SKYEPHARMA PLC
Form 20-F
June 30, 2006
As filed with the Securities and Exchange Commission on June 30, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

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

OR

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

For the fiscal year ended: December 31, 2005

OR

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

OR

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

Date of event requiring this shell company report: N/A

Commission file number: **0-29860**

SKYEPHARMA PLC

(Exact name of Registrant as specified in its charter)

England and Wales

(Jurisdiction of incorporation or organization)

105 Piccadilly, London W1J 7NJ, England

(Address of principal executive offices)

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

Securities registered or to be registered pursuant to Section 12(g) of the Act:

Ordinary Shares of 10p each (Ordinary Shares) represented by American Depositary Shares (ADSs) quoted on the NASDAQ National Market System, each ADS representing ten Ordinary Shares.

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

Indicate the number of outstanding shares of each of the issuer s classes of capital or common stock as of the close of the period covered by this Annual Report:

Ordinary Shares, nominal value 10p each 753,764,146

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes x No o

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

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

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

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

Item 17 x	Item 18 o

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes o No x

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PRESENTATION OF INFORMATION

In this Annual Report on Form 20-F (Form 20-F), the term Ordinary Shares refers to the Ordinary Shares, nominal value 10 pence each, of SkyePharma PLC (SkyePharma or the Company , and together with its consolidated subsidiaries, the Group) and the term ADSs ref American Depositary Shares each representing the right to receive 10 Ordinary Shares and evidenced by American Depositary Receipts (ADRs).

The Company publishes its consolidated financial statements expressed in pounds sterling. In this Annual Report, references to pounds sterling , £ , pence or p are to the lawful currency of the United Kingdom; references to U.S. dollars or $ are to the lawful currency of th references to Euro or e are to the lawful currency of the members of the European Union that have adopted the single European currency; references to $ Canadian or Cdn$ are to the lawful currency of Canada, references to Swiss or Chf are to the lawful currency of Switzerland and references to Swedish Krona or SKr are to the lawful cu Sweden. Solely for the convenience of the reader, this Annual Report contains translations of certain pound sterling amounts into U.S. dollar amounts at specified rates. Unless otherwise stated, the translations of pounds sterling into U.S. dollars have been made at the noon buying rate in New York City for cable transfers in pounds sterling, as certified for customs purposes by the Federal Reserve Bank of New York (the Noon Buying Rate). No representation is made that pounds sterling have been, could have been or could be converted into U.S. dollars at the rates indicated or at any other rate.

Unless otherwise indicated, historical consolidated financial information for the years ended December 31, 2004 and 2005 included herein has been prepared in accordance with International Financial Reporting Standards as adopted by the European Union (IFRS), with a reconciliation of significant differences between IFRS and generally accepted accounting principles in the United States (U.S. GAAP) . The transition date to IFRS for SkyePharma is January 1, 2004. For SkyePharma there are no differences between IFRS as adopted for use in the European Union and full IFRS as published by the International Accounting Standards Board. Prior to 2005, the Company prepared its annual consolidated financial statements under U.K. Generally Accepted Accounting Principles (U.K. GAAP). For the year ended December 31, 2005, the Company has prepared its annual consolidated financial statements in accordance with International Financial Reporting Standards and International Financial Reporting Interpretations Committee (IFRIC) interpretations as adopted by the European Union (EU) applicable to companies reporting under IFRS. The 2004 comparatives have been restated as part of the first-time adoption requirements of IFRS. As allowed by SEC rules in relation to first-time adoption of IFRS, only one year of comparatives is reported in this annual report.

IFRS differ in certain significant respects from U.S. GAAP. For a description of the principal differences between IFRS and U.S. GAAP as they relate to SkyePharma and a reconciliation to U.S. GAAP of the Company s IFRS loss for the years ended December 31, 2005 and 2004 and shareholders funds at December 31, 2005 and 2004, see Note 37 of the Notes to the Consolidated Financial Statements included in Item 17 of this Form 20-F.

Amounts previously reported in this Annual Report for the Company s consolidated shareholders funds in accordance with U.S. GAAP for the fiscal years ended December 31, 2001, 2002, 2003 and 2004 have been restated. This restatement reduced the Company s shareholders funds under U.S. GAAP but did not affect our net loss under U.S. GAAP or financial statements under IFRS. Further information is provided in Item 5: Operating and Financial Review and Prospects , Item 15: Controls and Procedures and Note 37 to the consolidated financial statements beginning on page F-1 of this Annual Report.

STATISTICAL DATA

Except where otherwise indicated, figures included in this Form 20-F relating to pharmaceutical market sales are obtained from the Company s collaborative partners.

FORWARD-LOOKING STATEMENTS

This Form 20-F contains certain forward-looking statements, as defined in Section 21E of the Securities Exchange Act of 1934, with respect to the financial condition, results of operations and business of the Company and certain of the plans and objectives of the Board of Directors of the Company with respect thereto. Such statements may generally, but not always, be identified by the use of words such as anticipates , should , expects , estimates , believes or similar expressions. Such statements in this Form 20-F include, but are not limited to, statements under the following headings: (1) Item 4: Information on the Company ; (2) Item 5: Operating and Financial Review and Prospects ; (3) Item 8: Financi Information ; and (4) Item 11: Quantitative and Qualitative Disclosures About Market Risk . Specific risks faced by the Company are described under Item 3: Key Information Risk Factors . The Company s intention to divest its injectable business interests is described under Item 4: Information on the Company Business Operations . Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, it can give no assurance that these expectations will materialize. By their nature, forward-looking statements involve risk and uncertainty, and the factors described in the context of such forward-looking statements in this Form 20-F could cause actual results and developments to differ materially from those expressed in or implied by such forward-looking statements.

STATEMENTS REGARDING COMPETITIVE POSITION

Statements made in Item 4: Information on the Company referring to the Company s competitive position are based on our beliefs, and in some cases rely on other publicly available information.

EXCHANGE RATE INFORMATION

The table below sets forth, for the periods and dates indicated, certain information concerning the Noon Buying Rates for pounds sterling expressed in U.S. dollars per pound. The period average data set forth below is the average of the Noon Buying Rates on the last day of each full month during the period.

Fluctuations in the exchange rate between the pound sterling and the U.S. dollar will affect, among other things, the U.S. dollar equivalent of the pound sterling price of the Company s Ordinary Shares on the London Stock Exchange (LSE), which is likely to affect the market prices of its ADSs in the United States.

	High	Low	Period Average	Period End
2001	1.5045	1.3730	1.4382	1.4543
2002	1.6095	1.4074	1.5025	1.6095
2003	1.7842	1.5500	1.6450	1.7842
2004	1.9482	1.7544	1.8356	1.9160
2005	1.9310	1.7114	1.8057	1.7188

	High	Low
December 2005	1.7726	1.7168
January 2006	1.7873	1.7388
February 2006	1.7796	1.7290
March 2006	1.7554	1.7260
April 2006	1.8318	1.7370
May 2006	1.8906	1.8397
On June 23, 2006 the Noon Buying Rate was 1.8204 per £1.00	1.8204	1.8204

For a discussion of the impact of exchange rate fluctuations on the Company s operating results, see Item 5: Operating and Financial Review and Prospects Operating Results .

PART I

Item 1: Identity of Directors, Senior Management and Advisers

Not applicable

Item 2: Offer Statistics and Expected Timetable

Not applicable

Item 3: Key Information

Selected Financial Data

As part of the European Commission s plan to develop a single European capital market, the application of IFRS is mandatory for the consolidated financial statements of all listed European Union companies for reporting periods beginning on or after January 1, 2005. Under the regulation passed by the European Union, January 1, 2004 is the transition date to IFRS for the Company. Under the IFRS transition provisions within the Securities and Exchange Commission s (SEC s) Form 20-F requirements, the Company is permitted to provide two years of comparable financial information under IFRS and reconciliations to U.S. GAAP for the periods presented.

The transition date to IFRS for SkyePharma PLC is January 1, 2004. Therefore, the 2005 and 2004 selected consolidated financial data presented below is in accordance with IFRS and has been derived from our audited consolidated financial statements, including the related Notes, contained elsewhere in this Annual Report. Additionally the selected consolidated financial data presented in accordance with U.S. GAAP below as of and for each of the last five fiscal years ended December 31, 2005 have been derived from our audited consolidated financial statements for the relevant periods.

As noted, we report our financial information in accordance with IFRS. The principal differences between IFRS and U.S. GAAP that are relevant to our consolidated financial statements are discussed in note 37 to our consolidated financial statements beginning on page F-1 of this Annual Report.

The Company has prepared its audited consolidated financial statements assuming that it will continue as a going concern. However, the Company s independent auditors, PricewaterhouseCoopers LLP, has included an emphasis of matter paragraph related to going concern in their auditors report, which refers to Note 1 to the consolidated financial statements beginning on page F-1 to this Annual Report stating that there is uncertainty as to when certain strategic initiatives may be concluded impacting the Group s working capital requirements. The audit opinion has not been qualified in this respect. The Company s audited consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. See Report of Independent Registered Public Accounting Firm and note 1 (a) to our consolidated financial statements beginning on page F-1 of this Annual Report.

The selected financial data set forth below for the Company, for the years ended December 31, 2005, 2004, 2003, 2002 and 2001, has been derived from, and should be read in conjunction with, the Company s audited Consolidated Financial Statements, including the Notes to those Statements included in this report.

For exchange rate information, see Exchange Rate Information on page 5 of this Form 20-F. Solely for the convenience of the reader, the pound sterling amounts as of and for the year ended December 31, 2005 have been translated into U.S. dollars at the Noon Buying Rate on December 31, 2005 of $1.7188 per £1.00.

For a discussion of the impact of exchange rate fluctuations on the Company s operating results, see Item 5: Operating and Financial Review and Prospects Operating Results .

The following table sets forth selected consolidated financial information as of and for the five years ended December 31, 2005.

SkyePharma PLC

The following table presents selected consolidated financial information of SkyePharma PLC. You should read this table together with Item 5: Operating and Financial Review and Prospects and our audited consolidated financial statements, including the related Notes, contained elsewhere in this annual report.

Consolidated Income Statement Data

	For the year ended December 31,		
	2004	2005	2005
	(in millions, except per share data)		
IFRS			
Revenue	£75.2	£61.3	$105.4
Cost of sales	(28.2)	(29.2)	(50.2)
Gross profit	47.0	32.1	55.2
Selling, marketing and distribution expenses	(1.7)	(5.9)	(10.1)
Administration expenses	(22.5)(1)	(37.3)(4)	(64.1)(4)
Research and development expenses	(28.0)	(26.0)	(44.7)
Other income/(expense)	2.1 (2)	(0.4)	(0.8)
Operating loss	(3.1)	(37.5)	(64.5)
Finance costs	(23.9)(3)	(22.3)	(38.3)
Finance income	8.6	10.0	17.2
Share of loss in associate		(0.8)	(1.4)
Loss before income tax	(18.4)	(50.6)	(87.0)
Income tax expense	(0.2)	(0.3)	(0.5)
Loss for the year	(18.6)	(50.9)	(87.5)
Basic and diluted weighted average number of shares in issue	615.2	624.9	624.9
Basic and diluted loss per Ordinary Share	(3.0 p)	(8.1 p)	(14.0 c)

	For the year ended December 31,					
	2001	2002	2003	2004	2005	2005
	(in millions, except per share data)					
U.S. GAAP						
Revenue	£44.2	£42.6	£66.6	£75.2	£56.3	$96.8
Operating loss	£(27.5)	£(36.2)	£(22.1)	£(1.3)	£(33.0)	$(56.7)
Net loss under U.S. GAAP	£(44.9)	£(50.0)	£(38.6)	£(20.8)	£(49.2)	$(84.6)
Basic and diluted net loss per share	(8.5 p)	(8.7 p)	(6.3 p)	(3.4 p)	(7.9 p)	(13.5 c)

(1) Administration expenses in 2004 include £1.2 million relating to the reorganization of some research and development operations and other business functions and a charge of £3.5 million for a provision for diminution in value of fixed asset investments.

(2) Other operating income in 2004 includes income of £2.0 million relating to the profit on disposal of the Group s investment in Transition Therapeutics.

(3) Finance costs in 2004 include an exceptional charge of £6.2 million relating to the exchange of convertible bonds.

(4) Administration expenses in 2005 include £19.4 million relating to an impairment of the investments in Astralis, Vital Living and Micap since following the Strategic Review and the Group s decision to focus on its core oral and pulmonary products and to divest its injectable business, the Group no longer views its collaborations with Astralis, Vital Living and Micap as strategic, and a £2.0 million charge for legal and professional fees relating to an aborted strategic transaction.

