Sandage held senior drug development positions DuPont Merck Pharmaceutical Company, DuPont Critical Care (formerly American Critical Care) and Merrell Dow Pharmaceuticals. Dr. Sandage is currently a member of the Board of Directors of Osteologix Inc., a public pharmaceutical company that focuses on the treatment and prevention of diseases of bone and joint tissue. He has also served as a member of the Board of Directors of Genta, Inc., also a public company. Dr. Sandage has a B.S. in Pharmacy from the University of Arkansas and Ph.D. in Clinical Pharmacy from Purdue University.

All of our directors' terms expire at the date of our ordinary shareholders' meeting approving our 2009 Italian GAAP financial statements, which will be held on April 26, 2010 (first call) and, if necessary, April 30, 2010 (second call). All of our current directors have been nominated for re-election.

COMPENSATION

Compensation of Directors and Executive Officers

For the year ended December 31, 2007, the aggregate cash compensation to our executive officers and directors as a group was approximately €1.29 million. For the year ended December 31, 2008, the cash compensation to our executive officers and directors were €0.90 million and €0.47 million, respectively. For the year ended December 31, 2009, the cash compensation to our executive officers and directors were €1.18 million and €0.30 million, respectively. 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. During the year ended December 31, 2008, we granted options to purchase an aggregate of 220,648 ordinary shares to executive officers and directors at exercise prices ranging from $5.20 to $13.98 that terminate on dates ranging from January 2, 2018 to May 9, 2018. We did not grant any options during the year ended December 31, 2009.

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, 2009, there were 1,355,000 shares underlying outstanding options, with a weighted average exercise price of $12.18. 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). 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.

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, 2009, there were 242,030 shares underlying outstanding options, with a weighted average exercise price of $7.45. 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, subject to certain limitations.

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 to employees 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.

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.

The board of directors has proposed that the shareholders approve an amendment to the 2007 Stock Option Plan increasing the number of shares authorized under such plan to 2,200,000 at our Annual Ordinary Shareholders' Meeting on April 26, 2010 (first call) and, if necessary, April 30, 2010 (second call). In addition, as part of the overall director compensation package, the board of the directors has proposed that the shareholders approve a stock option grant with an economic value of $110,000 using the Black-Scholes model. We expect these options to only be issued to our non-employee 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 six members: Ms. Bertoglio, Dr. Cooper, Mr. Codella, Dr. Ferro, Dr. Islam and Dr. Sandage. Ms. Bertoglio, Dr. Cooper and Dr. Sandage have never been employed by us or any of our subsidiaries and are independent directors. 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 and board of directors have approved the following total director compensation for the term from our October 2009 ordinary shareholders' meeting to our ordinary shareholders' meeting approving our 2009 Italian GAAP financial statements, prorated on an annualized basis:

- an annual cash retainer of $45 thousand for each non-employee director, subject to shareholder approval; and
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$20 thousand to the chairperson of the audit committee; $10 thousand to the chairperson of the compensation committee; $15 thousand to the chairperson of the scientific oversight committee; $7.5 thousand to the chairperson of the nominating and corporate governance committee; and $5 thousand to all the other non-employee members of committees.

Board Committees and Code of Ethics

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

Audit Committee. Our audit committee consists of Ms. Bertoglio, Dr. Cooper and Dr. Sandage, each of whom is an independent director. Ms. Bertoglio is an audit committee financial expert. 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.

Compensation Committee. Our compensation committee consists of Dr. Cooper and Ms. Bertoglio, each of whom is an 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 makes recommendations to our board of directors regarding salaries, benefits, and incentive compensation for our executive officers and directors. 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 Dr. Cooper and Ms. Bertoglio, 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.

Scientific Oversight Committee. Our scientific oversight committee consists of Dr. Sandage, Dr. Islam and Dr. Ferro. Our scientific oversight committee assists the board of directors in fulfilling its oversight responsibilities with respect to clinical and regulatory matters. The scientific oversight committee's primary purposes are to:

- oversee 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 bylaws, 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 June 30, 2009 for a term that ends at the date of the ordinary shareholders' meeting to approve our 2011 annual financial statements.

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

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

In 2007, they met six times and attended six board of director meetings and one shareholder meeting. In 2008, they met eight times and attended thirteen board of director meetings and one shareholder meeting. In 2009, they met thirteen times and attended ten board of director meetings and one shareholder meeting. In 2009, we accrued €31 thousand as compensation for their service as our board of statutory auditors and €200 thousand as compensation for the assumed responsibility for the ordinary administration of the company, from August 2009 until our board of directors was reconstituted in October 2009.

Indemnification of Directors and Executive Officers and Limitation of Liability

We have entered into or will enter 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, 2007, 2008 and 2009. As of the date of this report, 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.

	As of December 31,		
	2007	2008	2009
Administration, accounting, finance, business development	18	18	18
R&D, clinical, regulatory	23	17	14
Production, quality assurance control	39	39	35
Total	80	74	67

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 December 18, 2009 and expires on December 31, 2012. Our executive officers in Italy are subject to a collective bargaining agreement that was renewed on November 25, 2009 and expires on December 31, 2013. 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 €601 thousand at December 31, 2009. 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.

In 2009 the Company initiated a fifty-two week temporary lay-off program called Cassa Integrazione. Under the program, Italian social securities partially funds the payroll of the temporarily laid-off employees. During the course of 2009, 40 employees were affected by the temporary layoff program.

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, 2010, are vested as to 446,220 shares.

Mr. Gary Gemignani, our Chief Financial Officer, and Dr. Massimo Iacobelli, our Scientific Director, hold options that, within 60 days of March 31, 2010, are vested as to 222,561 and 235,918, respectively.

To our knowledge, none of our other directors and officers listed herein owned one percent or more of our ordinary shares at March 31, 2010. 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, 2010 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, 2010, 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, 2010 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		
Laura Ferro (1)	4,144,894	27.2%
FinSirton S.p.A.(2)	3,750,000	25.1%
Paolo Cavazza (3)	2,624,378	17.46%
Claudio Cavazza (4)	2,474,943	16.55%
Sigma-Tau Finanziaria S.p.A. (5)	2,311,011	15.45%
Defiante Farmaceutica, S.A. (6)	1,011,001	6.76%
All directors and executive officers as a group (9 persons) (7)	4,754,674	31.8%

(1) Dr. Laura Ferro, who is our former Chief Executive Officer and President and one of our current directors, may be deemed to share voting or dispositive control with FinSirton over the ordinary shares in Gentium that FinSirton beneficially owns. Dr. Ferro disclaims beneficial ownership of such shares.

(2) Address is Piazza XX Settembre 2, 22079 Villa Guardia (Como), Italy. The board of directors of FinSirton, including Dr. Laura Ferro, 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 and 2,300,000 ordinary shares in our company to IntesaSanpaolo S.p.A. to secure repayment of such loan.

(3) Based upon the 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 S.A.; and (iii) 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.

(4) Based upon the 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., and (iii) 163,942 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.

(5) Based upon the 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. and (ii) 1,011,001 outstanding ADSs 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.

(6) Based upon the information obtained from a Schedule 13G filed with the SEC, as amended. Address is Rua dos Ferreios, 260, Funchal-Madeira (Portugal) 9000-082.

(7) Assumes that Dr. Laura Ferro is deemed to beneficially own the ordinary shares beneficially owned by FinSirton and includes 446,220 ordinary shares issuable upon exercise of options currently exercisable and exercisable within 60 days of March 31, 2010.

As of March 31, 2010, 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, 2007 except for the following.

- 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 may be 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.

- From July 2005 to May 2008, our company issued stock option awards to our officers and directors. 1,120,306 ordinary shares are issuable upon exercise of these stock option awards within 60 days of March 31, 2010.

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, 2010.

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 FinSirton's arrangement to vote its ordinary shares in our company in favor of electing a nominee to our board of directors designated by Sigma-Tau Finanziaria S.p.A.

RELATED PARTY TRANSACTIONS

Other than described below, between January 1, 2007 and the date of this report, 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 former Chief Executive Officer and President and one of our current directors, along with 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, 2010.

Agreements with Various Entities

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. In July 2009, the agreement was amended to reduce space rented and annual fee was decreased to €15 thousand.

On January 7, 2010, we amended our existing license with Sigma-Tau Pharmaceuticals, Inc. to include a license for the intravenous formulation of defibrotide for the prevention of veno-occlusive disease in the Americas and to transfer the New Drug Application post approval in the United States. In addition, we agreed to establish a joint steering committee with Sigma-Tau to discuss in good faith, the development, filing and relevant funding of defibrotide for any therapeutic indication in the territory licensed to Sigma-Tau.

On October 12, 2007, we entered into a 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. This agreement was amended effective January 7, 2010. While Sigma-Tau will continue to share development costs for studies currently required for the filing of an NDA for defibrotide, we have agreed to negotiate in good faith with Sigma-Tau regarding the funding of certain additional costs that may be required to obtain regulatory approval in the U.S., and that $1,000,000 of costs reimbursed by Sigma-Tau will be deductible from its future royalty payments due to Gentium under the License and Supply Agreement.

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. We terminated this agreement in November 2008; however, Sirton continues to manufacture finished ampoules for use in our compassionate use programs and any future clinical trials that may be necessary. On February 2, 2009 we executed a technical services transfer agreement with Patheon S.p.A., whereby Patheon S.p.A. would take over the manufacture of the finished vials of defibrotide.

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 Farmaceutiche 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 and prevent 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

As of the date of this report, 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 to the shareholders and is subject to the approval of our shareholders at the annual ordinary shareholders' meeting. Before dividends may be paid out of our profit in any year, we must allocate an amount equal to 5% of the net profit to our legal reserve until such reserve is at least equal to 20% of the 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 distribute reserves deriving from 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 to the shareholders 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.

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 shareholders' meeting and will depend on a number of factors, including our future earnings, capital requirements, financial condition, future prospects and other factors as the shareholders' meeting 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 for the avoidance of double taxation between the United States and Italy, signed on August 25, 1999 and entered into force on December 16, 2009 (the "Income Tax Convention"); provided, however, that conditions set out in the Income Tax Convention are met and subject to the applicable anti-avoidance provisions. In order for you to benefit from that reduction, we are required to furnish certain information concerning you to the Italian tax authorities and, therefore 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 (beginning June 16, 2005)	$ 9.10	$ 6.92
2006	$ 22.74	$ 7.85
2007	$ 24.40	$ 13.51
2008		
First Quarter	$ 13.98	$ 6.36
Second Quarter	$ 7.60	$ 3.41
Third Quarter	$ 4.29	$ 1.62
Fourth quarter	$ 1.73	$ 0.44
Full Year	$ 13.98	$ 0.44
2009		
First Quarter	$ 0.90	$ 0.33
Second Quarter	$ 1.91	$ 0.58
Third Quarter	$ 3.87	$ 1.36
Fourth Quarter	$ 2.75	$ 1.89
Full Year	$ 3.87	$ 0.33
Month Ended		
January 31, 2010	$ 2.36	$ 1.93
February 28, 2010	$ 1.85	$ 1.32
March 31, 2010 (through March 29, 2010)	$ 3.23	$ 1.34

The closing price of the ADSs on Nasdaq on March 29, 2010 was $2.58.

