## Up to 3,300,000 Ordinary Shares



## FLAMEL TECHNOLOGIES, S.A.

#### Ordinary Shares in the Form of American Depositary Shares

The selling shareholder identified in this prospectus may offer and sell from time to time an aggregate of up to 3,300,000 ordinary shares of Flamel Technologies, S.A. represented by American Depositary Shares, or ADSs, that are issuable upon the exercise of certain warrants, or the Warrants. Each ADS represents one ordinary share or the right to receive one ordinary share. The Warrants were issued to the selling shareholder in connection with our acquisition of Éclat Pharmaceuticals, LLC in March 2012.

We are not offering any ordinary shares for sale under this prospectus and will not receive any of the proceeds of the sale or other disposition of the ordinary shares covered by this registration statement. However, we will receive the exercise price of any Warrants exercised for cash. To the extent that we receive cash upon the exercise of any Warrants, we expect to use that cash for working capital and general corporate purposes.

The selling shareholder identified in this prospectus, or its permitted pledgees, donees, transferees, or other successors-in-interest may, from time to time, sell, transfer, or otherwise dispose of any or all of their ordinary shares on any stock exchange, market, or trading facility on which the ordinary shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. See "Plan of Distribution" for additional information.

Each ordinary share of Flamel, approximately € 0.122 nominal value, referred to as ordinary shares, will be represented by one ADS. The ADSs are quoted under the symbol "FLML" on the NASDAQ Global Market. On September 17, 2012, the last reported sale price for our ADSs on the NASDAQ Global Market was \$4.48 per ADS.

We will pay the expenses related to the registration of the ordinary shares covered by this prospectus. The selling shareholder will pay any commissions and selling expenses they may incur.

Investing in the ADSs involves risks that are described in the "Risk Factors" section beginning on page 4 of this prospectus.

The date of this prospectus is October 1, 2012

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

# TABLE OF CONTENTS

	Page
About this Prospectus	2
Prospectus Summary	3
Risk Factors	4
Forward Looking Statements	5
<u>Use of Proceeds</u>	7
Where You Can Find More Information	7
<u>Incorporation by Reference</u>	7
Currency and Exchange Rates	8
Capitalization and Indebtedness	9
The Offer and Listing	10
<u>Plan of Distribution</u>	11
Selling Shareholder	13
Description of Share Capital	14
<u>Description of American Depositary Shares</u>	21
<u>Expenses</u>	28
<u>Legal Matters</u>	28
Experts	28
Enforcement of Civil Liabilities	29
Disclosure of Commission Position on Indemnification for Securities Act Liabilities	29

1

## **ABOUT THIS PROSPECTUS**

In this prospectus, "Flamel," "the Company," "we," "us" and "our" refer to Flamel Technologies, S.A., "\$", "dollar" and "US dollar" refer to the lawful currency of the United States, and "euro" or "€" refers to the currency established for participating member states of the European Union as of the beginning of stage three of the European Monetary Union.

You should rely only on the information contained or incorporated by reference in this prospectus and any prospectus supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus, any prospectus supplement, and the documents incorporated by reference is accurate only as of its respective date. Our business, financial condition, results of operations and prospects may have changed since those dates.

We may add, update, or change in a prospectus supplement any of the information contained in this prospectus or in documents we have incorporated by reference into this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in a prospectus supplement.

You should carefully read this prospectus and any prospectus supplement, together with additional information referenced under the headings "Where You Can Find More Information," "Incorporation By Reference" and "Risk Factors" before you invest in our securities.

This prospectus and any prospectus supplement are not being distributed in the context of a public offer in France within the meaning of Article L. 411-1 of the French Monetary and Financial Code (*Code monétaire et financier*), and thus this prospectus and any prospectus supplement have not been and will not be submitted to the *Autorité des Marchés Financiers* for approval in France.

The prospectus and any prospectus supplement are not to be further distributed or reproduced (in whole or in part) in France by the recipients thereof, and this prospectus and any prospectus supplement have been distributed on the understanding that such recipients will only participate in the issue or sale of the ADSs for their own account and undertake not to transfer, directly or indirectly, the ADSs to the public in France, other than in compliance with all applicable laws and regulations and in particular with Articles L. 411-1 *et seq.* of the French Monetary and Financial Code (*Code monétaire et financier*).

