Cardiogenesis Corp /CA
Form S-8 POS
May 17, 2011

As filed with the Securities and Exchange Commission on May 17, 2011

Registration No. 333-144359
Registration No. 333-122021
Registration No. 333-106082
Registration No. 333-90400
Registration No. 333-73170
Registration No. 333-82755
Registration No. 333-74733

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

POST-EFFECTIVE AMENDMENT NO. 1 TO
FORM S-8 REGISTRATION STATEMENT NO. 333-144359

POST-EFFECTIVE AMENDMENT NO. 1 TO
FORM S-8 REGISTRATION STATEMENT NO. 333-122021

POST-EFFECTIVE AMENDMENT NO. 1 TO
FORM S-8 REGISTRATION STATEMENT NO. 333-106082

POST-EFFECTIVE AMENDMENT NO. 1 TO
FORM S-8 REGISTRATION STATEMENT NO. 333-90400

POST-EFFECTIVE AMENDMENT NO. 1 TO
FORM S-8 REGISTRATION STATEMENT NO. 333-73170

POST-EFFECTIVE AMENDMENT NO. 1 TO
FORM S-8 REGISTRATION STATEMENT NO. 333-82755

POST-EFFECTIVE AMENDMENT NO. 1 TO
FORM S-8 REGISTRATION STATEMENT NO. 333-74733

UNDERTHE SECURITIES ACT OF 1933

CARDIOGENESIS CORPORATION

(Exact name of Registrant as specified in its charter)

California	77-0223740
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

c/o CryoLife, Inc.
1655 Roberts Boulevard, NW
Kennesaw, Georgia 30144
(770) 419-3355

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

EMPLOYEE STOCK PURCHASE PLAN
STOCK OPTION PLAN
DIRECTOR STOCK OPTION PLAN
1996 EMPLOYEE STOCK PURCHASE PLAN
CARDIOGENESIS 1996 EMPLOYEE STOCK PURCHASE PLAN
CARDIOGENESIS 1996 DIRECTORS STOCK OPTION PLAN
CARDIOGENESIS 1996 EQUITY INCENTIVE PLAN
CARDIOGENESIS 1993 EQUITY INCENTIVE PLAN

(Full title of the plans)

Steven G. Anderson
President and Chief Executive Officer
Cardiogenesis Corporation

c/o CryoLife, Inc.
1655 Roberts Boulevard, NW
Kennesaw, Georgia 30144
(770) 419-3355

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Copy to:

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Jeffrey W. Burris, Esq.
Vice President and General Counsel
CryoLife, Inc.
1655 Roberts Boulevard, NW
Kennesaw, Georgia 30144
(770) 419-3355

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b- 2 of the Exchange Act.

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	o (do not check if a smaller reporting company)	Smaller reporting company	þ

DEREGISTRATION OF SECURITIES

Cardiogenesis Corporation (the "Company") is filing these Post-Effective Amendments (these "Post-Effective Amendments") to the following Registration Statements on Form S-8 (collectively, the "Prior Registration Statements") in order to deregister certain shares of the Company's common stock, no par value (the "Common Stock"), thereby registered for offer or sale pursuant to the Company's Employee Stock Purchase Plan, Stock Option Plan, Director Stock Option Plan, 1996 Employee Stock Purchase Plan, Cardiogenesis 1996 Employee Stock Purchase Plan, Cardiogenesis 1996 Equity Incentive Plan, Cardiogenesis 1996 Directors Stock Option Plan and Cardiogenesis 1993 Equity Incentive Plan:

(i) Registration No. 333-144359, filed on July 5, 2007, registering an aggregate of 1,650,000 shares of Common Stock under the Stock Option Plan, Employee Stock Purchase Plan and Director Stock Option Plan.

(ii) Registration No. 333-122021, filed on January 13, 2005, registering an aggregate of 1,950,000 shares of Common Stock under Stock Option Plan, Employee Stock Purchase Plan and Director Stock Option Plan.

(iii) Registration No. 333-106082, filed on June 13, 2003, registering an aggregate of 6,803,171 shares of Common Stock under the Stock Option Plan, 1996 Employee Stock Purchase Plan and Director Stock Option Plan.

(iv) Registration No. 333-90400, filed on June 13, 2002, registering an aggregate of 1,750,000 shares of Common Stock under the Stock Option Plan and Director Stock Option Plan.

(v) Registration No. 333-73170, filed on November 13, 2001, registering an aggregate of 800,000 shares of Common Stock under the Stock Option Plan and 1996 Employee Stock Purchase Plan.

(vi) Registration No. 333-82755, filed on July 13, 1999, registering an aggregate of 1,375,000 shares of Common Stock under the Stock Option Plan, 1996 Employee Stock Purchase Plan and Director Stock Option Plan.

(vii) Registration No. 333-74733, filed on March 19, 1999, registering an aggregate of 1,739,000 shares of Common Stock under the Cardiogenesis 1993 Equity Incentive Plan, Cardiogenesis 1996 Equity Incentive Plan, Cardiogenesis 1996 Directors Stock Option Plan and Cardiogenesis 1996 Employee Stock Purchase Plan.

On May 17, 2010, pursuant to an Amended and Restated Agreement and Plan of Merger, dated as of April 14, 2011, by and among CryoLife, Inc., a Florida corporation ("Parent"), CL Falcon, Inc., a Florida corporation and a wholly-owned indirect subsidiary of Parent ("Merger Sub"), and the Company, Merger Sub merged with and into the Company, with the Company continuing as the surviving corporation (the "Merger").

In connection with the Merger, the offerings pursuant to the Prior Registration Statements have been terminated. In accordance with undertakings made by the Company in the Prior Registration Statements to remove from registration, by means of post-effective amendments, any of the securities registered pursuant to the Prior Registration Statements that remain unsold/unissued at the termination of the offerings, the Company hereby removes from registration all shares of Common Stock and options to purchase Common Stock registered under the Registration Statements but not sold/issued under the Registration Statements as of the date hereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused these Post-Effective Amendments to the Prior Registration Statements to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Irvine, State of California, on May 17, 2011.

CARDIOGENESIS CORPORATION.

By: /s/ D.A. Lee
D. Ashley Lee
Executive Vice President, CFO,
COO, and Treasurer

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the date indicated.

Signature	Title	Date
/s/ Steven G. Anderson Steven G. Anderson	President, Chief Executive Officer, and Director (Principal Executive Officer)	May 17, 2011
/s/ D.A. Lee D. Ashley Lee	Executive Vice President, CFO, COO and Treasurer and Secretary (Principal Financial and Accounting Officer)	May 17, 2011

#160;	4,324	7,609	7,438			
Operating costs and expenses:						
Cost of goods sold				3,092	4,584	5,596
Research and development				8,927	14,497	9,569
General and administrative				5,421	6,279	7,668
Depreciation and amortization				261	725	998
Charges from related parties				854	748	537
Write-down of assets				-	13,740	3,403
Operating loss				(14,231)	(32,964)	(20,333)
Interest income				708	1,674	587
Foreign currency exchange gain/(loss), net				(627)	(4,001)	173
Interest expense				(218)	(317)	(331)
Loss before income tax expense				(14,368)	(35,608)	(19,904)
Net loss				€(14,368)	€(35,608)	€(19,904)
Net loss per share:						
Basic and diluted net loss per share				€(1.33)	€(2.52)	€(1.33)
Weighted average shares used to compute basic and diluted net loss per share				10,808,890	14,105,128	14,956,263