SkyePharma PLC

Consolidated Balance Sheet Data

	For the year ended December 31, 2004	2005	2005
	(in millions, except number of shares)		
IFRS			
Fixed assets	£155.8	£134.4	$231.0
Cash and short term bank deposits	15.3	34.3	59.0
Total assets	191.9	186.9	321.2
Net Assets(1)	36.5	31.9	54.8
Share Capital	63.4	76.6	131.7
Number of shares	622,398,743	753,764,146	753,764,146

	For the year ended December 31, 2001 (restated)	2002 (restated)	2003 (restated)	2004 (restated)	2005	2005
	(in millions)					
U.S. GAAP						
Total assets(2)(3)	£ 281.4	£ 302.2	£ 271.4	£ 216.2	£ 222.8	$ 382.9
Net Assets(1)(2)(3)	117.9	109.8	69.6	58.9	50.0	85.9

(1) Net Assets is equivalent to shareholders funds.

(2) Under U.S. GAAP total assets and net assets have been restated to properly present changes in the Company s goodwill balances related to acquired subsidiaries which are outside the United Kingdom. In prior years the Company had made no adjustment for the difference in accounting treatment that exists between UK GAAP and U.S. GAAP in respect of the impact of foreign exchange translation upon consolidation of these subsidiaries. This restatement reduced the Company s shareholders funds under U.S. GAAP but did not affect its net loss under U.S. GAAP or financial statements under IFRS. Further information is provided in Item 5: Operating and Financial Review and Prospects , Item 15: Controls and Procedures and Note 37 to the consolidated financial statements beginning on page F-1 of this Annual Report.

(3) Under U.S. GAAP total assets and net assets have been restated due to a change in accounting principle relating to the investment in Astralis. This is caused by a change in classification from an available for sale to an equity method investment due to the ability to exercise significant influence.

For a reconciliation of the Company s IFRS shareholders funds to U.S. GAAP, see Note 37 of the Notes to the Consolidated Financial Statements.

RISK FACTORS

The Company is exposed to certain risks that arise from the activity of developing and manufacturing drug products.

Extensive government regulation may cause increased costs and delays in developing and marketing products

The Company is subject to extensive government regulation. The U.S. Food and Drug Administration (FDA), the European Medicines Evaluation Agency (EMEA) and other national regulatory authorities require rigorous pre-clinical testing, clinical trials and other procedures prior to approving drugs for human use. Numerous regulations also govern the manufacturing, safety, labeling, storage, record keeping, reporting and marketing of such drugs. These requirements vary widely from country to country, as does the time required to complete pre-clinical testing and clinical trials and to obtain regulatory approvals to sell drugs. The process of obtaining these approvals and complying with applicable government regulations is time consuming and expensive. If the FDA or other national regulatory authorities increase the number of clinical trials required for the approval of drugs, the Company could face increased costs and significant development delays before the Company will be able to sell its products commercially. In addition, changes in regulatory policy or additional regulations adopted during product development could also result in delays or rejections in obtaining marketing approvals from regulatory authorities.

Most of the products that the Company develops will require a new drug application (NDA) filing with the FDA before they can be marketed in the United States. Based on current practice, the Company generally expects it to take less than two years from the date of filing for the FDA to approve an NDA for a product formulation. However, the Company cannot predict the exact time required or the outcome of the approval process for any of its product candidates with any certainty.

A number of products using the Company s technologies have not yet been approved for marketing by regulators. These product candidates are at various stages of development, ranging from pre-clinical studies to Phase III clinical trials and those that have been filed for approval. The Company cannot be certain that its product candidates will prove safe and effective in clinical trials or that it will obtain further regulatory approvals of any such products. These products will require expensive and lengthy testing and regulatory clearances before they can be sold commercially.

Products for which the Company obtains regulatory approval may not succeed in the market

Although the Company carries out commercial feasibility assessments and extensive clinical trials on all its products before they are launched, newly launched products may not achieve broad market acceptance. The successful launch of a new pharmaceutical product involves a substantial investment in sales and marketing costs, launch stocks and other items. If a new product cannot be manufactured at an acceptable cost or does not succeed as anticipated or its rate of sales growth is slower than anticipated, there is a risk that it could have a material adverse effect on the Company s financial condition and results of operations.

In addition, pre-clinical testing or clinical testing may not accurately predict safety or effectiveness in broader human use. For a new product, it can be difficult to establish from available data a meaningful and reliable assessment of its eventual efficacy and/or safety in the market.

Competition and technological change may render the Company s products or technologies uncompetitive or obsolete

The drug development industry is highly competitive and rapidly evolving, with significant developments expected to continue at a rapid pace. The Company s success will depend on maintaining a

competitive position and developing efficient and cost-effective products and technologies. The Company s products will compete with other drugs and methods for delivering drugs. The Company cannot be certain that any of its products will have advantages that will be significant enough to cause medical professionals to prescribe or recommend them. New drugs or further development in alternative drug delivery methods may provide greater benefits or may offer comparable performance at lower cost than the Company s products or technologies. The Company cannot be certain that developments by other companies will not render its products or technologies uncompetitive or obsolete.

Many of the Company s competitors have longer operating histories and greater financial, marketing and other resources. Such competitors may prove to be more successful in developing competing technologies, obtaining regulatory approvals and marketing their products than the Company because of greater financial resources, stronger sales and marketing teams or other factors.

The Company will face competition with respect to the products it is developing under its collaborative arrangements with leading pharmaceutical companies including competition from other products developed and produced by the Company s collaborative partners and branded and generic products manufactured by other companies.

The Company s business may give rise to product liability claims not covered by insurance or indemnification

The design, development and manufacture of the Company s products involve an inherent risk of product liability claims.

Although the Company generally relies on indemnity provisions in its agreements with its collaborative partners to protect itself against the possibility of product liability claims, the Company has obtained product liability insurance in respect of pharmaceutical products it is developing in conjunction with such partners. This product liability insurance also covers liabilities associated with the commercial sale of products marketed by third parties using the Company s technology.

The Company has also obtained clinical trial insurance for current human clinical trials and bio-equivalence studies involving its products under development and intends to obtain insurance for future clinical trials and bio-equivalence studies of additional products under development.

The Company believes that its product liability and clinical trial insurance, together with the indemnity provisions in its collaborative agreements, is adequate for current operations. However, the coverage limits of this insurance and the indemnity provisions in the Company s collaborative agreements may not be adequate to cover all potential claims. Product liability and clinical trial insurance is expensive and may be difficult to obtain or maintain on commercially reasonable terms. A successful claim against the Company in excess of the Company s insurance coverage or outside the scope of the indemnity given by its collaborative partners could adversely affect the Company s results of operations.

The Company s revenues may be reduced and costs increased as a result of third-party payor cost containment measures

The Company s ability to achieve profitability in its businesses depends in part on the extent to which appropriate levels of reimbursement for products and related treatments are obtained from government authorities, private health insurers and other organizations, such as health maintenance organizations. These third-party payors are increasingly challenging the pricing of pharmaceutical products and seeking ways to replace more expensive pharmaceuticals with cheaper alternatives. The trend toward managed healthcare in the United States and the growth of organizations such as health maintenance organizations in the United States could significantly influence the purchase of pharmaceutical products, thereby resulting in lower prices and reduced demand for the Company s products under development. Such cost

containment measures could affect the Company s ability to sell products under development and may adversely affect the Company.

Healthcare reform proposals may adversely affect the Company s business

The efforts of governments to contain or reduce the cost of health care will continue to affect the business and financial condition of drug companies. A series of health care reform proposals announced in recent years have created uncertainty that could adversely affect the Company s ability to raise funds and to identify and reach agreements with potential partners. Such proposals could adversely affect the Company s business. Furthermore, the Company s ability to commercialize potential products may be adversely affected to the extent such proposals have an adverse effect on the business, financial condition and profitability of other companies that are the Company s current or prospective collaborators for some of such products.

The Company may not be able to divest its injectable business interests

In late 2005 and early 2006, the Board of Directors of the Company conducted a full strategic review and concluded that in the interests of achieving sustainable profitability in the near term, and in order to improve the Company s cash position, the Company should concentrate on oral and inhalation products, and divest its injectable business interests. A sale of these interests would include the sale of the manufacturing and other facilities in San Diego, California. However, there can be no assurance that the Company will be able to agree on suitable terms of sale with an appropriate purchaser, or that any sale would ultimately be completed. A failure to divest the Company s injectable business interests could prevent the Company from executing its strategy and adversely affect the Company s results of operations.

Moreover, until such time as the Company is able to divest its injectable business interests, it remains subject to certain risks inherent in the licensing and manufacturing of DepoFoam as described elsewhere in these Risk Factors.

The Company s near term working capital requirements are uncertain and sensitive to the timing of a number of initiatives required to provide the financial flexibility to implement its new strategy

The Company s working capital requirements continue to be affected by the timing and receipt of milestone payments and payments received on the signing of new contracts. The Company s future cash flows will also be impacted by the Company s change in strategy, principally its stated aim of moving to sustainable profitability in the near term and its refocus to concentrate on oral and pulmonary products. Consequently the Company s near term working capital requirements are uncertain and sensitive to the timing of a number of initiatives required to provide the financial flexibility to implement the new strategy. These initiatives include the licensing of Flutiform in Europe, the divestment of the Company s injectable business interests, which is expected to require shareholder approval, or the US licensing for DepoBupivacaine.

The Company s independent auditors, PricewaterhouseCoopers LLP, have included an emphasis of matter paragraph related to going concern in their auditors report, which refers to Note 1 to the consolidated financial statements beginning on page F-1 to this Annual Report stating that there is uncertainty as to when certain strategic initiatives may be concluded impacting the Group s working capital requirements. The audit opinion has not been qualified in this respect.

The Board of Directors has reviewed the working capital requirements of the Group for the next twelve months and has a reasonable expectation that sufficient funds will be raised from these initiatives and has therefore prepared the financial information contained herein on the basis that the Company will continue in operational existence for the foreseeable future. The financial statements do not reflect any

adjustments that would be required to be made if they were to be prepared on a basis other than a going concern basis.

In the event that sufficient funds are not raised by the Company s initiatives and currently available funds and internally generated cash flow are not sufficient to satisfy its financing needs, the Company will be required to seek additional funding through other arrangements with corporate collaborators, through bank borrowings or through public or private sales of its securities, including equity securities. Any such collaboration could result in limitations on the resources the Company could devote to research, development and commercialization of new products and product candidates, if any, as well as its profits therefrom. In addition, the terms of any future bank borrowings could place restrictions on the Company s ability to take certain actions, and any equity financing could result in dilution to the Company s shareholders. The Company does not currently have any committed sources of additional capital.

For more information on the Company s liquidity and capital resources, see Item 5: Operating and Financial Review and Prospects .

The Company s revenues tend to fluctuate

The Company s revenues principally derive from contract development. Contract development revenues include milestone payments and that portion of the Company s research and development expenses that the Company charges to its partners pursuant to collaborative arrangements with these partners. The amount of the Company s contract development revenue in any given period will depend on a number of unpredictable factors, including scientific developments, the ability of the Company to find suitable partners, the timing of the negotiation and conclusion of agreements with such partners, whether and when the Company achieves milestones agreed with its partners, such as the timing of regulatory approvals and the market introduction of new products, and other factors. As a result, the Company s revenues tend to fluctuate materially on a monthly, semi-annually and yearly basis. The Company believes that its revenues will continue to fluctuate in the near to medium term as a result of the factors described above.

The Company may not achieve and sustain profitability

In 2005, SkyePharma reported a full year net loss of £50.9 million and in 2004 a full year net loss of £18.6 million. As a result of these losses, the Company s consolidated net assets at December 31, 2005 declined to £31.9 million, compared with £36.5 million at December 31, 2004. If and when the Company achieves profitability is dependent upon a number of factors, including the timing and recognition of milestone payments and license fees received, the timing of contract development revenues and the amount of discretionary investment the Company chooses to make in furthering its own product portfolio. As a consequence, the Company cannot assure you that it will be able to achieve and sustain profitability. See Item 5: Operating and Financial Review and Prospects .

In late 2005 and early 2006, the Board of Directors of the Company conducted a full strategic review and concluded that in the interests of achieving sustainable profitability in the near term, and in order to improve the Company s cash flow position, the Company should concentrate on oral and inhalation products, and divest its injectable business interests. However, there can be no assurance that the Company will be able to agree on suitable terms of sale with an appropriate purchaser, or that any sale would ultimately be completed.

Other factors that will affect whether the Company achieves and sustains profitability include its ability, alone or together with its partners, to:

- develop products utilizing its technologies, either independently or in collaboration with other pharmaceutical companies;

- receive necessary regulatory and marketing approvals;
- establish and expand its manufacturing;
- achieve market acceptance for its products;
- receive royalties on products that have been approved, marketed or submitted for marketing approval with regulatory authorities in line with the Company s current forecasts; and
- maintain sufficient funds to finance its activities.

