PLEDGE PETROLEUM CORP
Form 10-Q
December 18, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended **June 30, 2017**

or

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

For the transition period from _________to ________

Commission File Number: **000-53488**

PLEDGE PETROLEUM CORP.

(Exact name of registrant as specified in its charter)

Delaware	**26-1856569**
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer Identification No.)

11811 North Freeway, 5th Floor,

Suite 513, Houston, TX 77060

(Address of principal executive offices) (Zip Code)

(832) 328- 0169

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ¨ No x

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No x

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨(Do not check if a smaller reporting company)	Smaller reporting company x
	Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the

Exchange Act. ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The Registrant has 268,558,931 shares of common stock outstanding as of December 15, 2017.

Documents incorporated by reference: None

PLEDGE PETROLEUM CORP.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In particular, statements contained in this Quarterly Report on Form 10-Q, including but not limited to, statements regarding the sufficiency of our cash, our ability to finance our operations and business initiatives and obtain funding for such activities; our future results of operations and financial position, business strategy and plan prospects, or costs and objectives of management for future acquisitions, are forward looking statements. These forward-looking statements relate to our future plans, objectives, expectations and intentions and may be identified by words such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “intends,” ’‘targets,” “projects,” “contemplates,” ’‘believes,” “seeks,” “goals,” “estimates,” ’‘predicts,” ’‘potential” and “continue” or similar words. Readers ar cautioned that these forward-looking statements are based on our current beliefs, expectations and assumptions and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those identified below, under Part II, Item 1A. “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q, and those identified under Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on August 7, 2017. Therefore, actual results may differ materially and adversely from those expressed, projected or implied in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

NOTE REGARDING COMPANY REFERENCES

Throughout this Quarterly Report on Form 10-Q, “Pledge,” the “Company,” “we,” “us” and “our” refer to Pledge Petroleum Corp.

PLEDGE PETROLEUM CORP.

FORM 10-Q

FOR THE SIX MONTHS ENDED JUNE 30, 2017

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

PLEDGE PETROLEUM CORP.

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2017 (Unaudited)	December 31, 2016
Assets		
Current Assets		
Cash	$8,891,239	$9,170,286
Prepaid expenses	34,066	25,940
Total Current Assets	8,925,305	9,196,226
Non-Current Assets		
Plant and equipment, net	11,460	14,326
Deposits	530	6,968
Total Non-Current Assets	11,990	21,294
Total Assets	$8,937,295	$9,217,520
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$79,438	$31,027
Accrued expenses and other payables	14,860	34,467
Net liabilities of discontinued operations	1,025,716	1,025,716
Notes payable	3,000	3,000
Total Current Liabilities	1,123,014	1,094,210
Stockholders' Equity		
Series A-1 Convertible Preferred stock, $0.01 par value; 5,000,000 shares designated, 3,137,500 shares issued and outstanding. (liquidation preference $251,000)	3,138	3,138
Series B Convertible, Redeemable Preferred Stock, $0.001 par value; 500,000 shares designated; 40,000 issued and outstanding. (liquidation preference $480,000)	40	40
Series C Convertible, Preferred Stock, $0.001 par value, 4,500,000 shares designated, 4,500,000 issued and outstanding (liquidation preference $14,750,000)	4,500	4,500
	268,559	268,559

Common stock, $0.001 par value; 500,000,000 shares authorized, 268,558,931 shares issued and outstanding.		
Additional paid-in-capital	26,377,580	26,359,514
Accumulated deficit	(18,839,536)	(18,512,441)
Total Stockholders' Equity	7,814,281	8,123,310
Total Liabilities and Stockholders' Equity	$8,937,295	$9,217,520

See notes to the unaudited condensed consolidated financial statements

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PLEDGE PETROLEUM CORP.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three months ended June 30 2017	Three months ended June 30 2016	Six months ended June 30 2017	Six months ended June 30 2016
Net Revenue	$25,000	$-	$25,000	$-
Cost of Goods Sold	-	-	-	-
Gross Profit	$25,000	$-	$25,000	$-
Sales and Marketing	1,497	1,497	2,994	6,765
Professional fees	83,606	77,009	148,361	169,557
Consulting fees	8,305	145,600	27,436	243,100
General and administrative	46,991	300,260	170,482	654,956
Depreciation, amortization and impairment charges	1,311	34,519	2,866	68,281
Total Expense	141,710	558,885	352,139	1,142,659
Loss from Operations	(116,710)	(558,885)	(327,139)	(1,142,659)
Other income (expense)	-	(763)	-	199,237
Finance costs	59	-	44	-
Loss before Provision for Income Taxes	(116,651)	(559,648)	(327,095)	(943,422)
Provision for Income Taxes	-	-	-	-
Net Loss from continuing operations	(116,651)	(559,648)	(327,095)	(943,422)
Loss for discontinued operations, net of tax	-	(400,863)	-	(1,064,736)
Net loss attributable to non-controlling interest of discontinued operation	-	-	-	249,339
Loss from discontinued operations, net of non-controlling interest	-	(400,863)	-	(815,397)
Net Loss Attributable to Controlling Interest	(116,651)	(960,511)	(327,095)	(1,758,819)
Undeclared Series B and Series C Preferred stock dividends	(156,071)	(156,071)	(310,427)	(312,142)
Net loss available to common stock holders	$(272,722)	$(1,116,582)	$(637,522)	$(2,070,961)

Net Loss Per Share from continuing operations - Basic and Diluted	$-	$-	$-	$(0.01)
Net Loss Per Share from discontinued operations - Basic and Diluted	$-	$-	$-	$-
Net Loss Per Share - Basic and Diluted	$-	$-	$-	$(0.01)
Weighted Average Number of Shares Outstanding - Basic and Diluted	268,558,931	268,558,931	268,558,931	268,558,931

See notes to the unaudited condensed consolidated financial statements

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PLEDGE PETROLEUM CORP.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six months ended June 30 2017	Six months ended June 30 2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(327,095)	$(1,758,819)
Net loss from discontinued operations	-	1,064,736
Less: loss attributable to non-controlling interest	-	(249,339)
Net loss from continuing operations	(327,095)	(943,422)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation expense	2,866	33,281
Deposit forfeited	6,968	-
Amortization expense	-	35,000
Loss on theft of fixed assets	-	1,248
Equity based compensation charge	18,066	42,895
Gain on debt forgiven	-	(200,000)
Changes in Assets and Liabilities		
Accounts receivable	-	(21,787)
Prepaid expenses and other current assets	(8,125)	16,087
Accounts payable	48,618	(88,850)
Accrued liabilities	(19,815)	(31,109)
Cash Used in Operating Activities - continuing operations	(278,517)	(1,156,657)
Cash used in operating activities - discontinued operations	-	(441,543)
	(278,517)	(1,598,200)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	-	(168,144)
Investment in deposit	(530)	(6,968)
Cash used in investing activities - continuing operations	(530)	(175,112)
Cash used in investing activities - discontinued operations	-	(3,358)
	(530)	(178,470)
NET DECREASE IN CASH	(279,047)	(1,776,670)
CASH AT BEGINNING OF PERIOD	$9,170,286	$11,700,143
CASH AT END OF PERIOD	$8,891,239	$9,923,473
CASH PAID FOR INTEREST AND TAXES:		
Cash paid for income taxes	$-	$-
Cash paid for interest	$-	$-

See notes to the unaudited condensed consolidated financial statements

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PLEDGE PETROLEUM CORP.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1 ACCOUNTING POLICIES AND ESTIMATES

a) Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information with the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, these unaudited condensed financial statements do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of management, the accompanying unaudited condensed financial statements include all adjustments (consisting only of normal recurring adjustments), which we consider necessary, for a fair presentation of those financial statements. The results of operations and cash flows for the three months and six months ended June 30, 2017 may not necessarily be indicative of results that may be expected for any succeeding quarter or for the entire fiscal year. The information contained in this quarterly report on Form 10-Q should be read in conjunction with our audited financial statements included in our annual report on Form 10-K as of and for the year ended December 31, 2016 as filed with the Securities and Exchange Commission (the "SEC").

Significant accounting policies are described in Note 2 to the consolidated financial statements included in Item 8 of our annual report on Form 10-K as of December 31, 2016.