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, 2006, 2007 AND 2008

Amounts in thousands except share and per share data	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive income/(loss)	Total Shareholders' Equity
Balance at December 31, 2005	9,611	€ 9,611	€ 33,090	€ (25,227)	€ -	€ 17,474
Unrealized gains on marketable securities					32	32
Issuance of ordinary shares in private placement, net	1,943	1,943	13,953			15,896
Issuance of ordinary shares upon exercise of options	22	22	75			97
Issuance of ordinary shares upon exercise of warrants	198	198	1,442			1,640
Stock based compensation			916			916
Net loss for 2006				(14,368)		(14,368)
Balance at December 31, 2006	11,774	€ 11,774	€ 49,476	€ (39,595)	€ 32	€ 21,687
Unrealized loss on marketable securities					(34)	(34)
Issuance of ordinary shares in private placement, net	2,354	2,354	32,129			34,483
Issuance of ordinary shares upon exercise of options	28	28	90			118
Issuance of ordinary shares upon exercise of warrants, net	790	790	5,119			5,909
Stock based compensation			1,804			1,804
Net loss for 2007				(35,608)		(35,608)
Balance at December 31, 2007	14,946	€ 14,946	€ 88,618	€ (75,203)	€ (2)	€ 28,359
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

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

GENTIUM S.p.A.
STATEMENTS OF CASH FLOWS

Amounts in thousands except share and per share data	For the Year Ended December 31, 2006	2007	2008
Cash Flows From Operating Activities:			
Net loss	€ (14,368)	€ (35,608)	€ (19,904)
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	-	-	1,228
Unrealized foreign exchange loss/(gain)	509	2,951	(337)
Depreciation and amortization	1,008	1,538	1,699
Stock based compensation	908	1,804	1,973
Deferred revenue	(143)	(140)	-
Loss/(Gain) on fixed asset disposal	(23)	(15)	7
Adjustment of inventory to net realizable value	-	206	-
Non cash interest expense	4	-	
Allowance for doubtful accounts	-	-	1,783
Changes in operating assets and liabilities:			
Accounts receivable	(1,830)	(1,249)	(1,001)
Inventories	129	(217)	(625)
Prepaid expenses and other current and noncurrent assets	(482)	(3,426)	568
Accounts payable and accrued expenses	2,165	10,243	(310)
Termination indemnities	(24)	4	(31)
Net cash used in operating activities	(12,147)	(10,169)	(12,775)
Cash Flows From Investing Activities:			
Capital expenditures	(1,445)	(2,890)	(437)
Intangible assets expenditures	(503)	(215)	(154)
Proceeds on disposal of fixed assets	23	15	-
Purchases of marketable securities	(530)	-	-
Restricted cash	(4,000)	4,000	-
Acquisition of Crinos Assets	(4,000)	(12,000)	-
Net cash used in investing activities	(10,455)	(11,090)	(591)
Cash Flows From Financing Activities:			
Proceeds from initial public offering and private placements, net of offering expenses	15,896	34,483	-

Proceeds from warrant and stock option exercises, net	1,736	6,027	38
Repayments of long-term debt	(681)	(724)	(1,216)
Proceeds (repayment) of/from short term borrowings	-	279	(279)
Principal payment of capital lease obligation	(42)	(89)	(107)
Early extinguishment of long term debt	(1,868)	-	-
Proceeds from long-term debt	5,518	-	147
Net cash/(used by financing activities)	20,559	39,976	(1,417)
Increase/(decrease) in cash and cash equivalents	(2,043)	18,717	(14,783)
Effect of exchange rate on cash and cash equivalents	(537)	(2,958)	310
Cash and cash equivalents, beginning of period	12,785	10,205	25,964
Cash and cash equivalents, end of period	€ 10,205	€ 25,964	€ 11,491

Amounts in thousands	For The Years Ended December 31,		
	2006	2007	2008
Supplemental disclosure of cash flow information:			
Cash paid for interest	€ 219	€ 320	€ 308
Supplemental disclosure of non cash investing and financing activities:			
Assets acquired under lease obligations	€ 132	€ 328	€ -
Fair value of warrants issued with shares	715	-	-

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

GENTIUM S.p.A.

NOTES TO FINANCIAL STATEMENTS

For the Three Years Ended December 31, 2008

(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 research, development and manufacture of drugs to treat and prevent a variety of vascular diseases and conditions related to cancer and cancer treatments. Our primary focus is on development of defibrotide, a DNA based drug derived from pig intestines, to treat and prevent a disease called hepatic veno-occlusive disease, or VOD, a condition in which some of the veins in the liver are blocked as a result of cancer treatments such as chemotherapy 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. We are concluding a Phase III clinical trial of defibrotide to treat severe VOD in the United States, Canada and Israel, but do not believe that this current Phase III clinical trial will produce sufficient data to obtain regulatory approval in the United States or Europe; however we do expect to utilize this data as supportive data for future clinical trials. We are also conducting a Phase II/III clinical trial of defibrotide in Europe to prevent VOD in children, which we believe could provide contingent regulatory approval in Europe upon positive data. We are currently working on a revised strategy with our commercial partner regarding the treatment indication of defibrotide.

We have a plant in Italy where we manufacture active pharmaceutical ingredients, which are used to make the finished forms of various drugs. One of those active pharmaceutical ingredients is defibrotide. The other active pharmaceutical ingredients that we manufacture for sale are urokinase, calcium heparin, sodium heparin and sulglicotide. We sell these other active pharmaceutical ingredients to other companies to be made into various drugs. All of the Company's operating assets are located in Italy.

The accompanying 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

Going Concern Uncertainty and Management's Plan: We have prepared our financial statements assuming that we will continue as a going concern, which contemplates realization of assets and satisfaction of liabilities in the normal course of business. We have accumulated a deficit €95,107 since inception and expect to continue to incur net operating losses for the foreseeable future and may never become profitable. We have not generated any revenues from our primary product candidate, other than for limited use in Italy using the same active pharmaceutical ingredient, and are dependent upon significant financing or alternative funding to provide the working capital necessary to execute our business plan. In addition, if we do not meet the requirements for continued listing on Nasdaq, the Company's ADR could be delisted from the Nasdaq Global Market. As of the date of this report, we have approximately €4.5 million of cash and cash equivalent to fund our operations. We currently anticipate that our cash and cash equivalents as of the date of this report are sufficient to meet our anticipated working capital and operating needs through August of 2009. This projection is based on the Company's current cost structure and the Company's current expectations regarding expenses and revenues. Accordingly, if we do not obtain sufficient funding in the near future, we will not be able to sustain our operations and would be required to cease our operations and/or seek bankruptcy protection. Given the difficult current economic environment, we believe that it will be difficult to raise

additional funds and there can be no assurance as to availability of additional financing or the terms upon which additional financing may be available. However, we will continue to explore all financing and partnering opportunities that are available to us, if any.

As a result of these conditions, there is substantial doubt regarding the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

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.

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

Segment information: Statement of Financial Accounting Standards ("SFAS") No. 131, "Disclosure about Segments of an Enterprise and Related Information," establishes standards for reporting information on operating segments in interim and annual financial statements. The Company's chief operating decision makers review the profit and loss and manage the operations of the Company on an aggregate basis. Accordingly, the Company operates in one segment, which is the biopharmaceutical industry.

Cash and Cash Equivalents: Cash and cash equivalents include highly liquid, temporary cash investments having original maturity dates of three months or less. For reporting purposes, cash equivalents are stated at cost plus accrued interest, which approximates fair value.