The Company is dependent on its various technologies, as to which further successful development is uncertain

The Company s ability to increase revenues and achieve profitability is largely dependent on certain of its technologies. Approximately 36% of the Company s revenues for the year ended December 31, 2005 derived from royalties, product sales, contract development and milestone payments relating to its Geomatrix technologies, approximately 20% from royalties, product sales, contract development and milestone payments relating to its inhalation technologies and approximately 17% from royalties, product sales, contract development and milestone payments relating to its DepoFoam technologies. In late 2005 and early 2006, the Board of Directors of the Company conducted a full strategic review and concluded that in the interests of achieving sustainable profitability in the near term, and in order to improve the Company s cash flow position, the Company should concentrate on oral and inhalation products, and divest its injectable business interests. In order to increase revenues from its technologies, the Company must continue to obtain new development contracts with third parties or develop, license and manufacture new formulations of commercially available drugs using these technologies. The Company cannot assure you that it will be able to obtain such contracts or successfully develop new formulations internally.

There can be no assurance that the Company will be able to develop successfully future products using its various technologies. The development and formulation of oral and injectable controlled release and inhalation products is difficult and time-consuming. Each drug compound is different, and there can be no assurance that a drug delivery system that works with one product will work with another.

Even after a product incorporating the Company s technologies has been successfully formulated and approved, its commercial success is not assured. In order to gain medical and commercial acceptance, a product generally must demonstrate some performance improvements and other benefits over products incorporating the same or similar drug compounds. In some cases, these benefits may be difficult to establish.

Failure by the Company s collaborative partners to fulfil their obligations to the Company to provide funding, obtain regulatory approvals and conduct marketing activities could adversely affect the Company s business

The Company s ability to develop and market its present and future products depends in large part on its ability to maintain its existing, and enter into new collaborations with third parties. If any of the Company s partners becomes insolvent or terminates or otherwise fails to fulfil its obligations with the Company, the Company s business could be adversely affected. In particular, the Company faces the following risks with respect to collaborative partners:

- *Funding.* The Company has entered into a number of collaborative arrangements with various pharmaceutical companies for the development and commercialization of products using its technologies. Some of the Company s collaborative partners are, however, development stage companies whose business prospects are uncertain and who face similar risks as the Company. If the Company becomes unable to continue to obtain funding for its development activities through its collaborative arrangements or if its collaborative partners fail to make payments due under the

development and commercialization agreements, the Company s business would be adversely affected.

- *Regulatory Approvals.* The Company generally depends upon its collaborative partners to secure the necessary regulatory approvals of new pharmaceutical formulations utilizing its technologies. In these cases, the Company has no control over the timing of the regulatory filings and in which countries they may be filed. Its partners may follow a regulatory strategy that does not maximize the royalty income that the Company may receive from its technologies. In addition, the Company s partners may choose not to file for regulatory approval of a product successfully formulated with its technologies. Even if the Company s partners do file for regulatory approval, they may fail to devote the necessary resources and expertise to secure approval.

- *Marketing.* At present, the Company is not involved in the direct marketing of new products formulated with its technologies and therefore depends on its collaborative partners for such marketing and sales from which it earns revenues including royalties. The Company s future revenues largely depend on the success of such marketing efforts, which are beyond its control. For example, Paxil CR was approved by the FDA in February 1999 but was not launched by GlaxoSmithKline PLC (GlaxoSmithKline) until April 2002 and in March 2005 GlaxoSmithKline announced that the FDA had halted supplies of Paxil CR due to manufacturing issues. GlaxoSmithKline announced the resupply of Paxil CR on June 27, 2005.

A failure to obtain and maintain patents and other proprietary rights may adversely affect the Company s business

The Company s success, competitive position and the amount of milestone and royalty income it receives each depend, in part, on its ability to obtain and maintain patent and other intellectual property protection, particularly for its drug delivery and formulation technologies. Such patent and other intellectual property protection is also important to the Company s business and its future performance will depend in part on its ability to obtain and maintain such protection. The Company s performance will also be affected by its ability to operate without infringing the intellectual property rights of others.

While the Company intends to obtain patents covering as many of its technologies as possible, the process of obtaining patents is lengthy and expensive. There can be no assurance that patents will be granted in connection with any of the Company s currently pending or future applications or that they will be valid and of sufficient scope and strength to provide the Company with meaningful legal protection or any commercial advantage. In addition, intellectual property protection may be unavailable or limited in some of the countries in which the Company does business. The laws of some foreign countries do not afford the Company s inventions the same degree of legal protection as the laws of the United States. In addition, patent laws may change over time. The Company cannot predict the effect that any such changes would have on its business and its ability to protect its current and future products and technologies. If the Company fails to obtain and maintain sufficient protection for its current and future products and technologies, its ability to successfully commercialize these products and technologies could be adversely affected.

The Company, from time to time, may receive notifications of alleged infringement of patents owned by third parties. The Company may not, in all cases, be able to successfully defend itself in court or resolve such allegations through licensing or settlement. Moreover, whether or not the Company is successful in enforcing its own patents or in defending itself against claims of alleged infringements of patents owned by third parties, doing so is time-consuming and costly and may result in the diversion of management resources.

The Company also relies on trade secrets and other unpatented proprietary information in its product and technology development activities. To the extent that the Company relies on trade secrets and

unpatented proprietary information to maintain its competitive position, there can be no assurance that others may not independently develop the same or similar products or technologies. The Company seeks to protect trade secrets and proprietary information, in some cases through clauses in confidentiality agreements with its employees, consultants, advisors and collaborators. Nevertheless, these agreements may not effectively prevent disclosure of the Company s proprietary information and may not provide the Company with an adequate remedy in the event of unauthorized disclosure of such information. If the Company s employees, scientific consultants or collaborators develop inventions or processes independently that may be applicable to the Company s products or technologies under development, disputes may arise about ownership of proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become the Company s property, but may remain the property of those persons or their employers. Protracted and costly litigation could be necessary to enforce and determine the scope of the Company s proprietary rights. Failure to protect patent or other unprotected proprietary information, for any reason, would adversely affect the Company s business.

The Company has entered into a number of collaborative arrangements with leading pharmaceutical companies for the development and commercialization of products. In connection therewith, the Company shares certain of its proprietary knowledge with such collaborative partners. Although the Company s patents and other proprietary rights are intended to protect the Company from infringement by such collaborative partners, there can be no assurance that the Company s patents or other proprietary rights will prevent its collaborative partners from developing similar or functionally equivalent products. In addition, the Company s arrangements with its collaborative partners frequently contain representations, warranties and other assurances given by the Company regarding the scope of its own intellectual property and the non-infringement by the Company of intellectual property owned by third parties. If the Company were found to be in breach of any of these provisions, its partners could sue the Company for damages, which could have a material adverse effect on the Company s business, results of operations and financial condition.

The Company also engages in collaborations, sponsored research agreements and other arrangements with academic researchers and institutions, some of which have received and may receive funding from government agencies. Although the Company seeks to retain ownership of all intellectual property rights pertaining to inventions which may result from such collaborations, there can be no assurance that the governments, institutions, researchers or other third parties will not also have certain rights to such inventions.

For more information on the Company s patents and proprietary rights, see Item 4: Information on the Company Patents and Proprietary Rights .

Failure to comply, or the costs of complying, with environmental, health and safety regulations could adversely affect the Company s business

The Company s business is subject to regulation relating to the protection of the environment and health and safety, including regulations governing air emission, effluent discharge, and the use, generation, manufacture, storage, handling and disposal of certain materials. The Company believes that it is in compliance in all material respects with all such laws, rules, regulations and policies applicable to the Company. However, there can be no assurance that the Company will not be required to incur significant costs to comply with such environmental and health and safety laws and regulations in the future.

A failure to manage expansion effectively could adversely affect the Company s business

Management of the Company s growth, as well as the commencement of commercial manufacturing and marketing of the Company s product candidates, will require continued expansion and improvement of the Company s systems and internal controls and an increase in the Company s manufacturing, marketing and sales operations. Any failure to manage growth effectively and on a timely basis could adversely affect the Company s business.

Failure by the Company to fulfil its obligations to its collaborative partners in respect of manufacturing or to enter into new or maintain its existing manufacturing arrangements could adversely affect the Company s business

The Company has its own manufacturing sites in Lyon, France, Muttenz, Switzerland and San Diego, California. However, for the manufacture of certain of its existing products, and certain of those currently in development, including the Foradil® Certihaler and Flutiform , the Company will depend on manufacturing partners who in some cases are the sole supplier of the services to the Company. If the Company loses one of its current manufacturing partners, fails to enter into agreements with new manufacturing partners, experiences delays in finding such partners or if existing manufacturing partners are unable to supply for any reason, the Company s ability to develop and manufacture products and to meet its obligations in its existing collaborative arrangements could be adversely affected.

Failure by the Company to keep its manufacturing facilities in compliance with required standards could result in delays in manufacturing and additional costs

The Company believes that each of its manufacturing facilities is substantially in compliance with current good manufacturing practices (cGMP) and the applicable regulatory standards. There can be no assurance, however, that the Company s facilities will be found to meet or, in those instances in which a facility has previously been approved for the manufacture of a particular drug, maintain cGMP or applicable regulatory standards. Failure of the Company s manufacturing facilities to meet or maintain such standards could delay or interfere with the Company s plans to scale-up manufacturing or manufacture commercial quantities of its product candidates.

In those instances in which a manufacturing facility has previously been approved, the Company s facilities will need to pass periodic follow-on inspections. The Company may be required to incur significant additional expenses in order to ensure that its facilities remain compliant with cGMP and the applicable regulatory standards.

Flutiform may not successfully complete the development process, achieve regulatory approval or succeed in the market if approved

Due to the inherent risk in the development of pharmaceuticals, it is possible that Flutiform may not successfully complete development and be launched. There can be no assurance that Flutiform will successfully complete clinical studies or that it will meet the regulatory requirements for commercial distribution. Flutiform will be the first product using the Company s metered dose aerosol inhaler (MDI) technology to attempt to access the U.S. market where regulatory barriers to entry are particularly steep. Even if Flutiform is approved for marketing, there can be no assurance that the Company will not experience delays in the development or approval process that could adversely affect the

commercial value of Flutiform . Similarly, there can be no assurance that any regulatory approvals will not be more limited in scope than the Company currently expects. The Company currently does not have its own sales and marketing capability and is currently therefore reliant on one or more marketing partners to market Flutiform .

In May 2006, the Company announced that it had entered into an agreement with Kos Pharmaceuticals to jointly develop Flutiform . Kos will have exclusive rights to market Flutiform in the United States and a right of first negotiation in Canada. SkyePharma remains in negotiations with potential partners for Europe and other markets around the world. If, however, the Company does not obtain one or more suitable partners for other territories, the successful marketing of Flutiform may be adversely affected. In addition, while the Company believes there is little prospect of additional competition in the combination market until 2012 at the earliest, Flutiform may not achieve the competitive position that the Company anticipates.

The Company may not be able to maintain its exclusive technology rights to DepoFoam from the Research Development Foundation

The Company s DepoFoam business depends in part on its ability to continue to use technology rights that the Research Development Foundation (RDF) assigned to a subsidiary of the Company on an exclusive basis. Under the agreement, RDF has the right to terminate the agreement or to convert the exclusive nature of the rights granted under the agreement into a non-exclusive right if the subsidiary does not satisfy its contractual obligations, including its obligation to make certain minimum annual payments. RDF may also terminate the agreement if the Company s subsidiary becomes bankrupt, breaches the agreement or contests the patents relating to this technology. The termination of the subsidiary s agreement with RDF or its conversion to a non-exclusive agreement would adversely affect the Company s DepoFoam business.

Failure by the Company to ensure adequate DepoFoam manufacturing capacity could adversely affect the Company s business

If the Company fails to maintain adequate manufacturing capacity in respect of its DepoFoam manufacturing operations, it may be unable to supply DepoCyt® to its marketing partners, Enzon Pharmaceuticals, Inc. (Enzon) for North America and Mundipharma International Holdings Limited (Mundipharma) for the European Union and certain other countries in Europe. Similarly the Company may be unable to supply DepoDur to its North American marketing partner, Endo Pharmaceuticals Inc. (Endo). DepoCyt® is currently marketed in the United States and Europe and DepoDur was launched in the United States in December 2004. The Company will need to expand its current manufacturing operations significantly in order to manufacture additional DepoFoam products. The Company will also need to comply with regulations in the United States and foreign countries relating to achieving the prescribed quality and required levels of production of its DepoFoam products and obtaining marketing approval.