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 bylaws (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 bylaws 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 bylaws 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, April 27, 2007, and June 30, 2009. The following summary takes into account the 2003 corporate law reform and the consequent amendments to our bylaws.

General

As of March 31, 2010 our issued and outstanding share capital consisted of 14,956,317 ordinary shares, without a par value. 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 para-pharmaceutical 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 (i.e., the shares already subscribed) 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:

- 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;

- 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

- in each case, exclude or limit the option right of our shareholders in favor of "strategic investors" (as defined by our bylaws) 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.

On June 30, 2009, our shareholders resolved to (i) remove the par value of our ordinary shares, including the par value of the ordinary shares previously issued by the company, and (ii) grant the board of directors with the power to increase the capital in cash up to an amount equal to Euro 100,000,000 on a separable basis, in one or more transactions, for a rights offering, through the issuance of up to a maximum of 120,000,000 shares, without par value, with the faculty to reserve all or part of such amount to the exercise of warrants issued by means of the same resolution of the Board of Directors approving the relevant capital increase, and with the faculty to reserve 1/4 of any such capital increase to employees as equity incentive under the Company's equity incentive plans in effect from time to time.

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 to the shareholders 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 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 to the shareholders 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 bylaws, 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 bylaws 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 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 certain 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 urgency, at least one day in advance. 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 in attendance. 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 video-conference, in any member state of the European Union or in the United States. The quorum for meetings of our board of directors is the attendance of the majority of the directors in office. Resolutions are adopted by the vote of the majority of the directors in attendance at a meeting at which a quorum is met.

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 board of directors, which in turn makes recommendations to our shareholders. 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/or 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 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 bylaws 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

Under Italian law, at least one effective statutory auditor and one alternate statutory auditor of a company shall be chosen among those registered with the Register of Auditors established with the Ministry of Justice. The other statutory auditors shall be chosen among those registered with any register established by decree of the Ministry of Justice or among University professors in economic and law matters, if they are not registered with the Register of Auditors. The following persons may not be appointed as statutory auditors:

- one who is legally incapacitated, bankrupted, or disqualified from holding public or executive offices under Italian law;

- a spouse, parent and relative-in-law of someone that is a director of the company, a director of a company that controls the company, or a director of a company that is under common control as the company; and

- one whose independence may be jeopardized due to an employment or consultant relationship or any other economic relationship with the company, a company that controls the company, or a company that is under common control as the company.

In addition to electing our board of directors, our shareholders elect the 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 bylaws currently provide that the board of statutory auditors shall consist of three effective statutory auditors and two alternate statutory auditors (who will automatically replace 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 bylaws;
- 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. In case a statutory auditor, without just cause, does not attend the shareholders' meetings or, during the same fiscal year, two consecutive meetings of the board of directors, such statutory auditor shall cease from his/her office. If the statutory auditors 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, an Italian joint stock company 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 bylaws 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

Italian law 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.

Meetings of shareholders

Shareholders are entitled to attend and vote at ordinary and extraordinary shareholders' meetings. Votes may be cast personally or by proxy. Shareholders' meetings may be called by our board of directors (or, in certain cases, by the 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 Republica 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 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 bylaws, 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 bylaws 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, the securities that have been subscribed 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 subscribed securities.

The quorum for an ordinary meeting of our shareholders on the first call is at least 50% of the outstanding ordinary shares, while on second call there is no quorum requirement. In either case, resolutions are adopted by the majority of ordinary shares in attendance or represented at the meeting. The quorum for an extraordinary shareholders' meeting is more than half of the outstanding ordinary shares on the first call and more than one-third of the outstanding shares on second call. Resolutions are adopted by the majority of the outstanding ordinary shares on first call and at least two-thirds of the holders of shares in attendance 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 bylaws) must be adopted by shareholders representing more than one-third of the outstanding ordinary shares (not just the ordinary shares in attendance or represented at the meeting).

Shareholders are entitled to one vote per ordinary share. Neither Italian law nor our bylaws 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 attorneys-in-fact by delivering in writing the relevant proxy to represent them in an ordinary or extraordinary shareholders' meeting. Our directors, auditors and employees may not be proxies. Italian law provides that each proxy cannot be granted to 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 European Union constitutes "making recourse to the risk capital market for the purpose of the application of the Italian Civil Code." 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, each proxy cannot be granted to represent more than 50 shareholders if the capital is equal to €5 million or less or more than 100 shareholders if the capital is more than €5 million but less than or equal to €25 million. If the capital is more than €25 million, each proxy cannot be granted to represent more than 200 shareholders. At December 31, 2009, we had 14,956,317 shares outstanding and a

capital equal to Euro 14,956,317 and so if we are deemed to make recourse to the risk capital market, each proxy may not be granted to 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 excluded 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 (including the power to exclude or limit the preemptive right), and such exclusion 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 bylaws permit such issuances. Our bylaws currently do allow us to issue these securities. We may also issue convertible and non-convertible debt securities. In order to issue convertible debt 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 of directors 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 shareholders' meeting to delegate to the board of directors the power to issue those securities from time to time, but not for more than five years from the date of the extraordinary shareholders' meeting.

Debt-equity ratio

Italian law provides that we may not issue debt securities for an amount exceeding twice the amount of our capital, of our legal reserve and of 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 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 amount of such ordinary shares that is allocated to 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 share premium 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 shareholders' meeting as soon as possible. The shareholders should take appropriate measures, which may include, inter alia, either the reduction of the legal reserves and capital by the amount of the remaining losses, or the carrying out of 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 capital, then we must reduce our capital by the amount of the losses. However, as an S.p.A., we must maintain a 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 liquidator, not necessarily an Italian citizen, to liquidate our company.

Segregation of assets and proceeds

Pursuant to Italian law, 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 the net worth of the company. 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 an amount resulting from the division of the positive liquidation balance by the number of 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 and the authorization may be issued for a period not exceed the term of eighteen (18) months. .

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 bylaws 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. 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 Italian law, 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 Italian law, 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 requires the approval of more than half of the share capital 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 more than half of the share capital at an extraordinary shareholders' meeting, except that certain extraordinary actions, such as change in our purpose, advanced 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 or no par value shares. 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 or no par value shares. 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.

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 met at an ordinary meeting of shareholders on first call if the holders of at least 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 met at an extraordinary meeting of shareholders on first call if the holders of more than half of the share capital is 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 shareholders entitled to vote in person or by proxy at an ordinary meeting of shareholders at which the relevant quorum is met.

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 of a joint stock company 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 video-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.

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 to the shareholders and is subject to the approval of our shareholders at the annual ordinary shareholders' meeting. Before dividends may be paid out of our profit in any year, we must allocate an amount equal to 5% of the net profit to our legal reserve until such reserve is at least equal to 20% of 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 distribute reserves deriving from 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 and the authorization may be issued for a period not exceeding eighteen (18) months. 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 bylaws. Officers may be chosen in any way and by any person or body if the bylaws 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, shareholders and holders of 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, except in case of contribution in kind. The preemptive rights may be excluded 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, in first and second call, and such exclusion 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 an amount resulting from the division of the positive liquidation balance by the number of shares or shareholders (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 bylaws 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 Italian law, 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 Italian law, 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. Once our shareholders have authorized the issuance of securities and the same have been subscribed, 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 ordinary shares and €10 million for ordinary shares issuable upon conversion of convertible bonds on April 28, 2006. In addition, on June 30, 2009, our shareholders resolved to grant the board of directors with the power to increase the capital in cash up to an amount equal to Euro 100,000,000 on a separable basis, in one or more transactions, with the faculty to reserve all or part of such amount to the exercise of warrants issued by means of the same resolution of the Board of Directors approving the relevant capital increase, and with the faculty to reserve 1/4 of any such capital increase to employees as equity incentive under the Company's equity incentive plans. Italian law provides, with respect to shareholders' resolutions approving capital increase, that, in the event of absence of the minutes of the meeting, any interested person may, for a period of 180 days following the filing of the shareholders' resolution with the Register of Companies, challenge such resolution. If a shareholders' meeting was not called to approve the capital increase, the relevant resolution should be considered invalid and any interested person may challenge the capital increase for a period of 90 days following the approval of the financial statements referring to the year during which the shareholders' resolution has been, also partially, executed. Finally, once our shareholders authorize a capital increase, all those authorized shares that have been subscribed need to be entirely paid-up before the shareholders may authorize a new capital increase.

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 our capital, of our legal reserve and of 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 amount of such ordinary shares that is allocated to 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 legal reserves and capital. If our capital is reduced for more than one-third as a result of losses, our board of directors must call a shareholders' meeting as soon as possible. The shareholders should take appropriate measures, which may include, inter alia, either the reduction of the legal reserves and capital by the amount of the remaining losses, or the carrying out of 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 capital, then we must reduce our 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 liquidator, not necessarily an Italian citizen to liquidate our company.

MATERIAL CONTRACTS

The contracts described below have been entered into by our company since January 1, 2008 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.

On January 7, 2010, we amended our existing license with Sigma-Tau Pharmaceuticals, Inc. to include a license for the intravenous formulation of defibrotide for the prevention of veno-occlusive disease in the Americas and to transfer the New Drug Application post approval in the United States. In addition, we agreed to establish a joint steering committee with Sigma-Tau to discuss in good faith, the development, filing and relevant funding of defibrotide for any therapeutic indication in the territory licensed to Sigma-Tau.

On September 29, 2009, we entered into a clinical research agreement with US Oncology Clinical Development, whereby US Oncology was contracted as a clinical research organization to help administer certain aspects of our expanded access program and associated cost recovery program. US Oncology is responsible for site activation, drug supply management, data collection/management, and adverse event reporting to Gentium as well as billing and invoicing. We pay US Oncology based on the amount of service performed each month as well as a fixed fee for each unit of drug product shipped. US Oncology does not pay Gentium until it receives payments from the hospitals/institutions.