Concentration of Credit Risk: Financial Instruments that potentially subject the Company to concentrations of credit risks consist principally of cash, cash equivalents, marketable securities and trade receivables. The Company has cash investments policies that limit investments to short-term low risk instruments. The Company performs ongoing credit evaluations of other customers and maintains allowances for potential credit losses. Collateral is generally not required. Trade receivables from one foreign customer are guaranteed by a letter of credit from a primary bank institution.

Inventories: Inventories consist of raw materials, semi-finished and finished active pharmaceutical ingredients. The Company capitalizes inventory costs associated with certain by-products, based on management's judgment of probable future commercial use and net realizable value. Inventories are stated at the lower of cost or market, cost being determined on an average cost basis. The Company periodically reviews its inventories and items that are considered outdated or obsolete are reduced to their estimated net realizable value. The Company estimates reserves for excess and obsolete inventories based on inventory levels on hand, future purchase commitments, and current and forecasted product demand. If an estimate of future product demand suggests that inventory levels are excessive, then inventories are reduced to their estimated net realizable value.

Property, Manufacturing Facility and Equipment: Property and equipment are carried at cost, subject to review for impairment of significant assets whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Repairs and maintenance are charged to operations as incurred, and significant expenditures for additions and improvements are capitalized if they extend the useful life or capacity of the asset. Leasehold improvements are amortized over the economic life of the asset or the lease term, whichever is shorter. Depreciation is calculated on a straight-line basis over the estimated useful life of the assets, 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, as required by SFAS No. 34, "Capitalization of Interest Cost". The amount of interest cost to be capitalized for qualifying assets is that portion of the interest cost incurred during the assets' acquisition periods that could have been avoided if expenditures for the assets had not been made. Interest expense capitalized is amortized over the same life as the underlying constructed asset.

Computer Software: The Company accounts for computer software costs in accordance with AICPA Statement of Position ("SOP") 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use". SOP 98-1 requires the capitalization of costs relating to certain activities of developing and obtaining internal use software that were incurred during the application development stage. Capitalized costs of computer software obtained for internal use are included in property, manufacturing facility and equipment and amortized over the estimated useful life of the software.

Intangibles: Intangible assets are stated at cost and amortized on a straight-line basis over their expected useful life, estimated to be five years for patent rights and five to ten years for licenses and trademarks.

Impairment of Long-lived Assets, including Intangibles: The Company's long-lived assets consist primarily of intangible assets and property and equipment. In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," the Company evaluates its ability to recover the carrying value of long-lived assets used in its business, considering changes in the business environment or other facts and circumstances that suggest their value may be impaired. If this evaluation indicates the carrying value will not be recoverable, based on the undiscounted expected future cash flows estimated to be generated by these assets, the Company will reduce the carrying amount to the estimated fair value.

Marketable Securities: The Company's marketable securities are classified as securities available for sale in non-current assets and are carried at fair value based on market prices. Unrealized gains and losses (which are deemed to be temporary), if any, are reported in other comprehensive income or loss as a separate component of shareholders' equity.

A decline in the market value of any available for sale securities below cost that is deemed to be other than temporary results in a reduction in the carrying amount to fair value. The impairment would be charged to earnings and a new cost basis for the securities established. Factors evaluated to determine if an impairment is other than temporary include significant deterioration in the credit rating, asset quality, or business prospects of the issuer; adverse changes in the general market condition in which the issuer operates; the intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment; and any concerns about the issuer's ability to continue as a going concern.

Revenue Recognition: The Company sells its products to a related party, Sirton (see Note 3). The Company also recognizes revenue from the sale of products to third parties and from collaborative arrangements. Revenues from product sales are recognized at the time of product shipment. Collaborative arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration received from these arrangements is allocated among the separate units based on their respective fair value, and the applicable revenue recognition criteria are applied to each separate unit. Advance payments received in excess of amounts earned are classified as deferred revenue until earned. The Company's revenue recognition policies for its various types of revenue streams are as follows:

The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred and title passes to the customer, the price is fixed or determinable, collectibility is reasonably assured, and the Company has no further obligations. Costs incurred by the Company for shipping and handling are included in cost of goods sold.

The Company recognizes revenue from royalties based on the licensees' sales of the Company's products or technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reliably measured and collectibility is reasonably assured.

Revenues from collaborative arrangements generally include upfront fees, performance milestone payments, reimbursement of research costs and continuing license and manufacturing fee arrangements if the research and development efforts ever reach the commercialization phase.

Sales of licensing rights for which no further performance obligations exist are recognized as revenues on the earlier of when the payment is received or collection is assured. Nonrefundable upfront licensing fees that require the Company's continuing involvement in the form of research and development or manufacturing efforts are recognized

as revenues:

- ratably over the development period if the development risk is significant,
- ratably over the manufacturing period or estimated product useful life if development risk has been substantially eliminated, or
- based upon the level of research services performed during the period of the research contract.

Performance based milestone payments are recognized as revenue when the performance obligation, as defined in the contract, is achieved. Performance obligations typically consist of significant milestones in the development life cycle of the related technology, such as initiation of clinical trials, filing for approval with regulatory agencies and obtaining such approvals.

Revenues are recorded net of applicable allowance for contractual adjustments entered into with customers. We establish a reserve for this discount, which is classified in accrued expenses and other current liabilities in our balance sheet and as a reduction of gross product revenue. Our product revenue reserve is based on estimates of the amounts earned or to be claimed on the related sales. These estimates take into consideration current contractual requirements, and forecasted customer buying patterns. If actual results vary, we may need to adjust these estimates, which could have an effect on earnings in the period of the adjustment.

Research and Development: Research and development expenditures are charged to operations as incurred. Research and development expenses consist of costs incurred for proprietary and collaborative research and development, including activities such as product registration and investigator-sponsored trials. Research and development expenses include salaries, benefits and other personnel related costs, clinical trial and related trial product manufacturing costs, contract and other outside service fees, employee stock based compensation expenses and allocated facilities and overhead costs, offset by research and development tax credit 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, as set forth in SFAS No. 109, “Accounting for Income Taxes.” Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences related to the temporary differences between the carrying amounts and the tax basis of assets and liabilities and net operating loss carry-forwards, all calculated using presently enacted tax rates. Valuation allowances are established when necessary to reduce deferred tax assets when it is considered more likely than not that tax assets will not be recoverable.

Foreign currency transactions: The Company has no foreign subsidiaries and, therefore, has no translation adjustment in the financial statements. However, net realized and unrealized gains and losses resulting from foreign currency transactions that are denominated in a currency other than the Company’s functional currency, the Euro, are included in the statements of operations.

Share Based Compensation: The Company has always accounted for share based compensation on the basis of fair value, previously under SFAS 123 and as of July 1, 2005, under SFAS 123I, “Share Based Payments”. The adoption of SFAS 123R did not have a significant impact on the Company as the fair valuations previously used to estimate the fair value of stock based compensation were unchanged. Compensation expense for awards that are ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period of the equity compensation award, which is generally the vesting period.

From time to time, the Company grants options to persons other than officers, employees and directors, such as consultants. Grants of equity instruments to such persons are also accounted for under EITF 96-18, “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services”. Under the EITF, equity instruments granted to such persons requires the measuring of the fair value of that instrument at the earlier of either i) the date at which a commitment for performance by the counterparty to earn the equity instruments is reached (a “performance commitment”); or ii) the date at which the counterparty’s performance is complete. Fair value of the option grant is estimated on the grant date using the Black-Scholes option-pricing model.