The Company may not be able to obtain the materials necessary to continue to manufacture its DepoFoam products

The Company currently relies on a limited number of suppliers for materials required to manufacture its DepoFoam products. If the Company cannot obtain the materials it needs from its existing suppliers, the Company may not be able to access alternative sources of supply within a reasonable period of time or at commercially reasonable rates. In addition, regulatory requirements applicable to drugs tend to make the substitution of suppliers costly and time-consuming. The unavailability of adequate commercial quantities, the inability to develop alternative sources, a reduction or interruption in supply or a significant increase in the price of materials could adversely affect the Company s ability to manufacture and market its DepoFoam products.

The Company s manufacturing process may not be suitable for all of the DepoFoam products the Company desires to commercialize

To date, SkyePharma Inc. has relied on a particular proprietary method of manufacturing its potential DepoFoam products. The Company cannot be certain that this method will be equally suitable to all DepoFoam products it desires to commercialize. The problems that may arise include:

- the Company may not be able to meet manufacturing challenges that arise concerning particular drugs to be incorporated in DepoFoam ;
- the Company s manufacturing process may not result in viable yields of DepoFoam products; and
- the physical and chemical stability of DepoFoam products may vary.

If the Company decides to pursue alternative manufacturing methods for some or all of its drugs, it cannot be certain that these methods will prove to be commercially practical or that it will have the right to use any alternative methods.

The Company may not be able to obtain the rights to the drugs it desires to deliver through its DepoFoam technologies

The Company s ability to develop and commercialize its DepoFoam technologies will depend on whether it and its partners can obtain the rights to the drugs, including small molecule chemical compounds and macromolecule biologics, that it intends to deliver through DepoFoam technology. At times, the Company intends to rely on its partners ability to provide this access. The Company cannot be certain, however, that its partners will have appropriate drug candidates for its DepoFoam technology. In addition, the Company or its partners may be alleged or determined to be infringing on third parties rights and may be prohibited from using such drugs or be found liable for damages. Any restriction on access or liability for damages would adversely affect the Company s growth prospects, financial condition and results of operations.

The Company may expend significant time and resources relating to existing and potential legal proceedings and the eventual outcome of such proceedings may differ materially from management s current estimates and beliefs

The Company is currently involved in various legal proceedings, including actions claiming alleged violations of antitrust laws and infringement of intellectual property rights. Although the Company cannot predict the outcome of these proceedings with certainty, the Company believes that these actions are without merit and is vigorously contesting these claims. Contesting these claims, however, may involve the expenditure of significant management time and resources of the Company. In addition, we cannot exclude the possibility that, contrary to management s current estimates and beliefs, the eventual outcome of such matters will have a material adverse effect on the Company s financial position, results of operations or liquidity. For further information on pending litigation, see Item 8: Financial Information Legal Proceedings .

The Company may incur substantial costs related to its use of hazardous materials

The Company s research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. Although the Company believes that its safety procedures for the handling and disposal of such materials comply with the standards prescribed by the applicable regulations, the Company cannot completely eliminate the risk of accidental contamination or injury from these materials. If such an accident occurs, the Company could be held liable for any damages that result and such liability could exceed the Company s resources and have a material adverse effect on its business, financial condition and results of operations.

If the Company is unable to retain key personnel or attract new personnel, it could have an adverse effect on the Company s business

The Company relies upon a number of key executives and employees and its ability to retain and attract other qualified management, scientific, technical, marketing and support personnel. Competition for such personnel is intense, and there can be no assurance that the Company will be able to continue to attract and retain such personnel. The loss of the services of any of the Company s key executives or employees could materially adversely affect its business. Associated with the Company s divestment of its injectable business interests the Company has established a retention plan for its employees within the injectables business.

The Company s efforts to comply with new regulatory requirements, including Section 404 of the Sarbanes-Oxley Act of 2002, could lead to the identification of deficiencies in its system of internal controls, and an inability to remedy such deficiencies could affect the Company s perception by investors

As part of the Company s efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 for the year ended December 31, 2006, the Company has committed substantial time and resources to evaluating and assessing the effectiveness of the Company s internal controls over financial reporting. The Company s evaluation and testing is ongoing, and the Company may identify deficiencies in its system of internal controls over financial reporting that require remediation. For example, the Company has identified an error made in respect of goodwill in its reconciliations to U.S. GAAP, where the Company inadvertently recorded the goodwill balances without considering the impact of foreign exchange translation upon consolidation of newly-acquired subsidiaries. As a result, the Company has restated its net assets and shareholders funds under U.S. GAAP to reflect the impact of the adjustments made to the Company s goodwill for the years ended December 31, 2001, 2002, 2003 and 2004. If the Company is not able to remediate this or other identified deficiencies that either alone or together constitute material weaknesses in our internal controls, senior management will not be able to determine that internal controls over financial reporting are effective and comply with Section 404 in a timely manner. This could result in a negative perception of the reliability of the Company s financial statements and a subsequent decline in the price of the Company s Ordinary Shares and ADSs.

Potential conflicts of interests may arise from related party transactions

The Company and certain of its principal shareholders or their affiliates and other formerly related parties have engaged in several significant transactions among themselves in the past. Certain of these historic transactions provide for significant payments to certain principal shareholders, former directors and executive officers upon achievement of specified milestones or profit hurdles. As a result of these arrangements, conflicts of interest may arise between and among the Company, certain principal shareholders, former directors and executive officers. While there is currently no intention to enter into future related party transactions, the Company may do so in the future.

The Company acquired Krypton Limited (Krypton) in a share-for-share exchange in January 1996 from a number of trusts in which Ian Gowrie-Smith, who was then Executive Chairman of the Company, certain former directors and a former employee of the Company had interests. See Item 7: Major Shareholders and Related Party Transactions Certain Arrangements in Respect of the Krypton Acquisition .

At June 23, 2006, the Company owned 39.8% of Astralis LTD (Astralis). Astralis and the Company are parties to several agreements concerning the development of Astralis novel injectable vaccine therapy, for the treatment of all forms of psoriasis, a chronic skin disorder. See Item 7: Major Shareholders and Related Party Transactions Other Arrangements .

At June 23, 2006, the Company owned 23.6% of Vital Living, Inc. (Vital Living). The Company has entered into a contract to develop certain products for Vital Living that incorporate its Geomatrix technology. See Item 7: Major Shareholders and Related Party Transactions Other Arrangements .

At June 23, 2006, the Company owned 9.4% of Micap PLC (Micap). During 2003 the Company investigated the pharmaceutical applications of Micap s micro-encapsulation technology in the areas of oral and topical drug delivery. The Company has exercised an option granted to it under one of its agreements with Micap to complete a technology access and license agreement with Micap and has selected ten nominated compounds pursuant to such license. However, it became clear that for those drugs currently under development there were limited applications and so in September 2005, the Company surrendered all rights under the license agreement back to Micap. See Item 7: Major Shareholders and Related Party Transactions Other Arrangements .

Although the Company anticipates that any future related party transactions and agreements will be on terms no less favorable to the Company than it could obtain in comparable contracts with unaffiliated third parties, there can be no assurance that conflicts of interest will not arise between the Company and the principal shareholders or their affiliates with whom they have entered into agreements.

Exchange rate fluctuations may adversely affect the Company s results of operations and financial position

Approximately 61% of the Company s revenues for the year ended December 31, 2005, were derived from customers located outside the United Kingdom. Since the revenue and expenses of the Company s foreign operations are generally denominated in U.S. dollars, Euros and Swiss francs, exchange rate fluctuations between such currencies and the pound sterling will subject the Company to foreign exchange risk with respect to the reported results of its foreign operations. The Company does not currently hedge against the effect of currency translation on its reported results, but does, where appropriate, seek to hedge its exchange rate risk on particular transactions. Fluctuations between local currencies and the pound sterling may materially adversely affect the Company s financial condition and results of operations. See Item 5: Operating and Financial Review and Prospects .

The Company s Ordinary Shares trade on the London Stock Exchange in pound sterling and the ADSs trade on The Nasdaq National Market in U.S. dollars. The value of the ADSs in U.S. dollars may fluctuate as a result of fluctuations in the U.S. dollar/pound sterling exchange rate.

The market price of the Company s Ordinary Shares and ADSs may be adversely affected by market volatility and liquidity

Companies like SkyePharma have, in recent years, experienced dramatic stock price volatility. The following factors may cause the market price of the Company s Ordinary Shares or ADSs to fluctuate significantly:

- announcements of technological innovations or new products by competitors and others;
- the status of submissions to the FDA or other regulatory authorities;
- variations in results of operations, market condition, analysts estimates and the stock market generally; and
- stock market perceptions of the pharmaceutical, biotechnology and/ or drug delivery industries.

The value of shares can go down as well as up and the market in the Company s Ordinary Shares and ADSs may have limited liquidity. The market price of an investment in the Company may not reflect the underlying value of the Company s net assets.

Issuances or sales of a substantial number of the Company s Ordinary Shares or ADSs could adversely affect their market price

Issuances or sales of a substantial number of Ordinary Shares or ADSs could adversely affect the market price of the Company s Ordinary Shares and ADSs. As of June 23, 2006, certain principal shareholders and the directors and officers of the Company, as a group, held 29.6% of the Company s outstanding Ordinary Shares. Shares may be eligible for future sale subject to the conditions imposed by

Rule 144 and Regulation S under the Securities Act of 1933. If one or more of the Company s principal shareholders were to sell a substantial portion of the Company s Ordinary Shares or ADSs, the trading price of the Company s Ordinary Shares or ADSs could be adversely affected.

Principal shareholders may influence the outcome of shareholder approvals and hinder a change in control that might be in other shareholders interest s

As of June 23, 2006, certain principal shareholders and the directors and officers of the Company as a group owned approximately 29.6% of the Company s outstanding Ordinary Shares. As a result, the directors and officers of the Company, together with such shareholders, may be in a position to influence the election of the Company s directors and officers and other corporate actions that require shareholder approval. This concentration of voting powers may hinder changes or corporate actions that are in the interests of other shareholders.

The Company s shareholders may not receive a return on their shares other than through the sale of their shares

Under current U.K. law, a company s accumulated realized profits must exceed its accumulated realized losses (on a non-consolidated basis) before dividends can be paid. The Company has not paid dividends in the past on its Ordinary Shares. The Company intends to retain earnings, if any, for use in its business and does not anticipate paying any cash dividends in the foreseeable future. Accordingly, other than through the sale of their shares, the Company s shareholders are unlikely to receive a return in the foreseeable future.

Item 4: Information on the Company

HISTORY AND DEVELOPMENT

Overview

SkyePharma PLC is a public limited company organized under the laws of England and Wales with its registered office at 105 Piccadilly, London W1J 7NJ, telephone number + 44 (0) 20 7491 1777.

SkyePharma PLC, which was formerly named Black & Edgington Group PLC, was incorporated on 18 February 1910. As Black & Edgington Group PLC, it was engaged in the provision of temporary structures for major events. In January 1996, the name of the Company was changed to SkyePharma PLC and the nature of its activities to pharmaceuticals. Today the Company is a speciality pharmaceutical company, using its multiple drug delivery technologies to create a product pipeline for out-licensing to marketing partners.

The Company, as currently operated, was formed substantially from the 1996 acquisition of Jago Holding AG, the 1999 acquisition of DepoTech Corporation, the 2001 acquisition of RTP Pharma Inc and the acquisition of certain other technologies as set out below.

Corporate Acquisitions

The Company acquired Jago, a Swiss drug delivery company which commenced operations in 1983, from Dr. Gonella in May 1996. The total consideration paid by the Company to acquire Jago was approximately £100.8 million in cash (plus a prepayment of £3.9 million ($6.0 million)) and approximately 30.7 million Ordinary Shares (valued at 75 pence per share). The Company agreed to pay additional consideration to Dr. Gonella pursuant to an earn-out arrangement. On March 31, 2000, a settlement agreement was signed establishing the full and final settlement of the deferred consideration payable to Dr. Gonella the last remaining provisions of which lapsed on 3, May 2006. See Item 7: Major Shareholders and Related Party Transactions Certain Arrangements in Respect of the Jago Acquisition . Through the acquisition of Jago, SkyePharma acquired the Geomatrix range of oral controlled release systems and a new generation of inhalation technologies.

In October 1998, the Company acquired 16% of the common stock of DepoTech Corporation (Depotech) of San Diego. In March 1999, the Company acquired the remaining 84% of the outstanding shares by issuing to the former DepoTech shareholders 28.3 million SkyePharma Ordinary Shares in the form of ADSs, plus the right to receive additional shares if certain conditions were satisfied. The conditions were satisfied in 1999 and 2000. Through this acquisition, the Company acquired the DepoFoam technology. DepoTech was renamed SkyePharma Inc. SkyePharma Inc. is SkyePharma s center for the development and manufacture of injectable, sustained-release therapeutic products.