## PROSPECTUS SUMMARY

This summary highlights information contained or incorporated by reference in this prospectus. It may not include all the information that is important to you. You should read the entire prospectus, any prospectus supplement delivered with the prospectus, and the documents incorporated by reference before making an investment decision.

## The Company

Flamel is a specialty pharmaceutical company focused on blending internally developed products with our drug delivery capabilities, frequently licensed to other pharmaceutical partners. Flamel's business is principally based on our legacy platform, including our drug delivery technologies and internal research and development, and a pipeline of niche specialty pharmaceutical products obtained through the acquisition of Éclat Pharmaceuticals, LLC, or Éclat, in March 2012. Our drug delivery platforms are focused on developing safer, more efficacious formulations of drugs that address unmet medical needs. The drug delivery technology business is built primarily on two technologies—the Medusa® and Micropump® proprietary platforms. The Medusa® drug delivery platform consists of proprietary hydrogels for the formulation and/or the extended release of a broad range of biologics (including proteins, antibodies, peptides and vaccines) and of small molecules (injectable drugs). Several Medusa-based products are at various clinical stages of development, including lead internal product candidate IFN-alpha XL (long-acting interferon alpha-2b) that is being evaluated in a Phase 2a trial in HCV patients. The Micropump® micro-encapsulation drug delivery platform (oral drugs) is designed to increase the absorption time of drugs, particularly for drugs only absorbed in the small intestine. We have developed approved products and manufacture Micropump-based microparticles under FDA-audited GMP guidelines. In addition to continuing Flamel's historical development and licensing efforts, our business strategy is focused on opportunities to blend internally developed products with these technologies.

Éclat was focused on developing and commercializing niche brands and generic products and, at the time of the acquisition, had one FDA-approved product on the market in the U.S., Hycet® (hydrocodone acetaminophen oral solution), as well as a portfolio of products in various stages of development. Flamel currently expects to submit a New Drug Application, or NDA, with the FDA in 2012.

Our principal executive offices are located at 33 Avenue du Docteur Georges Levy, 69693 Vénissieux Cedex, France, and our telephone number is 011 (33) 4 72 78 34 34.

#### The Securities the Selling Shareholder May Offer

This prospectus relates to the resale by the selling shareholder of up to an aggregate of 3,300,000 of our ordinary shares, in the form of ADSs, issuable upon the exercise of Warrants issued to the selling shareholder in connection with our acquisition of Éclat in March 2012. Each ADS represents one Ordinary Share or the right to receive one Ordinary Share. The ADSs are issued under a Deposit Agreement, dated as of June 6, 1996, as amended and restated as of August 10, 2001 (the "Deposit Agreement"), among Flamel, The Bank of New York Mellon, as depositary, (the "Depositary"), and holders of ADSs issued thereunder from time to time.

One Warrant is exercisable for 2,200,000 ADSs at an exercise price of \$7.44 per ADS. The second Warrant is exercisable for 1,100,000 shares at an exercise price of \$11.00 per ADS. The Warrants were approved by our shareholders at our annual shareholders meeting held on June 22, 2012. For the purposes of issuing the Ordinary Shares underlying the ADSs upon exercise of the Warrants, the Company's shareholders decided to issue Éclat Holdings 3,300,000 'bons de souscription d'actions' to be exercised immediately upon exercise of the Warrants. Both Warrants expire at 5:00 p.m., New York City time on March 13, 2018. This description is supplemented and qualified by the description of the Warrants in our Annual Report on Form 20-F for the year ended December 31, 2011, our Report of a Foreign Private Issuer on Form 6-K filed March 21, 2012 and the text of the Warrants filed as exhibits therewith.

## Listing

The ADSs are currently traded on the NASDAQ Global Market under the symbol "FLML."

## RISK FACTORS

Investing in the ADSs involves a high degree of risk. Before making an investment decision, you should carefully consider the risk factors set forth in this prospectus, together with all of the other information contained or incorporated by reference into this prospectus as well as the risks, uncertainties, and assumptions discussed under "Item 3. Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2011, which are incorporated herein by reference. These risk factors may be amended, supplemented, or superseded from time to time by future reports that we file with the Securities and Exchange Commission, or SEC, which are incorporated by reference into this prospectus. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations.

A large number of ordinary shares may be issued and subsequently sold in the form of ADSs upon the exercise of the Warrants. The sale or availability for sale of these ADSs may depress the price of the ADSs.