The Black-Scholes model takes into account volatility in the price of the Company's stock, the risk-free interest rate, the estimated life of the option, the closing market price of the Company's stock and the exercise price.

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: Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income, or SFAS130, requires us to display comprehensive income (loss) and its components as part of our financial statements. Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income or (loss) (or "OCI"). OCI includes certain changes in stockholders' equity that are excluded from net loss. Specifically, we include only unrealized gains or losses on our available for sale securities in OCI. Other comprehensive income (loss), net of tax, for the years ended December 31, 2006, 2007 and 2008, was €(14,336), €(35,642) and €(19,853), respectively.

Loss Per Share: The Company computes loss per share in accordance with the provisions of SFAS No. 128, "Earnings 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:

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

Effective January 1, 2008 we implemented SFAS No. 157, "Fair Value Measurements" (FAS 157), for our financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. In accordance with the provisions of FSP FAS 157-2, Effective Date of FASB Statement No. 157, we deferred the implementation of SFAS 157 as it relates to our non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a nonrecurring basis until January 1, 2009. We do not expect this pronouncement to have a material effect on our financial statements.

In March 2008, the FASB issued SFAS No. 161, Disclosure About Derivate Instruments and Hedging Activities- an amendment of SFAB Statement No. 133, which enhances the disclosure requirements for derivates instruments and hedging activities. This standard is effective for us beginning January 1, 2009. We do not expect this pronouncement to have a material effect on our financial statements.

3. RELATED PARTIES

The Company has significant relationships with two privately owned Italian companies, FinSirton and its wholly owned subsidiary, Sirton. FinSirton, the parent company of several businesses, is the Company's largest shareholder (approximately 25% ownership at December 31, 2008) and was originally the Company's sole shareholder. The Company's Chief Executive Officer serves in the same capacity for FinSirton and is a member of FinSirton's Board of Directors.

Historically, FinSirton and Sirton have provided the Company with a number of business services such as purchasing, logistics, quality assurance, quality control, analytical assistance for research and development, and regulatory services as well as office space, personnel, administrative services, information technology systems and accounting services. Although the Company has substantially reduced the functions and activities provided by FinSirton and Sirton, the Company still depends on Sirton for certain infrastructure costs and quality control. These service agreements have recurring one year terms that may be terminated by either party upon written notice to the other party at least one month prior to the expiration of the term. The cost of such services are included in charges from related parties in accompanying statements of operations.

The Company has historically sold the active pharmaceutical ingredient form of defibrotide 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. These costs have been classified as research and development costs.

Finally, the Company leases space for manufacturing, offices, laboratories and storage facilities from Sirton and FinSirton. These agreements expire on December 31, 2010 and 2013. Total expense under these operating leases for the years ended December 31, 2006, 2007 and 2008 amounted to €167, €199 and €199, respectively. See Note 18 for such operating lease commitments.

For the years ended December 31, 2006, 2007 and 2008, the Company had the following transactions with FinSirton and Sirton:

	For the Year Ended December 31,		
	2006	2007	2008
Revenues			
Product sales	€ 3,754	€ 2,704	€ 651
Expenses			
Cost of goods sold	-	248	353
Research and development	-	185	298
Charges from related parties	854	748	537
Total	854	1,181	1,188

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

	December 31,	
	2007	2008
Accounts Receivable – Sirton	€ 4,147	€ 2,103
Account Receivable FinSirton	2	-
	4,149	2,103
Allowance of doubtful accounts	-	(1,783)
Accounts Receivable, net	4,149	320
Accounts Payable Sirton	2,077	320
Account Payable FinSirton	18	5
	2,095	325

Sirton has been unable to make timely payments on outstanding receivables. At December 31, 2008, proceeds from collections of our accounts receivable from Sirton amounted to €999. For the year ended December 31, 2008, the Company and Sirton formally offset €3,227 of payables due to Sirton against the same amount of receivables due from Sirton. Prior to 2008 there was no allowance for the accounts receivable from Sirton as all amounts were received relating to those receivables.

We have been advised that Sirton is seeking to raise funds for payment of the amounts owed, including through the sale of real property or other assets; however, as of today, none of the actions planned have been successful, raising doubt about the realization of the net receivable. While the Company continues to pursue the collection of such net receivable, we have established an allowance for doubtful accounts of €1,783 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 ("collectibility 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 92%, 53% and 12% of the Company's product sales for the years ended December 31, 2006, 2007 and 2008, respectively, have been to Sirton. The Company recognized bad debt expense related to its receivables from Sirton in the amount of €1,783 for the year ended December 31, 2008. No bad debt expense was recognized in 2007.

The Company is also party to a License and Supply Agreement with Sigma-Tau Pharmaceuticals, Inc. pursuant to which we have licensed the right to market defibrotide to treat VOD in North America, Central America and South America to Sigma-Tau Pharmaceuticals, Inc. and pursuant to which Sigma-Tau Pharmaceuticals, Inc has agreed to purchase defibrotide for this use from us. Sigma-Tau Pharmaceuticals, Inc. is an affiliate of several of our large shareholders, including Sigma Tau Industrie Farmaceutiche 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.

The accounting policies applied to transactions with affiliates are consistent with those applied in transactions with independent third parties and management believes that all related party agreements are negotiated on an arm's length basis.

4. COLLABORATIVE ARRANGEMENTS

In December 2001, the Company entered into a license and supply agreement with Sigma-Tau Pharmaceuticals Inc. (as assignee of Sigma-Tau Industrie Farmaceutiche Riunite S.p.A., hereinafter referred to as "Sigma Tau"). Under the multi-year agreement, Sigma Tau obtained exclusive rights to distribute, market and sell defibrotide to treat VOD in the United States. In 2005, the Company expanded Sigma-Tau's current license territory to all of North America, Central America and South America. This license expires on the later of the eighth year of the Company's launch of the product or the expiration of the U.S. patent regarding the product, which expires in 2010. In return for the license, Sigma-Tau agreed to pay the Company an aggregate of $4,900, of which €3,826 ($4,000) has been received to date, based on the exchange rate in effect on the date of receipt. Sigma-Tau will owe the Company an additional $350 performance milestone payment within 30 days of the end of a Phase III pivotal study, and a $550 performance milestone payment within 30 days of obtaining an FDA New Drug Application or Biologic License Application and other approvals necessary for the marketing of defibrotide in the United States, if and when these events occur. 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, 2008, the Company recorded €1.97 million of contributions received from Sigma-Tau accounted as other revenue.

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,		
	2006	2007	2008
Research and development cost reimbursement	€ -	€ 2,360	€ 1,970
Upfront payments recognized ratably	€ 140	€ 140	€ -
	€ 140	€ 2,500	€ 1,970

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, the Company will now be able to manage defibrotide globally with control over the distribution of defibrotide and the flexibility to market defibrotide itself or seek marketing partners for the European market. As a result, the Company wrote off all but €2,260 of the €16,000 purchase price (€13,740 charge) based primarily on an analysis of the net present value of the estimated future cash flows from the sales of only the oral formulation of defibrotide through December 31, 2008, as well as other cash flows through 2012. These remaining assets, marketing authorizations and trademarks, are included in other intangible assets.

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, the Company wrote down the remaining net book value of such assets amounting to €847 and €848, respectively.

6. INVENTORIES

The Company's inventories consisted of:

	December 31,	
	2007	2008
Raw materials	€ 385	€ 526
Semi-finished goods	845	117
Finished goods	280	264
Total	€ 1,510	€ 907

At December 31, 2007 and 2008, respectively, the Company reserved €547 and €56 to adjust a by-product cost to its net realizable value and to account for excess inventory compared with forecasted sales. Additionally, at 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.

