

Ownership of Shares by Non-European Union Persons

A 'declaration administrative' or administrative declaration is required in The Republic of France to be filed with the French Ministry of the Economy, Finance and the Budget at the time of the acquisition of a controlling interest in Flamel by any non-EU resident or group of non-EU residents acting in concert or by any EU resident controlled by a non-EU resident. With respect to the acquisition (by a EU resident or a non-EU resident) of a controlling interest in a company that could affect 'public health,' the administrative declaration is replaced by a procedure that requires prior declaration of the acquisition to the French Ministry of Economy, Finance and the Budget with the ability for such Ministry to oppose the investment during a one-month period. As it is a pharmaceutical company, the acquisition of a controlling interest in Flamel could be deemed to affect 'public health.'

Under existing administrative rulings, ownership of 20% or more of a listed company's share capital is regarded as a controlling interest, but a lower percentage may be held to be a controlling interest in certain circumstances (such as when the shareholder has the ability to elect members of the board of directors). No administrative declaration is required where an EU resident or group of EU residents acts in concert to acquire a controlling interest in Flamel provided that the acquiring party or parties satisfy the requirements of EU residency.

Under French law, there is no limitation on the right of non-resident or foreign shareholders to vote securities of a French company.

Material Contracts

The Company has no material contracts on file with the SEC.

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, including the effect of any state, local or other national laws.

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 as French residents for these purposes.

Transfers of a listed company's shares will not be subject to French registration or transfer taxes, unless the transfer is effected by means of a written agreement that is executed within France. Should such written agreement be executed within France, a registration duty of 1.10% (rate applicable as from January 1, 2006) levied on the higher of either the purchase price or the market value of the transferred shares would be due, with a maximum duty of €4,000 per transaction.

Taxation of Dividends

Withholding Tax. In France, companies may only pay dividends out of income remaining after tax has been paid.

Under prior law and for information purposes only, the French tax system allowed a form of tax credit, known as the *avoir fiscal* to individuals and some entities receiving dividend distributions from a French corporation.

Pursuant to the French Finance act for 2004, French resident individuals no longer benefit from the *avoir fiscal* with respect to dividends paid after December 31, 2004. Instead, they are entitled to a 40% rebate of their tax basis as well as to a new tax credit (*credit d'impôt*) equal to 50% of the dividend, but with an overall annual cap of €230 or, as the case may be, €115 depending on the marital status of the individual.

French companies must, in principle, 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.

However, France has entered into tax treaties with various countries under which qualifying residents are entitled to obtain from the French tax authorities a reduction (generally to 15% or 5%) or an elimination of the French withholding tax.

According to the French tax guidelines, non-French resident individual shareholders who are currently benefiting from a treaty providing for the transfer of the abolished *avoir fiscal* will benefit from the *credit d'impôt* of 50% of the distributed amount capped at €230 or €115 depending on the marital status of this taxpayer in respect of dividends paid as from January 1, 2005.

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 transfer of the *crédit d'impôt* (referred to in the tax treaties as *avoir fiscal*):

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	
Burkina Faso	Italy	Mexico	Spain	
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	

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.

Estate and Gift Tax

France imposes estate and gift tax on shares of a French company that are acquired by inheritance or gift, this tax applying without regards to the residence of the transferor. However, France has entered into estate and gift tax treaties with a number of countries pursuant to which, provided that certain conditions are met, residents of the treaty country may be exempt from such tax or obtain a tax credit.

Non-residents should consult their own tax advisors whether French estate and gift tax would apply to them and whether they might be able to claim an exemption or tax credit pursuant to an applicable tax treaty.

Wealth Tax

French individual residents are taxable on their worldwide assets. Non-resident individuals may be subject to French wealth tax (*impôt de solidarité sur la fortune*) only on their assets which are located in France. However, financial investments made by non-resident individuals, other than in real estate companies, are exempt from wealth taxes long as the individuals own less than 10% of the French company's capital stock, either directly or indirectly, provided that their shares do not enable them to exercise influence on the French company.

Even if these conditions are not satisfied, a non-French resident holder may be exempt from French wealth tax if such holder is entitled to more favourable provisions pursuant to double tax treaty between France and the holder's country of residence.

Taxation of U.S. Holders

The following is a summary of the principal U.S. federal income tax considerations that are likely to be material to the ownership and disposition of Flamel Ordinary Shares or Flamel ADSs by a U.S. Holder. A "U.S. Holder" is a beneficial owner of the Flamel Ordinary Shares or Flamel ADSs who is (i) an individual citizen or resident of the United States; (ii) a corporation created or organized in the United States or under the laws of the United States or any political subdivision thereof; (iii) an estate whose income is includible in gross income for United States federal income tax purposes regardless of its source; or (iv) a trust whose administration is subject to the primary supervision of a United States court and over which one or more United States persons have the authority to control all substantial decisions of the trust. If an entity that is treated as a partnership for United States federal income tax purposes holds Flamel Ordinary Shares or Flamel ADSs, the tax treatment of a partner of such partnership will generally depend on the status of the partner and upon the activities and organization of the partnership. If you are a partner of such a partnership you are urged to consult your tax advisor. This discussion does not apply to a U.S. Holder who is also a resident of France for French tax purposes.

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 U.S. Holders for purposes of U.S. federal income tax and French tax, if all of the following five points apply:

- the U.S. Holder owns, directly or indirectly, less than 10% of Flamel's share capital;

- the U.S. Holder is entitled to the benefits of the U.S.-France tax treaty under the 'limitations on benefits' article of that treaty;
- the U.S. Holder holds Flamel Shares as capital assets; and
- the U.S. 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 who own 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 Ordinary Shares or Flamel ADSs 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 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 U.S. Holder's ownership of Flamel Shares is not effectively connected with a permanent establishment or a fixed base that the U.S. Holder has in France.