Up to 3,300,000 ordinary shares represented by ADSs are issuable upon the exercise of the Warrants. To the extent that holders of our outstanding Warrants sell the ADSs issued upon the exercise of the Warrants, the market price of our ADSs may decrease due to the additional selling pressure in the market. The risk of dilution from issuances of ordinary shares underlying the Warrants may cause shareholders to sell their ADSs, which could further contribute to any decline in the market price of our ADSs.

The sale of ADSs issued upon exercise of the Warrants could encourage short sales by third parties, which could further depress the price of the ADSs.

Any downward pressure on the price of the ADSs caused by the sale of ADSs issued upon the exercise of the Warrants could encourage short sales by third parties. In a short sale, a prospective seller borrows shares from a shareholder or broker and sells the borrowed shares. The prospective seller hopes that the share price will decline, at which time the seller can purchase shares at a lower price for delivery back to the lender. The seller profits when the share price declines because it is purchasing shares at a price lower than the sale price of the borrowed shares. Such sales could place downward pressure on the price of the ADSs by increasing the number of ADSs being sold, which could further contribute to any decline in the market price of the ADSs.

In the event of certain registration failures, we may have to pay liquidated damages to the Warrant holders, which would increase our expenses and reduce our cash resources.

Under the terms of the Warrants and the registration rights agreement that we entered into with the selling shareholder, subject to certain limited exceptions, in the event of certain "Registration Failures" identified in such agreements, we may be required to pay the Warrant holders, as liquidated damages and not as a penalty, certain "Failure Payments" (as defined in the Warrants). The "Registration Failures" include, without limitation, failure to file the registration statement with the SEC before certain filing deadlines, failure to use commercially reasonable efforts to obtain effectiveness of the registration statement from the SEC within certain time periods and to maintain effectiveness of the registration statement throughout the applicable registration period, failure to amend the registration statement if required within certain time periods, or failure to respond to comments from the SEC within certain time periods. The Failure Payments are payable, at the Company's option either in cash or in ADSs, in each case equal to 18% per annum (or the maximum rate permitted by applicable law, whichever is less), of the Black-Scholes value of the remaining unexercised portion of the Warrants for the period during which such failure continues. There can be no assurance that such registration failures may not occur. Any payment of liquidated damages would increase our expenses, reduce our cash resources and may limit or preclude us from advancing our product candidates through clinical trials or otherwise growing our business.

## FORWARD LOOKING STATEMENTS

This prospectus, any prospectus supplement, and the documents incorporated herein by reference, contain forward-looking statements. We may make additional written or oral forward-looking statements from time to time in filings with the SEC or otherwise. The words "will," "may," "believe," "expect," "anticipate," "estimate," "project," and similar expressions identify forward-looking statements, which speak only as of the date the statement is made. Such forward-looking statements are within the meaning of that term in Section 27A of the Securities Act of 1933 and Section 21E of the Exchange Act. Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks that may be beyond our control, and there can be no assurance that actual results of our development and manufacturing activities and our results of operations will not differ materially from our expectations.

Factors that could cause actual results to differ from expectations include, among others, those identified in "Risk Factors" in this prospectus and those in our Annual Report on Form 20-F for the year ended December 31, 2011, which are incorporated by reference into this prospectus, as well as the information contained in our other public filings with the SEC. Some of these risks are highlighted below:

- · we depend on a few customers for the majority of our revenues, and the loss of any one of these customers could reduce our revenues significantly.
- · our revenues from our drug delivery technology business depend on pharmaceutical and biotechnology companies successfully developing products that incorporate our drug delivery technologies.
- although products that incorporate our drug delivery technologies and development products acquired from Éclat may appear promising at their early stages of development and in clinical trials, none of these potential products may reach the commercial market for a number of reasons.
- · we must invest substantial sums in research and development in order to remain competitive, and we may not fully recover these investments.
- · we must comply with various covenants and obligations under the note agreement with Éclat Holdings, and our failure to do so could adversely affect our ability to operate our business, develop our product portfolio or pursue certain opportunities.
- · management transition to a new Chief Executive Officer may be disruptive to our business and personnel.
- · we depend upon a single site to manufacture our drug delivery products, and any interruption of operations could have a material adverse effect on our business...
- we depend upon a limited number of suppliers for certain raw materials used in our products, and any failure to deliver sufficient supplies could interrupt our production process and could have a material adverse effect on our business.
- if our competitors develop and market technologies or products that are more effective than ours, or obtain regulatory approval and market such technology or products before we do, our commercial opportunity will be diminished or eliminated.
- if we cannot keep pace with the rapid technological change in our industry, we may lose business, and our drug delivery systems could become obsolete or noncompetitive.
- · if we cannot adequately protect our technology and proprietary information, we may be unable to sustain a competitive advantage.
- · even if we and our partners obtain necessary regulatory approvals, our products and technologies may not gain market acceptance.