The preparation of unaudited consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions, which are evaluated on an ongoing basis, that affect the amounts reported in the unaudited consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on various other assumptions that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the amounts of revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and judgments. In particular, significant estimates and judgments include those related to: the estimated useful lives for plant and equipment, the fair value of warrants and stock options granted for services or compensation, estimates of the probability and potential magnitude of contingent liabilities, derivative liabilities, the valuation allowance for deferred tax assets due to continuing operating losses, those related to revenue recognition and the allowance for doubtful accounts.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the unaudited

consolidated financial statements, which management considered in formulating its estimate could change in the near-term due to one or more future confirming events. Accordingly, the actual results could differ significantly from our estimates.

All amounts referred to in the notes to the unaudited consolidated financial statements are in United States Dollars ($) unless stated otherwise.

b) Principles of Consolidation

The unaudited consolidated financial statements include the financial statements of the Company and its subsidiaries in which it has a majority voting interest. All significant inter-company accounts and transactions have been eliminated in the unaudited consolidated financial statements. The entities included in these unaudited consolidated financial statements are as follows:

Pledge Petroleum Corp (formerly Propell Technologies Group, Inc.) – Parent Company

Novas Energy USA Inc. (wholly owned)

Novas Energy North America, LLC (60% owned) – Discontinued operation.

PLEDGE PETROLEUM CORP.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1 ACCOUNTING POLICIES AND ESTIMATES (continued)

c) Recent Accounting Pronouncements

In May 2017, the FASB issued Accounting Standards Update No. (“ASU’’) 2017-09, Compensation – Stock Compensation, an amendment to Topic 718. The amendments in this Update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718.2. An entity should account for the effects of a modification unless all the following are met:

1. The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification.

2. The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified.

3. The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified.

The current disclosure requirements in Topic 718 apply regardless of whether an entity is required to apply modification accounting under the amendments in this Update. The amendments in this Update are effective for all entities for annual periods beginning after December 15, 2017. Early adoption is permitted and should be applied prospectively to an award modified on or after the adoption date. The amendments proposed in this ASU are not expected to have a material impact on our consolidated financial statements.

In May 2017, the FASB issued ASU 2017-10, service concession arrangements, an amendment to Topic 853. Topic 853 provides guidance for operating entities when they enter into a service concession arrangement with a public-sector grantor who both:

1. Controls or has the ability to modify or approve the services that the operating entity must provide with the infrastructure, to whom it must provide them, and at what price

2. Controls, through ownership, beneficial entitlement, or otherwise, any residual interest in the infrastructure at the end of the term of the arrangement.

In a service concession arrangement within the scope of Topic 853, the operating entity should not account for the infrastructure as a lease or as property, plant, and equipment. An operating entity should refer to other Topics to account for various aspects of a service concession arrangement. For example, an operating entity should account for revenue relating to construction, upgrade, or operation services in accordance with Topic 605, Revenue Recognition, or Topic 606, Revenue from Contracts with Customers.

The amendments in this Update apply to the accounting by operating entities for service concession arrangements within the scope of Topic 853. These updates are effective when the Company adopts the updates to Topic 606. The amendments proposed in this ASU are not expected to have an impact on our consolidated financial statements.

Any new accounting standards, not disclosed above, that have been issued or proposed by FASB that do not require adoption until a future date are not expected to have a material impact on the financial statements upon adoption.

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PLEDGE PETROLEUM CORP.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1 ACCOUNTING POLICIES AND ESTIMATES (continued)

d) Use of Estimates

The preparation of unaudited consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions, which are evaluated on an ongoing basis, that affect the amounts reported in the unaudited consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on various other assumptions that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the amounts of revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and judgments. In particular, significant estimates and judgments include those related to: the estimated useful lives for plant and equipment, the fair value of warrants and stock options granted for services or compensation, estimates of the probability and potential magnitude of contingent liabilities, derivative liabilities, the valuation allowance for deferred tax assets due to continuing operating losses, those related to revenue recognition and the allowance for doubtful accounts.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the unaudited consolidated financial statements, which management considered in formulating its estimate could change in the near-term due to one or more future confirming events. Accordingly, the actual results could differ significantly from our estimates.

e) Contingencies

Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to the Company, but which will only be resolved when one or more future events occur or fail to occur. The Company's management assesses such contingent liabilities, and such assessment inherently involves an exercise of judgment.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in the Company's financial statements. If the assessment indicates that a potential material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, together with an estimate of the range of

possible loss if determinable and material would be disclosed. Loss contingencies considered to be remote by management are generally not disclosed unless they involve guarantees, in which case the guarantee would be disclosed.

f) Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. At June 30, 2017 and December 31, 2016, respectively, the Company had no cash equivalents.

The Company assesses credit risk associated with cash by periodically evaluating the credit quality of its primary financial institution. The balance at times may exceed federally insured limits. At June 30, 2017, the Company had cash balances of $8,891,239, which exceeded the federally insured limits by $8,605,958.

PLEDGE PETROLEUM CORP.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

- the costs associated with protecting and expanding our patent and other intellectual property rights;
- future payments, if any, received or made under existing or possible future collaborative arrangements;
- the timing of regulatory approvals needed to market our product candidates; and
- market acceptance of our products.

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

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

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

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

We are highly dependent on our senior management, especially Dr. Laura Ferro, our President and Chief Executive Officer, and Dr. Massimo Iacobelli, our Senior Vice President and Scientific Director, whose services are critical to the successful implementation of our product acquisition, development and regulatory strategies. If we lose their services or the services of one or more of the other members of our senior management or other

key employees, our ability to successfully commercialize our product candidates or otherwise manage our business effectively could be seriously harmed. Dr. Ferro's employment agreement with us is for a period of three years with a two year renewal option and prohibits her from competing with us during the term of her employment and for a period of one year after the termination of her employment. Dr. Ferro's employment agreement provides that she is not obligated to spend more than 75% of her time working for our company

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

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

Our independent registered public accounting firm reported a material weakness in our internal controls and we may not be able to remedy this material weakness or prevent future weaknesses. If we fail to maintain effective internal controls, we may not be able to accurately report our financial results or prevent fraud. As a result, potential security holders could lose confidence in our financial reporting, which would harm our business and the trading price of our ordinary shares.

Prior to our initial public offering in June 2005, we were a relatively small, family run Italian business. We had not been required to close our accounting records on a monthly or even quarterly basis. A very small accounting team handled the accounts for not only us, but also our then-parent, FinSirton S.p.A., and sister companies, Sirton and Foltene Pharmaceuticals S.p.A., all of which are also private companies. Therefore, the internal control structure was not adequate for a company publicly listed and reporting in the United States. Also, the financial reporting environment in Italy for private companies is significantly different than for public companies in the United States.

As an Italian company publicly listed in the United States, we are required by Italian law to keep our books according to the local statutory accounting methods, but we also prepare U.S. GAAP based financial statements for our Securities Act registration statements and Exchange Act reports. The preparation of our U.S. GAAP based financial statements is a manual process which involves the transformation of our Italian statutory financial statements into U.S. GAAP through a significant number of complex accounting adjustments and processes. This process also requires an ongoing review and update of the applicable U.S. GAAP that should be applied to the underlying Italian financial statements. This process is complicated and time-consuming and requires significant attention and time of our senior accounting personnel. Moreover, U.S. GAAP accounting adjustments tend to result in large differences between our Italian statutory and U.S. GAAP based financial statements.

When we started the process of preparing for our initial public offering, one of the first needs we identified to solve these issues was that of a full time, dedicated finance professional with knowledge of both U.S. and Italian accounting principles. We believe we satisfied that need by hiring Mr. Salvatore Calabrese, our Vice-President, Finance, in February of 2005. However, our independent registered public accounting firm informed us during the course of auditing our 2005 financial statements that our financial statement close process and the transformation of our Italian statutory financial statements into U.S. GAAP still did not reduce to an acceptably low level the risk that errors in amounts that would be material in relation to those financial statements may occur and may not be detected within a timely period by management in the normal course of business at December 31, 2005. Our independent registered public accounting firm considered these deficiencies in determining the nature, timing and extent of their procedures in their audit of our 2005 financial

statements, and those deficiencies did not affect their report on our 2005 financial statements. The following highlights the issues identified and the steps that we are taking to remedy these items. We believe that all material weakness issues will be resolved during 2006.