On March 6, 2009, we entered into a supply and distribution agreement with IDIS Limited, whereby IDIS will be the exclusive supplier of defibrotide on a named-patient supply basis in all countries other than Europe and the Americas. This agreement was amended on April 15, 2009 to include all countries other than Italy and countries in the Americas, and further amended on May 22, 2009 to include all countries other than Italy and the U.S. Gentium will supply the

finished and labeled product to IDIS who will in turn provide the product directly to hospitals in countries outside Europe and the Americas. IDIS will maintain all relevant importation and regulatory licenses necessary to perform this service. IDIS will also assist Gentium with various clinical and regulatory obligations such as adverse event reporting. Gentium will instruct IDIS the price to charge for defibrotide, and in some cases, whether defibrotide will be given away free of charge. IDIS will invoice the hospitals directly and in turn pay Gentium once IDIS collects the receivable. Gentium will pay a fee to IDIS for each unit shipped and will also pay IDIS a monthly service fee.

On February 2, 2009, we entered into a technical transfer services agreement with Patheon International A.G., whereby its affiliate, Patheon Italia S.p.A. (as subcontractor) will assume the fill and finish of defibrotide in vials (currently performed by Sirton). Patheon will perform the transfer of all analytical methods, will run a feasibility batch and will eventually run validation batches which, if successful, will be used for commercial sale upon final regulatory approval of defibrotide. Patheon will also support Gentium in its regulatory filings by providing key documentation, review of Gentium's regulatory submissions and access to regulators from the FDA and/or EMEA to inspect Patheon's facility (the Pre-Approval Inspection). Gentium pays Patheon certain upfront and milestones to compensate Patheon for the services it performs as well as the capital expenditures it incurs. All equipment purchased by Patheon will reside at Patheon but will be owned by Gentium.

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 who:

- owns ADSs representing 10% or more of our voting shares (either directly or through attribution);
- holds ADSs in connection with a permanent establishment or fixed base of business located in Italy;
- 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;
- 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
- is a resident of Italy for purposes of Italian domestic law or the Income Tax Convention, as defined above, 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 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:

- an individual citizen or resident of the United States;

- 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;

- an estate the income of which is includible in gross income for US federal income tax purposes regardless of its source;

- 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

- 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.

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% for individuals not engaged in an entrepreneurial activity. 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 to:

- 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,

- produce a statement whereby the US owner represents that it is a US owner that does not maintain a permanent establishment in Italy, and

- 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. Ministerial Decree April 2, 2008 – issued pursuant to Article 1, paragraph 38 of the Law December 24, 2007 (Budget Law 2008) – sets out that 49.72% (it was 40% until 2008) of the capital gains would contribute to determine the overall taxable income.

This rate applies to capital gains realized as from January 1, 2009. The 40%, previously in effect, still applies to capital gains realized in connection with disposal deeds executed before January 1, 2009. 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. 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, save for any applicable anti-avoidance provision, 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 than those mentioned under (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).

The US dollar amount of dividends received by individuals prior to January 1, 2011 with respect to our shares or ADSs will be subject to taxation at a maximum rate, 15 percent, 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 January 1, 2011 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 tradable 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 2010, 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 are required to file annual reports on Form 20-F within six months of our fiscal year end, and we submit other reports and information under cover on 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, 2009, 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, accounts receivable and accounts payable that are denominated in the U.S. dollar. As of December 31, 2009 we held a cash balance of $0.50 million, accounts receivable of $0.96 million and accounts payable of $1.99 million that were denominated in U.S. dollars. As the net positions of our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. As of December 31, 2009, our foreign currency transactions are minimal and changes to the exchange rate between the US dollar and Euro would have an immaterial affect on our earnings. If the US dollar were 10% stronger against the Euro, our net liabilities balance would increase by approximately €0.04 million as of December 31, 2009.

As of December 31, 2009, we had €3,276 thousand principal amount of floating debts. Our exposure includes changes in interest rates, as borrowing under our debts bear interest at floating rates based on Euribor plus an applicable margin. We have managed our interest rate risk by entering into interest cap agreements. 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 15T. CONTROLS AND PROCEDURES

Management's Evaluation of Disclosure Controls and Procedures

(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.

(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, 2009. 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 this assessment, management concluded our internal control over financial reporting was effective as of December 31, 2009.

(c) Because a material weakness was identified in our controls and procedures as of December 31, 2008, management has taken the necessary steps to address such material weakness for the period covered by this report, which included an earlier review process by qualified professionals for certain non-routine and estimation processes. Except for the foregoing, 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) This annual report on Form 20-F does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting pursuant to temporary rules of the Securities and

Exchange Commission that permit us to provide only management's report in this annual report.

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 qualifies as an "audit committee financial expert" within the meaning of this Item 16A.

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, 2008 and 2009:

(in thousands of Euros)	Year ended December 31,	
	2008	2009
Audit Fees	€ 155	€ 120
Audit-Related Fees	-	-
Tax Fees	-	-
All Other Fees	-	-
Total fees	€ 155	€ 120

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, 2008 and 2009.

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.

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.

ITEM 16F.CHANGE IN CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G.CORPORATE GOVERNANCE

The Nasdaq Listing Rules set forth the corporate governance requirements of companies listed on The Nasdaq Stock Market. Subsection (a)(3) of Listing Rule 5615 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 Listing Rule 5615(a)(3), we follow Italian practices in lieu of six of the Nasdaq Stock Market's corporate governance requirements pertaining to: (1) independent directors, (2) our audit committee, (3) solicitation of proxies and provision of proxy statements, (4) quorum requirements, (5) shareholder approval requirements, and (6) executive sessions. In addition, while we currently comply with Nasdaq's requirement to have a majority of our independent directors or a committee comprised solely of independent directors determine or recommend compensation for our executive officers and select or recommend director nominees, we are not required to follow these rules, nor does Italian law provide for such requirements.

Majority of Independent Directors

The Nasdaq Stock Market: Listing Rule 5605(b)(1) requires that a majority of the board of directors be "independent." In order for a director to be considered "independent," a director may not be an employee of the company or have a relationship with the company which, in the opinion of the company's board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Italian practices: The presence of a prescribed number of independent directors on the company's board is neither mandated by any Italian law applicable to the company nor required by the company's bylaws.

However, Italian law sets forth certain independence requirements applicable to the company's statutory auditors. The following persons may not be appointed as statutory auditors: a person who is (i) legally incapacitated, bankrupted, or disqualified from holding public or executive offices under Italian law (ii) a spouse, parent and relative-in-law of someone that is a director of the company, a director of a company that controls the company, or a director of a company that is under common control as the company, or (iii) one whose independence may be jeopardized due to an employment or consultant relationship or any other economic relationship with the company, a company that controls the company, or a company that is under common control as the company. The Italian Civil Code mandates that at least one effective statutory auditor be a chartered public accountant. Each of the current members of the board of statutory auditors is a chartered public accountant.

Audit committee.

The Nasdaq Stock Market: Listing Rule 5605(c)(3) 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.

Following the termination of our former board of directors in August 2009, our board of statutory auditors temporarily assumed responsibility for the ordinary administration of the company. During this temporary period, we relied on this exemption from both the audit committee requirements provided by Nasdaq and the audit committee requirements provided by Exchange Act Rule 10A-3 for foreign private issuers with a board of statutory auditors established in accordance with local law or listing requirements and subject to independence requirements under local law or listing requirements.

Proxy Solicitation and Proxy Statements

The Nasdaq Stock Market: Listing Rule 5620(b) 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.

Quorum requirements.

The Nasdaq Stock Market: Listing Rule 5620(c) 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 at least 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 the majority of the capital on the first call and more than one-third of the outstanding capital on a second call.

Shareholder approval requirements.

The Nasdaq Stock Market: Listing Rule 5635 sets forth certain Nasdaq Stock Market's shareholder approval requirements in connection with the acquisition of stock or assets of another company, equity based compensation of officers, directors, employees or consultants, a change of control, and private placements. Specifically, Listing Rule 5635(a) requires shareholder approval prior to the issuance of securities in connection with the acquisition of the stock or assets of another company if the issuance of securities will have voting power equal to or greater than 20%, number of shares to be issued will be equal to or in excess of 20% of the outstanding number of shares before the issuance of such securities, or any director, officer or "substantial shareholder" gains an increase in outstanding common shares or voting power of 5% or more in connection with such transaction. Listing Rule 5635(b) requires shareholder approval prior to the issuance of securities when such issuance or potential issuance will result in a change of control. Listing Rule 5635(c) requires shareholder approval when an equity incentive plan is established or materially amended or other equity compensation is made or materially amended. Listing Rule 5635(d) requires shareholder approval in connection with a private placement at a price less than the greater of book or market value which results in the issuance of 20% or more of the outstanding common stock prior to the issuance or 20% or more of the outstanding voting power prior to the issuance.

Italian Practice: Although the Company's shareholders must authorize the issuance of shares in connection with any capital increase, such power can be granted to the board of directors in advance of any of the above mentioned transactions, if necessary, and none of the Listing Rule 5635 requirements discussed above require specific shareholder approval under Italian law.

Executive Sessions

The Nasdaq Market: Listing Rule 5602(b)(2) requires that independent directors have regularly scheduled meetings in which only independent directors are present.

Italian Practice: Under Italian law, neither non-executive directors nor independent directors are required to meet in executive sessions. The members of the Company's board of statutory auditors are required to meet at least every 90 days.

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.
	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.

Exhibit	Description
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.
4.12.3*	Amendments to License and Supply Agreement and Letter Agreement, dated December 7, 2001 and October 12, 2007, respectively, effective January 7, 2010, between Gentium S.p.A. and Sigma-Tau Pharmaceuticals, Inc., incorporated by reference to Exhibit 2 to the Form 6-K, previously filed with the SEC on January 11, 2010.
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.
4.21*	Technical Transfer Services Agreement, dated February 2, 2009, between Gentium S.p.A. and Patheon Italia S.p.A, incorporated by reference to Exhibit 4.21 to the Annual Report on Form 20-F for the year ended December 31, 2008, previously filed with the SEC on March 31, 2009.

Exhibit	Description
4.22.1	Technical Agreement, dated February 26, 2009, between Gentium S.p.A. and IDIS Limited, incorporated by reference to Exhibit 4.22.1 to the Annual Report on Form 20-F for the year ended December 31, 2008, previously filed with the SEC on March 31, 2009.
4.22.2*	Supply and Distribution Agreement, dated March 6, 2009, between Gentium S.p.A. and IDIS Limited, incorporated by reference to Exhibit 4.22.2 to the Annual Report on Form 20-F for the year ended December 31, 2008, previously filed with the SEC on March 31, 2009.
4.23*	Master Contract Clinical Research Agreement, dated September 29, 2009, between US Oncology Clinical Development and Gentium S.p.A., incorporated by reference to Exhibit 2 to the report on Form 6-K, previously filed with the SEC on December 8, 2009.
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 31, 2010.

* Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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, 2009 and 2008, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. 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 audits 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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. at December 31, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

Reconta Ernst & Young S.p.A.

Milan, Italy

March 31, 2010

GENTIUM S.p.A.
BALANCE SHEETS

Amounts in thousands except share and per share data	As of December 31, 2008	2009
ASSETS		
Cash and cash equivalents	€ 11,491	€ 1,392
Accounts receivable	625	3,213
Accounts receivable from related parties, net	816	501
Inventories, net	907	1,551
Prepaid expenses and other current assets	1,682	1,431
Total Current Assets	15,521	8,088
Property, manufacturing facility and equipment, at cost	21,019	21,262
Less: Accumulated depreciation	10,268	11,545
Property, manufacturing facility and equipment, net	10,751	9,717
Intangible assets, net of amortization	95	76
Available for sale securities	510	263
Other non-current assets	24	23
Total Assets	€ 26,901	€ 18,167
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable	€ 5,823	€ 4,379
Accounts payable to Crinos	4,000	-
Accounts payable to related parties	325	286
Accrued expenses and other current liabilities	810	1,907
Current portion of capital lease obligations	65	67
Current maturities of long-term debt	1,346	408
Total Current Liabilities	12,369	7,047
Long-term debt, net of current maturities	3,268	3,098
Capital lease obligations	158	91
Termination indemnities	655	601
Total Liabilities	16,450	10,837
Share capital (€1.00 and no par value as of December 31, 2008 and 2009, respectively; 18,454,292 and 18,302,617 shares authorized as of December 31, 2008 and 2009, respectively; 14,956,317 shares issued and outstanding at December 31, 2008 and 2009)	14,956	106,962
Additional paid in capital	90,619	-
Accumulated other comprehensive loss	(17)	-
Accumulated deficit	(95,107)	(99,632)
Total Shareholders' Equity	10,451	7,330
Total Liabilities and Shareholders' Equity	€ 26,901	€ 18,167

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, 2007	2008	2009
Revenues:			
Product sales to related party	€ 2,704	€ 651	€ 195
Product sales to third parties	2,390	4,792	9,507
Total product sales	5,094	5,443	9,702
Other revenues	15	25	129
Other revenues from related party	2,500	1,970	337
Total Revenues	7,609	7,438	10,168
Operating costs and expenses:			
Cost of goods sold	4,584	5,596	4,002
Research and development	14,497	9,569	3,512
General and administrative	6,279	7,668	6,036
Depreciation and amortization	725	998	916
Charges from related parties	748	537	279
Write-down of assets	13,740	3,403	-
	40,573	27,771	14,745
Operating loss	(32,964)	(20,333)	(4,577)
Interest income	1,674	587	49
Foreign currency exchange gain/(loss), net	(4,001)	173	162
Interest expense	(317)	(331)	(159)
Net loss	€ (35,608)	€ (19,904)	€ (4,525)
Net loss per share:			
Basic and diluted net loss per share	€ (2.52)	€ (1.33)	€ (0.30)
Weighted average shares used to compute basic and diluted net loss per share	14,105,128	14,956,263	14,956,317

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

GENTIUM S.p.A.

STATEMENTS OF SHAREHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2007, 2008 AND 2009

Amounts in thousands	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive income/(loss)	Total Shareholders' Equity
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
Unrealized loss on marketable securities					(15)	(15)
Issuance of ordinary shares upon exercise of options	10	10	28			38
Stock based compensation			1,973			1,973
Net loss for 2008				(19,904)		(19,904)
Balance at December 31, 2008	14,956	€ 14,956	€ 90,619	€ (95,107)	(17)	€ 10,451
Unrealized gain on marketable securities					17	17
Stock based compensation prior to no par value resolution			717			717
Resolution of no par value		91,336	(91,336)			-
Stock based compensation subsequent to no par value resolution		670				670
Net loss for 2009				(4,525)		(4,525)
Balance at December 31, 2009	14,956	€ 106,962	€ -	€ (99,632)	-	€ 7,330

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

GENTIUM S.p.A.
STATEMENTS OF CASH FLOWS

Amounts in thousands	For the Year Ended December 31,		
	2007	2008	2009
Cash Flows From Operating Activities:			
Net loss	€ (35,608)	€ (19,904)	€ (4,525)
Adjustments to reconcile net loss to net cash used in operating activities:			
Write-down of intangible assets	13,740	2,175	-
Write-down of inventory	206	1,228	19
Unrealized foreign exchange loss/(gain)	2,951	(337)	(223)
Depreciation and amortization	1,538	1,699	1,300
Stock based compensation	1,804	1,973	1,386
Loss/(Gain) on fixed asset disposal	(15)	7	2
Allowance/(Release) for doubtful accounts	-	1,783	(684)
Loss on marketable securities	-	-	2
Changes in operating assets and liabilities:			
Accounts receivable	(1,249)	(1,001)	(2,603)
Inventories	(217)	(625)	(663)
Prepaid expenses and other current and noncurrent assets	(3,426)	568	524
Accounts payable, accrued expenses and deferred revenues	6,103	(310)	363
Termination indemnities	4	(31)	(54)
Net cash used in operating activities	(14,169)	(12,775)	(5,156)
Cash Flows From Investing Activities:			
Capital expenditures	(2,890)	(437)	(245)
Intangible assets expenditures	(215)	(154)	(3)
Proceeds on disposal of fixed assets	15	-	-
Sales of marketable securities	-	-	262
Restricted cash	4,000	-	-
Acquisition of Crinos Assets	(8,000)	-	(4,000)
Net cash used in investing activities	(7,090)	(591)	(3,986)
Cash Flows From Financing Activities:			
Proceeds from private placements, net of offering expenses	34,483	-	-
Proceeds from warrant and stock option exercises, net	6,027	38	-
Repayments of long-term debt	(724)	(1,216)	(1,108)
Proceeds (repayment) from/of short term borrowings	279	(279)	-
Principal payment of capital lease obligation	(89)	(107)	(65)
Proceeds from long-term debt	-	147	-
Net cash provided by/used in financing activities	39,976	(1,417)	(1,173)
Increase/(decrease) in cash and cash equivalents	18,717	(14,783)	(10,315)
Effect of exchange rate on cash and cash equivalents	(2,958)	310	216
Cash and cash equivalents, beginning of period	10,205	25,964	11,491
Cash and cash equivalents, end of period	€ 25,964	€ 11,491	€ 1,392

Amounts in thousands	For The Years Ended December 31,

	2007	2008	2009
Supplemental disclosure of cash flow information:			
Cash paid for interest	€ 320	€ 308	€ 143
Supplemental disclosure of non cash investing and financing activities:			
Assets acquired under lease obligations	€ 328	€ -	€ -
Non cash item related to asset acquisition	4,000		
Offset noncash assets and liabilities with Crinos and Sirton	-	5,327	744

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, 2009
(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," "we," or "our") is a biopharmaceutical company focused on the development and manufacture of our primary product candidate, defibrotide, an investigational drug based on single-stranded DNA extracted from pig intestines. Our development of defibrotide has been focused on the treatment and prevention of a disease VOD, a condition in which some of the veins in the liver are blocked as a result of cancer treatments, such as chemotherapy or radiation treatments, that are given prior to stem cell transplantation. Severe VOD is the most extreme form of VOD and is associated with multiple-organ failure and high rates of morbidity and mortality. We have completed two clinical trials, a Phase III trial of defibrotide for the treatment of severe VOD in the U.S., Canada and Israel and a Phase II/III pediatric trial in Europe for the prevention of VOD. Defibrotide has been given orphan status by the FDA and EMEA, which means that we will have limited market exclusivity upon regulatory approval. Defibrotide has also been granted fast-track product designation by the FDA for the treatment of VOD. While we have not yet obtained regulatory approval to market defibrotide, we are authorized to distribute defibrotide on a pre-approved basis under a treatment IND protocol in the U.S. and through a named-patient program throughout the rest of the world. We do not know of any FDA or EMEA approved treatments for VOD.

We are currently completing certain preclinical and clinical studies requested by regulatory authorities. As part of our overall strategy, we anticipate filing for regulatory approval for defibrotide in the U.S. and Europe by the end of our second quarter in 2011. We are also working closely on our U.S. regulatory strategy with our commercial partner, Sigma-Tau Finanziaria S.p.A. and its affiliate Sigma-Tau Pharmaceuticals, Inc., to which we have licensed our commercial rights to defibrotide for both the treatment and prevention of VOD in the Americas.

We have a manufacturing plant in Italy where we produce active pharmaceutical ingredients, which are subsequently used to make the finished forms of various drugs. We believe that we are the sole worldwide producer of defibrotide. In addition to defibrotide, we manufacture urokinase and sulglicotide, both of which are sold to third parties. All of the Company's operating assets are located in Italy.

In 2009, we entered into a supply and distribution agreement with IDIS Limited, whereby IDIS was contracted to be the exclusive supplier of defibrotide on a named-patient supply basis in all countries except other than Italy and the United States of America. We have also instituted an expanded access program for patients diagnosed with severe VOD in the United States 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 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 expect to collect additional usage tolerability and safety data from patients of this program to support our planned New Drug Application for the treatment of Severe VOD and/or the prevention of VOD.

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. Management performed an evaluation of the Company's activities through the date of filing of this

annual report on Form 20-F, and has concluded that there are no subsequent events requiring disclosure through the date except for transactions discussed in Note 19.

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business for the twelve-month period following the date of the balance sheet. Through December 31, 2009, the Company had accumulated losses of approximately €100 million. The Company expects to continue to incur net losses as it continues the development of defibrotide, apply for regulatory approvals and expand our operations. However, absent the need to fund any additional clinical trials, management believes that the Company's cash and cash equivalents, including the upfront payment received from Sigma-Tau Pharmaceuticals, Inc. in connection with the expansion of the license agreement for defibrotide in the Americas, together with revenues generated from the Company's named-patient and cost recovery programs, will be sufficient to meet the Company's obligations for at least the next twelve months. If the Company elects to increase its spending above current plans or perform additional clinical trials, the Company may need to obtain additional capital through equity or debt financings, loans and collaborative agreements with corporate partners, which may not be available to the Company on favorable terms, if at all.

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.

