Material Contracts

The Company’s material contracts are described in “Item 4. Information on the Company” under the heading “Strategic Alliances”.

Exchange Controls

The payment of any dividends to foreign shareholders must be effected through an authorized intermediary bank. All registered banks and credit establishments in the Republic of France are authorized intermediaries. Under current French exchange control regulations, there are no limitations on the amount of cash payments that may be remitted by Flamel to residents of the United States. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an authorized intermediary bank.

Taxation

French Taxation

The following is a description of the French tax consequences of owning and disposing of Flamel Ordinary Shares. This description may only be relevant to holders of Flamel Ordinary Shares who are not residents of France and do not hold their shares in connection with a permanent establishment or a fixed base in France through which the holders carry on a business or perform personal services.

This description may not address all aspects of French tax laws that may be relevant in light of the particular circumstances of individual holders of Flamel Ordinary Shares. It is based on the laws, conventions and treaties in force as of the date of this annual report, all of which are subject to change, possibly with retroactive effect, or different interpretations.

Holders of Flamel Ordinary Shares should consult their own tax advisors about the potential tax effects of owning or disposing of Ordinary Shares in any particular situation.

Taxation on Sale or Disposal of Flamel Ordinary Shares

Generally, a holder of Flamel Ordinary Shares will not be subject to any French income tax or capital gains tax when the holder sells or disposes of Flamel Ordinary Shares if both of the following apply:

- the holder is not a French resident for French tax purposes; and
- the holder has held not more than 25% of Flamel’s dividend rights, known as *droits aux benefices sociaux*, at any time during the preceding five years, either directly or indirectly.

If a double tax treaty between France and the country of residence of a holder of Flamel Ordinary Shares contains more favorable provisions, a holder may not be subject to any French income tax or capital gains tax when the holder sells or disposes of any Flamel Ordinary Shares, even if one or both of the above statements does not apply to the holder. Subject to various conditions, foreign states, international organizations and a number of foreign public bodies are not considered French residents for these purposes.

If a holder of Flamel Ordinary Shares transfers shares using a written agreement, that agreement must generally be registered. The holder will be required to pay a registration duty of 1% of either the purchase price or the market value of the Ordinary Shares transferred, whichever is higher. The maximum duty is #3.049 per transfer. However, if the agreement is executed outside France, the holder of Flamel Ordinary Shares will not be required to pay this duty.

Taxation of Dividends

Withholding Tax and Avoir Fiscal. In France, companies may only pay dividends out of income remaining after tax has been paid. When shareholders resident in France receive dividends from French companies, they are entitled to a tax credit, known as the *avoir fiscal*. The amount of the *avoir fiscal* is generally equal to:

- 50% of the dividend paid for shareholders who are individuals or corporate shareholders that benefit from the participation exemption regime defined in Articles 145 and 216 of the French Tax Code; or

- 15% of the dividend paid for shareholders who are not individuals.

Shareholders resident in France and entitled to the *avoir fiscal* at the rate of 15% may generally be entitled to an additional tax credit equal to 70% of any *prŠcompte* actually paid in cash by a company upon distribution of dividends paid out of specified profits. See “íThe *PrŠcompte*.”

Under French domestic law, shareholders who are not residents of France are not eligible for the *avoir fiscal* unless the double tax treaty between France and the country of residence of the shareholder provides for a transfer of the avoir fiscal.

French companies must generally deduct a 25% French withholding tax from dividends paid to non-residents. Under most tax treaties between France and other countries, the rate of this withholding tax may be reduced or eliminated in some circumstances. Generally, if dividends are subject to a French withholding tax, a holder who is a non-French resident is subsequently entitled to a tax credit in that holder’s country of residence for the amount of tax actually withheld.