· ***Issue:*** **For the first six months of 2005, we still relied on FinSirton for most of the data processing related to our significant processes, such as inventory costing, payroll and general ledger. We also had limited control over FinSirton's information technology system related to the input or output of data. Additionally, we had no direct control over the security of data and access controls related to the control environment.**

Remedy: **During the second six months of 2005, we established our own six (6) person accounting, controlling and reporting department, separate from FinSirton, which includes not only Mr. Calabrese but also Roberta Grandini as our controller. Ms. Grandini is experienced in U.S. GAAP and was previously the controller for the Italian subsidiary of a U.S. public biotechnology company. In addition, we purchased and have installed our own information technology system which will allow us to have full control, including information security control, over our data processing, including our underlying books and records. At June 30, 2006, this transition from FinSirton's accounting department and information technology system to our accounting department and information technology system had been completed.**

· ***Issue:*** **Our process for budgeting, awarding, tracking and verifying research and development contracts and costs has historically been handled outside of the general accounting system. We have not had controls surrounding this process to closely monitor such areas as actual costs versus budgeted costs, actual costs billed versus the contractual amounts and the timing of when those costs have been incurred.**

Remedy: **As mentioned above, during the second half of 2005, we established and expanded our own independent accounting department. In addition to Mr. Calabrese and Ms. Grandini, this department includes a contract administrator who now has primary responsibility for controlling the research and development contracts and costs. We also established internal procedures for purchases, cash disbursements, limits of authorization and segregation of duties. These procedures include requirements that all research and development expenditures be accompanied by a budget estimate, and any deviations be adequately explained. Additionally, the procedures require that expenses over €2,500 not previously budgeted must be approved by the internal control department, Mr. Calabrese and by our medical director before any purchase requests or contracts may be signed. Furthermore, on a quarterly basis, we perform an analysis of actual expenses versus budgeted expenses, and such analysis is presented and discussed with our management, our Audit Committee and the Board of Directors as a whole.**

· ***Issue*: Our overall control environment continued to have difficulties in 2005 in closing our accounting records on a timely basis, given (i) the lack of personnel dedicated to performing such services for us, separate from our affiliated companies, (ii) our reliance upon FinSirton's information technology system and (iii) the need for us to prepare Italian statutory financial statements and then manually convert those statements into U.S. GAAP financial statements.**

Remedy: **We believe that our establishment of and expansion of our own, independent accounting department, including Mr. Calabrese and Ms. Grandini, and the acquisition of our own independent information technology system, will solve points (i) and (ii) above. In addition, although we will continue to need to prepare both Italian statutory financial statements and U.S. GAAP based financial statements, we believe that the expansion of our accounting department will help us close our records more quickly and that the establishment of our new information technology system will reduce the overall complexity of the process and the risk of errors.**

Any failure to implement new or improved internal controls, or resolve difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ordinary shares.

Our revenues, expenses and results of operations have been and will continue to be subject to significant fluctuations, which makes it difficult to compare our operating results from period to period.

Since 2003, our revenues have fluctuated significantly due to the need to temporarily cease operations at our manufacturing facility for an upgrade to the facility for seven months in 2004 and increase production at the facility in 2003 to stockpile inventory in anticipation of this cessation. Our revenues have also fluctuated due to changes in the amounts of each of our products that we sell in different periods. Due to the fact that we do not sell directly to the end-user, the timing of manufacturer orders can cause variability in sales. In 2005, we experienced higher sales volume in the second and in the fourth quarters; however we cannot predict if such fluctuation will happened in future years. Until we have successfully developed and commercialized a product candidate, we expect that substantially all of our revenues will result from the sale of our existing products. We expect that our operating results will vary significantly from quarter to quarter and year to year as a result of

the timing and extent of:

- our research and development efforts;
- the revenues generated from the sale or licensing of our products;
- the execution or termination of collaborative arrangements;
- the receipt of grants;
- the initiation, success or failure of clinical trials; and
- the manufacture of our product candidates, or other development related factors.

Some of Series A senior convertible promissory notes we issued in the fourth quarter of 2004 and the first quarter of 2005 were converted into our ordinary shares upon the closing of our initial public offering in June 2005 and the remainder were repaid in June and July 2005. Our results of operations in 2004 and 2005 reflect the interest expense we incurred on those notes. That interest expense included the amortization of the debt issue costs and of the original issue discount resulting from the inclusion of the warrants with the notes and the amortization of the value of the beneficial conversion feature resulting from the effective conversion price since the conversion ratio, which is equal to the principal amount of the notes divided by $8.10 (ninety percent (90%) of the initial offering price per ADS in our initial public offering), was less than the fair value of our ordinary shares at the time of issuance of the notes, which was $10.00. During 2004 and 2005, we incurred €1.828 million and €4.095 million, respectively, of interest expense on these notes (including amortization of original issue discount and debt issue costs). As a result, our interest expense, pre-tax income (loss) and net income (loss) for those periods was less than it would have been otherwise.

Accordingly, our revenues and results of operations for any period may not be comparable to the revenues or results of operations for any other period.

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

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

We obtain office and manufacturing space and certain administrative, financial, information technology, human resources, regulatory and quality control services from affiliates. This structure creates inherent conflicts of interest that may adversely affect us.

Our largest shareholder is FinSirton, which owned approximately 32% of our ordinary shares at September 30, 2006. Dr. Ferro, who is our Chief Executive Officer and President and one of our directors, together with members of her family, controls FinSirton. FinSirton provides some of our office space, and corporate, payroll and information technology services. Sirton, which is a wholly owned subsidiary of FinSirton, has been and currently is our principal customer. Sirton also provides us with a number of business services such as, quality control and infrastructure services, and leases us office and manufacturing space.

If either of these affiliates failed to perform services for us adequately or caused us damage through their negligent conduct, our management would be presented with inherent conflicts of interest due to their ownership and oversight of FinSirton. We may have limited recourse in the event of such conflicts, and our business may be adversely affected by their occurrence.

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

Our industry is highly competitive and subject to significant and rapid technological change as researchers learn more about diseases and develop new technologies and treatments. While we are unaware of any other products or product candidates that treat or prevent VOD or the apoptosis that our product candidate oligotide is designed to treat, we believe that other companies have products or are currently developing products to treat some of the same disorders and diseases that our other product candidates are designed to treat. These companies include AnorMED Inc., AstraZeneca International, British Biotech plc, Abbott Laboratories, The Bayer Group, GlaxoSmithKline plc, Bristol-Myers Squibb Company, Eli Lilly Company, Boehringer Ingelheim, Axcan Pharma Inc., The Proctor & Gamble Company, Solvay Pharmaceuticals, Inc., Millenium Pharmaceuticals, Inc., ARIAD Pharmaceuticals, Inc., Celgene Corp., Titan Pharmaceuticals, Inc., Cell Genesys, Inc., Human Genome Sciences, Inc., Chugai Pharmaceutical Co., Ltd., The National Cancer Institute, Seattle Genetics, Inc., EntreMed, Inc., NeoRxx Corporation, Xcyte Therapies, Inc., Amgen, Inc., CuraGen Corporation, Aesgen, Inc. and Endo Pharmaceutical Holdings Inc.

In addition, low molecular weight heparin, made by Aventis and other companies, competes with calcium heparin, which is one of the active pharmaceutical ingredients that we sell to Sirton which makes it into a finished product for sale by Crinos.

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

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

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

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

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

Because of the extensive time required for the development, testing and regulatory review of a product candidate, it is possible that before any of our product candidates can be approved for sale and commercialized, our relevant patent rights may expire or remain in force for only a short period following commercialization. Our issued United States patents expire between 2008 and 2019, and our United States

patents for which we have submitted applications will expire between 2008 and 2026. Our United States patent covering defibrotide expires in 2010, and our U.S. patent covering the chemical process for extracting defibrotide expires in 2008. Our European patent covering both defibrotide and the chemical process for extracting defibrotide expires in 2007. There may be no opportunities to extend these patents and thereby extend FDA approval exclusivity, in which case we could face increased competition for our products that are derived from defibrotide. Patent expiration could adversely affect our ability to protect future product development and, consequently, our operating results and financial position.

