SKYEPHARMA PLC
Form 6-K
September 06, 2006

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a - 16 OR 15d - 16 OF
THE SECURITIES EXCHANGE ACT OF 1934

For the month of September, 2006

SkyePharma PLC

(Translation of registrant's name into English)

SkyePharma PLC, 105 Piccadilly, London W1J 7NJ England

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40F.

Form 20-F X Form 40-F

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes No X

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-
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For Immediate Release 6 September, 2006

SkyePharma PLC

SkyePharma and Mundipharma Announce Exclusive Licence Agreement for Marketing and Distribution of Flutiform in Europe

15 million upfront and 70 million in milestones
Double Digit Royalties

LONDON, ENGLAND, 6 September, 2006 -- SkyePharma PLC (LSE: SKP; Nasdaq: SKYE) announces today that it has entered into an agreement with Mundipharma International Corporation Limited ("Mundipharma") for the development, marketing and distribution in Europe and certain other international markets of Flutiform , its novel combination product for asthma and chronic obstructive pulmonary disease ("COPD").

Mundipharma will have exclusive rights to market Flutiform in Europe and other territories outside North, Central and South America, with an option to negotiate for exclusive rights in Japan. Mundipharma is a privately-owned pharmaceutical company that is already SkyePharma's licensee for its oncology drug DepoCyte®, in Europe and certain other markets.

SkyePharma's Chief Executive, Frank Condella, said: "I am pleased to announce another significant step in the strategic plan that we announced to shareholders earlier this year. We expect to reach the market with Flutiform in 2009, by which time the European market for combination treatments for asthma and COPD is expected to exceed $3 billion.

"We are delighted to build on our existing relationship with Mundipharma in Europe with a licence for Flutiform , our leading pipeline product. Mundipharma has demonstrated its ability to market products effectively in the complex European pharmaceutical market and they are well placed to introduce Flutiform , which will be a key product for them."

Ake Wikstrom, Regional Director, Europe, Mundipharma International Limited, said: "This agreement is important to us for two reasons. Firstly, Flutiform offers the potential of an excellent therapeutic option in the management of asthma and COPD and thus represents a major opportunity for our continued growth. Secondly, having previously partnered with SkyePharma, this clearly demonstrates Mundipharma's ability to commit to licensing opportunities and really deliver on those commitments."

SkyePharma has received an upfront payment of 15 million ($19 million) on signature and will receive additional milestone payments of up to a further 70 million ($90 million) on attainment of various development and revenue targets. SkyePharma will receive royalties on sales by Mundipharma, with the royalty rate in double digits and escalating on attainment of various sales targets. In addition SkyePharma and Mundipharma's associate company, Mundipharma Medical Company, will be entering into a manufacturing and supply agreement under which SkyePharma will supply commercial goods and samples to Mundipharma Medical Company at cost plus an applicable margin.

SkyePharma is currently conducting the clinical trials required for US approval of Flutiform in adult asthma. Mundipharma will have access to data from these trials, which will be used as the basis for obtaining European approval of Flutiform . Mundipharma will also conduct, at its own expense, an additional clinical study needed for regulatory approval in Europe and also the studies that will be needed to extend the indication to paediatric patients and to a higher dose strength. The costs of these studies will be recouped from future royalty and milestone payments to SkyePharma.

Flutiform consists of a unique fixed-dose combination of the long-acting

bronchodilator formoterol with the inhaled steroid fluticasone in a proprietary metered-dose aerosol inhaler with a dose counter. The product is taken twice a day. SkyePharma's proprietary formulation technology, designed to stabilise the active components and thereby ensure a reproducible dose even after prolonged storage, provides patent protection for Flutiform to 2019. Flutiform is currently in Phase III development for the indication of asthma in adults and adolescents and is expected to be submitted for approval in the USA in the second half of 2007 and in Europe in 2008 and to reach these markets in 2009.

In May SkyePharma announced that it had licensed Flutiform to Kos Pharmaceuticals, Inc. (NASDAQ: KOSP) for the US market, with an option on the Canadian market. SkyePharma remains in negotiations with potential partners for the remaining markets around the world.

For further information please contact:

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Peter Laing, Director of Corporate Communications	**+44 207 491 5124**
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Mundipharma International Ltd	
Rob Cohen, European Communications Director	**+44 1223 424211**

Notes for editors

About SkyePharma
SkyePharma PLC develops pharmaceutical products benefiting from world-leading drug delivery technologies that provide easier-to-use and more effective drug formulations. There are now twelve approved products incorporating SkyePharma's technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit www.skyepharma.com.