The following countries, French overseas territories, known as *Territoires d’Outre-Mer*, and other territories have entered into income tax treaties with France that provide for the arrangements summarized below:

Australia	Germany	Luxembourg	Norway	United Kingdom
Austria	Ghana	Malaysia	Pakistan	United States
Belgium	Iceland	Mali	Senegal	Ukraine
Bolivia	India	Malta	Singapore	Venezuela
Brazil	Israel	Mauritius	South Korea	French Territoires

Burkina Faso	Italy	Mexico	Spain	d'Outre-Mer and Other
Cameroon	Ivory Coast	Namibia	Sweden	Mayotte
Canada	Japan	Netherlands	Switzerland	New Caledonia
Finland	Latvia	New Zealand	Togo	Saint-Pierre et Miquelon
Gabon	Lithuania	Niger	Turkey	

Under these treaties, a shareholder who fulfills specified conditions may generally apply to the French tax authorities for the following:

- lower rate of withholding tax, generally 15%; and
- refund of the *avoir fiscal*, after deduction of withholding tax payable on the *avoir fiscal*.

Except for the United States, none of the countries or territories listed above has a treaty granting benefits to holders of Flamel ADSs, as opposed to Ordinary Shares. Accordingly, this discussion of treaty benefits does not apply to Flamel ADS holders. If these arrangements apply to a shareholder, Flamel will withhold tax from the dividend at the lower rate, provided that the shareholder has established, before the date of payment of the dividend, that the shareholder is entitled to the lower rate and has complied with the filing formalities. Otherwise, Flamel must withhold tax at the full rate of 25%, and the shareholder may subsequently claim the excess tax paid.

German corporate shareholders and German investment funds, in receipt of French-source dividends, are no longer entitled to the *avoir fiscal* retroactively, as of January 1, 2001, provided they own less than 10% of the share capital of the corporation distributing dividends. German and French authorities are still carrying on discussions as to the suspension of the *avoir fiscal* for individual shareholders.

Some of the countries and territories listed above impose additional conditions for corporate entities wishing to receive the *avoir fiscal*. In other countries and territories, individual residents may receive the *avoir fiscal* but corporate entities may not.

The Précompte. A French company must pay an equalization tax known as the *précompte* to the French tax authorities if it distributes dividends which give rise to avoir fiscal and whenever dividends are distributed out of

- profits which have not been taxed at the ordinary corporate income tax rate; or
- profits which have been earned during a tax year closed more than five years before the distribution.

The amount of the *précompte* is 50% of the net dividends.

A shareholder that is not a French resident for French tax purposes may generally obtain a refund of the amount of any *précompte* Flamel actually pays in cash, net of applicable withholding tax, if the shareholder is entitled to the benefits of a tax treaty and the treaty does not provide for the transfer of the *avoir fiscal.*

Estate and Gift Tax

France imposes estate and gift tax where an individual or entity acquires real and personal property from a non-resident of France by way of inheritance or gift. France has entered into estate and gift tax treaties with a number of countries. Under these treaties, residents of those countries may be exempted from this tax or obtain a tax credit, assuming specified conditions are met. Holders of Flamel Ordinary Shares should consult their own tax advisors about whether French estate and gift tax will apply and whether they may claim an exemption or tax credit.

Wealth Tax

French individual residents are taxable on their worldwide assets. Non-resident individuals are taxable only on their assets which are located in France. However, financial investments made by non-resident individuals, other than in real property companies, are exempt from wealth tax under certain conditions.

If a double tax treaty between France and a holder’s country of residence contains more favorable provisions, the holder may not be subject to French wealth tax.

Taxation of U.S. Investors

On August 31, 1994, the United States and France signed a tax treaty, which generally became effective on December 30, 1995. The following is a general summary of the principal tax effects on holders of Flamel Shares for purposes of U.S. federal income tax and French tax, if all of the following five points apply:

- the holder owns, directly or indirectly, less than 10% of Flamel’s share capital;
- the holder is any one of (a), (b) or (c) below:

  (a) a citizen or resident of the United States for U.S. federal income tax purposes, or

  (b) a U.S. domestic corporation, or

  (c) otherwise subject to U.S. federal income taxation on a net income basis in respect of its Flamel Shares;
- the holder is entitled to the benefits of the U.S.-France tax treaty under the “limitations on benefits” article of that treaty;
- the holder holds Flamel Shares as capital assets; and
- the holder’s functional currency is the U.S. dollar.

For purposes of the U.S.-France tax treaty and U.S. federal income tax, holders of Flamel ADSs will be treated as holders of the Flamel Ordinary Shares which their Flamel ADSs represent.