In July 2001, the Company acquired an initial 40.2% of the voting shares of RTP Pharma Inc. (RTP) of Montreal, Canada in return for the issue of SkyePharma Ordinary Shares and acquired $5.0 million (£3.5 million) of preferred shares in RTP for cash. During the following 90 days the Company acquired an additional $10 million (£6.9 million) of preferred shares in RTP in return for the issue of additional SkyePharma Ordinary Shares. In March 2002, the Company announced the completion of the acquisition of the outstanding voting shares in RTP in return for the issue of SkyePharma Ordinary Shares plus deferred consideration which was settled in June 2003. RTP was renamed SkyePharma Canada Inc. (SkyePharma Canada) and specialized in improving the solubility of drugs using its Insoluble Drug Delivery (IDD) technology platform. Durin 2003, the Company substantially reduced the staff of SkyePharma Canada and outsourced its activities to other SkyePharma sites.

In January 1996, the Company acquired 100% of the outstanding share capital of Krypton, a Gibraltar-based company which holds development rights to certain generic drugs, in return for the issue of Ordinary Shares and warrants to subscribe for additional Ordinary Shares. The Company agreed to pay additional consideration in respect of the Krypton acquisition. See Item 7: Major Shareholders and Related Party Transactions Certain Arrangements in Respect of the Krypton Acquisition .

In January 1997, the Company acquired a pharmaceutical manufacturing and production facility near Lyon, France by acquiring 100% of the issued and outstanding share capital of Laboratories Novalis Production SAS (Novalis), a French company, from Wyeth-Ayerst International Inc., (Wyeth). After the acquisition, Novalis changed its name to Jago Production SAS and later to SkyePharma Production SAS.

In January 2004, SkyePharma converted its 2 million series A convertible preferred shares that it had previously held in Astralis Limited (Astralis), an emerging biotechnology company based and incorporated in the United States, into 25 million common shares, 12.5 million of these being in escrow. In December 2004, SkyePharma signed conditional stock purchase and assignment agreements with two former Astralis directors to acquire 11.2 million common shares of Astralis and appoint a further two directors representing SkyePharma to the Astralis Board. As a result of these events, the investment has been treated as an associated undertaking from December 2004. In March 2005, the conditions of the stock purchase and assignment agreements were satisfied and the Company completed the purchase of 11.2 million shares from the two former directors of Astralis in exchange for approximately 5.5 million common shares in the Company. As at December 31, 2005, the total SkyePharma holding was 36,393,900 common shares and 20,000 warrants, representing approximately 40% of the common shares of Astralis.

Technology Acquisitions

In July 1999, the Company acquired intellectual property, license agreements, know-how and trademarks related to nano-particulate drug delivery technology for the delivery of poorly soluble drugs from Medac GmbH (Medac), a private German pharmaceutical company. As consideration for the acquisition, the Company paid cash and issued Ordinary Shares to Medac. In addition, future royalties will be paid to Medac on net sales of marketed products using nano-particulate technology.

In October 1999, the Company acquired the tangible assets and intellectual property of Hyal Pharmaceutical Corporation in Canada (Hyal) from the court-appointed receiver and administrator of Hyal. Hyal was a drug delivery company that developed products using its topical drug delivery technologies based on hyaluronan (also called hyaluronic acid or hyaluronate, HA), a natural polymer, which are primarily designed to maintain efficacy and localize delivery of drugs to the skin for the treatment of a variety of skin disorders.

In December 2000, SkyePharma licensed rights to three topical drug delivery technologies, Crystalip, DermaStick and the ES-Gel system, from Bioglan AB, a Swedish subsidiary of Bioglan Pharma PLC (Bioglan). Under the terms of the agreement, SkyePharma paid cash and obtained certain exclusive development and commercial rights in relation to new products from the Crystalip and DermaStick technologies and also the right to develop with Bioglan two new products using the ES-Gel system.

In May 2002, SkyePharma acquired the entire drug delivery business of Bioglan AB for cash, including acquisition costs, and the assumption of £0.4 million of net liabilities. The acquired rights included Bioglan s Biosphere injectable technology and those rights to DermaStick, Crystalip and ES-Gel topical drug delivery technologies that had remained with Bioglan after the December 2000 licensing agreement with Bioglan. During 2004 the Company completed the transfer of the activities of SkyePharma AB to other SkyePharma sites.

In January 2003, SkyePharma announced a strategic investment in Micap PLC (Micap), a private company providing patented micro-encapsulation technology. Micro-encapsulation technology is a process by which tiny droplets or particles of liquid or solid material are surrounded or coated with a continuous film of polymeric material. During 2003, SkyePharma investigated the pharmaceutical applications of Micap s micro-encapsulation technology in the areas of oral and topical drug delivery. In March 2004, the Company exercised an option to enter into a technology access and license agreement with Micap that allows the Company to use Micap s encapsulation technology in up to ten nominated pharmaceutical products to be selected by SkyePharma. However, it became clear that for those drugs currently under development there were limited applications and so in September 2005, the Company surrendered all rights under the license agreement back to Micap.

In June 2004, SkyePharma announced that it had entered into a strategic alliance with Vectura Limited (Vectura) in the area of pulmonary delivery technologies. Through this alliance, SkyePharma acquired rights to use Vectura s Aspirair dry powder inhaler device for certain macromolecules on a non-exclusive basis. As part of the alliance, SkyePharma also made an equity investment in Vectura, subscribing for 800,000 ordinary shares at a price of £2.50 per share. In June 2004, Vectura undertook an initial public offering and the Company s shareholding was converted into 3.2 million ordinary shares, representing approximately 3% of Vectura s ordinary share capital. In October 2005, SkyePharma sold 2.0 million of its shares in Vectura. The remaining 1.2 million shares were sold in January 2006. Due to the Company s focus on other inhalation projects, the Company did not progress the alliance on Aspirair and the agreement has now lapsed.

Recent Developments

Flutiform

The Company believes that its inhalation product Flutiform has substantial commercial value. However, during 2005 the Company did not complete a development agreement for Flutiform . Faced with the prospect of a delay to the development of this important product, which might have impaired its commercial potential, the Company took the decision in September to raise £35 million (net of expenses) by means of a rights issue to keep Flutiform on its planned development timeline through Phase III. As such, the target launch date for Flutiform in the United States remains 2009.

Prior to reaching the decision to ask shareholders for funding, the Company explored a number of financing alternatives to fund the development of Flutiform and also a variety of strategic options for the Company. These included discussions concerning a transaction that, had it been successful, would have created a combined company that could have marketed Flutiform itself in some markets. The discussions were called off by the Company due to uncertainties over the other party s prospects.

In May 2006 the Company announced that it had entered into an agreement with Kos Pharmaceuticals, to jointly develop Flutiform . Kos will have exclusive rights to market Flutiform in the United States and a right of first negotiation in Canada. SkyePharma remains in negotiations with potential partners for Europe and other markets around the world.

Strategic Review

In November 2005, the Company received a takeover approach from Innovata PLC. As a result, the Board of Directors felt that it was in shareholders interests to explore all options and consequently undertook a full strategic review of all the options open to the Company.

The conclusion of this review in early 2006 did not lead to an offer for the entire Company on terms that the Board of Directors felt able to recommend to shareholders. However, there were expressions of interest in individual parts of the business. The Board announced the outcome of the strategic review on February 2, 2006. The Board concluded that in the interests of achieving sustainable profitability in the near term, and in order to improve the Company s cash flow position, the Company should concentrate on oral and inhalation products and divest its injectable business interests.

Changes in Board of Directors

In January 2006, certain shareholders requisitioned an Extraordinary General Meeting (EGM) seeking to remove the Company s then Chairman and to appoint a nominated director to the Company s Board of Directors with the ultimate aim of having him appointed as Executive Chairman. Although this motion was defeated at the EGM in early March 2006, the Board of Directors has since made a number of changes and introduced a process whereby major investors are now involved in the selection of new Non-Executive Directors. Jerry Karabelas was appointed as Non-Executive Chairman in February 2006, Frank Condella was appointed as Chief Executive Officer in March 2006 and Ken Cunningham was appointed as Chief Operating Officer in April 2006. The changes to the membership of the Company s Board of Directors are set out in Item 6: Directors, Senior Management and Employees Directors and Senior Management.

BUSINESS OPERATIONS

Overview

The Company is a specialty pharmaceutical company, using its multiple drug delivery technologies to create a product pipeline for out-licensing to marketing partners. The Company develops novel therapeutic drugs based on its technology platforms for delivering drugs to the human body.

The following table shows the Company s turnover, operating loss and net loss for the two years ending December 31, 2005.

	Year ended December 31,	
	2004	2005
	(in £ millions)	
Revenue		
Oral, Inhalation and Other	49.6	50.8
Injectable	25.6	10.5
	75.2	61.3
Operating loss pre impairments and abortive transaction costs items		
Oral, Inhalation and Other	1.0	2.5
Injectable	(1.4)	(18.6)
	(0.4)	(16.1)
Loss for the Year	(18.6)	(50.9)

Strategy

The Company s strategy is to become a leading specialty pharmaceutical company powered through excellence in drug delivery. It uses multiple technologies to build a product pipeline for commercialization through out-licensing to co-development and marketing partners. The Company continually strives to acquire and develop new technologies and products to grow its position in the oral and inhalation drug delivery areas. The Company ultimately plans to selectively market its own products in targeted therapeutic areas.

In late 2005 and early 2006, the Board of Directors conducted a full strategic review of all the options open to the Company and announced the outcome on 2 February 2006. The Board concluded that in the interests of achieving sustainable profitability in the near term, and in order to improve the Company s cash flow position, the Company should concentrate on oral and inhalation products, and divest its injectable business interests.

The Company s strategy for achieving these objectives consists of the following elements:

- *Divest the injectables business and focus on oral and inhalation products*. The proposed divestment of the injectable business interests, which the Company expects to be subject to approval by shareholders, would not only provide cash but also relieve the Company of a significant cash requirement and future capital expenditure. The Company believes that the remaining oral and inhalation business may be able to achieve profitability in the near term. Furthermore, with a more focused use of resources the Company would be in a better position to further develop its pipeline of oral and inhalation products. Funds raised by the divestment of the injectables business will be available to accelerate the development of certain pipeline products whose development has had to be delayed in recent years. Several of these products are at an early stage of development but would address important therapeutic areas. Following the divestment of the injectables business, development activities will continue to be based in Muttenz, Switzerland and manufacturing in Muttenz and Lyon, France.

- *Selectively Fund a Number of Key Projects to a Later Stage of Development*. The Company s strategy in recent years has been to self-fund certain products to a late stage of development, prior to licensing the products to marketing partners. This has allowed the Company to increase its share of the potential revenue streams from these products and gain greater control over the development process. A recent example of this is the Board s decision in September 2005 to fund Phase III clinical trials of Flutiform with the proceeds of a rights issue prior to entering into an out-licensing arrangement with Kos for the North American marketing and distribution rights of Flutiform in May 2006.

- *Develop Existing and New Collaborative Agreements*. In order to increase the market exposure of its products and to capitalise on its collaborative partners market position and distribution capabilities, the Company intends to continue to develop its projects with its existing collaborative partners, expand its collaborations with existing partners to include new projects, and to seek new partners. In addition, the Company will focus its efforts on working with partners to maximise revenues from existing and future marketed products. The Company has increasingly focused on undertaking additional value added services, such as assuming responsibility for development and regulatory activities and seeking to retain manufacturing and co-marketing rights, which may allow it to increase its share of the potential revenue stream from these collaborations. As part of this strategy, the Company has also reduced its focus on up-front and milestone payments and aimed instead to gain an increased share of royalties and longer term revenues.

- *Seek to Retain Manufacturing Rights/and or Marketing Rights on Future Collaborations*. The Company employs personnel who specialize in manufacturing products utilizing the Company s technologies in commercial quantities. Where it makes commercial sense, it will pursue long-term manufacturing and supply agreements with licensees of the Company s products. The Company may also seek to retain marketing rights in respect of future products which it could co-market or ultimately market itself in specific targeted therapeutic areas. Currently the Company has no direct marketing capability but at the appropriate time may seek to develop or acquire its own marketing capability. This strategy should not only give it greater control over revenue generation but could also improve gross profit margins.

- *Expand the Application of the Company s Core Technologies.* The Company intends to continue to expand the application, increase the value and extend the commercial life of its oral, inhalation and enhanced solubilization technologies, by seeking to develop technology improvements, expand patent coverage, acquire complementary technologies and realise synergies between these technologies. The Company may seek to acquire additional add-on technologies, that are complementary to its existing technologies. The Company intends to focus on technologies it believes are capable of commercial realisation in the near term and will also seek to acquire or license new drug delivery platforms and enabling technologies that the Company believes have significant commercial applicability.

Drug Delivery Platforms

The Company s business is comprised of two reportable segments within the meaning of SFAS 131, Oral, Inhalation and Other and Injectable.