- · our collaborative arrangements may give rise to disputes over commercial terms, contract interpretation and ownership of our intellectual property and may adversely affect the commercial success of our products.
- third parties have claimed, and may claim in the future, that our technologies, or the products in which they are used, infringe on their rights and we may incur significant costs resolving these claims.
- · we can offer no assurance that any patents issued to us will provide us with competitive advantages or will not be infringed, challenged, invalidated or circumvented by others, or that the patents or proprietary rights of others will not have an adverse effect on our ability to do business.
- · if our third party collaborative partners face generic competition for their products, our revenues and royalties from such products may be adversely affected.
- · healthcare reform and restrictions on reimbursements may limit our financial returns.
- · fluctuations in foreign currency exchange rates and the impact of the European sovereign debt crisis may clause fluctuations in our financial results.
- products that incorporate our drug delivery technologies and development products acquired from Éclat are subject to regulatory approval. If our pharmaceutical and biotechnology company partners do not obtain such approvals, or if such approvals are delayed, our revenues may be adversely affected.
- · we are subject to federal and state laws prohibiting "kickbacks" and false claims that, if violated, could subject us to substantial penalties, and any challenges to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.
- · companies to which we have licensed our technology are subject to extensive regulation by the FDA and other regulatory authorities. Their failure to meet strict regulatory requirements could adversely affect our business.
- · we may face product liability claims related to participation in clinical trials or the use or misuse of our products or third party products that incorporate our technologies.
- · if we use biological and hazardous materials in a manner that causes injury, we may be liable for significant damages.
- · we may fail to realize the anticipated benefits expected from the acquisition of Éclat and its portfolio of pipeline products.
- · if we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or to successfully integrate them in a cost effective and non-disruptive manner.
- · our share price has been volatile and may continue to be volatile.
- because we have had limited commercial sales, investors in our shares may have difficulty evaluating our prospects.
- · if we are not profitable in the future, the value of our shares may fall.
- our operating results may fluctuate, which may adversely affect our share price.
- · we currently do not intend to pay dividends, and cannot assure shareholders that we will make dividend payments in the future.
- · our largest shareholders own a significant percentage of the share capital and voting rights of the Company.

Forward-looking statements are subject to inherent risks and uncertainties, some of which cannot be predicted or quantified. Future events and actual results could differ materially from those set forth in, contemplated by or underlying the forward-looking statements. We undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise. You should not place undue reliance on these forward-looking statements.

## **USE OF PROCEEDS**

We will not receive any of the proceeds from the sale or other disposition of the ordinary shares represented by ADSs offered hereby, but we will receive the exercise price of any Warrants exercised for cash. To the extent that we receive cash upon the exercise of any of the Warrants, we intend to use that cash for general corporate purposes, including working capital. Under the terms of the Warrants, the Warrant holder may elect a cashless exercise of the Warrants in certain circumstances, including in the event of a Major Transaction (as defined in the Warrants) or in the event of a default under the Note Agreement among us, Flamel US Holdings, Inc. and Éclat Holdings, LLC.

## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly, and special reports and other information with the SEC under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). You may read and copy this registration statement and any other document we file at the SEC's Public Reference Room located at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. We file information electronically with the SEC. Our SEC filings are available from the SEC's Internet site at http://www.sec.gov, which contains reports and other information regarding issuers that file electronically. Additional information about Flamel may be obtained on our website at www.flamel.com. Flamel is not incorporating the contents of its or the SEC's websites or the website of any other person into this document.

You should rely only on the information that we provide or incorporate by reference in this prospectus. We have not authorized anyone to provide you with different information, and you should not assume that the information in this prospectus is accurate as of any date other than the date indicated in the relevant documents.