7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

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

	December 31,	
	2007	2008
VAT receivables	€ 3,776	€ 1,161
Tax credit	-	299
Other prepaid expenses and current assets	1,068	718
Total prepaid expenses and current assets	€ 4,844	€ 2,178

The value added tax (or "VAT") amounts represent a tax on the value of consumption. VAT has no effect on the Company's operating results, as payments and receipts are allowed to be netted against each other in periodic filings with the tax authorities. The VAT payment system is a "custodial" relationship. VAT liabilities are generated when the Company invoices customers, including the VAT amount, and VAT receivables are created when the Company purchases goods and services subject to VAT. The decrease in VAT receivable is primarily due to the assignment, on June 23, 2008, of €2,100 VAT credit to Crinos. As a result of the assignment of such VAT credit to Crinos, the Company offset an equivalent amount of accounts payable due to Crinos. Additionally, in 2008, we obtained from the Italian Tax Authorities reimbursement of VAT credit in the amount of €1,153.

At December 31, 2008, other prepaid expenses and current assets include the accrual of a €496 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 tax credit includes a residual amount of €299 as government grants received, in the form of a tax credit, for 2007 research and development activities. 2007 tax credit amounted to €791 of which €499 was utilized to offset social securities and withholding taxes. These benefits have been accounted for in the first half of 2008 based on reliable estimates of the amount of tax credit to which the Company is entitled. The credit was accounted 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 Centre). The tax credit, disclosed in the annual tax return, could have been utilized automatically to offset any tax disbursement (including VAT and withholding taxes).

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 new law indicates that preventive approval (so called "nulla osta") by the Tax Authority is now 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. As of today, the qualification for the tax credit is not clear, because the law provides for different procedures and treatment based on the commencement date of research and development activities. Specifically, it is not clear whether such preventive approval by the Tax Authority will affect the Company's ability to receive a tax credit on research and development activities commenced prior to November 29, 2008. For these reasons, the tax credit on 2008 research and development activities, amounting to €631, has not been recognized as of December 31, 2008.

8. PROPERTY, MANUFACTURING FACILITY AND EQUIPMENT

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

	December 31,					
	2007			2008		
	Cost	Accumulated Depreciation	Net book value	Cost	Accumulated Depreciation	Net book value
Land and building	€ 2,683	1,185	1,498	€ 2,686	1,254	1,432
Plant and machinery	14,434	6,700	7,734	14,977	7,587	7,390
Industrial equipment	1,085	635	450	1,264	695	569
Other	1,047	380	667	1,060	473	587
Leasehold improvements	295	78	217	322	154	168
Internally Developed Software	458	68	390	674	105	569
Construction in progress	588	-	588	36	-	36
	€ 20,590	9,046	11,544	€ 21,019	10,268	10,751

As of December 31, 2007 and December 31, 2008, property, manufacturing facility and equipment include €460 of lab instruments acquired under capital lease agreements. The related accumulated depreciation at December 31, 2007 and December 31, 2008 was €47 and €45, respectively.

9. INTANGIBLE ASSETS

The Company's intangible assets consisted of:

	December 31,						
	2007			2008			
	Cost	Accumulated amortization	Net book value	Cost	Accumulated amortization	Impairment	Net book value
Patent rights	€ 1,093	595	498	€ 1,230	750	480	-
Licenses and trademarks	1,280	184	1,096	1,297	355	847	95
Marketing authorizations	1,131	133	998	1,131	283	848	-
Total	€ 3,504	912	2,592	€ 3,658	1,388	2,175	95

The amount of amortization expense for the years ended December 31, 2007 and 2008 was €479 and €476, respectively. We estimate that we will incur amortization for the years ended December 31, 2009, 2010, 2011, 2012 and 2013 of €23, €23, €16, €11 and €11, respectively.

The Company terminated the distribution agreement entered into with Crinos and plans to submit a request for the withdrawal of Prociclide and Noravid (both forms of defibrotide) from the Italian market. Such plan raised doubt concerning the recoverability of these assets expected to be derived from future cash flows, which has required the Company 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

10. FAIR VALUE MEASUREMENT

Effective January 1, 2008, we implemented SFAS 157, "Fair Value Measurements," for our financial assets and liabilities that are re-measured and reported at fair value at each reporting period. The adoption of SFAS 157 to our financial assets and liabilities did not have a material impact on our financial position and results of operations.

SFAS 157 defines fair value, provides a framework for measuring fair value, and requires expanded disclosures regarding fair value measurements. SFAS 157 does not require assets and liabilities that were previously recorded at cost to be recorded at fair value. For assets and liabilities that are already required to be disclosed at fair value, SFAS 157 introduced, or reiterated, a number of key concepts which form the foundation of the fair value measurement approach to be used for financial reporting purposes. The statement indicates, among other things, that a fair value measurement assumes that the transaction to sell an asset or transfer a liability occurs in the principal market for the asset or liability or, in the absence of a principal market, the most advantageous market for the asset or liability. SFAS 157 defines fair value based upon an exit price model.

Relative to SFAS 157, the FASB issued FASB Staff Positions (FSP) 157-1 and 157-2. FSP 157-1 amends SFAS 157 to exclude SFAS No. 13, "Accounting for Leases," (SFAS 13) and its related interpretive accounting pronouncements that address leasing transactions, while FSP 157-2 delays the effective date of the application of SFAS 157 to fiscal years beginning after November 15, 2008 for all non-financial assets and non-financial liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis. In October 2008, the FASB issued FASB Staff Position (FSP) No. 157-3, Determining the Fair Value of a Financial Asset When the Market for that Asset is Not Active, that clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key consideration in determining the fair value of a financial asset when the market for that financial asset is not active. We are evaluating the impact, if any, FSP 157-3 will have on our non-financial assets and liabilities.

SFAS 157 establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows:

Level 1 inputs, which include quoted prices in active markets for identical assets or liabilities.

Level 2 inputs, which include observable inputs other than Level 1 inputs, such as quoted prices for similar assets and liabilities; quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability; and

Level 3 inputs, which include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. 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.

A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

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The following table sets forth our financial assets that were accounted for at fair value on a recurring basis as of December 31, 2008:

			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, 2007		2008	
Due to employees	€	802	€	268
Due to social security		220		218
Withholding tax due		160		133
Other payables		41		191
Total	€	1,223	€	810

12. CREDIT FACILITY, LONG-TERM DEBT AND LEASES

Long term debt, net of current maturities consists of:

		December 31, 2007	2008
a)	Mortgage loan bearing interest at the Euribor 6 month rate plus 1.0% due June 2014 (5.71% and 3.97% at December 31, 2007 and 2008 respectively)	2,600	2,200
b)	Equipment loan secured by marketable securities, bearing interest at the Euribor 3 months rate plus 1.70% due April 2011 (6.38% and 4.59% at December 31, 2007 and 2008 respectively)	919	656
c)	Equipment loan bearing interest at the Euribor 3 months rate plus 1.20% due June 2011 (5.88% and 4.09% at December 31, 2007 and 2008 respectively)	750	625
d)	Financing loan bearing interest at the Euribor 1 months rate plus 1.00% due December 2011 (5.29% and 3.60% at December 31, 2007 and 2008, respectively)	409	314
e)	Equipment loans secured by the underlying equipment pursuant to the Sabatini Law, interest at 2.1%	306	131
f)	Research loan from the Italian Ministry for University and Research, interest at 1% per annum, due January 2012	318	249
g)	Financing loan bearing interest at the Euribor 3 months rate plus 1.00% due December 2011 (4.68% and 3.89% at December 31, 2007 and 2008, respectively)	193	148
h)	Equipment loan bearing interest at the Euribor 3 months rate plus 0.80% due December 2011 (5.48% and 3.69% at December 31, 2007 and 2008, respectively)	188	144
i)	Research loan from the Italian Ministry for University and Research, interest at 1% per annum, due January 2012	-	147
		5,683	4,614
	Less current maturities	1,262	1,346
	Total	€ 4,421	€ 3,268

The equipment loan in the amount of €750 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.