Reclassifications: Certain prior year amounts have been reclassified to be consistent with the current year presentation. We have reclassified €4.0 million related to our investment in certain assets of Crinos from operating activities to investing activities in our 2007 statement of cash flows, and separately disclosed the related non-cash component in the supplemental disclosure of non-cash investing and financing activities, which was previously only separately disclosed in the notes to the 2007 financial statements. This reclassification did not have any impact our balance sheets or statement of operations. Additionally, we have separately disclosed certain non-cash items in the supplemental disclosure of non-cash investing and financing activities in the 2008 statement of cash flows to be consistent with the current period presentation. These items were all separately disclosed throughout the notes of the financial statements for the prior year. In 2009, we began separately disclosing revenue received pursuant to a collaborative agreement with our related party Sigma-Tau in the statement of operations and included amounts due from Sigma-Tau under accounts receivable from related parties. This reclassification did not impact total revenues, but had the effect of reducing other revenues by €2,500 and €1,970 for the years ended 2007 and 2008, respectively. This reclassification also increased accounts receivable from related parties, net and decreased prepaid and other current assets by €496 as of December 31, 2008.

Segment information: The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of business or separate business entities with respect to any of its product or product candidates. 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 and Other Risks and Uncertainties: 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 limits investments to short-term low risk instruments. Trade receivables from one foreign customer are guaranteed by a letter of credit from a primary bank institution. The Company has an exposure to credit

risk in its trade accounts receivable, which are typically unsecured, from sales of defibrotide through its named-patient and cost recovery programs. As of December 31, 2009 two distributors accounted for approximately 65% and 15% of our accounts receivable, respectively. As of December 31, 2008, two customers accounted for approximately 62% and 31% of our accounts receivable, respectively. We are exposed to risks associated with foreign currency transactions to use U.S. dollars to make contract payments denominated in euros and vice versa. As the net positions of our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. We currently do not utilize forward exchange contracts or any type of hedging instruments to hedge foreign exchange risk as we believe our overall exposure is relatively limited. For the year ended December 31, 2009, three customers accounted for 47%, 28% and 12% of our product sales to third parties, respectively. For the year ended December 31, 2008, two customers accounted for 56% and 40% of our product sales to third parties, respectively. For the year ended December 31, 2007, two customers accounted for 71% and 29% of our product sales to third parties, respectively.

The Company is subject to a number of risks, including its ability to successfully obtain regulatory approval for defibrotide, the uncertainty that defibrotide will become a successful commercial product, its ability to generate projected revenue through its named-patient and cost recovery programs, its dependence on corporate partners, its ability to obtain financing, if necessary, and potential changes in the health care industry.

Trade accounts receivable: Trade accounts receivable are recorded net of allowances for distributors' fees where we are not invoiced directly and doubtful accounts. Estimates for distributors' fees are based on contractual terms. Estimates for our allowance for doubtful accounts is determined based on existing contractual payment terms, historical payment patterns of our customers and individual customer circumstances.

Inventories: Inventories consist of raw materials, semi-finished and finished active pharmaceutical ingredients and defibrotide distributed through the named-patient and treatment IND programs. Inventories are stated at the lower of cost or market, cost being determined on an average cost basis, which approximates the first-in-first-out method. Prior to commencement of selling defibrotide through the named-patient and cost recovery programs, we had expensed all costs associated with the production of defibrotide as research and development expenses. Subsequent to signing the agreements associated with the named-patient and cost recovery programs, we capitalized the subsequent costs of manufacturing defibrotide as inventory, including costs to convert existing raw materials to active pharmaceutical ingredients and costs to package and label previously manufactured inventory whose costs had already been expensed as a research and development expense. Until we sell the inventory for which a portion of the costs were previously expensed, the carrying value of our inventories and our cost of sales will reflect only incremental costs incurred subsequent to the signing of these agreements.

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. We also review our inventory for quality assurance and quality control issues identified in the manufacturing process and determine if a write-down is necessary.

We expense costs relating to the production of clinical products as research and development expense in the period incurred, which are not expected to be sold through the named-patient and cost recovery programs and will continue to do so until we receive an approval letter from the United States Food and Drug Administration, or FDA, or European Medicines Agency, or EMEA, for a new product or product configuration. Upon receipt of an approval letter from FDA or EMEA for a new product or product configuration, we will begin to capitalize the subsequent inventory costs relating to that product configuration.

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 respective assets, ranging from five to twenty years.

The cost of property, manufacturing facility and equipment also includes a proportionate share of the Company's financing costs. 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 We capitalize costs of computer software obtained for internal use. Such costs 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 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. 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 recognizes revenue from the sale of products to a related party, Sirton, third parties and from collaborative arrangements.

Product Sales: Revenues from product sales are recognized when there is persuasive evidence that an arrangement exists, delivery to the customer has occurred and title passes to the customer, the price is fixed or determinable and collectability is reasonably assured. Upon recognition of revenue from product sales, provisions are made for customer incentives such as cash discounts for minimum amounts ordered, distributor fees and expected returns of expired products, as appropriate.

Items deducted from Gross Product Sales:

- Distributor fees: We entered into an agreement with distributors to manage defibrotide as an investigational drug on a named-patient and cost recovery basis. We recognize a fee to distributors based on a contractually determined fixed percentage of sales. These fees are accrued at the time of the sale and offset against product sales and are typically granted within 60 days after the issuance of a sales report. Distributor fees that are invoiced directly to us are recorded in accrued expenses and other current liabilities in our balance sheets.

- Cash discounts: We recognize a price discount to a customer if a minimum number of purchase quantities are purchased in a calendar year. We establish a reserve based on estimates of the amounts earned or to be claimed on the related sales, which is classified as accrued expenses and other current liabilities in our balance sheets, and as a reduction of product sales.

- Product returns: We do not provide our customers with a general right of product return, but permit returns if the product is damaged or defective when received by the customer or if the product has expired. Our estimates for expected returns of expired products are based primarily on an ongoing analysis of historical return patterns. To date there have been no returns due to product expiration.

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. Revenues from collaborative arrangements generally include manufacturing fee arrangements if the research and development efforts ever reach the commercialization phase.

Revenue from non-refundable up-front license fees and milestone payments are recognized as performance occurs and our obligations are completed. In accordance with the specific terms of the Company's obligations under these arrangements, revenue is recognized as the obligation is fulfilled or ratably over the development or manufacturing

period. Revenue associated with substantive at-risk milestones is recognized based upon the achievement of the milestones as defined in the respective agreements. Revenue from reimbursement of research costs under collaborative arrangements is recognized as the related research and development costs are incurred, as provided for under the terms of these arrangements. Advance payments received in excess of amounts earned are classified as deferred revenue until earned in the balance sheets.

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 collectability is reasonably assured.

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, offset by research and development tax credits due from the Italian Tax Authorities.

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. 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. 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. Equity instruments granted to such persons requires the measuring of the fair value of that instrument at the earlier of either the date at which a commitment for performance by the counterparty to earn the equity instruments is reached, or the date at which the counterparty's performance is complete. Fair value of all option grants are 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.

Comprehensive Income: Comprehensive loss is comprised of net 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 loss, net of tax, for the years ended December 31, 2007, 2008 and 2009, was €(35,642), € (19,853) and €(4,508), respectively.

Loss Per Share: Basic net loss per share is based upon the weighted-average number of common shares outstanding and excludes the effect of dilutive common stock issuable from stock options and warrants. In computing diluted loss per share, only potential common shares that are dilutive, or those that reduce earnings per share, are included. The issuance of common stock from stock options and warrants, is not assumed if the result is anti-dilutive, such as when a loss is reported

Recently Issued Accounting Standards:

The FASB issued the ASC (Accounting Standard Codification), which defines the new hierarchy for U.S. GAAP. The ASC is now the sole source for all authoritative non-governmental accounting guidance, with the exception of grandfathered guidance, SEC rules and interpretive releases and Statement of Financial Accounting Standards No. 166 and No. 167. The ASC did not change U.S. GAAP. The ASC was effective for all reporting periods that ended after September 15, 2009. The Company adopted the ASC in 2009.

In January 2010, the FASB issued Accounting Standards Update (ASU) 2010-6, Fair Value Measurements and Disclosures (Topic 820), Improving Disclosures about Fair Value Measurements, which expands fair value disclosure requirements. Transition will be in two phases with expanded disclosures regarding activity for Level 1 and 2 applicable for the Company on January 1, 2010 and expanded disclosures for Level 3 activity effective on January 1, 2011.

In December 2009, the FASB issued ASU 2009-17, Consolidations (Topic 810): Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities. This ASU amends the FASB Accounting Standards Codification for Statement 167. In June 2009, the FASB issued Statement of Financial Accounting Standards No.167, Amendments to FASB Interpretation No. 46(R) (SFAS No. 167). SFAS No.167 eliminates FASB Interpretation No. 46(R)'s exceptions to consolidating qualifying special-purpose entities, contains new criteria for determining the primary beneficiary, and increases the frequency of required reassessments to determine whether a company is the primary beneficiary of a variable interest entity. SFAS No. 167 is effective for fiscal years beginning after November 15, 2009, which for the Company is January 1, 2010, with earlier adoption prohibited. The Company does not expect the adoption of ASU 2009-17 to have an effect on its financial statements.

In December 2009, the FASB issued ASU 2009-16, Accounting for Transfers of Financial Assets. This ASU amends the FASB Accounting Standards Codification for Statement 166. In June 2009, the FASB issued Statement of Financial Accounting Standards No. 166, Accounting for Transfers of Financial Assets—an amendment of FASB Statement No. 140 (SFAS No. 166). SFAS No. 166 eliminates the concept of a qualifying special-purpose entity, creates more stringent conditions for reporting a transfer of a portion of a financial asset as a sale, clarifies other sale-accounting criteria, and changes the initial measurement of a transferor's interest in transferred financial assets. SFAS No. 166 will be effective for transfers of financial assets in fiscal years beginning after November 15, 2009, which for the Company is 2010, and in interim periods within those fiscal years, with earlier adoption prohibited. The Company does not expect the adoption of ASU 2009-16 to have an effect on its financial statements.

In October 2009, the FASB issued ASU 2009-13, Multiple Deliverable Revenue Arrangements (ASU 2009-13), which amended the accounting standards for multiple element arrangements to:

- provide updated guidance on whether multiple deliverables exist, how the elements in an arrangement should be separated, and how the consideration should be allocated;

- require an entity to allocate revenue in an arrangement using estimated selling prices (ESP) of each element if a vendor does not have vendor-specific objective evidence of selling price (VSOE) or third-party evidence of selling price (TPE); and

- eliminate the use of the residual method and require a vendor to allocate revenue using the relative selling price method.