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

Risks Related to Ownership of the ADSs

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

Our largest shareholder, FinSirton, owned approximately 32% of our outstanding ordinary shares at September 30, 2006. Dr. Laura Ferro, who is our Chief Executive Officer and President and one of our directors, together with members of her family, controls FinSirton. As a result, Dr. Ferro and her family, through FinSirton, will substantially control the outcome of all matters requiring approval by our security holders, including the election of directors and the approval of mergers or other important corporate events. They may exercise this ability in a manner that advances their best interests and not necessarily yours. In particular, Dr. Ferro may use her control over FinSirton's shareholdings in our company to resist any attempts to replace her or other members of our board of directors or management or approve or reject mergers and other important corporate events. Also, the concentration of our beneficial ownership may have the effect of delaying, deterring or preventing a change in our control, or may discourage bids for the ADSs or our ordinary shares at a premium over the market price of the ADSs. The significant concentration of share ownership may adversely affect the trading price of the ADSs due to investors' perception that conflicts of interest may exist or arise.

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

Some of our executive officers and directors and our current largest shareholder, FinSirton, agreed with the underwriters of our initial public offering to a lock-up of an aggregate of 3,750,000 outstanding ordinary shares and 822,000 ordinary shares issuable upon exercise of certain options for a period of 18 months after the effective date of the registration statement relating to our initial public offering of securities, provided, however, that if the average price per ADS equals or exceeds 200% of the initial public offering price of the ADSs in our initial public offering for a minimum of twenty continuous trading days, the ordinary shares may be released from the lock-up at the request of the holder, which could result in the release from the lock-up restrictions of the 3,750,000 outstanding shares held by FinSirton and the 822,000 ordinary shares issuable upon exercise of the options. Sales of a substantial number of ADSs representing these ordinary shares in the public market could depress the market price of the ADSs and impair our ability to raise capital through the sale of additional equity securities. The underwriters, in their sole discretion and at any time without notice, may release all or any portion of the ordinary shares held by our officers, directors, and FinSirton subject to these lockup agreements. Our other outstanding ordinary shares, ordinary shares issuable upon exercise of warrants and ordinary shares issuable upon exercise of options are not subject to lock-up agreements. This prospectus offers the resale of 1,459,505 outstanding ordinary shares and 484,964 ordinary shares issuable

upon the exercise of warrants by certain selling security holders. We have filed registration statements including prospectuses offering the resale of most of our other outstanding restricted ADSs and most ADSs issuable upon exercise of outstanding warrants. Such offer and ultimate sale of the securities in the markets may adversely affect the market for the ADSs.

Risks Relating to Being an Italian Corporation

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

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

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

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

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

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

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

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

Italian law provides that we may not issue debt securities for an amount exceeding twice the amount of the sum of the aggregate par value of our ordinary shares (which we call our capital), our legal reserve and any other disposable reserves appearing on our latest Italian GAAP balance sheet approved by our security holders. The

legal reserve is a reserve to which we allocate 5% of our Italian GAAP net income each year until it equals at least 20% of our Italian GAAP capital. One of the other reserves that we maintain on our balance sheet is a "share premium reserve", meaning amounts paid for our ordinary shares in excess of the capital. At December 31, 2005, the sum of our capital, legal reserves and other reserves on our Italian GAAP balance sheet was €29.6 million. If we issue debt securities in the future, until such debt securities are repaid in full, we may not voluntarily reduce our capital or our reserves (such as by declaring dividends) if it results in the aggregate of the capital and reserves being less than half of the outstanding amount of the debt. If our equity is reduced by losses or otherwise such that the amount of the outstanding debt securities is more than twice the amount of our equity, some legal scholars are of the opinion that the ratio must be restored by a recapitalization of our company. If our equity is reduced, we could recapitalize by issuing new shares or having our security holders contribute additional capital to our company, although there can be no assurance that we would be able to find purchasers for new shares or that any of our current security holders would be willing to contribute additional capital.

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

Italian law requires us to reduce our security holders' equity and, in particular, our capital (aggregate par value of our ordinary shares) to reflect on-going losses. We are also required to maintain a minimum capital of €120 thousand. At December 31, 2005, our Italian GAAP capital was approximately €9.611 million. If we suffer losses from operations that would reduce our capital to less than €120 thousand, then either we must increase our capital (which we could do by issuing new shares or having our security holders contribute additional capital to our company) or convert the form of our company into an S.r.l., which has a lower capital requirement of €10 thousand. If we did not take these steps, a court could liquidate our company.

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

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

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

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

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

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

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

We are incorporated under the laws of the Republic of Italy. As a result, the rights and obligations of our security holders are governed by Italian law and our bylaws, and are in some ways different from those that apply to U.S. corporations. Some of these differences may result in the depositary (on your behalf) having fewer rights as a shareholder than you would if you were a shareholder of a U.S. corporation. We have presented a detailed comparison of the Italian laws applicable to our company against Delaware law in "*Item 10, Additional Information, Comparison of Italian and Delaware Corporate Laws*" of our annual report on Form 20-F for the year ended December 31, 2005, which is incorporated herein by reference. We compared the Italian laws applicable to our company against Delaware law because Delaware is the most common state of incorporation for U.S. public companies.

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

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

FORWARD-LOOKING STATEMENTS

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

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. We are offering to sell and seeking offers to buy our ordinary shares only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our ordinary shares.

PRESENTATION OF FINANCIAL INFORMATION

Our financial statements are all expressed in euros. Assets and liabilities denominated in United States dollars or other foreign currencies have been converted into euros at the Noon Buying Rate in New York City as certified by the Federal Reserve Bank of New York on the date of the applicable financial statement. Transactions that were conducted in United States dollars or other foreign currencies have been converted into euros at the Noon Buying Rate in New York City as certified by the Federal Reserve Bank of New York on the date of such transactions. On October 30, 2006, the Noon Buying Rate was euro 1.00 to U.S.$1.2717.

Our fiscal year ends on December 31 of each year. Where this prospectus refers to a particular year, this means the fiscal year unless otherwise indicated.

INCORPORATION BY REFERENCE

The SEC allows us to incorporate by reference documents we file with the SEC, which means that we can disclose information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and certain later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the following documents:

(i) our Annual Report on Form 20-F for the fiscal year ended December 31, 2005, filed with the SEC on May 30, 2006; and

(ii) all of our Reports on Form 6-K furnished to the SEC between the date of filing of our Annual Report on Form 20-F with the SEC and the date of this prospectus.

All annual reports we file with the SEC pursuant to the Exchange Act on Form 20-F after the date of this prospectus and prior to the termination of the offering shall be deemed to be incorporated by reference into this prospectus and to be part hereof from the date of filing of such documents. We may incorporate by reference any Form 6-K subsequently submitted to the SEC by identifying in such Form that it is being incorporated by reference into this prospectus. Any statement made in this prospectus, a prospectus supplement or a document incorporated by reference in this prospectus or a prospectus supplement will be deemed to be modified or superseded for purposes of this prospectus and any applicable prospectus supplement to the extent that a statement contained in an amendment to the registration statement, any subsequent prospectus supplement or in any other subsequently filed document incorporated by reference herein or therein adds, updates or changes that statement. Any statement so affected will not be deemed, except as so affected, to constitute a part of this prospectus or any applicable prospectus supplement.

We shall undertake to provide without charge to each person, including any beneficial owner, to whom a copy of this prospectus has been delivered, upon the written or oral request of any such person to us, a copy of any or all of the information referred to above that have been or may be incorporated into this prospectus by reference, including exhibits that are specifically incorporated by reference to such information. Requests for such copies should be directed to Gentium S.p.A., Piazza XX September 2, Villa Guardia (Como), Italy, Attention: Salvatore Calabrese, Vice-President Finance, telephone +39-031-385-287.

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone else to provide you with different information. This prospectus is an offer to sell or to buy only the securities referred to in this prospectus, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or any prospectus supplement is current only as of the date on the front page of those documents. Also, you should not assume that there has been no change in our affairs since the date of this prospectus or any applicable prospectus supplement,

WHERE YOU CAN FIND MORE INFORMATION

We file and submit reports, including annual reports on Form 20-F, and other information with the Securities and Exchange Commission pursuant to the rules and regulations of the SEC that apply to foreign private issuers. You may read and copy any materials filed with the SEC at its Public Reference Room at 100 F Street N.E., Washington, D.C. 20459. You may obtain information on the operation of the Public Reference Room by calling the SEC at l-800-SEC-0330. The registration statement of which this prospectus is a part, and other public filings with the SEC, are also available on the website maintained by the SEC at http://www.sec.gov. Our website is located at www.gentium.it. The information contained on our website is not part of this prospectus.