About Mundipharma
Mundipharma is one of the Purdue/Mundipharma/Napp independent associated companies - privately owned companies and joint ventures covering the world's pharmaceutical markets. The companies worldwide are dedicated to bringing to patients with severe and debilitating diseases the benefits of novel treatment options in fields such as severe pain, haemato-oncology and respiratory disease. For more information: *www.mundipharma.co.uk*

About the treatment of asthma
Asthma is an inflammatory condition that makes the airways in the lung (bronchi) abnormally responsive to external stimuli such as dust, pollen or cold air, resulting in constriction of the bronchi and difficulty in breathing. Patients with asthma are normally treated with two types of therapy: an anti-inflammatory drug that addresses the underlying cause of the condition and a bronchodilator that opens the airways, relieving the symptoms and allowing patients to breathe normally. The older short-acting bronchodilators have now largely been displaced by long-acting bronchodilators that provide symptom relief for 12 hours (particularly valuable overnight). Asthma drugs can be taken orally but most are inhaled, with the active drug delivered to the inner surface of the lung by means of an inhaler device, either a metered-dose aerosol inhaler (MDI) or a breath-actuated dry powder inhaler (DPI). The world market for asthma drugs is expected to exceed $20 billion by 2010, with use in COPD, another inflammatory lung condition, expected to add a further $10 billion. The US market accounts for approximately half of the global total.

The fastest-growing part of this market is combination treatments, which combine a long-acting bronchodilator with an inhaled steroid in a single delivery device. Combinations are not only more convenient for patients than carrying two separate inhalers but also optimise the efficacy of the individual agents. Sales of GlaxoSmithKline's combination *Advair (Seretide* in Europe) already exceed $6 billion, of which half is in the US, and AstraZeneca's *Symbicort* (which has recently been approved by the FDA but which is not yet on the US market) add another $1 billion. By 2010 the combination category is expected to account for over half of the asthma/COPD market by value.

About Flutiform

SkyePharma's product Flutiform consists of a unique fixed-dose combination of the long-acting bronchodilator formoterol with the inhaled steroid fluticasone in a proprietary non-CFC metered-dose aerosol inhaler with a dose counter. Formoterol provides 12 hours of bronchodilation and has a rapid onset of action (1-3 minutes). By contrast salmeterol, the bronchodilator used in GlaxoSmithKline's *Advair/Seretide*, also provides 12 hours of bronchodilation but has the drawback of needing up to 30 minutes after inhalation to take effect. The inhaled steroid fluticasone (a component of *Advair/Seretide*) has low systemic absorption and is perceived to have a better safety and efficacy profile than budesonide, the steroid used in AstraZeneca's Symbicort, and is the physician-preferred inhaled steroid in the US. The proprietary SkyeDry(TM) formulation technology employed in Flutiform , designed to stabilise the active components and thereby ensure a reproducible dose even after prolonged storage, provides patent protection to 2019. The product will be available in two dose combinations with each dose delivering 10 micrograms of formoterol with either 100 or 250 micrograms of fluticasone. A version with a higher dose of fluticasone is also being developed for the European market.

Flutiform completed its Phase II trial in asthma in 2005. The results confirmed that Flutiform behaved exactly as if the two component drugs had been taken separately, with rapid onset of bronchodilation that was maintained for 12 hours, no evidence of drug-drug interactions and no safety concerns.

Following discussions with the FDA on the Phase II trial results, the Phase III trial of Flutiform started on schedule in February 2006. The trial programme is on track for SkyePharma's target of regulatory submission to the FDA in the second half of 2007. SkyePharma believes that Flutiform should reach the US market in 2009. Mundipharma expects to file in Europe by the end of 2008 and Flutiform to reach the market by the end of 2009.

Certain statements in this news release are forward-looking statements and are made in reliance on the safe harbour provisions of the U.S. Private Securities Litigation Act of 1995. Although SkyePharma believes that the expectations reflected in these forward-looking statements are reasonable, it can give no assurance that these expectations will materialize. Because the expectations are subject to risks and uncertainties, actual results may vary significantly from those expressed or implied by the forward-looking statements based upon a number of factors, which are described in SkyePharma's 20-F and other documents on file with the SEC. Factors that could cause differences between actual results and those implied by the forward-looking statements contained in this news release include, without limitation, risks related to the development of new products, risks related to obtaining and maintaining regulatory approval for existing, new or expanded indications of existing and new products, risks related to SkyePharma's ability to manufacture products on a large scale or at all, risks related to SkyePharma's and its marketing partners' ability to market products on a large scale to maintain or expand market share in the face of changes in customer requirements, competition and technological change, risks related to regulatory compliance, the risk of product liability claims, risks related to the ownership and use of intellectual property, and risks related to

SkyePharma's ability to manage growth. SkyePharma undertakes no obligation to revise or update any such forward-looking statement to reflect events or circumstances after the date of this release.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SkyePharma PLC

By: /s/ Douglas Parkhill

Name: Douglas Parkhill
Title: Company Secretary

Date: September 6, 2006

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(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the Securities Act), this registration statement on Form S-8 (Registration Statement) shall also cover any additional shares of common stock (hereinafter, the Common Stock) of Varian Medical Systems, Inc. (the Registrant) which become issuable under the plan being registered pursuant to this Registration Statement by reason of any stock dividend, stock split, recapitalization or any other similar transaction effected without the receipt of consideration which results in an increase in the number of the Registrant s outstanding shares of Common Stock.