Oral, Inhalation and Other

Oral

The original Geomatrix technology was developed by a team of researchers at the University of Pavia in Italy in the early 1980s. The Company acquired the technology through its acquisition of Jago in 1996 and has subsequently pursued the development of the Geomatrix platform of oral controlled-release systems. Geomatrix is a range of technologies by which drugs taken orally in tablet form are

formulated so as to control the amount, timing and location of the release of the drug in the body. There are currently eight Geomatrix technologies designed to meet a wide range of therapeutic objectives through different release mechanisms. The technologies are flexible and can be modified to apply to a variety of pharmaceutical products.

The Company collaborates with large pharmaceutical companies to develop Geomatrix formulations of its collaborative partners proprietary products. The Company focuses its research and development efforts on the reformulation of existing drugs using its technologies rather than the discovery of new chemical compounds. In reformulating an existing drug, the Company seeks to enhance the therapeutic and commercial value of the product by creating an improved outcome formulation that may mitigate certain side effects, reduce dosing and extended patent protection.

Approved Geomatrix Products

The following table summarizes certain information on the Company s approved products that utilize Geomatrix technologies. The major marketed products are discussed further below.

Product	**Indication**	**Regulatory Approvals and Year of First Approval**	**Collaborative Partner**
Paxil CR	CNS	United States (1999)	GlaxoSmithKline
Xatral® OD/Uroxatral®	Genito-Urinary	United States (2003) Europe (2000)	Sanofi-Aventis
Coruno	Angina	Belgium (2002)	Therabel
Madopar DR	Parkinson s Disease	Luxembourg (2003)	Hoffmann-La Roche
Diclofenac-ratiopharm-uno	Arthritis	Germany (1995)	ratiopharm

Paxil CR is marketed in the United States, Canada and certain other countries. It is a modified release version of Paxil®/Seroxat (paroxetine HCL) which uses a combination of two Geomatrix release systems. Paxil® is an FDA-approved drug that is currently marketed primarily in the United States and Europe and is an immediate release formulation prescribed for central nervous system disorders.

An application for approval of Paxil CR was filed with the FDA by SmithKline Beecham (now part of GlaxoSmithKline) in December 1997 and approved by the FDA in February 1999 for the 12.5 and 25mg dosage forms. In early 2001, GlaxoSmithKline, the Company s collaborative partner in the development of Paxil CR , announced that it had received an approvable letter from the FDA for a second CR indication, panic disorder. On April 19, 2002, Paxil CR was launched in the United States for the treatment of central nervous system and panic disorders. The FDA has subsequently approved Paxil CR for the continuous treatment of premenstrual dysphoric disorder (PMDD) (September 2003), social anxiety disorder (October 2003) and the intermittent treatment of PMDD (February 2004). In January 2004, the Therapeutic Products Directorate of Health Canada approved Paxil CR for the treatment of central nervous system disorders, panic disorder and social anxiety disorder.

On March 4, 2005, GlaxoSmithKline announced that the FDA had halted supplies of Paxil CR due to manufacturing issues. SkyePharma provided the formulation of Paxil CR , but has no involvement in its manufacturing. GlaxoSmithKline announced the resupply of Paxil CR on June 27, 2005.

On April 28, 2005, the Company announced that it had entered into an amendment agreement with GlaxoSmithKline in respect of Paxil CR . Under the terms of the amendment agreement, GlaxoSmithKline made a one-time payment of approximately $10 million to the Company. In addition, the Company became entitled to an increase in the royalty rate from 3% to 4% on actual net sales of Paxil CR , with effect from March 4, 2005. As GlaxoSmithKline was unable to supply Paxil CR in the United

States between March 4, 2005 and June 27, 2005, when GlaxoSmithkline announced the resupply of Paxil CR in the United States, GlaxoSmithKline also agreed to pay SkyePharma the same level of royalty on GlaxoSmithKline s budgeted sales of Paxil CR from March 4, 2005, while the product remained off the market, subject to other terms of the agreement.

Xatral® OD is marketed in the United States (under the name Uroxatral®), Europe, Canada and certain countries in Africa, Asia and Latin America. It is a once daily Geomatrix formulation of alfuzosin used for the treatment of the functional symptoms of benign prostatic hyperplasia, a common condition in men over the age of 50, which was developed in conjunction with Sanofi-Synthelabo (now Sanofi-Aventis). In January 2000, Sanofi-Aventis announced that it had received the first batch of European marketing approvals for Xatral® OD. Uroxatral® was launched in the United States in November 2003. In March 2004, Sanofi-Aventis announced that it had begun to market Uroxatral® directly to primary care physicians in the United States. In addition to the United States, the product is now launched throughout Europe, Canada and certain countries in Africa, Asia and Latin America. Xatral® OD is now approved for a second indication, acute urinary retention, in more than 50 countries, including 24 in Europe. However Sanofi-Aventis is no longer pursuing U.S. approval for this indication.

Coruno® is a once per day Geomatrix formulation of molsidomine, currently marketed in Europe and used to treat angina pectoris, a common symptom of coronary heart disease. The Geomatrix controlled release technology in Coruno® enhances patient compliance and convenience by reducing the dosing requirement to once per day. Coruno® was developed in conjunction with the Therabel Group (Therabel) and was approved by the Belgian regulatory authorities in 2002 for marketing in Belgium. In April 2003, Therabel launched Coruno® in Belgium. Subsequently, Coruno® was approved and launched in Luxembourg.

Geomatrix Products in Development

The following table summarizes certain information on the Company s products under development that utilize Geomatrix technologies. The major products in development are discussed further below.

Product	Modified	Therapeutic Category	Development Status	Collaborative Partner
Requip® Once-a-Day	Yes	Parkinson s Disease	Phase III completed	GlaxoSmithKline
zileuton CR	Yes	Asthma/COPD	Phase III completed	Critical Therapeutics
Lodotra	Yes	Inflammatory Conditions	Phase III completed	Nitec
nisoldipine CR	Yes	Cardiovascular	Phase I completed	Sciele Pharma

Requip® Once-a-day is a once daily dosage form of Requip® (ropinirole), which is an FDA-approved drug that is currently marketed, primarily in the United States and Europe by GlaxoSmithKline. As it is currently marketed, Requip® is an immediate release formulation administered three times daily and is prescribed for Parkinson s disease, a chronic progressive disease in which the degeneration of nerve cells in the brain eventually impairs the ability to control body movements. In December 2005, GlaxoSmithKline submitted Requip® Once-a-day for approval by U.S. and European regulatory authorities for the treatment of Parkinson s disease. This new once-daily oral formulation of Requip® incorporates the Company s Geomatrix oral controlled-release delivery technology, which is expected to improve patient convenience. The FDA has raised some administrative issues that were identified in the preliminary initial review and which led GlaxoSmithKline to withdraw the U.S. filing. The Company has been informed that it is the intention of GlaxoSmithKline to resubmit in late 2006. It is not expected that the European regulatory review process will be affected by FDA issues.

Zileuton is an FDA-approved drug for asthma and Chronic Obstructive Pulmonary Disease (COPD). A four times a day immediate-release version of zileuton was marketed by Abbott Laboratories (Abbott) as Zyflo® Filmtab (zileuton tablets). SkyePharma, together with Abbott, developed a controlled-release formulation of zileuton using its Geomatrix technology for twice daily administration. Abbott completed Phase III trials to use this product to treat asthma. In January 2004, SkyePharma announced an agreement with Critical Therapeutics Inc. (CTI), to whom Abbott sub-licensed zileuton, to collaborate on the further development of this formulation for the indications of moderate to severe asthma and COPD. Because of changes in the active pharmaceutical ingredient supplier and manufacturer, the formulation will need further in vivo (human) testing before an application may be filed. CTI announced in January 2006 that it had initiated two studies designed to support an NDA for the twice-daily version of Zyflo® (zileuton). These studies were recently completed and CTI expects to file the controlled release version with the FDA in the third quarter of 2006. Once approved by the FDA, CTI intends to market this product in the United States through its own specialist sales force.

Other Oral Products in Development

In addition to the products in the above table, the Company has a number of other Geomatrix projects in earlier stages of development. For a description of the development process, including definitions for development status stages, see Research and Development Development Process for Brand-Name Pharmaceuticals .

Inhalation

The Company is developing advanced technologies to deliver medicines via a patient s lungs without relying on chlorofluorocarbon CFC based propellants, which are considered environmentally harmful. The Company is working with two types of such inhalation systems:

- MDI Technologies Metered dose aerosol inhalers (MDI), the most widely used systems for inhalation drug delivery, have been in existence for more than 40 years and are primarily used to deliver asthma medications and other small molecule drugs to the lung, although significant advances have been made in recent years in the delivery of large molecule drugs, such as peptides and proteins, via the lung. MDI technologies rely on stable drug formulations with non-CFC propellants, hydrofluroalkanes (HFAs), to deliver the required therapy. In its MDI development work, the Company focuses on the formulation of drugs for use in MDIs manufactured by others.

- DPI Technologies Dry powder inhaler (DPI) technology has emerged as an effective means of delivering asthma medications to the pulmonary system without the use of CFC propellants. Under the brand name SkyeHaler , the Company is developing a DPI that requires no propellant but instead is breath-actuated to deliver drugs in a fine powder suspension. In its dry powder inhaler development work, the Company focuses both on the development of the device and associated dry powder formulations.

In both its MDI and DPI development work, the Company s objective is to maximize the efficiency of the delivery system while addressing commercial requirements for reproducibility, formulation, stability, safety and convenience. The Company has assembled a team of researchers with substantial experience to develop proprietary techniques and methods that it believes will produce stable and reproducible dry powder and aerosol formulations. To achieve this goal, the Company is combining an understanding of lung biology, aerosol science, chemical engineering and mechanical engineering.

Approved Inhalation Products

There are two approved drugs that use the Company s Inhalation technologies

Product	Indication	Regulatory Approvals and Year of First Approval	Collaborative Partner
Foradil® Certihaler	Asthma	Switzerland (2005)	Novartis
Pulmicort® HFA-MDI	Asthma	Finland (2006)	AstraZeneca

Foradil® Certihaler . The Company has developed a DPI device with the compound formoterol pursuant to a collaborative agreement with Novartis. The Foradil® Certihaler has now been approved in 24 countries in Europe, the Middle East and Latin America. The product was launched in Germany and Switzerland in September 2005, but a batch recall from these markets was initiated in January 2006 because of concerns that accidental mishandling of the device had resulted in inaccurate dosing in a small number of cases. SkyePharma is collaborating with Novartis and the relevant health authorities to investigate the matter and the actions necessary before the product can be returned to the market. These are likely to include minor modifications of the device to prevent the occurrence of inaccurate dosing, while the key device characteristics are expected to be left unchanged. In the United States, Novartis received an approvable letter for the Foradil® Certihaler from the FDA in October 2003, a second approvable letter in December 2004 and a third approvable letter in April 2006 requiring device modification to prevent inaccurate dosing following accidental mishandling as a prerequisite for approval, in line with the European requirements. Novartis is currently working with the FDA on the most effective way to address its concerns.

Pulmicort® HFA-MDI . The Company has entered into a collaborative agreement with AstraZeneca to develop the next generation of AstraZeneca s Pulmicort® (budesonide) HFA MDIs for the European market. Phase III clinical studies in Europe were completed in July 2004 and on June 28, 2005 AstraZeneca announced that it had filed an application for approval of this product for the first country in Europe. In February 2006, the product received approval in Finland, its first European market and other European approvals may be received in 2006. The currently available MDI formulation of Pulmicort® has been on the market since 1981 and uses CFCs as the propellant, which will now be replaced by the non-ozone depleting device using HFAs as the propellant. SkyePharma developed this new HFA-MDI formulation, which employs its proprietary formulation technology, and also conducted the clinical development programme for AstraZeneca.

Inhalation Products in Development

The table below summarizes inhalation products currently under development.

Product	Therapeutic Category	Development Status	Inhalation System	Collaborative Partner
Flutiform	Asthma/COPD	Phase III in progress	HFA-MDI	Kos/SkyePharma
QAB 149	Asthma/COPD	Phase II completed	DPI	Novartis
HFA-formoterol	Asthma/COPD	Phase II completed	HFA-MDI	SkyePharma

Flutiform . The Company is developing Flutiform , a CFC-free metered-dose aerosol inhaler containing a fixed-dose combination of the long-acting bronchodilator formoterol with the inhaled steroid fluticasone for the treatment of asthma and COPD. A single delivery device containing two separate agents with complementary therapeutic roles (steroids are anti-inflammatory and address the underlying causes of asthma, whereas bronchodilators control the remaining symptoms of those attacks) brings convenience benefits for patients. In 2005, the Company completed phase II trials and a review of development activities with the FDA and European regulatory agencies and subsequently the Company initiated Phase III trials for Flutiform in February 2006. The product is on track for its target filing date

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with the FDA in the second half of 2007 with U.S. market entry expected in early 2009. In May 2006 the Company announced that had entered into an agreement with Kos Pharmaceuticals to jointly develop Flutiform . Kos will have exclusive rights to market Flutiform in the United States and a right of first negotiation in Canada. SkyePharma could receive up to $165 million in milestone payments on the achievement of all regulatory and revenue targets (of which $25 million has been paid upfront) together with royalties on sales by Kos. SkyePharma remains in negotiations with potential partners for Europe and other markets around the world.