Special rules may apply to United States expatriates, insurance companies, pass-through entities and investors in such entities, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, securities broker-dealers and persons holding their Flamel Shares as part of a conversion transaction, among others. Those special rules are not discussed in this annual report.

Holders of Flamel Shares should consult their own tax advisers as to the particular tax consequences to them of owning Flamel Shares, including their eligibility for the benefits of the U.S.-France tax treaty, the applicability and effect of state, local, foreign and other tax laws and possible changes in tax law.

Taxation of Dividends

Withholding Tax and Avoir Fiscal. Dividends paid to non-residents by French companies are subject to a 25% French withholding tax. Under the U.S.-France tax treaty, this withholding tax is reduced to 15% if a holder's ownership of Flamel Shares is not effectively connected with a permanent establishment or a fixed base that the holder has in France.

Specific provisions apply if the holder is considered an "eligible" U.S. holder of Flamel Shares. A holder is "eligible" if its ownership of Flamel Shares is not effectively connected with a permanent establishment or a fixed base that the holder has in France and any one of the following four points applies:

- the holder is an individual or other non-corporate holder that is a resident of the United States for purposes of the U.S.-France tax treaty;

- the holder is a U.S. corporation, other than a regulated investment company;

- the holder is a U.S. corporation which is a regulated investment company, provided that less than 20% of the holder's shares are beneficially owned by persons who are neither citizens nor residents of the United States; or

- the holder is a partnership or trust that is a resident of the United States for purposes of the U.S.-France tax treaty, but only to the extent that the holder's partners, beneficiaries or grantors would qualify as "eligible" under one of the first two points in this list.

If a holder is an "eligible" U.S. holder, dividends distributed by Flamel will be subject to a withholding tax at the reduced rate of 15%, provided that the holder has previously established that it is a resident of the United States under the U.S.-France tax treaty in accordance with the following procedures:

- The holder must complete French Treasury Form RF1 A EU-No. 5052 and send it to the paying establishment before the date of payment of the dividend. If the holder is not an individual, the holder must also send the paying establishment an affidavit attesting that the holder is the beneficial owner of all the rights attached to the full ownership of Flamel Shares, including, among other things, the dividend rights.

- If the holder cannot complete Form RF1 A EU-No. 5052 before the date of payment of the dividend, the holder may complete a simplified certificate and send it to the French tax authorities or the institution which holds the shares on his behalf. This certificate must state all of the following five points:

(a) the holder is a resident of the United States for purposes of the U.S.-France tax treaty;

(b) the holder's ownership of Flamel Shares is not effectively connected with a permanent establishment or a fixed base in France;

(c) the holder owns all the rights attached to the full ownership of Flamel Shares, including, among other things, the dividend rights;

(d) the holder fulfills all the requirements under the U.S.-France tax treaty to be entitled to the reduced rate of withholding tax and to be entitled to the transfer of the *avoir fiscal*; and

(e) the holder claims the reduced rate of withholding tax and payment of the *avoir fiscal*.

If a holder is not an "eligible" U.S. holder, or if the holder has not completed Form RF1 A EU-No. 5052 or the five-point certificate before the dividend payment date, Flamel will deduct French withholding tax at the rate of 25%. In that case, a holder may claim a refund of the excess withholding tax.

If a holder is an "eligible" U.S. holder, the holder may also claim the *avoir fiscal*, by completing Form RF1 A EU-No. 5052 and sending it to the paying establishment before December 31 of the year following the year during which the dividend is paid. The holder will be entitled to a payment equal to the *avoir fiscal*, less a 15% withholding tax on the *avoir fiscal*. As noted below, the holder will not receive this payment until after the close of the calendar year in which the dividend was paid. To receive the payment, the holder must submit a claim to the French tax authorities and attest that they are subject to U.S. federal income taxes on the payment of the avoir fiscal and the related dividend. For partnerships or trusts, the partners, beneficiaries or grantors must make the attestation.