ASU 2009-13 is effective for fiscal years beginning after June 15, 2010, which for the Company is January 1, 2011, with early application permitted. The Company is currently evaluating the impact, if any, ASU 2009-13 will have on the Company's financial statements.

In August 2009, the FASB issued ASU 2009-05, Fair Value Measurements and Disclosures (ASU 2009-05), which amends ASC Topic 820, Fair Value Measurements (ASC 820). The update addresses practice difficulties caused by tension between fair-value measurements based on the price that would be paid to transfer a liability to a new obligor and contractual or legal requirements that prevent such transfers from taking place. ASU 2009-05 was adopted on October 1, 2009 and did not have a material impact on our financial position, results of operations or cash flows.

In May 2009, ASC 855 established principles and requirements for the evaluation, recognition and disclosure of subsequent events. In particular, this topic sets forth the period after the balance sheet date during which management of reporting entity shall evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity shall recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity shall make about events or transactions that occurred after the balance sheet date. Our adoption of ASC 855 in the year ended December 31, 2009 did not have an impact on its financial position or results of operations.

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, 2009) and was originally the Company's sole shareholder. The Company's former Chief Executive Officer and President and a current member on our board of directors, Dr. Laura Ferro, together with members of her family control FinSirton, and previously served as a member of Sirton's Board of Directors.

Historically, FinSirton and Sirton 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 Sirton for certain infrastructure costs, manufacturing capacity 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 Company has historically sold the active pharmaceutical ingredient form of defibrotide to Sirton, who then manufactured and sold the finished products primarily to one customer, Crinos S.p.A ("Crinos"). Crinos, pursuant to its distribution agreement with the Company, then sold the finished products throughout Italy under the trademarks Prociclide and Noravid. In 2007, we changed our relationship with Sirton, from customer to a contract manufacturer, and sold the finished forms of Prociclide and Noravid to Crinos directly. On December 31, 2008, the distribution agreement with Crinos expired and, consistent with the Company's overall strategy, the Company chose not to renew this agreement and discontinued the manufacture of defibrotide to be finished into Prociclide and Noravid.

In connection with the expiration of the distribution agreement with Crinos, in November 2008, we began limiting Sirton's manufacturing of defibrotide to uses for our clinical trials and compassionate use programs.

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, 2007, 2008 and 2009 amounted to €199, €199 and €198, respectively. See Note 18 for such operating lease commitments.

For the years ended December 31, 2007, 2008 and 2009, the Company had the following transactions with FinSirton and Sirton:

	For the Year Ended December 31,		
	2007	2008	2009
Revenues			
Product sales	€ 2,704	€ 651	€ 195
Expenses			
Cost of goods sold	248	353	296
Research and development	185	298	-
Charges from related parties	748	537	279
Total	1,181	1,188	575

As of December 31, 2008 and 2009 the Company had the following balances with FinSirton and Sirton:

	December 31, 2008	2009
Accounts Receivable – Sirton	€ 2,103	€ 1,382
Allowance of doubtful accounts	(1,783)	(1,099)
Accounts Receivable, net	320	283
Accounts Payable Sirton	320	283
Account Payable FinSirton	5	3
	325	286

Sirton has been unable to make timely payments on outstanding receivables. At December 31, 2009, proceeds from collections of our accounts receivable from Sirton amounted to €202. The Company and Sirton formally offset €744 and €3,227 of payables due to Sirton against the same amount of receivables due from Sirton, for the year ended December 31, 2009 and 2008, respectively. Outstanding payables due to Sirton can be legally offset with accounts receivables due from Sirton.

Currently, Sirton is evaluating its strategic options in order to avoid bankruptcy, which raises doubt regarding the ability to realize the net receivable outstanding. Prior to 2008 there was no allowance for the accounts receivables due from Sirton as whole amounts were received relating to those receivables. While the Company continues to pursue the collection of such net receivable, in 2008 we established an allowance for doubtful accounts of €1,783, which was partially released in 2009 for €684, as general and administrative expenses, and we have not recognized revenue from product sales to Sirton that occurred after March 2008, unless such sales were paid in advance, because one of the criteria indicated by SAB 104 (“collectability is reasonably assured”), was not met. As a result, the Company has significantly eliminated its ongoing activities which result in additional receivables from Sirton and is entering into agreements with alternative customers and contract manufacturers. Approximately 53%, 12% and 2% of the Company’s product sales for the years ended December 31, 2007, 2008 and 2009, respectively, have been to Sirton.

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 and prevent 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 Sigma-Tau Finanziaria S.p.A. One of our board members, Marco Codella, is the Chief Financial Officer of Sigma-Tau Industrie Farmaceutice Riunite S.p.A., which is a wholly-owned subsidiary of Sigma-Tau Finanziaria S.p.A. See Note 4 for more discussion on our relationship with Sigma-Tau.

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 (collectively, the “Americas”). As reported in footnote 19, effective January 7, 2010, the Company expanded the license agreement to include the intravenous formulation of defibrotide to prevent

VOD in the Americas. 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 $19,350, of which €9,173 ($11,350) has been received to date, based on the exchange rate in effect on the date of receipt. As reported in footnote 19, the amount that has not been received, equal to $8,000, represents milestone payment due upon approval from the FDA and the transfer of the approved NDA to Sigma-Tau. 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, 2009, the Company recorded €0.10 million of contributions received from Sigma-Tau accounted as other revenue.

In December 2009, we recognized €234 ($350) as a milestone payment from Sigma-Tau for completing the phase III pivotal study.

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

	For the Year Ended December 31,		
	2007	2008	2009
Research and development cost reimbursement	€ 2,360	€ 1,970	€ 103
Upfront payments recognized ratably	€ 140	€ -	€ -
Milestone payments	€ -	€ -	€ 234
	€ 2,500	€ 1,970	€ 337

The following table outlines the 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. The balance was classified as accounts receivable from related parties in the accompanying financial statements:

	December 31,	
	2008	2009
Accounts Receivable from Sigma-Tau	€ 496	€ 218

5. ACQUISITION OF MARKETING AUTHORIZATION AND TRADEMARKS

On December 28, 2006, the Company entered into a Master Agreement with Crinos S.p.A. to acquire the Italian marketing authorizations and related trademarks to Prociclide and Noravid (both forms of defibrotide) for €16,000. Prociclide and Noravid have been 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, to allow the Company to 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, in 2007 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 to treat vascular disease of thrombosis through December 31, 2008, as well as other cash flows through 2012.

In 2008, the Company decided not to renew the agreements entered into with Crinos for the distribution of Prociclide and Noravid in Italy, and allowed such agreements to expire on December 31, 2008. Accordingly, the Company evaluated the recoverability of the marketing authorizations and trademarks from its expected future cash flows and, as reported in footnote 9, as of December 31, 2008, the Company wrote down the remaining net book value of such assets amounting to €847 and €848, respectively.

On August 19, 2009, the Italian Agency accepted the Company's request to withdraw the marketing authorization for Prociclide and Noravid. On September 30, 2009, the Italian Agency granted an additional 180 days to complete the sale of products that were previously distributed. The Company made the request to withdraw the marketing authorization of these forms of defibrotide as part of the Company's overall strategy regarding the development of defibrotide to treat and prevent VOD.

6. INVENTORIES

The Company's inventories consisted of:

	December 31,	
	2008	2009
Raw materials	€ 526	€ 407
Semi-finished goods	117	136
Finished goods	264	1,008
Total	€ 907	€ 1,551

At December 31, 2008 and 2009, respectively, the Company reserved €56 and €75 to adjust a by-product cost to its net realizable value. As of December 31, 2008, the Company, in connection with the expiration and non-renewal of the distribution agreement entered into with Crinos, wrote down €1,228 of semi-finished and finished Prociclide and Noravid in our inventory which included products returned by Crinos in January 2009. Prior to signing the named-patient and cost recovery agreements, all costs associated with the production of defibrotide were expensed as research and development expenses.

7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	December 31,	
	2008	2009
VAT receivables	€ 1,161	€ 581
Tax credit	299	582
Other prepaid expenses and current assets	222	268
Total prepaid expenses and current assets	€ 1,682	€ 1,431

The value added tax ("VAT") amounts represent a tax on the value of consumption. VAT has no effect on the Company's operating results, as payments and receipts are allowed to be netted against each other in periodic filings with the tax authorities. The VAT payment system is a "custodial" relationship. VAT liabilities are generated when the Company invoices customers, including the VAT amount, and VAT receivables are created when the Company purchases goods and services subject to VAT. The decrease in VAT receivable is due to the utilization of €516 to offset the payment of an equivalent amount of social securities and withholding tax, reimbursement of quarterly VAT credit of €516 and the increase in 2009 VAT receivables of €452.

The tax credit includes a residual amount of €350 as government grants received, in the form of a tax credit, for 2008 research and development activities, which is expected to be utilized in the first quarter of 2010 to offset social securities and withholding tax due. Additionally, the tax credit includes €232 of government grants due in the form of a tax credit for 2009 research and development activities, which will be utilized in the fourth quarter of 2010 after the Company has filed its 2009 tax return.

2008 and 2009 tax credit benefits have been accounted for in the second quarter of 2009 based on reliable estimates of the amount of tax credit to which the Company is entitled. The credits were accounted for in compliance with Law 244/07 and Law 296/06 enacted by the Italian Parliament, which established a tax credit in the measure of 10% of the research and development costs incurred in taxable year 2007/2009 (increased to 40% of the costs incurred on contracts entered into with University and Public Research Centers). On January 28, 2009, Decree N. 185/2008, released by the Italian Authorities, which amended Law 244/07 and Law 296/06 regarding the utilization of the tax credit, was converted into Law N. 2/2009. The law indicates that pre-approval (so called "nulla osta") by the Tax Authority is required for the utilization of the tax credit and that filing the annual tax return is not alone sufficient to claim the utilization of such credit. On June 15 2009, we obtained such pre-approval for our 2008 and 2009 tax credits, which eliminated the uncertainty on the recoverability of such credit. For these reasons, the tax credit on 2008 and 2009 research and development activities, were recognized in the second quarter of 2009.

8. PROPERTY, MANUFACTURING FACILITY AND EQUIPMENT

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

	December 31,					
	2008			2009		
	Cost	Accumulated Depreciation	Net book value	Cost	Accumulated Depreciation	Net book value
Land and building	€ 2,686	1,254	1,432	€ 2,687	1,327	1,360
Plant and machinery	14,977	7,587	7,390	15,184	8,508	6,676
Industrial equipment	1,264	695	569	1,269	764	505
Furniture and fixtures	1,060	473	587	1,084	562	522
Leasehold improvements	322	154	168	325	231	94
Internally Developed Software	674	105	569	685	153	532
Construction in progress	36	-	36	28	-	28
	€ 21,019	10,268	10,751	€ 21,262	11,545	9,717

As of December 31, 2007, 2008 and 2009, property, manufacturing facility and equipment include €460 of lab instruments acquired under capital lease agreements. The related accumulated depreciation at December 31, 2007, 2008 and 2009 was €47, €92 and €138, respectively.