QAB 149 (indacaterol) is Novartis novel inhaled long-acting bronchodilator with rapid onset of action, which has completed Phase II development for both asthma and COPD. The QAB 149 development used the Company s Certihaler and related formulation technology in this second collaboration with Novartis. After the report of inaccurate dosing following accidental mishandling of the device, Novartis is currently revising future QAB 149 development plans. The Company cannot be certain that such plans will include the use of the Company s Certihaler .

Formoterol HFA-MDI is a formulation of the long-acting bronchodilator formoterol in an HFA-MDI. This product has completed Phase II development. However, because of the growing use of combination products for asthma and COPD, there is now a correspondingly diminishing market opportunity for single agent bronchodilators. The Company is undertaking a strategic review of the commercial viability of this product.

The Company also has a number of other projects at earlier stages of development utilizing its inhalation technology.

Topical

The Company s topical drug delivery technologies are primarily designed to maintain efficacy and localise delivery of drugs to the skin for the treatment of a variety of skin disorders. The Company s portfolio of topical drug delivery technologies consist of HA-based technologies, Crystalip, DermaStick and the ES-Gel system.

HA-based technologies are topical drug delivery technologies based on HA, a natural polymer, which is designed to maintain efficacy and localize the delivery of drugs to the skin for the treatment of a variety of skin disorders. The properties of HA enables drugs to potentially be targeted to and held at the site where the drug is needed. As a result, the Company believes formulations employing HA-based technologies may result in decreased systemic side effects or enhanced therapeutic effect.

Approved Topical Products

The Company has one approved topical product:

Product	Indication	Regulatory Approvals and Year of First Approval	Marketing Partner
Solaraze®	Actinic Keratosis	United Kingdom (1997)	Shire Pharmaceuticals
		United States (2000)	Bradley Pharmaceuticals

Solaraze® is a topical gel used to treat actinic keratosis, a pre-cancerous skin condition caused by over-exposure to the sun. It is a formulation of HA and the non-steroidal anti-inflammatory drug diclofenac. Solaraze® has been shown to be an effective topical product for actinic keratosis. Compared with other actinic keratosis treatments, Solaraze® is non-invasive, non-scarring and is well tolerated by patients. Solaraze® is licensed to Bradley Pharmaceuticals Inc. in the United States and to Shire Pharmaceuticals PLC in Europe and Australia. It is currently marketed in the United States and various countries in Europe. Shire filed for approval in Australia in 2005 and in June 2006, Shire learned that the Australian regulatory agency has recommended rejection of the application. Shire is currently considering whether to appeal this decision.

Topical Products in Development

On April 29, 2004, the Company announced that it had licensed the rights to its dermatology assets, which account for substantially all of its topical drug delivery technologies, for those territories that are not covered by existing licenses, to Trigenesis Therapeutics, Inc. (Trigenesis). The rights relate to three marketed drugs, including Solaraze® for those territories not already licensed, rights to six pipeline products, including Hyclinda and Acyclovir, and a range of six proprietary and complementary delivery technologies, including HA-based technologies, Crystalip, Dermastick, ES-Gel, Dissocubes and Solid Lipid Nanoparticles. Under the agreement, Trigenesis is obligated to exploit the dermatology assets covered by the license and to continue the development of those drug candidates that are currently in the pipeline stage. Trigenesis has also assumed the majority of SkyePharma s existing obligations to third parties with respect to the development of these drug candidates. All rights granted by the Company to licensees under existing licenses remain unaffected by the agreement. In addition, the Company has retained the right to use the technologies subject to the license for the development of a number of new chemical entities in the dermatology area and, in certain cases, also for non-dermal applications. In May 2004, Trigenesis was acquired by Dr Reddy s Laboratories Limited (Dr Reddy s), an Indian pharmaceutical company. Dr Reddy s assumed all the obligations of Trigenesis.

Solubilisation

Solubility of drugs is an essential factor for all drug delivery systems, independent of the route of administration. Poor solubility may lead to a range of problems including poor bioavailability, increased toxicity, variability of absorption when taken with food and poor efficacy. The Company believes that a large number of existing marketed drugs and newly synthesised compounds have solubility problems. The Company s solubilisation technologies consist of two complementary technologies, the nano-particulate and the Insoluble Drug Delivery (IDD) technologies. Both technologies aim to improve a drug s solubility by reducing the size of the particules. It has been demonstrated in laboratory testing that the saturation solubility of many drugs can be improved by reducing particle size below one micron in diameter. The Company is using its solubilisation technology platform to enhance the uptake and safety of water –insoluble drugs across a broad range of therapeutic classes including anaesthetics, anti-cancer agents and immune suppressants. It is intended that the solubilisation technologies will be used to complement and enhance the Company s other drug delivery systems.

Approved Solubilisation Products

The Company has one approved solubilization product.

Product	Indication	Regulatory Approvals and Year of First Approval	Marketing Partner
Triglide®	Cardiovascular	United States (2005)	Sciele Pharma

Triglide® is an IDD formulation of fenofibrate which the Company was initially developing in partnership with an undisclosed pharmaceutical company. During 2003, the Company and its partner re-negotiated the terms of their agreement and the Company re-acquired rights to the product for an unspecified amount. Triglide® is a lipid-lowering agent launched by Abbott under the trade name Tricor® in the United States in 1998. The IDD formulation is a lower dose product providing blood levels similar to the original 200mg Tricor® product and that can be taken with or without food. On May 17, 2004, the Company announced an exclusive agreement with First Horizon Pharmaceutical Corporation, now renamed Sciele Pharma, Inc. (Sciele Pharma) through which the Company granted Sciele Pharma the exclusive U.S. marketing and distribution rights for Triglide®. Following FDA approval in May 2005, Sciele Pharma launched Triglide® on the U.S. market in July 2005.

Solubilization Products in Development

The Company granted an exclusive license to the United States and Canadian marketing and distribution rights for Propofol IDD-D to Endo. Propofol IDD-D is our novel formulation of propofol, a widely-used injectable anaesthetic and sedative. Our formulation was designed to avoid the need for a preservative and to be suitable for long-term use in intensive care units. Although this product satisfactorily completed Phase II trials in 2004, the Phase III trial has not yet commenced and in April 2006 we agreed with our North American partner Endo to terminate the joint development of Propofol IDD-D as the product was unlikely to achieve its target profile. As a result, the Company believes this product has limited commercial potential.

Injectable

The Company has two injectable technologies

DepoFoam The Company s primary injectable technology is DepoFoam . DepoFoam consists of lipid-based particles composed of hundreds to thousands of discrete water-filled chambers containing the encapsulated drug, with each chamber separated from adjacent chambers by a lipid membrane. The particles are suspended in saline for injection. DepoFoam formulations can be delivered into the body by a number of routes, including under the skin, within muscle tissue, into brain and spinal fluid, within eyes, within joints and within the abdominal cavity. The Company has combined many drugs with DepoFoam in the laboratory and clinic and has two commercialized products based on this technology. Clinical studies show that DepoFoam techonologies often achieve sustained controlled release of the drugs. This feature allows the Company to develop new formulations of drug products aimed at treating different diseases and symptoms or allows for more convenient administration by reducing the number or frequency of injections. The drug candidates include drugs that have already been shown to be useful or potentially useful in humans, as well as new drugs in development at other pharmaceutical companies, which may potentially benefit from DepoFoam . The Company does not conduct research and development to discover new drugs to use in combination with DepoFoam .

Biosphere The Company s second sustained-release injectable technology is the Biosphere drug delivery system. The Biosphere drug delivery system provides sustained-release of injectable proteins and peptides. The technology encapsulates the drug substance in highly purified starch in microscopic spheres that are then coated with a copolymer of lactic and glycolic acid. After injection, the coating and core erode and the drug content is released over a controlled period that can range from days to months. In contrast with conventional microspheres, the coating used in Biosphere does not contain any drug so there is a low burst even at high drug loadings. In 2003, the Company announced that the Biosphere technology had been successfully used in pre-clinical studies to deliver a protein drug human growth hormone over an extended period of time. The product has now successfully completed Phase I trials. In addition to the human growth hormone, the Company is also evaluating Biosphere formulations of other proteins and peptides.

Approved Injectable Products

The following table summarizes certain information on the Company s two approved products that utilize its injectable technologies.

Product	Indication	Regulatory Approvals and Year of First Approval	Marketing Partner
DepoCyt®	Oncology	United States (1999)	Enzon
		Europe (2001)	Mundipharma
DepoDur	Acute Pain	United States (2004)	Endo

DepoCyt® combines the Company s DepoFoam technology with cytarabine, a drug used to treat neoplastic meningitis from lymphomas and solid tumors. It is currently marketed in North America by Enzon and in the European Union and certain other countries in Europe by Mundipharma for the treatment of lymphomatous meningitis. DepoCyt® was developed in collaboration with Chiron Corporation (Chiron) in the United States and, until June 2000, with Pharmacia & Upjohn S.p.A., an affiliate of Pharmacia Corporation. We have completed a Phase IV clinical trial required by the FDA and have submitted the results to the FDA. We have also filed with the EMEA in Europe for the additional indication of the most common form of neoplastic meningitis, associated with solid tumours. The file has been withdrawn as the EMEA needed additional clinical data to make a positive risk-benefit assessment.

DepoDur (previously referred to as DepoMorphine) has been developed for the control of moderate to severe post-operative pain. DepoDur is given as a single epidural injection in the peri-operative period and provides pain relief for up to 48 hours following surgery. The Company s U.S. marketing partner Endo Pharmaceuticals launched DepoDur in December 2004. The product is still in the launch phase but has now been accepted on more than 400 hospital formularies, the first gateway to routine hospital use. In the U.K., we have recently been granted approval for DepoDur by the U.K. Committee on Safety of Medicines, the CSM. This will be used as the basis for seeking approval throughout the European Union under the EU s Mutual Recognition procedure. Zeneus Pharmaceuticals, SkyePharma s European licensee for DepoDur , announced in December 2005 that it had reached agreement to be acquired by the U.S. company Cephalon Inc. SkyePharma has regained the European rights for DepoDur and is now seeking a new sales and distribution partner for the EU and other territories outside North America.

Injectable Products in Development

The following table summarizes certain information on the Company s products under development that utilize its injectable technologies. The major products in development are discussed further below.

Product (Active Compound)	**Therapeutic category**	**Development Status**	**Collaborative Partner**
DepoBupivacaine	Post surgical/post injury pain	Phase II completed	SkyePharma/Maruho
Psoraxine	Psoriasis	Phase II completed	Astralis
HgH	Growth Disorders	Phase I completed	SkyePharma
Interferon alpha-2b	Anti-viral/Oncology	Pre-clinical	SkyePharma
GCSF	Oncology	Pre-clinical	SkyePharma

DepoBupivacaine is a DepoFoam formulation of the local anaesthetic bupivacaine, for the treatment of regional pain. In April 2005, the Company entered into a development and licensing agreement for DepoBupivacaine with MundiPharma for Europe and certain other international markets excluding the United States and Japan. In November 2005, SkyePharma announced that it had entered into an exclusive marketing and distribution agreement with Maruho Company Limited (Maruho) for Japan.

The product successfully completed Phase II clinical trials in 2005. In June 2006, the Company completed negotiations with Mundipharma the result of which is that the Company will reacquire the rights for the marketing and distribution of DepoBupivacaine and the clinical data from the Phase II trials of DepoBupivacaine for $ 5 million. Endo Pharmaceuticals, our North American partner for DepoDur , had a right of first negotiation for commercial rights to DepoBupivacaine for North America, but has now relinquished this right. The reacquisition of rights from Mundipharma and the relinquishment of rights by Endo means that the Company can now offer unrestricted global rights to DepoBupivacaine (outside Japan) to parties interested in acquiring the injectables business. Maruho will

conduct the clinical development of DepoBupivacaine required for regulatory approval in Japan at its own cost.

The Company is also evaluating, in conjunction with undisclosed corporate partners, DepoFoam and Biosphere formulations of several additional compounds, including small molecule chemical compounds and macromolecule biologics.