(2) In addition to the 4,000,000 shares provided in the fee table the following additional shares are available for award under the 2005 Omnibus Stock Plan; (i) such number of shares as may be granted in substitution of other options in connection with a transaction described in Section 424(a) of the Internal Revenue Code, (ii) such number of shares authorized for issuance but not yet issued under the Varian Medical Systems, Inc. Omnibus Stock Plan (the Omnibus Plan) and the Varian Medical Systems, Inc. 2000 Stock Option Plan (the 2000 Plan) and (iii) such number of shares subject to any awards granted under the Omnibus Plan and the 2000 Plan that terminate, lapse or expire for any reason. As of February 28, 2005, shares authorized for issuance but not yet issued totaled 975,984 (plus an additional 28,000,000 shares registered under the Securities Act for issuance as substitute options in connection with any transaction under section 424(a) of the Internal Revenue Code) under the Omnibus Plan and 2,164,521 under the 2000 Plan. In connection with this Registration Statement on Form S-8, the Registrant is therefore, transferring 28,975,984 shares from the Form S-8 for the Omnibus Plan (333-75531) for which the previously paid filing fee was $35,493.77 and 2,164,521 shares from the 2000 Plan (333-57006) for which the previously paid filing fee was $8,965.85. In each case the transfer includes the related Preferred Stock Purchase Rights. The Registrant is simultaneously filing a post-effective amendment to each such Registration Statement to reflect such transfer.

(3) Pursuant to Rule 457(h)(1) under the Securities Act, the proposed maximum offering price per share and the proposed maximum aggregate offering price have been calculated on the basis of $34.375 per share, the average of the high and low price of the Common Stock on the New York Stock Exchange on March 31, 2005.

(4) Includes Preferred Stock Purchase Rights which, prior to the occurrence of certain events, will not be exercisable or evidenced separately from the Common Stock.

PART I

Item 1. **Plan Information.***

Item 2. **Registrant Information and Employee Plan Annual Information.***

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* Information required by Part I to be contained in the Section 10(a) prospectus is omitted from this Registration Statement in accordance with Rule 428 under the Securities Act and the Note to Part I of Form S-8.

PART II

Item 3. **Incorporation of Documents by Reference.**

The Registrant hereby incorporates by reference into this Registration Statement the following documents filed with the Securities and Exchange Commission (the Commission):

(a) The Registrant s Annual Report on Form 10-K (File No. 1-7598) for the fiscal year ended October 1, 2004.

(b) All reports filed by the Registrant pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act) (File No. 1-7598), since October 1, 2004.

(c) The descriptions of Registrant s Common Stock and preferred stock purchase rights contained in the Registrant s Registration Statements on Form 8-A filed with the Commission under Section 12 of the Exchange Act, including any subsequent amendments or reports filed for the purpose of updating such descriptions.

All documents subsequently filed by the Registrant pursuant to Sections 13(a), 13(c), 14 and 15 (d) of the Exchange Act shall be deemed incorporated by reference in this Registration Statement and to be a part hereof from the date of filing such documents until a post-effective amendment of this Registration Statement is filed which indicates that all securities being offered hereby have been sold or which deregisters all securities then remaining unsold.

Any statement contained in a document incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained in a subsequently filed document which is also incorporated by reference herein modifies or supersedes such statement.

Item 4. **Description of Securities.** Not applicable.

Item 5. **Interests of Named Experts and Counsel.**

The legality of the securities offered hereby has been passed on for the Registrant by Joseph B. Phair. Mr. Phair is Corporate Vice President, Administration and General Counsel of the Registrant, and as of February 28, 2005, beneficially owned 754,234 shares of the Registrant s Common Stock, which included 654,544 shares which may be acquired within 60 days upon the exercise of options and 8300 shares owned by his children living in his household.

Item 6. **Indemnification of Directors and Officers.**

Section 102 of the Delaware General Corporation Law allows a corporation to eliminate the personal liability of a director to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, subject to certain exceptions. Article TENTH of the Registrant s Restated Certificate of Incorporation eliminates the personal liability of the Registrant s directors to the Registrant or its stockholders for monetary damages for breach of a director s fiduciary duty, except for liability: (1) under Section 174 of the Delaware

General Corporation Law; (2) for breach of a director s duty of loyalty to the Registrant or its stockholders; (3) for acts or omissions not in good faith or involving intentional misconduct or knowing violations of law; or (4) for any transaction from which the director derived an improper personal benefit.