The Company's marketable securities consist of debt securities, which have been pledged to secure the Company's repayment of the loan from Banca Intesa-Mediocredito S.p.A. The loan agreement requires that pledged securities equal at least 50% of the remaining loan principal at all times. Accordingly, such securities will gradually be released from the pledge as the Company repays the principal of the loan.

In December 2008, we received a loan from the Minister for University and Research granted through IntesaSanpaolo. The loan is to be used for the research and development of defibrotide to treat and prevent VOD, and bears interest at 1.0% per annum. We will repay this loan in seven installments due every six months beginning January 2009. At December 31, 2008, the amount outstanding under this loan was €147.

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The maturities of long-term debt are as follows:

	December 31,
2010	1,192
2011	983
2012	493
2013	400
Thereafter	200
Total	€ 3,268

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, 2008 is €(19).

On July 4, 2006 the Company entered into an interest rate cap agreement with San Paolo IMI S.p.A. providing protection against fluctuations in interest rates with respect to 50% of the total loan commitment. The Euribor rate portion of the interest rate was capped at 3.75%. The agreement expires on July 6, 2009. At that time 50% of the principal is scheduled to be repaid. The fair market value of the interest cap agreement as of December 31, 2008 is €3.

On July 5, 2006 the Company entered into an interest rate cap agreement with Banca Intesa S.p.A. providing protection against fluctuations in interest rates with respect to 50% of the total loan commitment. The Euribor rate portion of the interest rate was capped at 3.70%. The agreement expires on July 5, 2009. At that time 50% of the principal is scheduled to be repaid. The fair market value of the interest cap agreement as of December 31, 2008 is €1.

14. INCOME TAXES

The Company has not had income tax expenses for the years ended December 31, 2006, 2007 and 2008.

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

	As of December 31,	
	2007	2008
Deferred tax assets:		
Net operating losses	€ 12,067	€ 15,532
Capitalization of research & development costs	4,698	5,865
Property, plant and equipment	--	744
Write down of intangible assets	3,190	3,658
Allowance on doubtful account	--	477
Inventory write-off	--	249
Other	106	18
Deferred tax assets	20,061	26,534
Deferred tax liabilities:		
Other	--	--
Deferred tax liabilities	--	--
Net deferred tax assets	20,061	26,534
Valuation Allowance	(20,061)	(26,534)
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, 2008, the Company's tax position and relative carry-forward is as follows:

Year	Tax loss	Tax benefit	Expiring date
2004	3,128	1,032	2009
2005	7,580	2,502	2010
2006	12,997	4,289	2011
2007	20,059	6,218	2012
2008	12,683	3,932	2013

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

15. SHAREHOLDERS' EQUITY

The Company had 14,946,317 and 14,956,317 ordinary shares of €1.00 par value per share issued and outstanding as of December 31, 2007 and December 31, 2008, respectively. On December 31, 2008, the authorized shares were 18,464,292. Authorized capital is as follows:

	December 31	
	2007	2008
Issued and outstanding	14,946,317	14,956,317
Reserved for share option plans	2,510,000	2,510,000
Reserved for exercise of warrants	846,300	846,300
Reserved for future offerings	151,675	151,675
	18,454,292	18,464,292

In conjunction with the convertible promissory notes sold in a private placement from October 2004 to January 2005, the Company issued warrants for the purchase of an aggregate of 503,298 ordinary shares at a purchase price (as adjusted) of $9.52 per share. The warrants are fully vested, exercisable at the option of the holder, in whole or in part, and expire five years from the date of grant. Through December 31, 2008, the Company issued 22,734 ordinary shares upon exercise of these warrants for proceeds of $216 (€170).

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, 2008, we had issued 107,990 ordinary shares upon exercise of these warrants at a price per share of $11.25, for proceeds of $1,215 (€914).

In connection with 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, 2008, all of the warrants had been exercised and the Company had issued 713,518 ordinary shares underlying these warrants for aggregate proceeds of $6,914 (€5,000).

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

Warrants

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

	Warrants	Weighted Average Exercise Price	
Balance, December 31, 2005	1,216,816	€ 8.14	$ 9.61
Granted	617,646	€ 12.13	$ 14.07

Exercised	(197,458)	€	8.29	$	10.52
Cancelled	-				
Balance, December 31, 2006	1,637,004	€	9.63	$	11.18
Granted	--		--		--
Exercised	(790,704)	€	7.51	$	10.57
Cancelled	--		--		--
Balance, December 31, 2007	846,300	€	6.29	$	11.75
Granted	-		-		-
Exercised	-		-		-
Cancelled	-		-		-
Balance, December 31, 2008	846,300	€	6.29	$	11.75

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. The Plans were initially adopted on September 30, 2004 and amended on April 27, 2007. The Plans provide for the issue of incentives awards for up to 1,500,000 ordinary shares to employees, consultants, directors, and non-employee directors. Awards may be in the form of either incentive and non-qualified options, restricted share grants, share appreciate rights and share bonuses. Our compensation committee determines the price of share options granted under the incentive plan, provided that the exercise price for an incentive share option cannot be less than 100% of the fair market value of our ordinary shares on the date of grant. The term of share options granted under the incentive plan generally may not exceed ten years, although the capital increase relating to the ordinary shares issuable upon exercise of such options expires on September 30, 2019.

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

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

2004 Italy Stock Award Sub-Plan

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

Amended and Restated Nonstatutory Stock Option Plan and Agreement

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

2007 Stock Option Plan

On April 27, 2007, the Company's shareholders approved the 2007 Stock Option Plan providing for options that may be granted to the Company's directors, employees and consultants to purchase up to 1,000,000 ordinary shares, and a related capital increase of the Company in cash for a maximum amount of €1.00 of par value for such shares.

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The following table lists the balance available by the Plans at December 31, 2008.

	Amended and Restated Nonstatutory Plan and Agreement	Amended and Restated 2004 Stock Option Plan	2007 Stock Option Plan
Number of shares authorized	60,000	1,500,000	1,000,000
Number of option granted since inception	60,000	1,500,000	327,178
Number of options exercised	60,000	-	-
Number of shares cancelled/expired	-	25,000	5,000
Number of shares available for grant	-	-	672,822

In accordance with the provision of SFAS No. 123R, stock-based compensation cost is measured at the grant date based on the fair value of the award ultimately expected to vest and is recognized as expense over the service period, which is generally the vesting period. The Company recorded non-cash compensation expense of €908, €1,804 and €1,973 for the years ended December 31, 2006, 2007 and 2008, respectively.

	Year ended December 31, 2006	Year ended December 31, 2007	Year ended December 31, 2008
Cost of goods sold	-	5	87
Research and development	289	437	385
General and administrative	619	1,362	1,501
Total stock based compensation	908	1,804	1,973

The Company expects to incur significant non-cash compensation expense for option grants in the future. As of December 31, 2008 total compensation cost not yet recognized was €2,208, which is expected to be expensed over a maximum vesting period of 36 months.