9. INTANGIBLE ASSETS

The Company's intangible assets consisted of:

	December 31,							
	2008					2009		
	Cost	Accumulated amortization	Impairment	Net book value	Cost	Accumulated amortization	Net book value
Patent rights	€ 1,230	750	480	-	€ -	-	-
Licenses and trademarks	1,297	355	847	95	171	95	76
Marketing authorizations	1,131	283	848	-	-	-	-
Total	€ 3,658	1,388	2,175	95	€ 171	95	76

The amount of amortization expense for the years ended December 31, 2007, 2008 and 2009 was €479, €476 and €22, respectively. We estimate that we will incur amortization for the years ended December 31, 2010, 2011, 2012, 2013, and 2014 of €23, €20, €11, €11, and €11, respectively.

As of December 31, 2008, the Company terminated the distribution agreement entered into with Crinos and in 2009 submitted a request for the withdrawal of Prociclide and Noravid (both forms of defibrotide) from the Italian market. Such plan raised significant doubt concerning the recoverability of these assets expected to be derived from future cash flows, which required the Company, as of December 31, 2008, to write-down the remaining net book value of the trademark and Italian marketing authorizations for Prociclide and Noravid of €847 and €848, respectively.

In connection with the expiration and non-renewal of the distribution agreement with Crinos and the Company's plan to withdraw Prociclide and Noravid from the Italian market, the Company revised the asset value of the capitalized cost of patents for which no future benefits are reasonably assured. Changes in the carrying value are the result of the lack of future benefits to be derived over the remaining useful life from these assets. The impact of the change

resulted in an increase of net loss of €480, which has been included in the write-down of assets in the statement of operations for the year ended December 31, 2008.

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10. FAIR VALUE MEASUREMENT

The table below presents information about assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2009 and 2008 with the valuation techniques the Company utilized to determine such fair value, as required since accounting pronouncement revisions adopted by the Company in 2008. Fair values determined based on Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. The Company's Level 1 assets consist of cash and marketable debt securities. Fair values determined based on Level 2 inputs utilize observable quoted prices for similar assets and liabilities in active markets and observable quoted prices for identical or similar assets in markets that are not very active. Fair values determined based on Level 3 inputs utilize unobservable inputs and include valuations of assets or liabilities for which there is little, if any, market activity. Level 3 assets or liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

			Fair Value Measurements at December 31, 2009 using	
	Total Carrying Value at December 31, 2009	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash and cash equivalents	€ 1,392	€ 1,392	€ -	€ -
Available for sale securities	263	263		
Total	€ 1,655	€ 1,655	€ -	€ -

			Fair Value Measurements at December 31, 2008 using	
	Total Carrying Value at December 31, 2008	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash and cash equivalents	€ 11,491	€ 11,491	€ -	€ -
Available for sale securities	510	510		
Total	€ 12,001	€ 12,001	€ -	€ -

The fair values of our cash and cash equivalents and available for sale securities are determined through market, observable and corroborated sources. Available for sale securities refers to Banca IntesaSanpaolo bond TV05/10/2004-11.

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

11. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of:

	December 31, 2008	2009
Accrued compensation and employee benefits	€ 268	€ 1,320
Due to social security	218	134
Withholding tax due	133	131
Other payables	191	322
Total	€ 810	€ 1,907

Accrued compensation and employee benefits includes accruals related to employee, director and management compensation.

12. CREDIT FACILITY, LONG-TERM DEBT AND LEASES

Long term debt, net of current maturities consists of:

	December 31, 2008	2009
a) Mortgage loan bearing interest at the Euribor 6 month rate plus 1.0% due June 2015 (3.97% and 1.99% at December 31, 2008 and 2009, respectively)	2,200	2,000
b) Equipment loan secured by marketable securities, bearing interest at the Euribor 3 months rate plus 1.70% due April 2012 (4.59% and 2.40% at December 31, 2008 and 2009, respectively)	656	394
c) Equipment loan bearing interest at the Euribor 3 months rate plus 1.20% due June 2012 (4.09% and 1.90% at December 31, 2008 and 2009, respectively)	625	437
d) Financing loan bearing interest at the Euribor 1 months rate plus 1.00% due December 2012 (3.60% and 1.453% at December 31, 2008 and 2009, respectively)	314	222
e) Equipment loans secured by the underlying equipment pursuant to the Sabatini Law, interest at 2.1%	131	-
f) Research loan from the Italian Ministry for University and Research, interest at 1% per annum, due January 2012	249	145
g) Financing loan bearing interest at the Euribor 3 months rate plus 1.00% due December 2012 (3.89% and 1.70% at December 31, 2008 and 2009, respectively)	148	113
h) Equipment loan bearing interest at the Euribor 3 months rate plus 0.80% due December 2012 (3.69% and 1.50% at December 31, 2008 and 2009, respectively)	144	110
i) Research loan from the Italian Ministry for University and Research, interest at 1% per annum, due January 2012	147	85
	4,614	3,506
Less current maturities	(1,346)	(408)
Total	€ 3,268	€ 3,098

The equipment loan in the amount of €437 requires the Company to maintain €5,000 of net shareholders' equity determined in accordance with Italian generally accepted accounting principles. The Company was in compliance with the covenant at December 31, 2008 and 2009.

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 have been gradually released from the pledge as the Company repaid the principal of the loan. The total amount of pledged securities as of December 31, 2008 and 2009 was €510 and €263, respectively.

In December 2009, in connection with a national agreement among the Italian Bank Association and the Italian Ministry of Economics and Enterprise Organizations, companies that met certain criteria, such as good standing, qualification of small and medium enterprises, were eligible to apply for a deferment on the payment of principal debt outstanding for a twelve-month period. Except for our research loan incurred with the Italian Ministry for University and Research, which was not eligible, we requested and obtained deferment on payment of our principal loan payment originally due in the next twelve months for €1,113.

The maturities of long-term debt are as follows:

	December 31,
2011	1,231
2012	867
2013	400
2014	400
Thereafter	200
Total	€ 3,098

13. 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, 2009 is (€12).

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 expired on July 6, 2009.

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 expired on July 5, 2009.

14. INCOME TAXES

The Company has not had income tax expenses for the years ended December 31, 2007, 2008 and 2009.

The components of the Company's deferred tax assets and liabilities are as follows:

	As of December 31,	
	2008	2009
Deferred tax assets:		
Net operating losses	€ 15,532	€ 15,455
Capitalization of research & development costs	5,865	6,925
Property, plant and equipment	744	642
Write down of intangible assets	3,658	2,765
Allowance on doubtful account	477	289
Inventory write-off	249	209
Other	18	116
Deferred tax assets	26,534	26,401
Deferred tax liabilities:		
Other	--	
Deferred tax liabilities	--	
Net deferred tax assets	26,534	26,401
Valuation Allowance	(26,534)	(26,401)
Net deferred taxes	€ --	€ --

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, 2009, the Company's tax position and relative carry-forward is as follows:

Year	Tax loss	Tax benefit	Expiring date
2005	5,883	1,618	2010
2006	11,248	3,093	2011
2007	18,956	5,213	2012
2008	13,520	3,718	2013
2009	6,593	1,813	2014

The Company provided no benefit for its operating losses due to the accumulated losses noted above.

15. SHAREHOLDERS' EQUITY

The Company had 14,956,317 ordinary shares, €1.00 par value per share, and 14,956,317 ordinary shares, no par value per share, issued and outstanding as of December 31, 2008 and December 31, 2009, respectively. On December 31, 2009, the authorized shares were 18,302,617. Authorized capital is as follows:

	December 31	
	2008	2009
Issued and outstanding	14,956,317	14,956,317
Reserved for share option plans	2,500,000	2,500,000
Reserved for exercise of warrants	846,300	846,300
Reserved for future offerings	151,675	-
	18,454,292	18,302,617

On April 28, 2006, our shareholders granted our board of directors the power to 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. As of December 31, 2009, our board of directors has authorized the issuance of 4,915,171 ordinary shares in connection with this resolution by our shareholders.

On June 30, 2009, our shareholders granted our board of directors the power to increase the capital of our company in cash, up to an amount equal to €100 million on a separable basis, in one or more transactions, for a rights offering, 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. With the same resolution our shareholders granted our board of directors the power to cancel the par value of the ordinary shares of the Company, which was completed on June 30, 2009. As of December 31, 2009, our board of directors has not authorized the issuance of any shares pursuant to this resolution by our shareholders.

Warrants

A summary of the warrant activity for the three years ended December 31, 2009 is presented below.

	Warrants	Weighted Average Exercise Price	
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
Granted	-	-	-
Exercised	-	-	-
Cancelled	-	-	-
Balance, December 31, 2008	846,300	€ 6.29	$ 11.75
Granted	-	-	-
Exercised	-	-	-
Cancelled			
Balance, December 31, 2009	846,300	€ 6.29	$ 11.75

The following is a summary of outstanding warrants as of December 31, 2009:

	Number of warrants issued	Number of warrants exercised	Number of warrants cancelled	Number of warrants outstanding
Warrant issued in conjunction with Promissory note	503,298	22,734	-	480,564
Initial Public Offering	151,200	107,990	-	43,210
2005 private placement	713,518	713,518	-	-
2006 private placement	466,446	143,920	-	322,526
Total	1,834,462	988,162		846,300

In conjunction with the convertible promissory notes sold in a private placement from October 2004 to January 2005, the Company issued warrants for the purchase of an aggregate of 503,298 ordinary shares at a purchase price (as adjusted) of $9.52 per share. The warrants are fully vested, exercisable at the option of the holder, in whole or in part, and expire on the later of five years and three months from the date of grant or four years and three months from our initial public offering date. Through December 31, 2009, the Company issued 22,734 ordinary shares upon exercise of these warrants for proceeds of $216 (€170). As of the date of the filing of these financial statements 395,586 warrants expired.

In connection with its initial public offering ("IPO"), the Company granted warrants to purchase 151,200 ordinary shares to the underwriters for services rendered during the IPO. The warrants are fully vested, exercisable at the option of the holder, in whole or in part, and expire five years from the date of grant. Through December 31, 2009, we had issued 107,990 ordinary shares upon exercise of these warrants at a price per share of $11.25, for proceeds of $1,215 (€914).