Section 145 of the Delaware General Corporation Law grants to each corporation organized thereunder the power to indemnify its officers and directors for certain acts. Article NINTH of the Registrant s By-laws sets forth the extent to which officers and directors of the Registrant may be indemnified against any liabilities which they may incur in their capacities as directors or officers of the Registrant. Article NINTH provides, in part, that each person who was or is made a party or is threatened to be made a party or is involved in any action, suit or proceeding by reason of the fact that he or she is or was a director or officer of the Registrant or is or was serving at the request of the Registrant as a director, officer, employee or agent of another corporation, limited liability company, partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan, shall be indemnified and held harmless by the Registrant, to the fullest extent authorized by the Delaware General Corporation Law and any other applicable laws, against all expense, liability and loss (including attorneys fees, judgments, fines, ERISA excise taxes or penalties and amounts paid or to be paid in settlement) reasonably incurred or suffered by such person in connection with such proceeding; provided, however, that if the person seeking indemnification initiated the proceeding in respect to which he or she is seeking indemnification from the Registrant, the Registrant shall provide such indemnification only if such proceeding was authorized by the Registrant s Board of Directors.

The Registrant has, and intends in the future to enter into, agreements to provide indemnification for directors and officers in addition to that contained in the Restated Certificate of Incorporation and By-laws. The indemnification agreements require the Registrant, among other things, to indemnify officers and directors against liabilities that may arise by reason of their status or service as officers, directors, employees, trustees, partners, agents or fiduciaries of the Registrant (but not for liabilities arising from conduct entered into in bad faith or conduct which the officer or director did not reasonably believe to be in the best interest of the Registrant), and to advance sums covering the expenses they incurred as a result of any proceeding against them with respect to which they are indemnified under such indemnification agreement.

Item 7. **Exemption from Registration Claimed.** Not applicable.

Item 8. **Exhibits.**

Exhibit Number	
5.1	Opinion of Joseph B. Phair, Esq., Corporate Vice President, Administration and General Counsel to Registrant.
23.1	Consent of Joseph B. Phair, Esq., Corporate Vice President, Administration and General Counsel to Registrant (included in Exhibit 5.1).
23.2	Consent of Independent Registered Public Accounting Firm.
24.1	Powers of Attorney.

Item 9. **Undertakings.**

(a) The Registrant hereby undertakes:

(1) to file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) to include therein any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) to reflect in such prospectus any facts or events arising after the effective date of this Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth herein; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in this Registration Statement or any material change to such information in this Registration Statement;

provided, however, that clauses (a)(1)(i) and (a)(1)(ii) do not apply if the information required to be included in a post-effective amendment by those clauses is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to section 13 or section 15(d) of the Exchange Act that are incorporated by reference into this Registration Statement;

(2) that, for purposes of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof; and

(3) to remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the 2005 Omnibus Stock Plan.

(b) The Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Registrant s annual report pursuant to section 13(a) or section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan s annual report pursuant to section 15(d) of the Exchange Act) that is incorporated by reference into this Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as the indemnification for liabilities arising under the Securities Act may be permitted for directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the

Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in a successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, the Registrant will, unless in the opinion of its counsel the question has already been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant, a corporation organized and existing under the laws of the State of Delaware, certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Palo Alto, State of California, on this 1st day of April, 2005.

VARIAN MEDICAL SYSTEMS, INC.

By: /s/ Joseph B. Phair
Joseph B. Phair
Corporate Vice President, Administration
and General Counsel

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	**Title**	**Date**
/s/ Richard M. Levy Richard M. Levy	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)	April 1, 2005
/s/ Elisha W. Finney Elisha W. Finney	Corporate Senior Vice President and Chief Financial Officer (Principal Financial Officer)	April 1, 2005
/s/ Crisanto C. Raimundo Crisanto C. Raimundo	Corporate Vice President and Corporate Controller (Principal Accounting Officer)	April 1, 2005
*Susan L. Bostrom	Director	April 1, 2005
*John Seely Brown	Director	April 1, 2005
*R. Andrew Eckert	Director	April 1, 2005
*Samuel Hellman	Director	April 1, 2005
*Allen S. Lichter	Director	April 1, 2005
*David W. Martin, Jr.	Director	April 1, 2005
*Ruediger Naumann-Etienne	Director	April 1, 2005

*By: /s/ Joseph B. Phair
Joseph B. Phair
Attorney-in-fact

EXHIBIT INDEX

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