Dividends paid to a U.S. Holder by French companies are immediately subject to a reduced rate of 15%, provided that such U.S. Holder establishes before the date of payment that he is a U.S. resident under the Treaty by completing and providing the depositary with a simplified certificate (the "Certificate") in accordance with the French tax guidelines (4 J-1-05 released on February 25, 2005) with the "Certificate". Dividends paid to a U.S. Holder that has not filed the Certificate before the dividend payment date will be subject to French withholding tax at the rate of 25% and then reduced at a later date to 15%, provided that such U.S. Holder duly completes and provides the French tax authorities with the relevant form described in the tax guidelines mentioned above (the "Form") before December 31 of the second calendar year following the year during which the dividend is paid. U.S. Pension Funds and other Tax-Exempt Entities are subject to the same general filing requirements as the U.S. Holders except that they may have supply additional documentation evidencing their entitlement to these benefits.

The Certificate and the Form, together with instructions, will be provided by the depositary to all U.S. Holders registered with the depositary and is also available from the U.S. Internal Revenue Service. The depositary will arrange for the filing with the French Tax authorities of all certificates properly completed and executed by U.S. Holders of Shares and returned to the depositary in sufficient time that they may be filed with French Tax authorities before the distribution so as to obtain an immediate reduced withholding tax rate.

U.S. Holders may also claim the *credit d'impôt* of 50% of the distributed amount capped at €230 or €115 depending on the marital status of this taxpayer, after application of the 15% withholding tax. This specific provision applies to any of the following U.S. Holders (if the ownership of Flamel Shares is not effectively connected with a permanent establishment or a fixed base that the U.S. Holder has in France):

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

- the U.S. Holder is a U.S. corporation which is a regulated investment company, provided that less than 20% of the U.S. Holder's shares are beneficially owned by persons who are neither citizens nor residents of the United States; or
- the U.S. 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 U.S. Holder's partners, beneficiaries or grantors would qualify as 'eligible' under one of the first two points in this list.

For U.S. federal income tax purposes, the gross amount of a dividend and any *crédit d'impôt* (referred to in the U.S.-France tax treaty as *avoir fiscal*), including any French withholding tax, will be included in each U.S. Holder's gross income as dividend income when payment is received by them (or the custodian, if the U.S. 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.

Under current guidance by the U.S. Internal Revenue Service, amounts distributed as dividends by Flamel with respect to Flamel Shares or ADSs will constitute "qualified dividend income" and will be subject to a U.S. Federal income tax at the same preferential rates as long-term capital gains, provided that certain holding period and other requirements are met and Flamel is not treated as a PFIC (as defined below under "Taxation of Capital Gains").

Also for U.S. federal income tax purposes, the amount of any dividend paid in Euros, including any French withholding taxes, will be equal to the U.S. dollar value of the Euro on the date the dividend is included in income, regardless of whether the payment is in fact converted into U.S. dollars. A U.S. Holder will generally be required to recognize U.S. source ordinary income or loss when the U.S. Holder sells or disposes of the Euros. A U.S. Holder may also be required to recognize foreign currency gain or loss if that U.S. 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 U.S. Holder's Flamel Shares. This adjustment will increase the amount of gain, or decrease the amount of loss, which a U.S. Holder will recognize if such U.S. 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 U.S. Holder receives and on any *crédit d'impôt* (referred to in the U.S.-France tax treaty as *avoir fiscal*) at 15% under the U.S.-France tax treaty is treated as payment of a foreign income tax. A U.S. Holder may take this amount as a credit or deduction against the U.S. Holder's U.S. federal income tax liability. The foreign tax credit is subject to various conditions and limitations, including minimum holding period requirements.

Taxation of Capital Gains

A U.S. Holder who is a resident of the United States for purposes of the U.S.-France tax treaty will not be subject to French tax on any capital gain if such U.S. Holder sells or exchanges its Flamel Shares, unless the U.S. Holder has a permanent establishment or fixed base in France and the Flamel Shares the U.S. 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 U.S. Holder will recognize capital gain or loss if the U.S. Holder sells or exchanges its Flamel Ordinary Shares or ADSs. Any such gain or loss will generally be U.S. source gain or loss. If a U.S. Holder is an individual, any capital gain will generally be subject to U.S. federal income tax at preferential rates if the U.S. 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 factual 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 Flamel Ordinary Shares and ADSs, and any gains a U.S. Holder realizes when the U.S. Holder disposes of such Flamel Ordinary Shares or ADSs, may be less favorable to the U.S. Holder. Each U.S. Holder should consult its own tax advisors regarding the PFIC rules and their effect on the U.S. Holder if they purchase Flamel Ordinary Shares or ADSs.

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 U.S. Holder transfers their Flamel Shares by gift, or if they are transferred by reason of the U.S. Holder's death, that transfer will only be subject to French gift or inheritance tax if one of the following applies:

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

French Wealth Tax

The French wealth tax does not generally apply to Flamel Shares if the U.S. Holder is a 'resident' of the United States for purposes of the U.S.-France tax treaty. It will be the case if the Flamel U.S. Holder does not own a substantial interest (*participation substantielle*). Pursuant to article 23 §2 of the tax treaty, "an individual is considered to have a substantial interest if he or she owns, alone or with related persons, directly or indirectly, shares, rights, or interests the total of which gives right to at least 25% of the corporate earnings".

United States Information Reporting and Backup Withholding

A U.S. Holder may be required to report dividend payments and proceeds from the sale or disposal of such U.S. Holder's Flamel Shares to the Internal Revenue Service. U.S. federal backup withholding generally is a withholding tax imposed at current rate of 28% on some payments to persons that fail to furnish required information. Backup withholding will not apply to a U.S. 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.