The weighted average grant-date fair market value of options granted to officers, employees, directors and consultants for the years ended December 31, 2006, 2007 and 2008, as of the date of the grants, was $4.42, $10.03 and $5.37, respectively. The fair value of each option grant is estimated on the grant date using the Black-Scholes option-pricing model. The valuation of options granted was based on the following weighted average assumptions:

	Year ended December 31, 2006	Year ended December 31, 2007	Year ended December 31, 2008
Risk free interest rate	4.96%	4.47%	2.60%
Expected dividend yield	0%	0%	0%
Expected stock price volatility	40%	60%	60%
Expected term	3 years	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, 2008. Once vested, options become exercisable immediately.

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

As share-based compensation expense recognized in the statement of operations for the year ended December 31, 2008 is based on awards ultimately expected to vest, reduced for estimated forfeitures. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeiture percentage was estimated to be approximately zero in the year ended December 31, 2008. If pre-vesting forfeitures occur in the future, the Company will record the effect of such forfeitures as the forfeitures occur.

The Company applies EITF 96-18 in accounting for options granted to consultants. For the years ended December 31, 2006, 2007 and 2008, the Company issued 15,000, 5,000 and nil options, respectively, to consultants and recorded non-cash compensation expense of approximately €94, €44 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, 2005	568,000	992,000	€ 7.36	$ 8.72
Granted	(145,000)	145,000	€ 10.12	$ 13.45
Exercised	-	(22,000)	€ 4.23	$ 5.58
Cancellations	-	-	-	-
Options outstanding at December 31, 2006	423,000	1,115,000	€ 7.15	$ 9.45
Options available under 2007 Plan	1,000,000	-		
Granted	(529,500)	529,500	€ 13.56	$ 18.34
Exercised	-	(28,000)	€ 4.21	$ 5.58
Cancellations	-	-	-	-
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

Cash received on stock options exercised amounted to $156 and $56 in the years ended December 31, 2007 and 2008, respectively. The intrinsic value of options exercised in 2006, 2007 and 2008 was $185, $423 and $74, respectively. The estimated fair value of shares vested during 2006, 2007 and 2008 was $1,813, $3,981 and $6,431, respectively.

The following table summarizes outstanding and exercisable options as of December 31, 2008, based on the exchange rate in effect on December 31, 2008:

	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
€3.74 ($5.20)	106,118	9.35	€3.74 ($5.20)	20,634	€3.74 ($5.20)
€5.09 ($7.08)	15,000	6.82	€5.07 ($7.08)	15,000	€5.09 ($7.08)
€5.75 ($8.00)	50,000	1.82	€5.75 ($8.00)	50,000	€5.75 ($8.00)
€6.47 ($9.00)	832,000	6.51	€6.47 ($9.00)	832,000	€6.47 ($9.00)
€6.86 ($9.55)	9,528	9.16	€6.86 ($9.55)	3,176	€6.86 ($9.55)
€7.19 ($10.00)	25,000	0.96	€7.18 ($10.00)	25,000	€7.19 ($10.00)
€8.62 ($12.00)	15,000	0.72	€8.62 ($12.00)	15,000	€8.62 ($12.00)
€9.05 ($12.60)	90,000	7.42	€9.05 ($12.60)	77,500	€9.05 ($12.60)
€10.05 ($13.98)	105,032	9.00	€10.04 ($13.98)	35,011	€10.05 ($13.98)
€10.63 ($14.80)	22,500	8.96	€10.63 ($14.80)	7,813	€10.63 ($14.80)
€11.87 ($16.52)	84,000	8.64	€11.87 ($16.52)	35,060	€11.87 ($16.52)
€12.47 ($17.35)	35,000	7.32	€12.46($17.35)	33,889	€12.47 ($17.35)
€13.44 ($18.71)	40,000	8.32	€13.44 ($18.71)	35,603	€13.44 ($18.71)
€13.62 ($18.95)	368,000	8.23	€9.25 ($18.95)	216,302	€13.62 ($18.95)
	1,797,178			1,401,987	

At December 31, 2008 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 antidilutive, 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, 2008 are:

	Operating Leases	Capital Leases
2009	199	74
2010	199	73
2011	191	73
2012	31	21
Thereafter	30	
Total minimum lease payments	€ 650	241
Less: imputed interest		18
Present value of net minimum lease payment		223
Less: Current portion of capital lease payment		65
Long term portion of capital lease payment		158

As of December 31, 2008, we had €1,981 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.

19. SUBSEQUENT EVENTS

In January 2009, we obtained from the Italian Tax Authorities a reimbursement of VAT credit in the amount of €244 and paid the last installment of €4,000 pursuant to the Master Agreement entered into with Crinos.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

GENTIUM S.P.A.
(Registrant)

By: /s/ Laura Ferro, M.D.
Dr. Laura Ferro
President and Chief Executive Officer

Date: March 31, 2009

INDEX OF EXHIBITS

Exhibit	Description
Charter documents	
1(i)	Articles of Association of Gentium S.p.A., formerly known as Pharma Research S.r.l. dated November 11, 1993, incorporated by reference to Exhibit 3(i) to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
1(ii)	Amended and Restated Bylaws of Gentium S.p.A. dated April 27, 2007, incorporated by reference to Exhibit 1(ii) to the Annual Report on Form 20-F previously filed with the SEC on April 30, 2007.
American Depositary Share Documents	
2.1	Form of Deposit Agreement among Gentium S.p.A., The Bank of New York and the owners and beneficial owners from time to time of American Depositary Receipts (including as an exhibit the form of American Depositary Receipt), incorporated by reference to Exhibit 4.6 to Amendment No. 5 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on June 9, 2005.
2.2	Form of American Depositary Receipt (see Exhibit 2.1).
Security Subscription Agreements	
2.3	Securities Subscription Agreement among Gentium S.p.A. and the other parties thereto dated as of May 31, 2006, incorporated by reference to Exhibit 4.9.1 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.
2.4	Securities Subscription Agreement among Gentium S.p.A. and the other parties thereto, dated as of February 6, 2007, incorporated by reference to Exhibit 2 to the report on Form 6-K, previously filed with the SEC on February 7, 2007.
Warrants	
2.5	Form of warrant (regarding Series A financing), incorporated by reference to Exhibit 4.2.2 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
2.6	Form of Representatives' Purchase Option between Gentium S.p.A. and Maxim Group LLC and I-Bankers Securities Inc., incorporated

	by reference to Exhibit 1.2 to Amendment No. 5 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on June 9, 2005.
2.7	Form of American Depositary Shares Purchase Warrant by Gentium S.p.A. dated October 14, 2005, incorporated by reference to Exhibit 4.8.2 to the Registration Statement on Form F-1, Registration No. 333-130796, previously filed with the SEC on December 30, 2005.
2.8.1	Form of American Depositary Shares Purchase Warrant by Gentium S.p.A. dated June 6, 2006, incorporated by reference to Exhibit 4.9.2 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.