In connection with a private placement in 2005, the Company issued warrants for the purchase of an aggregate of 620,450 ordinary shares at an exercise price of $9.69 per ordinary share. The warrants are fully vested, exercisable at the option of the holder, in whole or in part, and expire five years from the date of grant. In addition, the Company issued to one of the placement agents a five year warrant for the purchase of 93,068 ordinary shares at an exercise price of $9.69 per ordinary share. As of December 31, 2009, all of the warrants had been exercised and the Company had issued 713,518 ordinary shares underlying these warrants for aggregate proceeds of $6,914 (€5,000).

In connection with a private placement in 2006, the Company issued warrants for the purchase of an aggregate of 388,705 ordinary shares at an exercise price of $14.50 per ordinary share. In addition, the Company issued to one of the placement agents a five year warrant for the purchase of 77,741 ordinary shares at an exercise price of $17.40 per ordinary share. The warrants are fully vested, exercisable at the option of the holder, in whole or in part, and expire five years from the date of grant. Through December 31, 2009, we had issued 143,920 ordinary shares upon exercise of these warrants for proceeds of $2,087 (€1,490).

16. 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. These 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 or non-qualified options. 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. As of December 31, 2009, there were 1,355,000 shares underlying outstanding options and 145,000 shares available for future grants under this plan.

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.

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.

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. As of December 31, 2009, there were 242,030 shares underlying outstanding options and 757,970 shares available for future grants under this plan. Shares subject to options that have expired or otherwise terminated without being exercised in full again become available for issuance under the plan.

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 or March 26, 2022. Our compensation committee determines the price of share options granted under the 2007 Stock Option Plan, subject to certain limitations.

Options granted under the 2007 Stock Option Plan vest at the rate determined by our compensation committee. Typically, options granted to employees 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.

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.

The following table lists the balance available by the Plans at December 31, 2009.

	Amended and Restated Nonstatutory Plan and Agreement	Amended and Restated 2004 Stock Option Plan	2007 Stock Option Plan
Number of shares authorized	60,000	1,500,000	1,000,000
Number of option granted since inception	60,000	1,500,000	327,178
Number of options exercised	60,000	-	-
Number of shares cancelled/expired	-	145,000	85,148
Number of shares available for grant	-	145,000	757,970

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 €1,804, €1,973 and €1,386 for the years ended December 31, 2007, 2008 and 2009, respectively.

	Year ended December 31, 2007	Year ended December 31, 2008	Year ended December 31, 2009
Cost of goods sold	5	87	59
Research and development	437	385	267
General and administrative	1,362	1,501	1,060
Total stock based compensation	1,804	1,973	1,386

The Company expects to incur significant non-cash compensation expense for option grants in the future. As of December 31, 2009 total compensation cost not yet recognized was €602, which is expected to be expensed over a maximum vesting period of 24 months.

The weighted average grant-date fair market value of options granted to officers, employees, directors and consultants for the years ended December 31, 2007 and 2008, as of the date of the grants, was $10.03 and $5.37, respectively. There were no options granted to officers, employees, directors and consultants for the year ended December 31, 2009. 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, 2007	Year ended December 31, 2008	Year ended December 31, 2009
Risk free interest rate	4.47%	2.60%	-
Expected dividend yield	0%	0%	-
Expected stock price volatility	60%	60%	-
Expected term	4.9 years	5.62 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, 2009. Once vested, options become exercisable immediately.

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

Share-based compensation expense recognized in the statement of operations is based on awards ultimately expected to vest, reduced for estimated forfeitures. Pre-vesting forfeiture percentage was estimated to be approximately zero. If pre-vesting forfeitures occur in the future, the Company will record the effect of such forfeitures as the forfeitures occur.

For the years ended December 31, 2007, 2008 and 2009, the Company issued 5,000, nil and nil options, respectively, to consultants and recorded non-cash compensation expense of approximately €44, €nil and €nil, 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 outstanding at December 31, 2006	423,000	1,115,000	€ 7.15	$ 9.45
Options available under 2007 Plan	1,000,000	-		
Granted	(529,500)	529,500	€ 13.56	$ 18.34
Exercised	-	(28,000)	€ 4.21	$ 5.58
Options outstanding at December 31, 2007	893,500	1,616,500	€ 9.31	$ 12.43
Granted	(220,678)	220,678	€ 6.43	$ 9.57
Exercised	-	(10,000)	€ 3.78	$ 5.58
Cancellations	-	(30,000)	€ 11.08	$ 14.56
Options outstanding at December 31, 2008	672,822	1,797,178	€ 8.96	$ 12.08
Granted	-	-	-	-
Exercised	-	-	-	-
Cancellations	-	(200.148)	€ 8.88	$ 11.82
Options outstanding at December 31, 2009	672,822	1.597.030	€ 8.96	$ 12.12

Cash received on stock options exercised amounted to $156 and $56 in the years ended December 31, 2007 and 2008, respectively. No stock options were exercised in the year ended December 31, 2009. The intrinsic value of options exercised in 2007, 2008 was $423 and $74, respectively. The estimated fair value of shares vested during 2007, 2008 and 2009 was $3,981, $6,431 and $7,607, respectively.

The following table summarizes outstanding and exercisable options as of December 31, 2009, based on the exchange rate in effect on December 31, 2009:

	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
€3.63 ($5.20)	36,970	8.35	€3.63 ($5.20)	19,519	€3.63 ($5.20)
€4.94 ($7.08)	15,000	5.82	€4.94 ($7.08)	15,000	€4.94 ($7.08)
€5.58 ($8.00)	50,000	0.82	€5.58 ($8.00)	50,000	€5.58 ($8.00)
€6.28 ($9.00)	802,000	5.51	€6.28 ($9.00)	802,000	€6.28 ($9.00)
€6.66 ($9.55)	9,528	8.16	€6.66 ($9.55)	5,826	€6.66 ($9.55)
€6.98 ($10.00)	25,000	0.96	€6.98 ($10.00)	25,000	€6.98 ($10.00)
€8.79 ($12.60)	90,000	6.42	€8.79 ($12.60)	90,000	€8.79 ($12.60)
€9.75 ($13.98)	105,032	8.00	€9.75 ($13.98)	67,089	€9.75 ($13.98)
€10.33 ($14.80)	22,500	7.96	€10.33 ($14.80)	15,000	€10.33 ($14.80)
€11.53 ($16.52)	73,000	7.64	€11.53 ($16.52)	52,324	€11.53 ($16.52)
€12.11 ($17.35)	10,000	6.32	€12.11($17.35)	10,000	€12.11 ($17.35)
€13.05 ($18.71)	10,000	7.32	€13.05 ($18.71)	10,000	€13.05 ($18.71)
€13.22 ($18.95)	348,000	7.23	€13.22 ($18.95)	319,008	€13.22 ($18.95)
	1,597,030			1,480,766	

At December 31, 2009 the aggregate intrinsic value of the outstanding options was nil and the aggregate intrinsic value of the exercisable options was nil.

17. 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 anti-dilutive, the Company has excluded from the calculation of diluted net loss per share the impact of 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.

18. 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 instalments 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 instalments 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, 2009 are:

	Operating Leases	Capital Leases
2010	192	73
2011	16	73
2012	16	21
2013	15	-
Thereafter	-	-
Total minimum lease payments	€ 239	167
Less: imputed interest		(9)
Present value of net minimum lease payment		158
Less: Current portion of capital lease payment		(67)
Long term portion of capital lease payment		91

As of December 31, 2009, we had €323 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.

19. SUBSEQUENT EVENTS

Effective January 7, 2010, the Company announced that it had amended its existing License and Supply and Cost Sharing Agreements with Sigma-Tau Pharmaceuticals, Inc. for the development and commercialization of Defibrotide in North America, Central and South America. The License and Supply Agreement has been amended to include a license to Sigma-Tau for the intravenous formulation of Defibrotide for the prevention of veno-occlusive disease in the Americas and to transfer the New Drug Application (NDA) post approval in the United States. In return for the amended terms, Gentium will receive an initial payment of $7,000, in execution of the amended agreements, an additional payment of $6,000 following approval from the FDA to market Defibrotide in the US and a further $2,000 following the transfer of the approved NDA to Sigma-Tau. Gentium will receive a 7% royalty on net sale and a supply margin equal to the greater of 31% of net sales of Defibrotide or €.050 per unit in the Americas. Gentium will reimburse $1,000 of costs reimbursed by Sigma-Tau from its future royalty payments due to Gentium under the License and Supply Agreement.

On February 5, 2010, the Company received its first installment of $7,000 under the amended license and supply agreement entered with Sigma-Tau Pharmaceuticals Inc.

As of February 22, 2010, 395,586 warrants issued in connection with our Series A financing expired unexercised.

On March 1, 2010 the Company announced management and corporate restructuring changes resulting from a strategic decision to close down its New York office and consolidate the Company's resources and operations into its headquarters in Como, Italy. The closure of the New York office and consolidation of corporate operations are expected to result in one-time payments of approximately €1.51 ($1.71) million.

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)

Date: March 31, 2010

By: /s/ Khalid Islam
Dr. Khalid Islam
Chief Executive Officer

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.
4.12.3*	Amendments to License and Supply Agreement and Letter Agreement, dated December 7, 2001 and October 12, 2007, respectively, effective January 7, 2010, between Gentium S.p.A. and Sigma-Tau Pharmaceuticals, Inc., incorporated by reference to Exhibit 2 to the Form 6-K, previously filed with the SEC on January 11, 2010.
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.
4.21*	Technical Transfer Services Agreement, dated February 2, 2009, between Gentium S.p.A. and Patheon Italia S.p.A, incorporated by reference to Exhibit 4.21 to the Annual Report on Form 20-F for the year ended December 31, 2008, previously filed with the SEC on March 31, 2009.
4.22.1	Technical Agreement, dated February 26, 2009, between Gentium S.p.A. and IDIS Limited, incorporated by reference to Exhibit 4.22.1 to the Annual Report on Form 20-F for the year ended December 31, 2008, previously filed with the SEC on March 31, 2009.
4.22.2*	Supply and Distribution Agreement, dated March 6, 2009, between Gentium S.p.A. and IDIS Limited, incorporated by reference to Exhibit 4.22.2 to the Annual Report on Form 20-F for the year ended December 31, 2008, previously filed with the SEC on March 31, 2009.

4.23*	Master Contract Clinical Research Agreement, dated September 29, 2009, between US Oncology Clinical Development and Gentium S.p.A., incorporated by reference to Exhibit 2 to the report on Form 6-K, previously filed with the SEC on December 8, 2009.
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.

Exhibit	Description
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 31, 2010.

* Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.