As a foreign private issuer, we and our shareholders are exempt from some SEC reporting requirements, including proxy solicitation rules, short-swing insider profit disclosure rules of Section 16 of the Exchange Act with respect to our Ordinary Shares, and the rules regarding the furnishing of quarterly reports, among others.

#### INCORPORATION BY REFERENCE

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

- · our Annual Report on Form 20-F for the fiscal year ended December 31, 2011;
- · our Reports of Foreign Private Issuer on Form 6-K pursuant to Rules 13a-16 and 15d-16 filed with the Commission on March 15, March 21, May 7, June 26, July 27 and September 13, 2012;
- · all documents we subsequently file under Sections 13(a), 13(c) or 15(d) of the Exchange Act after the date of this prospectus and before the termination of the offerings using this prospectus, including Annual Reports on Form 20-F, provided, that with respect to any Report of Foreign Private Issuer on Form 6-K, we will only incorporate these documents to the extent that any report is specifically designated as being incorporated by reference into this prospectus; and

Year Ended December 31,

the description of our Ordinary Shares, and the American Depositary Shares representing the Ordinary Shares, contained in our Registration Statement on Form F-1 filed on April 19, 1996, as amended, pursuant to the Securities Act.

All information appearing in this prospectus is qualified in its entirety by the information and financial statements, including the notes, contained in the documents that we incorporate by reference into this prospectus.

We will provide a copy of the documents we incorporate by reference, at no cost, to any person who receives this prospectus. To request a copy of any or all of these documents, you should write or telephone us at: Flamel Technologies, S.A., 33 Avenue du Docteur, Georges Levy, 69693 Venissieux Cedex, France, (202) 862-8400.

## **CURRENCY AND EXCHANGE RATES**

The following table sets forth the high, low and average exchange rates for the Euro against the U.S. dollar in each of the last five years and in each of the previous six months.

Euro to U.S. Dollar:	High	Low	Average Rate*
2011	1.4882	1.2889	1.3917
2010	1.4563	1.1942	1.3268
2009	1.512	1.2555	1.3933
2008	1.599	1.246	1.4706
2007	1.4874	1.2893	1.37064
Previous Six Months,			
Euro to U.S. Dollar:	High	Low	Average Rate*
A	1 2611	1 2245	1 2400

Euro to U.S. Dollar:	High	Low	Average Rate*
August 2012	1.2611	1.2245	1.2400
July 2012	1.2593	1.2089	1.2288
June 2012	1.2704	1.2322	1.2526
May 2012	1.3132	1.2403	1.2789
April 2012	1.3319	1.3024	1.3162
March 2012	1.3356	1.3057	1.3201

<sup>\*</sup> Annual totals represent the average of the noon buying rates for Euros of each business day during the relevant period, according to the 'Banque de France'. Monthly totals represent the average of the noon buying rates for Euros for each business day during the relevant month according to the 'Banque de France'.

The exchange rate for the Euro against the U.S. dollar as of September 7, 2012, was \$1.2706 to € 1.00. The Company makes no representation that Euro amounts have been, could have been or could be converted into U.S. dollars at any of the exchange rates referred to herein as of a given date.

Total Other Long-term Liabilities

## CAPITALIZATION AND INDEBTEDNESS

The following table sets forth our unaudited consolidated indebtedness and capitalization as of June 30, 2012 in accordance with U.S. GAAP:

June 30, 2012 \$ Actual\* (in thousands, **Unaudited**) Total long-term liabilities (1) 92,110 Shareholders' equity: Ordinary Shares; 34,012,490 authorized; 25,157,250 issued and outstanding 3,673 Additional paid-in capital 207,602 Accumulated deficit (195,298)Cumulative other comprehensive income (loss) 9,384 Total shareholders' equity 25,361 **Total Capitalization** 117,471 (1) Long-term Liabilities: Long-term debt, less current portion (2) 47,840 Capital Lease obligations, less current portion 208 Deferred Revenue, less current portion 1,052 Deferred Tax Liabilities 20,733 Other Long-term Liabilities (3) 22,277 Total Long-term Liabilities 92,110 (2) Long-term debt, less current portion Fair Value of Acquisition Consideration 46,029 Government financing of R&D 1,811 Total long-term debt, less current portion 47,840 (3) Other Long-term Liabilities Funding from partner GSK long-term 6,351 Provision for retirement indemnity 1,878 R&D tax credit financing long-term 12,081 Employee service award provision long-term 1,941 Other 26

22,277

This table should be read in conjunction with the financial statements in our Annual Report on Form 20-F for the year ended December 31, 2011 and our Report of a Foreign Private Issuer on Form 6-K filed September 13, 2012, which are incorporated by reference into this prospectus.