Specified rules apply to the following:

- tax-exempt U.S. pension funds, which include the exempt pension funds established and managed in order to pay retirement benefits subject to the provisions of Section 401(a) of the Internal Revenue Code (qualified retirement plans), Section 403(b) of the U.S. Internal Revenue Code (tax deferred annuity contracts) or Section 457 of the U.S. Internal Revenue Code (deferred compensation plans); and

- various other tax-exempt entities, including specified state-owned institutions, not-for-profit organizations and individuals for dividends which they beneficially own and which are derived from an investment retirement account.

Entities in these two categories are eligible for the reduced withholding tax rate of 15% on dividends, subject to the same withholding tax filing requirements as "eligible" U.S. holders, except that they may have to supply additional documentation evidencing their entitlement to these benefits. These entities are not entitled to the full *avoir fiscal*. These entities may claim a partial avoir fiscal equal to 30/85 of the gross *avoir fiscal*, provided that they own, directly or indirectly, less than 10% of the company's capital and they satisfy the filing formalities contained in U.S. Internal Revenue Service regulations.

The *avoir fiscal* or partial *avoir fiscal* and any French withholding tax refund are generally expected to be paid within 12 months after the holder of Flamel Shares files Form RF1 A EU-No.

5052. However, they will not be paid before January 15 following the end of the calendar year in which the dividend is paid.

For U.S. federal income tax purposes, the gross amount of a dividend and any *avoir fiscal*, including any French withholding tax, will be included in each holder's gross income as dividend income when payment is received by them (or the custodian, if the holder owns Flamel ADSs), to the extent they are paid or deemed paid out of Flamel's current or accumulated earnings and profits as calculated for U.S. federal income tax purposes. Dividends paid by Flamel will not give rise to any dividends received deduction. They will generally constitute foreign source “passive” income for foreign tax credit purposes. For some recipients, they will constitute foreign source “financial services” income for foreign tax credit purposes.

Also for U.S. federal income tax purposes, the amount of any dividend paid in Euro or French francs, including any French withholding taxes, will be equal to the U.S. dollar value of the Euro or French francs on the date the dividend is included in income, regardless of whether the payment is in fact converted into U.S. dollars. A holder will generally be required to recognize U.S. source ordinary income or loss when the holder sells or disposes of the Euros or French francs. A holder may also be required to recognize foreign currency gain or loss if that holder receives a refund under the U.S.-France tax treaty of tax withheld in excess of the treaty rate. This foreign currency gain or loss will generally be U.S. source ordinary income or loss.

To the extent that any dividends paid exceed Flamel's current and accumulated earnings and profits as calculated for U.S. federal income tax purposes, the distribution will be treated as follows:

- First, as a tax-free return of capital, which will cause a reduction in the adjusted basis of a holder's Flamel Shares. This adjustment will increase the amount of gain, or decrease the amount of loss, which a holder will recognize if such holder later disposes of those Flamel Shares.

- Second, the balance of the dividend in excess of the adjusted basis will be taxed as capital gain recognized on a sale or exchange.

French withholding tax imposed on the dividends a holder receives and on any *avoir fiscal* at 15% under the U.S.-France tax treaty is treated as payment of a foreign income tax. A holder may take this amount as a credit against the holder's U.S. federal income tax liability, subject to various conditions and limitations, including minimum holding period requirements.

The Précompte. A French company must pay an equalization tax known as the précompte to the French tax authorities if it distributes dividends which give rise to *avoir fiscal* and whenever dividends are distributed out of:

- profits which have not been taxed at the ordinary corporate income tax rate; or

- profits which have been earned during a tax year closed more than five years before the distribution.

The amount of the précompte is 50% of the net dividends.

If a holder is not entitled to the full *avoir fiscal*, the holder may generally obtain a refund from the French tax authorities of any précompte paid by Flamel with respect to dividends distributed to them. Under the U.S.-France tax treaty, the amount of the précompte refunded to U.S. residents is reduced by the 15% withholding tax applicable to dividends and by the partial *avoir fiscal*, if any. A holder is entitled to a refund of any précompte which Flamel actually pays in cash, but not to any précompte which Flamel pays by off-setting French and/or foreign tax credits. To apply for a refund of the précompte, a holder should file French Treasury Form RF1 B EU-No. 5053 before December 31 of the year following the year in which the dividend was paid. The form and its instructions are available from the Internal Revenue Service in the United States or from the French Centre des Impots des Non-Residents whose address is 9, rue d’Uzes, 75094 Paris Cedex 2, France.