SERVICE OF PROCESS AND ENFORCEMENT OF JUDGMENTS

We are a *società per azioni* (stock company) organized under the laws of the Republic of Italy. Substantially all of our directors, executive officers, and certain experts named herein, reside in the Republic of Italy. All or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon us or such persons or to enforce judgments obtained in the United States courts predicated upon the civil liability provisions of the Federal securities laws of the United States against us or such persons in United States courts. We have been advised that (a) enforceability in Italy, in actions for enforcement of final judgments of United States courts, of civil liabilities predicated upon the Federal securities laws of the United States is subject, among other things, to the Italian courts' determination that certain jurisdictional and procedural standards were satisfied in the U.S. proceeding, that the U.S. decision is not contrary to an existing Italian decision, that the matter is not the subject of a concurrent proceeding in Italy, and that enforcement would not violate Italian public policy; and (b) in original actions in Italy to enforce such liabilities, an Italian court would examine the merits of the claim in accordance with Italian substantive law and procedure and not necessarily apply United States substantive law. We have expressly submitted to the nonexclusive jurisdiction of New York State and United States federal courts sitting in The City of New York for the purpose of any suit, action or proceeding arising out of the this public offering. We have appointed CT Corporation System, 111 Eighth Avenue, 13th Floor, New York, New York 10011, as our agent upon whom process may be served in any action.

DETERMINATION OF OFFERING PRICE

The selling security holders may offer and sell their ADSs on the Nasdaq National Market System at prevailing market prices. The selling security holders may also offer and sell their ADSs in privately negotiated transactions at prices other than the market price.

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CAPITALIZATION AND INDEBTEDNESS

The following table summarizes our capitalization and indebtedness as of June 30, 2006 on an actual basis. No securities were issued after June 30, 2006.

You should read the following table in conjunction with our financial statements and related notes from our annual report on Form 20-F and other reports on Form 6-K incorporated by reference into this prospectus.

		As of June 30, 2006 *(unaudited)*
Indebtedness:		
Mortgage loans secured by real property	€	2,800
Equipment loans		1,800
Loans secured by equipment		569
Capital lease obligation		150
Other		413
		5,732
Less current maturities		311
		5,421
Security holders' equity:		
Ordinary shares, par value €1.00 per share, 15,100,299 shares authorized, 11,666,013 shares issued and outstanding		11,666
Additional paid-in capital		48,247
Accumulated deficit		(31,566)
Accumulated other comprehensive loss		(11)
Total Security holders' Equity		28,336
Total Capitalization	€	33,757

PRICE HISTORY

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

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

	Price Range of ADSs			
	High		Low	
2005				
Second Quarter (beginning June 16, 2005)	$	9.10	$	8.77
Third Quarter	$	8.99	$	6.92
Fourth Quarter	$	8.68	$	7.05
2006				
First Quarter	$	13.25	$	7.85
Second Quarter	$	19.76	$	12.17
Month Ended				
April 30, 2006	$	19.76	$	13.01
May 31, 2006	$	17.45	$	11.48
June 30, 2006	$	15.00	$	12.60
July 31, 2006	$	14.33	$	12.97
August 31, 2006	$	15.11	$	12.95
September 30, 2006	$	15.49	$	13.82
October 31, 2006 (through October 30, 2006)	$	14.29	$	13.64

The closing price of the ADSs on Nasdaq on October 30, 2006 was $13.78.

Sources: American Stock Exchange and the Nasdaq Stock Market.

SHARE CAPITAL

Authorized Shares

At September 30, 2006, our authorized ordinary shares consisted of 15,100,292 ordinary shares, par value one euro per share, and 11,666,013 ordinary shares were outstanding.

Of our 15,100,292 authorized ordinary shares at September 30, 2006:

· 11,666,013 are outstanding;

· 1,560,000 are reserved for issuance upon exercise of options granted and available for grant under our share option plans;

· 484,964 are reserved for issuance upon exercise of warrants issued in connection with our Series A senior convertible promissory notes;

· 151,200 are reserved for issuance upon exercise of warrants granted to the underwriters of our initial public offering;

· 619,994 are reserved for issuance upon the exercise of warrants issued in connection with our October 2005 private placement;

· 466,446 are reserved for issuance upon the exercise of warrants issued in connection with our June 2006 private placement, including warrants issued to one of our placement agents; and

· 151,675 shares are available for future issuance in certain situations.

Warrants

As of September 30, 2006, we had outstanding the following warrants:

· warrants to purchase 484,964 ordinary shares at a price of $9.52 per share, issued in connection with the issuance of our Series A notes;

· warrants to purchase 151,200 ordinary shares at a price of $11.25 per share issued to our underwriters in connection with our initial public offering;

· warrants to purchase 619,994 ordinary shares at a price of $9.69 per share, issued in connection with our October 2005 private placement;

· warrants to purchase 388,705 ordinary shares at a price of $14.50 per share, issued in connection with our June 2006 private placement; and

· warrants to purchase 77,741 ordinary shares at a price of $17.40 per share, issued to one of our placement agents for the June 2006 private placement.

Options

As of September 30, 2006 we had outstanding options to purchase a total of 1,137,000 ordinary shares. Our share option plans authorize the issuance of up to 1,560,000 ordinary shares. At September 30, 2006, 423,000 ordinary shares were available for future issuance under our share option plans.

Share History

The following history of our share capital for the years ended December 31, 2003, 2004 and 2005, as well as January 1, 2006 through June 30, 2006 supplements the disclosure in our annual report on Form 20-F for the year ended December 31, 2005, which we incorporate by reference herein.

Increase in Authorized Capital

On May 31, 2006, pursuant to the April 28, 2006 amendment to our bylaws, our board of directors approved a capital increase to allow for the issuance of 1,943,525 ordinary shares and 466,446 ordinary shares upon the exercise of warrants in connection with our June 2006 private placement.

Exercises of Warrants

In April 2006, we issued 18,334 ordinary shares upon exercise of a warrant issued in connection with our Series A senior convertible promissory notes at a price per share of $9.52, for proceeds of $174,539.68.

In April 2006, we issued 93,524 ordinary shares upon the exercise of warrants issued in connection with our October 2005 private placement at a price per share of $9.69, for aggregate proceeds of $906,247.56.

June 2006 Private Placement

In June 2006, we issued 1,943,525 ordinary shares at $11.39 per share for gross proceeds of $22,136,749.75 together with warrants to purchase an aggregate of 388,705 ordinary shares at an exercise price of $14.50 per share in a private placement. We also issued warrants to purchase 77,741 ordinary shares at an exercise price of $17.40 to one of our placement agents for the private placement.

Options

In March 2006, we issued options to purchase 15,000 ordinary shares at a price of $12.00 per share to a consultant under our 2004 Equity Incentive Plan.

In April 2006, we issued options to purchase an aggregate of 40,000 ordinary shares at a price of $17.35 per share to our non-employee directors as automatic grants under our 2004 Equity Incentive Plan.

In June 2006, we issued options to purchase 90,000 ordinary shares at a price of $12.60 to an executive officer under our 2004 Equity Incentive Plan.

USE OF PROCEEDS

We will not receive any proceeds from the sale by the selling security holders of the securities offered in this prospectus. Although we will receive proceeds from any exercise of outstanding warrants, we will not receive any proceeds from sales of the underlying ADSs by the selling security holders. We will pay all of the expenses of the offering, including the expenses of the selling security holders, other than any underwriters' discounts and commissions and any fees and disbursements of counsel to the selling security holders. We expect that the selling security holders will sell their ADSs as described under "Plan of Distribution".

SELLING SECURITY HOLDERS

Our ADSs to which this prospectus relates are being registered for resale by the selling security holders.