<sup>\*</sup> This table does not reflect the issuance of the Ordinary Shares underlying the Warrants or the receipt of proceeds, if any, upon the exercise thereof.

## THE OFFER AND LISTING

The following table shows the high and low closing sales prices of the ADSs on the NASDAQ Global Market for the periods indicated.

	Price Per A	Price Per ADS (\$)		
Quarter Ended	High	Low		
1 <sup>st</sup> Quarter, 2010	9.60	7.52		
2 <sup>nd</sup> Quarter, 2010	9.06	6.52		
3 <sup>rd</sup> Quarter, 2010	8.00	6.02		
4 <sup>th</sup> Quarter, 2010	7.90	6.64		
1 <sup>st</sup> Quarter, 2011	6.97	5.82		
2 <sup>nd</sup> Quarter, 2011	6.63	5.02		
3 <sup>rd</sup> Quarter, 2011	5.44	3.85		
4 <sup>th</sup> Quarter, 2011	5.26	4.08		
1 <sup>st</sup> Quarter, 2012	7.67	5.11		
2 <sup>nd</sup> Quarter, 2012	5.65	4.05		
3 <sup>rd</sup> Ouarter 2012 through September 17, 2012	5.50	4.29		

	Price Per A	Price Per ADS (\$)	
Month Ended	High	Low	
February 29, 2012	6.96	6.27	
March 31, 2012	7.67	5.11	
April 30, 2012	5.65	4.74	
May 31, 2012	5.23	4.31	
June 30, 2012	4.55	4.05	
July 31, 2012	5.50	4.29	
August 31, 2012	5.06	4.69	

## PLAN OF DISTRIBUTION

We are registering the ordinary shares offered in this prospectus on behalf of the selling shareholder. A "selling shareholder", which term as used herein includes pledgees, donees, transferees or other successors-in-interest selling shares received from the selling shareholder as a gift, pledge, partnership distribution or transfer after the date of this prospectus, may, from time to time, sell, transfer or otherwise dispose of any or all of its ordinary shares or interests in ordinary shares on any stock exchange, market or trading facility on which the shares are traded or in private transactions. The selling shareholder will pay any brokerage commissions and similar selling expenses attributable to the sale of the shares. We will not receive any of the proceeds from the sale of the shares by the selling shareholder. However, upon a cash exercise of the Warrants by the selling shareholder, we will receive the exercise price per ordinary share exercised. If the Warrants are exercised in a cashless exercise, we will not receive any proceeds from the exercise of the Warrants.

These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. To the extent the selling shareholder gifts, pledges or otherwise transfers the shares offered hereby, such transferees may offer and sell the shares from time to time under this prospectus, provided that this prospectus has been amended under Rule 424(b)(3) or other applicable provision of the Securities Act to include the name of such transferee in the list of selling shareholder(s) under this prospectus.

The selling shareholder will act independently of us in making decisions with respect to the timing, manner and size of each sale. The selling shareholder may use any one or more of the following methods when disposing of shares or interests therein:

- · transactions on any national securities exchange or quotation service on which the shares may be listed or quoted at the time of sale;
- · transactions on the over-the-counter market;
- · transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- · ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- · purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- · an exchange distribution in accordance with the rules of the applicable exchange;
- · privately negotiated transactions;
- · short sales;
- · through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- · broker-dealers may agree with the selling shareholder to sell a specified number of such shares at a stipulated price per share;

- · a combination of any such methods of sale; and
- · any other method permitted pursuant to applicable law.

The selling shareholder may, from time to time, pledge or grant a security interest in some or all of the shares owned by it and, if it defaults in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling shareholders to include the pledgee, transferee or other successors in interest as selling shareholder under this prospectus.

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

The aggregate proceeds to the selling shareholder from the sale of the ordinary shares offered by it will be the purchase price of the common stock less discounts or commissions, if any. The selling shareholder reserves the right to accept and, together with its agents from time to time, to reject, in whole or in part, any proposed purchase of ordinary shares to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the Warrants by payment of cash, however, we will receive the exercise price of the Warrants.