For U.S. federal income tax purposes, the amount of the précompte will be included in a holder’s gross income as dividend income in the year the holder receives it. It will generally constitute foreign source “passive” income for foreign tax credit purposes. For some recipients, it will constitute foreign source “financial services” income for foreign tax credit purposes. The amount of any précompte paid in Euro or French francs, including any French withholding taxes, will be equal to the U.S. dollar value of the Euro or French francs on the date the précompte is included in income, regardless of whether the payment is in fact converted into U.S. dollars. A holder will generally be required to recognize a U.S. source ordinary income or loss when the holder sells or disposes of the Euro or French francs.

Taxation of Capital Gains

If a holder is a resident of the United States for purposes of the U.S.-France tax treaty, the holder will not be subject to French tax on any capital gain if the holder sells or exchanges its Flamel Shares, unless the holder has a permanent establishment or fixed base in France and the Flamel Shares the holder sold or exchanged were part of the business property of that permanent establishment or fixed base. Special rules apply to individuals who are residents of more than one country.

In general, for U.S. federal income tax purposes, a holder will recognize capital gain or loss if the holder sells or exchanges its Flamel Shares in the same manner as the holder would if it were to sell or exchange any other shares held as capital assets. Any gain or loss will generally be U.S. source gain or loss. If a holder is an individual, any capital gain will generally be subject to U.S. federal income tax at preferential rates if the holder meets the minimum holding periods.

Flamel believes that it will not be treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for the current taxable year or for future taxable years. However, an actual determination of PFIC status is fundamentally factual in nature and cannot be made until the close of the applicable taxable year. Flamel will be a PFIC for any taxable year in which either:

- 75% or more of its gross income is passive income; or
- its assets which produce passive income or which are held for the production of passive income amount to at least 50% of the value of its total assets on average.

If Flamel were to become a PFIC, the tax applicable to distributions on its Shares and any gains a holder realizes when the holder disposes of its Shares may be less favorable to the holder. Each holder should consult its own tax advisors regarding the PFIC rules and their effect on the holder if they purchase Shares.

French Estate and Gift Taxes

Under “The Convention Between the United States of America and the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritance and Gifts of November 24, 1978”, if a holder transfers their Flamel Shares by gift, or if they are transferred by reason of the holder’s death, that transfer will only be subject to French gift or inheritance tax if one of the following applies:

- the holder is domiciled in France at the time of making the gift, or at the time of the holder’s death; or
- the holder used the Flamel Shares in conducting a business through a permanent establishment or fixed base in France, or the holder held the Flamel Shares for that use.

French Wealth Tax

The French wealth tax does not generally apply to Flamel Shares if the holder is a “resident” of the United States for purposes of the U.S.-France tax treaty.

United States Information Reporting and Backup Withholding

A holder may be required to report dividend payments and proceeds from the sale or disposal of such holder’s Flamel Shares to the Internal Revenue Service. U.S. federal backup withholding generally is a withholding tax imposed at the rate of 30% on some payments to persons that fail to furnish required information. Backup withholding will not apply to a holder who furnishes a correct taxpayer identification number or certificate of foreign status and makes any other required certification, or who is otherwise exempt from backup withholding. Any U.S. persons required to establish their exempt status generally must file Internal Revenue Service Form W-9, entitled Request for Taxpayer Identification Number and Certification. Finalized Treasury regulations, which are applicable to payments made after December 31, 2000, have generally expanded the circumstances under which information reporting and backup withholding may apply.

Amounts withheld as backup withholding may be credited against a holder’s U.S. federal income tax liability. A holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information.

Documents on Display

Flamel is subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and, in accordance with those requirements, files reports and other information with the U.S. Securities and Exchange Commission. The information filed with the Commission may be inspected and copied at the Commission’s Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549 Copies of the materials may be obtained from the Commission’s Public Reference Room in Washington, D.C. at prescribed rates. Certain of the reports that the Company files with the Commission may be available from time to time on the Company’s internet website, at www.flamel.com.