The selling security holders may resell all, a portion or none of such ADSs from time to time. The table below sets forth with respect to each selling security holder, based upon information available to us as of June 30, 2006, the number and percentage of ADSs (or, in the case of security holders who currently hold ordinary shares or securities exercisable into ordinary shares, the number and percentage of ordinary shares) beneficially owned before this offering, the number of ADSs registered for resale by this prospectus and the number and percent of ADSs that will be beneficially owned immediately after this offering assuming the sale of all of the registered ADSs.

Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC. ADSs or ordinary shares underlying our convertible securities that are exercisable within 60 days from June 30, 2006 are deemed outstanding for computing the amount and percentage owned by the person or group holding such convertible securities, but are not deemed outstanding for computing the percentage owned by any other person or group.

	ADSs Beneficially Owned Before The Offering		**ADSs Offered**	**ADSs Beneficially Owned After The Offering**	
Holder	ADSs	Percent		ADSs	Percent
Lea Adar (1)	4,400	*	4,400	0	0
Alexandra Global Master Fund Ltd. (2)	484,978	4.1	384,978	100,000	*
Amy Elise Garber Trust (3)	3,667	*	3,667	0	0
William R. Annis (4)	367	*	367	0	0
Attar Family Ltd. (5)	5,500	*	5,500	0	0
Richard Bassin (6)	1,834	*	1,834	0	0
Marc and Ellen Becker, Tenants in Common (7)	1,834	*	1,834	0	0
Ronald J. and Judith Ripka Berk, JTROS (8)	7,334	*	7,334	0	0
Bishterne Limited (9)	73,334	*	73,334	0	0
Fred A. Brasch (10)	125,207	1.1	954	0	0
Diana Budzanoski (11)	5,500	*	5,500	0	0
Bushrod Burns (12)	1,834	*	1,834	0	0
Robert E. Buxbaum & Sonia Gluckman C/F Evan Buxbaum UNYUGMA (13)	734	*	734	0	0
Defiante Farmaceutica L.d.a. (14)	432,839	3.7	432,839	0	0
Barbara H. & Peter R. Ducoffe, JTWROS (15)	7,334	*	7,334	0	0
Kenneth & Joceline Elan, JTWROS (16)	1,834	*	1,834	0	0
Estate of Louis Spanier (17)	7,334	*	7,334	0	0
Finrex S.A. (18)	33,000	*	33,000	0	0
David J. Forsyth (19)	1,834	*	1,834	0	0
Samuel H. and Betty H. Franklin, Tenants in Common (20)	3,667	*	3,667	0	0
Robert Fredricks (21)	734	*	734	0	0

Stephen W. & Marianne E. Garber, JTWROS (22)	3,667	*	3,667	0	0
Joseph Gatti, Jr. (23)	3,667	*	3,667	0	0
Generation Capital Associates (24)	124,253	1.1	44,000	36,253	*
Sonia Gluckman (25)	6,600	*	6,600	0	0
Stephen M. Greenberg (26)	734	*	734	0	0
Amos Hall (27)	734	*	734	0	0
Hart Family Revocable Trust (28)	1,834	*	1,834	0	0
Mary L. Hart (29)	7,334	*	7,334	0	0
David and Joan Herskovits, JTWROS (30)	1,467	*	1,467	0	0

Holder	ADSs Beneficially Owned Before The Offering		ADSs Offered	ADSs Beneficially Owned After The Offering	
	ADSs	Percent		ADSs	Percent
Elsie S. Howard (31)	3,667	*	3,667	0	0
InSight Productions, L.L.C. (32)	367	*	367	0	0
Susan Kaplan (33)	3,667	*	3,667	0	0
Gerald S. Leeseberg (34)	5,500	*	5,500	0	0
Jeffrey J. Leon (35)	3,667	*	3,667	0	0
Edgar O. Mandeville (36)	1,834	*	1,834	0	0
Alexander Michaels (37)	7,334	*	7,334	0	0
James J. Noonan (38)	3,667	*	3,667	0	0
One Walton Place, L.L.C. (39)	1,834	*	1,834	0	0
David A. Rapaport (40)	126,087	1.1	1,834	0	0
Sidney & Carol Strickland, JTWROS (41)	3,667	*	3,667	0	0
Sigma Tau Finanziaria S.p.A. (42)	1,232,839	10.5	800,000	432,839	3.7
The Hart Organization Corp. (43)	133,054	1.1	8,801	0	0
Frances N. Veilette (44)	954	*	954	0	0
John L. & Jo Lynn Waller, JTWROS (45)	734	*	734	0	0
Gary W. Williams (46)	880	*	880	0	0
Kenneth F. Zadeck (47)	734	*	734	0	0
Zarum SA (48)	44,445	*	44,445	0	0
Total ADSs Offered:			1,944,469		

*** Less than 1%**

(1) Address is 43 Brook Ridge Road, New Rochelle, New York 10804. ADSs beneficially owned before the offering and ADSs offered consist of 4,400 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(2) Address is c/o Alexandra Investment Management, LLC, 467 Third Avenue, 39th Floor, New York, New York 10016. ADSs beneficially owned before the offering and ADSs offered include 84,978 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable. Alexandra Investment Management, LLC, serves as investment advisor to Alexandra Global Master Fund Ltd. By reason of such relationship, Alexandra Investment Management, LLC, may be deemed to share dispositive control over the ADSs beneficially owned and offered by Alexandra Global Master Fund Ltd. and therefore may be deemed to be a beneficial owner of such securities. Alexandra Investment Management, LLC disclaims such beneficial ownership. Mikhail A. Filimonov and Dimitri Sogoloff are managing members of Alexandra Investment Management, LLC. By reason of such relationship, Mr. Filimonov and Mr. Sogoloff may be deemed to share dispositive control over the ADSs beneficially owned and offered by Alexandra Global Master Fund Ltd. and therefore may be deemed to be a beneficial owner of such securities. Mr. Filimonov and Mr. Sogoloff disclaims such beneficial ownership.

(3) Address is 780 Tanglewood Trail, Atlanta, Georgia 30327. ADSs beneficially owned before the offering and ADSs offered consist of 3,667 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(4) Address is 2814 Baccarate Drive, Marietta, Georgia 30062. ADSs beneficially owned before the offering and ADSs offered consist of 367 ADSs representing ordinary shares issuable upon exercise of warrants that are

currently exercisable.

(5) Address is 1155 Dairy Ashford #650, Houston, Texas 77079. ADSs beneficially owned before the offering and ADSs offered consist of 5,500 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(6) Address is 300 South Pointe Drive, Unit 1701, Miami Beach, Florida 33139. ADSs beneficially owned before the offering and ADSs offered consist of 1,834 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(7) Address is 3847 Broussard, Baton Rouge, Louisiana 70808. ADSs beneficially owned before the offering and ADSs offered consist of 1,834 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(8) Address is 945 Fifth Avenue, New York, New York 10021. ADSs beneficially owned before the offering and ADSs offered consist of 7,334 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(9) Address is 7th Floor, Home House, Ballsbridge, Dublin, Ireland. ADSs beneficially owned before the offering and ADSs offered consist of 73,334 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable. Elizabeth M. Fox is the director of Bishterne Limited, may be deemed to have voting or dispositive control over the ADSs beneficially owned and offered by Bishterne Limited and therefore may be deemed to be a beneficial owner of such securities.

(10) Address is 255 Walhalla Court, Atlanta, Georgia 30350. ADSs beneficially owned before the offering include 954 ADSs issuable upon exercise of warrants that are currently exercisable and 124,253 ADSs beneficially owned by Generation Capital Associates. Mr. Brasch is an executive officer of Profit Concepts, Ltd., which is the manager of High Capital Funding, LLC, which is the 100% shareholder of Generation Capital Associates. Mr. Brasch may be deemed to have voting and/or dispositive control over ADSs beneficially owned by Generation Capital Associates and so may be deemed to beneficially own such ADSs. ADSs offered consist of 954 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable. ADSs beneficially owned after the offering assumes that Generation Capital Associates sells all of its ADSs as part of this offering and other offerings.