Collaborative Arrangements

The Company has collaborative arrangements with each of its pharmaceutical partners, the terms of which vary considerably. Pursuant to these arrangements, the Company s partners typically fund all or a large part of the research and development expenses incurred in the development of new formulations of their products. This funding typically takes the form of a flat fee for the Company s research and development efforts, an agreed research and development budget charged at an hourly rate, or milestone payments on signing and on the achievement of technical or commercial milestones. Some agreements have involved equity investments in the Company by the Company s partners. In negotiating contracts with its partners, the Company s strategy generally has been to cover its costs in the research and development process. Substantially all potential profits are expected to be generated by royalty payments or manufacturing fees for successfully developed and marketed products. In some cases, milestone payments may be deducted from future royalty payments for successfully developed and marketed products.

In return the Company gives each of its partners an exclusive license to market the products incorporating the Company s technologies. In some cases the licenses are worldwide. In others they are limited to specific territories. In most cases, partners are free to sublicense the technologies, although the Company s consent may be required and royalties on all sales must be paid to the Company. In addition, the majority of the collaborative agreements do not restrict the Company from developing formulations of competitive products. In some cases, however, the Company will agree not to develop formulations of specified compounds for an agreed period of time.

The Company s collaborative partners frequently take responsibility for conducting clinical trials and for preparing and pursuing all necessary regulatory approvals, although more recently the Company has taken responsibility for managing clinical trials in some collaborations. The Company may assist its partners in the conduct of such trials and the preparation of regulatory filings. Its partners may ultimately control the process, including the selection of the jurisdictions in which regulatory approval will be sought, if at all.

The collaborative agreements frequently do not obligate the partners to market any successfully developed and approved products. The Company does not have any control over whether and to what extent a partner will elect to commercialise a product. A client may choose not to market a product for reasons wholly independent of the Company s technologies. In most cases, if a client does not proceed to market the product once it has been successfully formulated and approved, the Company will not receive any additional income in respect of the product. In some more recent collaborations, however, contracts have included certain commitments from the Company s partners to use specified minimum resources to market the product or to pay a minimum royalty in lieu of sales of the product or failing that to return the product rights to the Company.

During the formulation and development stages, the Company s partners are generally free to terminate the collaborative relationship at any time and for any reason after providing the Company with a notice period.

The Company s key license, development, marketing and distribution relationships are set out in the table below.

Product	Collaborative Partner	Technology Platform	Territory Covered
Paxil CR	GlaxoSmithKline	Oral	Worldwide
Xatral® OD	Sanofi-Aventis	Oral	Worldwide
Coruno	Therabel	Oral	Worldwide
Requip®	GlaxoSmithKline	Oral	Worldwide
Zileuton CR	Critical Therapeutics	Oral	United States
Foradil® Certihaler	Novartis	Inhalation	Worldwide
Pulmicort® HFA-MDI	AstraZeneca	Inhalation	Worldwide (except United States)
Flutiform	Kos	Inhalation	United States
DepoCyt®	Enzon	Injectable	United States and Canada
DepoCyte®	Mundipharma	Injectable	E.U. and certain other countries in Europe
DepoDur	Endo	Injectable	United States and Canada
DepoBupivacaine	Maruho	Injectable	Japan
Triglide®	Sciele Pharma	Solubilisation	United States

Other Significant Collaborative Arrangements

In December 2000, SkyePharma entered into an agreement with Paul Capital Royalty Acquisition Fund (Paul Capital). Under the agreement, Paul Capital provided a total of $30 million between 2000 and 2002, in return for the sale of a portion of potential future royalty and revenue streams from DepoDur , Xatral® OD, Solaraze® and DepoCyt®. The monies were used to fund the clinical development of DepoDur . Between January 2003 and December 2014, Paul Capital will receive 15% of the annual royalties and revenues from the stated products up to an agreed ceiling. Once the predetermined ceiling is reached, the percentage participation will fall to 3% for the remainder of the period until December 31, 2014.

In March 2002, SkyePharma entered into a second agreement with Paul Capital. Under the terms of the agreement, Paul Capital paid SkyePharma $30 million during 2002 and 2003, in return for a portion of the future royalty and revenue streams from nine products in the Company s pipeline. The monies have been used principally to fund the clinical development of Propofol IDD-D and HFA-formoterol. The nine products referred to are Propofol IDD-D and HFA-formoterol, the lipid-lowering drug Triglide®, an anti-cancer agent busulfan, an intravenous formulation of the antibiotic oxytetracycline, oral budesonide to treat inflammatory bowel disease, HFA-budesonide and Foradil®, for the treatment of asthma, and the anti-depressant Paxil CR . Between January 2002 and December 2015, Paul Capital will receive between 4% and 20% of the annual royalties and revenues from the total of nine products. The 20% rate applies first. The percentage then falls, when an agreed return is achieved, to 12.5% until a second ceiling is reached, before falling to 4% for the remainder of the period until December 31, 2015. During 2002 and 2003, the 20% rate was reduced based on the percentage of the total $30 million already funded. Also under the terms of these agreements, Paul Capital has been issued warrants carrying rights to subscribe for 5 million SkyePharma Ordinary Shares at an exercise price of 73.75 pence.

Research and Development

The Company s research and development activities are conducted in Muttenz, Switzerland and in San Diego, United States. As of December 31, 2005, the Company had 282 employees at these two facilities, the majority of whom were engaged in research and development and manufacturing. In late 2005 and early 2006, the Board of Directors of the Company conducted a full strategic review and

concluded that in the interests of achieving sustainable profitability in the near term, and in order to improve the Company s cash flow position, the Company should concentrate on oral and inhalation products, and divest its injectables business in San Diego.

The Company conducts research and development both with respect to its own internally funded products as well as for third parties. The Company accounts for costs incurred in conducting internal research and development activities as research and development expenses and for costs incurred on development work for third party customers as cost of sales. The Company s self-sponsored research and development costs are expensed as incurred.

The Company records amounts received from third parties under the Company s contract development arrangements within turnover, as contract development income. Contract development income represents amounts invoiced to customers for services rendered under development contracts or for milestone payments in accordance with the contract terms. Such amounts are only treated as revenue when the services have been rendered or the specified milestone has been met. Certain refundable income is treated as deferred income until the Company has no further obligations to make refunds. The Company generally attempts to break even on its development work for third party customers. Therefore, product development activities do not currently have a significant impact on the Company s operating profit/(loss).

The Company s development processes are described below. Specific development steps for a product may vary or be unnecessary depending on a number of factors, including the drug delivery technology used and whether the product incorporates an active ingredient already available on the market.

Development Process for Brand Name Pharmaceuticals

In order to obtain approval of a new drug or a new formulation of an existing drug it is necessary to undertake a series of tests and trials. Specific development steps for a product may vary or be unnecessary depending on a number of factors, including the drug delivery technology used and whether the product incorporates an existing marketed active ingredient. A typical development process may include the following series of tests and trials:

Preclinical tests encompass the laboratory evaluation of a new pharmaceutical, its chemistry, formulation and stability, as well as animal studies to assess its potential safety and efficacy. Following the conclusion of preclinical tests, the results of these studies, which have to demonstrate that the pharmaceutical delivers sufficient quantities of the drug to the bloodstream to create the desired therapeutic results, are submitted to the relevant regulatory authority, which must be approved before human clinical trials may begin.

Human clinical trials are typically conducted in three sequential phases:

- Phase I. During this phase, the drug is initially introduced into a relatively small number of healthy humans or patients and is tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

- Phase II. This phase involves studies in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the drug for specific targeted diseases or conditions, and to determine dosage tolerance and optimal dosage.

- Phase III. When Phase II evaluations demonstrate that a dosage range of the drug is effective and has an acceptable safety profile, Phase III trials are undertaken to further evaluate dosage, clinical efficacy and test for safety in an expanded patient population at geographically dispersed clinical sites.

- *Regulatory Filing.* The Company alone, or in collaboration with its partner, or its partner manages regulatory activities during product development phases. These activities include developing regulatory strategies, information submissions and meetings with health authorities and preparation

of marketing approval applications. Post-approval product development may necessitate additional regulatory filings.

Patents and Proprietary Rights

The Company believes that patent and other intellectual property protection of its drug delivery and formulation technologies is critical to its business and that its future performance will depend in part on its ability to obtain patents, maintain confidential and trade secret information and to operate without infringing the intellectual property rights of others.

Oral Controlled Release Technology

The Company has two patent families in respect of its core Geomatrix technologies. The first patent family was issued in Australia, New Zealand, Italy, Europe, Japan, the United States and Canada. It expired in 2002 in Australia and New Zealand, 2005 in Italy, and will expire in 2006 in the rest of Europe, Japan and the United States, and in 2009 in Canada. The second patent family relating to the Company s Geomatrix technologies was granted in Italy, the United States and Europe, Canada and Japan. These patents expire between 2009 and 2012.

In addition, the Company holds several other patents related to its oral controlled release technology, and has applications filed in markets including Europe, the United States, Japan, Canada, Australia and New Zealand, which continue to protect the technology to 2018. These patents and applications cover the variety of different tablet formulations containing an active drug core and various surface coatings covering the core. These cores and coatings contain excipients that enable a variety of release profiles to be achieved. Later applications cover recent innovations and/or improvements to the original inventions.

In total, the Company has 175 patents protecting the Geomatrix technology, which represents 27 patent families. The Company continues to file additional patent applications relating to oral drug delivery technologies in order to secure protection for its activities in this area.

Inhalation Technology

The Company has 17 patent families in respect of its inhalation technology. One family covers SkyeHaler itself as well as several of the structural elements and features incorporated therein, and has been granted in the United States, Europe, Japan and certain other countries. Each of these patents expires no earlier than 2015. Other patent families relate to a dry powder, for use with the Dry Powder Inhalers.

The Company has, together with other companies working in the same area, been involved in several European patent oppositions related to the use of environmentally friendly HFA as propellants. Of these oppositions four have been settled and the remaining four are in various stages within the European Patent Office. There are currently six oppositions in which SkyePharma is participating in relation to various aspects of inhalation technologies. As with all contentious proceedings, the outcome of patent oppositions is uncertain and, if negative, could have an adverse effect on the Company s business.

Topical Technology

The Company owns a wide range of intellectual property rights covering its topical technology. Patents and applications covering many and varied uses of hyaluronic acid have been filed throughout the world. Following these filings, patents have been granted in the United States, Europe, Japan and certain other countries expiring between 2010 and 2013. On 29 April 2004, the Company announced that it had licensed the bulk of its Topical Technology to Trigenesis.

Solubilisation

The Company has rights to a total of 7 patent families related to its solubilisation technology. The Company owns two patent families covering solid lipid nanoparticles and nano-suspensions, each of which are useful for drug delivery. These two patent families, as well as applications filed, protect the Company s technologies in the area of solid lipid nanoparticles and nano-suspensions in the United States, Europe, Japan and certain other countries until 2015. The Company also has an exclusive license under two further patent families: one relating to solid polymer nano-particulate technology and the other to further developments in the areas of solid lipid nano-particles and nano-suspensions.

In addition, the Company owns a large portfolio of patents and patent applications covering three broad patent families relating to:

(i) Lipid stabilised microparticle technology (where the drug is a solid particle);

(ii) Lipid stabilised microdroplet technology (where the drug is a liquid); and

(iii) Omega-3 oil stabilised drug technology, which is useful for drug delivery.

The Company s solubilisation technology is protected by numerous patent and patent applications worldwide including: 15 patents in the United States and 70 corresponding patents in countries outside the United States. In addition, the portfolio contains many pending applications, including 23 patent applications in the United States, 23 regional (European and PCT) patent applications and 35 applications in other countries.

Injectable Technology

The Company owns a large portfolio of patents relating to the DepoFoam delivery technology in the United States, Europe, Japan and certain other countries. The majority of these patents will continue in force until 2014. Additional filings of patent applications have been made for improvements of the initial technology and for innovative technology relating to this subject matter in the United States, Europe, Japan and certain other countries. In late 2005 and early 2006, the Board of Directors of the Company conducted a full strategic review and concluded that in the interests of achieving sustainable profitability in the near term, and in order to improve the Company s cash flow position, the Company should concentrate on oral and inhalation products, and divest its injectables business interests.

In addition, through a prior agreement entered into by SkyePharma Inc. with the Research Development Foundation (RDF), RDF granted certain rights, on an exclusive basis, relating to the DepoFoam technology to SkyePharma Inc. Under the agreement SkyePharma Inc. is obliged to prosecute certain patent applications and maintain issued patents relating to the licensed intellectual property. RDF retains the right to terminate the agreement or to convert the exclusive nature of the rights granted under the agreement, into a non-exclusive license in the event that SkyePharma Inc. does not satisfy its contractual obligations including making certain minimum annual payments. Additional termination events include bankruptcy and a material breach of the agreement, which is not remedied within a specified period. The termination of this agreement or the conversion to a non-exclusive agreement would have a material adverse effect on the Company. In April 2004, the Company entered into an amendment agreement with RDF pursuant to which certain commercial terms of the RDF agreement were re-negotiated. As part of the re-negotiation of these terms, 3.25 million Ordinary Shares of the Company were issued to RDF.