Exhibit	Description
2.8.2	Form of Ordinary Share Warrant by Gentium S.p.A. dated June 6, 2006, incorporated by reference to Exhibit 4.9.3 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.
Investor Rights and Registration Rights Agreements	
2.9.1	Form of Investors' Rights Agreement between Gentium S.p.A. and holders of the Series A senior convertible promissory notes and warrants dated October 15, 2004, incorporated by reference to Exhibit 4.2.4 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
2.9.2	Amendment No. 1 to Gentium S.p.A. Series A Senior Convertible Promissory Notes, Warrants, Subscription Agreements and Investor Rights Agreements among Gentium S.p.A. and the other parties thereto dated May 27, 2005, incorporated by reference to Exhibit 4.2.6 to Amendment No. 4 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on May 31, 2005.
2.10	Investors' Rights Agreement by and among Gentium S.p.A., Alexandra Global Master Fund Ltd. and Generation Capital Associates made as of January 10, 2005, incorporated by reference to Exhibit 4.3 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
2.11	Investors' Rights Agreement by and among Gentium S.p.A. and Sigma Tau Finanziaria S.p.A. made as of April 4, 2005, incorporated by reference to Exhibit 4.5 to Amendment No. 1 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on April 7, 2005.
2.12	Registration Rights Agreement among Gentium S.p.A. and the other parties thereto made and entered into as of October 14, 2005, incorporated by reference to Exhibit 4.8.3 to the Registration Statement on Form F-1, Registration No. 333-130796, previously filed with the SEC on December 30, 2005.
2.13	Registration Rights Agreement among Gentium S.p.A. and the other parties thereto made and entered into as of June 6, 2006, incorporated by reference to Exhibit 4.9.4 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.
2.14	Registration Rights Agreement among Gentium S.p.A. and the other parties thereto made and entered into as of February 9, 2007,

	incorporated by reference to Exhibit 4.10.3 to the Registration Statement on Form F-3, Registration No. 333-141198, previously filed with the SEC on March 9, 2007.
Equity Incentive and Stock Option Plans	
4.1.1	Amended and Restated 2004 Equity Incentive Plan, incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-8, Registration No. 333-137534, previously filed with the SEC on September 22, 2006.
4.1.2	Amendment No. 1 to Amended and Restated 2004 Equity Incentive Plan, made as of March 26, 2007, incorporated by reference to Exhibit 4.1.2 to the Annual Report on Form 20-F for the year ended December 31, 2007, previously filed with the SEC on April 30, 2007.
4.2.1	Amended and Restated Nonstatutory Share Option Plan and Agreement dated March 23, 2006, incorporated by reference to Exhibit 4.2 to the Annual Report on Form 20-F for the year ended December 31, 2005, previously filed with the SEC on May 30, 2006.

Exhibit	Description
4.2.2	Amendment No. 1 to Amended and Restated Nonstatutory Share Option Plan and Agreement, made as of March 26, 2007, incorporated by reference to Exhibit 4.2.2 to the Annual Report on Form 20-F for the year ended December 31, 2007, previously filed with the SEC on April 30, 2007.
4.3	2007 Stock Option Plan, dated March 26, 2007, incorporated by reference to Exhibit 4.42 to the Annual Report on Form 20-F for the year ended December 31, 2007, previously filed with the SEC on April 30, 2007.
Loan Agreements	
4.4	Ministry for Universities, Scientific and Technological Research Loan granted to Gentium S.p.A., successor in interest to Crinos Industria Farmacobiologica S.p.A., by Sanpaolo Imi S.p.A., dated September 27, 2000, incorporated by reference to Exhibit 10.6 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
4.5	Loan Agreement between Banca Nazionale del Lavoro S.p.A. and Gentium S.p.A. dated June 14, 2006 incorporated by reference to Exhibit 10.7.3 to the Registration Statement on Form F-3, Registration No. 333-135622, previously filed with the SEC on July 6, 2006.
4.6	Loan Agreement for €230,000 with Banca Intesa S.p.A., dated December 20, 2006, incorporated by reference to Exhibit 2 to the report on Form 6-K, previously filed with the SEC on February 2, 2007.
4.7	Loan Agreement for €500,000 with Banca Intesa S.p.A., dated December 20, 2006, incorporated by reference to Exhibit 3 to the report on Form 6-K, previously filed with the SEC on February 2, 2007.
4.8	Loan Agreement for €225,000 with Banca Intesa S.p.A., dated December 20, 2006, incorporated by reference to Exhibit 4 to the report on Form 6-K, previously filed with the SEC on February 2, 2007.
4.9	Financing Contract between Banca Intesa Mediocredito S.p.A. and Gentium S.p.A. dated April 20, 2006, incorporated by reference to Exhibit 4.36.2 to the Annual Report on Form 20-F for the year ended December 31, 2005, previously filed with the SEC on May 30, 2006.
4.10	Loan Agreement, dated June 30, 2006, between San Paolo IMI S.p.A. and Gentium S.p.A. , incorporated by reference to Exhibit

	4.43 to the Annual Report on Form 20-F for the year ended December 31, 2006, previously filed with the SEC on April 30, 2007.
Clinical Trial Agreements	
4.11.1	Master Services Agreement, dated March 14, 2007, between MDS Pharma Services (US), Inc. and Gentium S.p.A., incorporated by reference to Exhibit 1 to the report on Form 6-K, previously filed with the SEC on March 20, 2007.
4.11.2	Statement of Work, effective August 8, 2007, between Gentium S.p.A. and MDS Pharma Services, Inc. (prospective arm), incorporated by reference to Exhibit 3 to the report on Form 6-K, previously filed with the SEC on August 22, 2007.
4.11.3	Statement of Work, effective August 8, 2007, between Gentium S.p.A. and MDS Pharma Services, Inc. (historical arm), incorporated by reference to Exhibit 4 to the report on Form 6-K, previously filed with the SEC on August 22, 2007.

Exhibit	Description
License and Distribution Agreements	
4.12.1	License and Supply Agreement by and between Gentium S.p.A. and Sigma-Tau Pharmaceuticals, Inc. (assignee of Sigma Tau Industrie Farmaceutiche Riunite S.p.A.) dated December 7, 2001, incorporated by reference to Exhibit 10.15 to the Registration Statement on Form F-1, Registration No. 333-122233, previously filed with the SEC on January 24, 2005.
4.12.2	Letter Agreement, dated October 12, 2007, between Gentium S.p.A. and Sigma-Tau Pharmaceuticals, Inc., incorporated by reference to Exhibit 99.4 to the report on Form 6-K, previously filed with the SEC on December 12, 2007.
4.13.1	Contract to Supply Active Ingredients between Sirton Pharmaceuticals S.p.A. and Gentium S.p.A. dated January 2, 2006, incorporated by reference to Exhibit 4.24.2 to the Annual Report on Form 20-F for the year ended December 31, 2005, previously filed with the SEC on May 30, 2006.
4.13.2	Amendment No. 1 to Contract to Supply Active Ingredients, effective as of December 7, 2007, by and between Gentium S.p.A. and Sirton Pharmaceuticals S.p.A.
4.14.1	Master Agreement, dated December 28, 2006, among Gentium S.p.A., Crinos S.p.A., SFI Stada Financial Investments Ltd. and SFS Stada Financial Services International Ltd., incorporated by reference to Exhibit 2 to the report on Form 6-K, previously filed with the SEC on January 3, 2007.
4.14.2	Distribution Agreement, dated December 28, 2006, between Gentium S.p.A. and Crinos S.p.A., incorporated by reference to Exhibit 6 to the report on Form 6-K, previously filed with the SEC on January 3, 2007.
4.21*	Technical Transfer Services Agreement, dated February 2, 2009, between Gentium S.p.A. and Patheon Italia S.p.A.
4.22.1	Technical Agreement, dated February 26, 2009, between Gentium S.p.A. and IDIS Limited.
4.22.2*	Supply and Distribution Agreement, dated March 6, 2009, between Gentium S.p.A. and IDIS Limited.
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.

Exhibit	Description
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 30, 2009.

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