(11) Address is 300 Central Park West # 9H, New York, New York 10024-1591. ADSs beneficially owned before the offering and ADSs offered consist of 5,500 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(12) Address is 6885 North Ocean Boulevard, Apt. 102, Ocean Ridge, Florida, 33435. ADSs beneficially owned before the offering and ADSs offered consist of 1,834 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(13) Address is 35 West 92nd Street #6E, New York, New York 10025. ADSs beneficially owned before the offering and ADSs offered consist of 734 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(14) Address is Rua dos Ferreiros 260, Funchal-Madeira, SI 9000-082, Portugal. ADSs beneficially owned before the offering and ADSs offered include 73,334 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(15) Address is 470 Cambridge Way, Atlanta, Georgia 30328. ADSs beneficially owned before the offering and ADSs offered consist of 7,334 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(16) Address is 59 Driftwood Drive, Port Washington, New York 11050. ADSs beneficially owned before the offering and ADSs offered consist of 1,834 ADSs representing ordinary shares issuable upon exercise of warrants that are

currently exercisable.

(17) Address is c/o Howard Commander, as Trustee, Box 635, New Lebanon, New York 12125. ADSs beneficially owned before the offering and ADSs offered consist of 7,334 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(18) Address is Via Cattori 6, 6902 Lugano, Switzerland. ADSs beneficially owned before the offering and ADSs offered consist of 33,000 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable. Paolo Floriani is the director of Finrex S.A., may be deemed to have voting or dispositive control over the ADSs beneficially owned and offered by Finrex S.A. and therefore may be deemed to be a beneficial owner of such securities.

(19) Address is 194 East Oakridge Park, Metairie, Louisiana 70005. ADSs beneficially owned before the offering and ADSs offered consist of 1,834 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(20) Address is 2504 Manor Place, Birmingham, Alabama 35223. ADSs beneficially owned before the offering and ADSs offered consist of 3,667 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(21) Address is 567 Bloomfield Avenue, Nutley, New Jersey 07110. ADSs beneficially owned before the offering and ADSs offered consist of 734 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(22) Address is 780 Tanglewood Trail, Atlanta, Georgia 30327. ADSs beneficially owned before the offering and ADSs offered consist of 3,667 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(23) Address is 41 Crest Drive, White Plains, New York 10607. ADSs beneficially owned before the offering and ADSs offered consist of 3,667 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(24) Address is 1085 Riverside Trace, Atlanta, Georgia, 30328. ADSs beneficially owned before the offering and ADSs offered include 44,000 ADSs issuable upon exercise of warrants that are currently exercisable. Fred A. Brasch, David A. Rapaport and Frank E. Hart are each an executive officer of, and Mr. Hart is the indirect beneficial owner of, Profit Concepts, Ltd., which is the manager of High Capital Funding, LLC, which is the 100% shareholder of Generation Capital Associates. Mr. Brasch, Mr. Rapaport and Mr. Hart may be deemed to have voting and/or dispositive control over ADSs or ordinary shares beneficially owned by Generation Capital Associates and so may be deemed to beneficially own such ADSs or ordinary shares.

(25) Address is 35 West 92nd Street #6E, New York, New York 10025. ADSs beneficially owned before the offering and ADSs offered consist of 6,600 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(26) Address is 547 Balsam Road, Cherry Hill, New Jersey 08003. ADSs beneficially owned before the offering and ADSs offered consist of 734 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(27) Address is c/o Buckhead Muscular Pain Center, 110 E. Andrews Drive, Atlanta, Georgia 30305. ADSs beneficially owned before the offering and ADSs offered consist of 734 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(28) Address is 42 Woodland Avenue #4, San Francisco, California 94117. ADSs beneficially owned before the offering and ADSs offered consist of 1,834 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable. Van E. Hart Jr. is the trustee of the Hart Family Revocable Trust, may be deemed to have voting or dispositive control over the ADSs beneficially owned and offered by the Hart Family Revocable

Trust and therefore may be deemed to be a beneficial owner of such securities.

(29) Address is 1085 Riverside Trace, Atlanta, Georgia 30328. ADSs beneficially owned before the offering and ADSs offered consist of 7,334 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(30) Address is 705 Whitemere Court, Atlanta, Georgia 30377. ADSs beneficially owned before the offering and ADSs offered consist of 1,467 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(31) Address is 4825 Lakeview Drive, Miami Beach, Florida 33140. ADSs beneficially owned before the offering and ADSs offered consist of 3,667 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(32) Address is 650 Prydras Street, Suite 2750, New Orleans, Louisiana 70130. ADSs beneficially owned before the offering and ADSs offered consist of 367 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(33) Address is 1432 Autumn Road, Jenkintown, Pennsylvania 19046. ADSs beneficially owned before the offering and ADSs offered consist of 3,667 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(34) Address is 175 South Third Street, PH-1, Columbus, Ohio 43215. ADSs beneficially owned before the offering and ADSs offered consist of 5,500 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(35) Address is 240 Cranes Hollow Road, Amsterdam, New York 12010. ADSs beneficially owned before the offering and ADSs offered consist of 3,667 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(36) Address is 84-06 Chevy Chase Street, Jamaica Estates, New York 11432. ADSs beneficially owned before the offering and ADSs offered consist of 1,834 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(37) Address is 9W Parsonage Way, Manalapan, New Jersey 07726. ADSs beneficially owned before the offering and ADSs offered consist of 7,334 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(38) Address is PO Box 272, Oldwick, New Jersey 08858. ADSs beneficially owned before the offering and ADSs offered consist of 3,667 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(39) Address is 401 Edwards Street, Suite 900, Shreveport, Louisiana 71101. ADSs beneficially owned before the offering and ADSs offered consist of 1,834 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(40) Address is 435 Watergate Way, Roswell, Georgia 30076. ADSs beneficially owned before the offering include 1,834 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable and 124,253 ordinary shares beneficially owned by Generation Capital Associates. Mr. Rapaport is an executive officer of Profit Concepts, Ltd., which is the manager of High Capital Funding, LLC, which is the 100% shareholder of Generation Capital Associates. Mr. Rapaport may be deemed to have voting and/or dispositive control over ADSs or ordinary shares beneficially owned by Generation Capital Associates and so may be deemed to beneficially own such ADSs or ordinary shares. ADSs offered consist of 1,834 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable. ADSs beneficially owned after the offering assumes that Generation Capital Associates sells all of its ADSs as part of this offering and other offerings.

(41) Address is 504 E. 63rd Street, Apt. 35P, New York, New York 10021. ADSs beneficially owned before the offering and ADSs offered consist of 3,667 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

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(42) Based upon information obtained from a Schedule 13D filed with the Securities and Exchange Commission, as amended. Address is Via Sudafrica 20, 00144 Roma, Italy. Consists of (i) 800,000 outstanding ordinary shares held by Sigma Tau Finanziaria S.p.A., (ii) 359,505 outstanding ordinary shares held by Defiante Farmaceutica L.d.A. and (iii) 73,334 ordinary shares issuable upon exercise of warrants currently exercisable held by Defiante Farmaceutica L.d.A. Sigma Tau Finanziaria S.p.A. owns, directly and indirectly, 100% of the outstanding equity of Defiante Farmaceutica L.d.A. and so may be deemed to be the beneficial owner of the outstanding ordinary shares held by Defiante Farmaceutica L.d.A. and issuable upon exercise of Defiante Farmaceutica L.d.A.'s warrants. The board of directors of Sigma Tau Finanziaria S.p.A. may be deemed to share voting or dispositive power with Sigma Tau Finanziaria S.p.A. over the ordinary shares in our company that Sigma Tau Finanziaria S.p.A. beneficially owns, and so may be deemed to beneficially own the ordinary shares that Sigma Tau Finanziaria S.p.A. beneficially owns. In connection with a purchase by Sigma Tau Finanziaria S.p.A. of 800,000 ordinary shares from FinSirton S.p.A. in April 2005, FinSirton S.p.A. agreed that, if the per share price in a sale by our shareholders of all of our ordinary shares is less than approximately $5.00 per share, FinSirton S.p.A. will transfer to Sigma Tau Finanziaria S.p.A. an additional number of ordinary shares equal to (x) $3.2 million divided by the product determined by multiplying (i) 0.8 by (ii) the per share sale price less (y) 800,000 ordinary shares.

(43) Address is 1085 Riverside Trace, Atlanta, Georgia 30328. ADSs beneficially owned before the offering include 8,801 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable and 124,253 ordinary shares beneficially owned by Generation Capital Associates. The Hart Organization Corp. is the 100% shareholder of Profit Concepts, Ltd., which is the manager of High Capital Funding, LLC, which is the 100% shareholder of Generation Capital Associates. The Hart Organization Corp. may be deemed to have voting and/or dispositive control over ADSs or ordinary shares beneficially owned by Generation Capital Associates and so may be deemed to beneficially own such ADSs or ordinary shares. ADSs offered consist of 8,801 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable. ADSs beneficially owned after the offering assumes that Generation Capital Associates sells all of its ADSs as part of this offering and other offerings.

(44) Address is 86 Elliot Road, East Chatham, New York 12060. ADSs beneficially owned before the offering and ADSs offered consist of 954 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(45) Address is 747 Navigators Run, Mt. Pleasant, South Carolina 29464. ADSs beneficially owned before the offering and ADSs offered consist of 734 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(46) Address is c/o GWW, Inc., 6075 Lake Forrest Drive, Suite 110, Atlanta, Georgia 30328. ADSs beneficially owned before the offering and ADSs offered consist of 880 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(47) Address is 123 Devoe Road, Chappaqua, New York 10514. ADSs beneficially owned before the offering and ADSs offered consist of 734 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

(48) Address is Pierfrancesco Campana, Corso San Gottardo, 31, Chiasso, Switzerland, CH 6830. ADSs beneficially owned before the offering and ADSs offered consist of 44,445 ADSs representing ordinary shares issuable upon exercise of warrants that are currently exercisable.

The selling security holders have not within the past three years had any position, office or other material relationship with our company , except that Defiante Farmaceutica L.d.A., one of the selling security holders, is a subsidiary of Sigma-Tau Finanziaria S.p.A., another one of the selling security holders. Sigma-Tau

Finanziaria S.p.A. and certain of its affiliates have relationships with our company as described in our annual report for the year ended December 31, 2005 on Form 20-F in "Related Party Transactions - Agreements with FinSirton, Sirton, Alexandra and Sigma-Tau."

The information provided above with respect to the selling security holders has been obtained from such selling security holders. Because the selling security holders may sell all or some portion of the ADSs or ordinary shares beneficially owned by them, only an estimate (assuming the selling security holders sell all of the ADSs or ordinary shares offered in this prospectus) can be given as to the number of ADSs or ordinary shares that will be beneficially owned by the selling security holders after this offering, and as to the percentage of all outstanding ADSs or ordinary shares constituted by such ADSs or ordinary shares. In addition, the selling security holders may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time or from time to time since the dates on which they provided the information regarding the ADSs or ordinary shares beneficially owned by them, all or a portion of the ADSs or ordinary shares beneficially owned by them in transactions exempt from the registration requirements of the Securities Act.

PLAN OF DISTRIBUTION

Each selling security holder and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their ADSs on the Nasdaq National Market System or any other stock exchange, market or trading facility on which the ADSs are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling security holder may use any one or more of the following methods when selling ADSs:

· ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

· block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

· purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

· an exchange distribution in accordance with the rules of the applicable exchange;

· public or privately negotiated transactions;

· settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;

· on the Nasdaq National Market System (or through facilities of any national securities exchange or US inter-dealer quotation system of a registered national securities association on which the ADSs are then listed, admitted to unlisted trading privileges or included for quotation);

· broker-dealers may agree with the selling security holders to sell a specified number of such ADSs at a stipulated price per ADSs;

· through underwriters, brokers or dealers (who may act as agents or principals) or directly to one or more purchasers;

· through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

· a combination of any such methods of sale; or

· any other method permitted pursuant to applicable law.

The selling security holders may also sell shares under Rule 144 under the Securities Act of 1933, as amended, if available, rather than under this prospectus.

Broker-dealers engaged by the selling security holders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling security holders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with NASDR Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASDR IM-2440.

In connection with the sale of the ADSs or interests therein, the selling security holders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the ADSs in the course of hedging the positions they assume. The selling security holders may also sell the ADSs short and deliver these securities to close out their short positions, or loan or pledge the ADSs to broker-dealers that in turn may sell these securities. The selling security holders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of ADSs offered by this prospectus, which ADSs such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The selling security holders may also pledge ADSs to a broker-dealer or other financial institution which, upon default, they may in turn resell.

In addition to the foregoing methods, the selling security holders may offer their ADSs from time to time in transactions involving principals or brokers not otherwise contemplated above, in a combination of such methods or described above or any other lawful methods. The selling security holders may also transfer, donate or assign their ADSs to lenders, family members and others and each of such persons will be deemed to be a selling security holder for purposes of this prospectus. The selling security holders or their successors in interest may from time to time pledge or grant a security interest in some or all of the ADSs, and if the selling security holders default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the ADSs from to time under this prospectus; provided however in the event of a pledge or then default on a secured obligation by the selling security holder, in order for the ADSs to be sold under this prospectus, unless permitted by law, we must distribute a prospectus supplement and/or amendment to the registration statement of which this prospectus forms a part amending the list of selling security holders to include the pledgee, secured party or other successors in interest of the selling security holder under this prospectus.

The selling security holders may also sell their ADSs pursuant to Rule 144 under the Securities Act, which permits limited resale of ADSs purchased in a private placement subject to the satisfaction of certain conditions, including, among other things, the availability of certain current public information concerning the issuer, the resale occurring following the required holding period under Rule 144 and the number of shares being sold during any three-month period not exceeding certain limitations.

Sales through brokers may be made by any method of trading authorized by any stock exchange or market on which the ADSs may be listed or quoted, including block trading in negotiated transactions. Without limiting the foregoing, such brokers may act as dealers by purchasing any or all of the ADSs covered by this prospectus, either as agents for others or as principals for their own accounts, and reselling such ADSs pursuant to this prospectus. The selling security holders may effect such transactions directly, or indirectly through underwriters, broker-dealers or agents acting on their behalf, in effecting sales, broker-dealers or agents engaged by the selling security holders may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the selling security holders, in amounts to be negotiated immediately prior to the sale (which compensation as to a particular broker-dealer might be in excess of customary commissions for routine market transactions).

The selling security holders and any broker-dealers or agents that are involved in selling the ADSs may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any profits received by the selling security holders or such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We are required to pay certain fees and expenses incurred by us incident to the registration of the ADSs. We have agreed to indemnify the selling security holders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the ADSs may be resold by the selling security holders without registration and without regard to any volume limitations by reason of Rule 144(e) under the Securities Act or any other rule of similar effect or (ii) all of the ADSs have been sold pursuant to the prospectus or Rule 144 under the Securities Act or any other rule of similar effect.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the ordinary shares or ADSs for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling security holders will be subject to applicable provisions of the Exchange

Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the ordinary shares or ADSs by the selling security holders or any other person.

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OFFERING EXPENSES

We will bear all costs, expenses and fees in connection with the registration of the ADSs offered by this prospectus. The selling security holders will bear brokerage commissions and similar selling expenses, if any, attributable to the sale of ADSs, as well as any fees and disbursements of counsel to the selling security holders.

The following table sets forth the estimated expenses payable by us in connection with the offering described in this registration statement. All amounts are subject to future contingencies other than the SEC registration fee.

Securities and Exchange Commission Registration Fee	$	2,903
Legal Fees and Expenses	$	50,000
Accounting Fees and Expenses	$	5,000
Total	$	57,903

FINANCIAL STATEMENTS

Audited financial statements for the fiscal year ended December 31, 2005 are contained in our Annual Report on Form 20-F for the fiscal year ended December 31, 2005, which is incorporated by reference herein.

EXPERTS

The financial statements of Gentium at December 31, 2003, 2004, 2005 and for each of the three years in the period ended December 31, 2005 appearing in this prospectus and in the registration statement of which this prospectus forms a part have been audited by Reconta Ernst & Young S.p.A., independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The address of Reconta Ernst & Young S.p.A. is Via della Chiusa, 2, 20123, Milan, Italy. Reconta Ernst & Young S.p.A. is registered with the Public Company Accounting Oversight Board.

LEGAL MATTERS

The validity of the ordinary shares underlying the ADSs offered hereby have been passed upon for us by Gianni, Origoni, Grippo & Partners, Piazza Belgioioso, 2, 20121 Milan, Italy.

Gentium S.p.A.

1,944,469
American Depositary
Shares

Representing 1,944,469
Ordinary Shares

PROSPECTUS

October 31, 2006