To the extent required, the ordinary shares to be sold, the name(s) of the selling shareholder(s), the respective purchase prices and public offering prices, the names of any agent, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the ordinary shares may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the ordinary shares may not be sold unless they have been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling shareholder that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling shareholder and its affiliates. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling shareholder for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling shareholder may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling shareholder against liabilities, including liabilities under the Securities Act, and state securities laws, relating to the registration of the shares offered by this prospectus. We may be indemnified by the selling shareholder against civil liabilities, including liabilities under the Securities Act, arising from any written information furnished to us by the selling shareholder specifically for use in this prospectus, in accordance with the registration rights agreement, or we may be entitled to contribution.

We have agreed with the selling shareholder to keep the registration statement that includes this prospectus current and effective until the earlier of (1) the date on which all of the shares covered by this prospectus have been sold pursuant to and in accordance with the registration statement that contains this prospectus and (2) the date on which the shares may be sold without registration or restriction under the Securities Act.

The selling shareholder and any broker dealers that act in connection with the sale of the shares might be deemed to be "underwriters" as the term is defined in Section 2(11) of the Securities Act. Consequently, any commissions received by these broker dealers and any profit on the resale of the shares sold by them while acting as principals might be deemed to be underwriting discounts or commissions under the Securities Act. Because the selling shareholder may be deemed to be an "underwriter" as defined in Section 2(11) of the Securities Act, the selling shareholder may be subject to the prospectus delivery requirements of the Securities Act.

The selling shareholder also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that it meets the criteria and conforms to the requirements of that Rule.

#### SELLING SHAREHOLDER

The table below identifies the selling shareholder, Breaking Stick Holdings, LLC ("Breaking Stick"), with an address at c/o Deerfield Mgmt, L.P., 780 Third Avenue, 37th Floor, New York, New York 10017, and other information regarding the beneficial ownership of our securities by the selling shareholder. Prior to its acquisition by Flamel, Éclat Pharmaceuticals, LLC was owned by Éclat Holdings, LLC, (the former name of Breaking Stick), an affiliate of Deerfield Mgmt L.P. ("Deerfield Mgmt"). The manager of Breaking Stick is Deerfield Management Company, L.P. ("Deerfield Management"), an affiliate of Deerfield Mgmt. Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P., both affiliates of Deerfield Mgmt, are members of Breaking Stick. As of September 5, 2012, entities controlled by Deerfield Mgmt owned 4,333,475 shares, representing 17.23% of the total outstanding shares of the Company. Michael S. Anderson, Chief Executive Officer and a director of the Company, retains a minority interest in Breaking Stick and does not have the ability to control Breaking Stick by virtue of his minority interest.

The second column of the chart lists the number of our securities beneficially owned by the selling shareholder as of September 5, 2012, assuming full exercise of the Warrants, without regard to limitations on exercise. The third column lists the maximum number of ordinary shares that may be sold by the selling shareholder pursuant to this prospectus upon exercise of the Warrants. The fourth column assumes the sale of all of the securities offered by the selling shareholder pursuant to this prospectus. Under the terms of the Warrants, the selling shareholder may not exercise the Warrants to the extent that the exercise would result in the selling shareholder, together with its affiliates, and any other persons or entities whose beneficial ownership of Flamel's ordinary shares would be aggregated with those of the selling shareholder for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the applicable regulations of the SEC, beneficially owning more than 19.985% (or 9.985% at any time that the Company does not qualify as a "foreign private issuer" as defined under Rule 3b-4 under the Exchange Act of the total number of Flamel's Ordinary Shares then issued and outstanding. The selling shareholder may sell all, some or none of their ordinary shares registered pursuant to the registration statement of which this prospectus forms a part. See "Plan of Distribution".

If the selling shareholder identified below transfers some or all of its securities to a pledgee, donee, transferee or other successor-in-interest, we may be required to file a prospectus supplement or a post-effective amendment to the registration statement of which this prospectus is a part.

	Number of	Maximum Number of Ordinary	Number of	
	Ordinary Shares	Shares to be Sold Pursuant to	<b>Ordinary Shares</b>	
	Owned Prior to	this Prospectus Upon Exercise	Owned After	
Name of Selling Shareholder	Offering	of Warrants	Offering	
Breaking Stick Holdings, LLC (1)	3,300,000 (2)(3)	3,300,000	<u> </u>	1)

- (1) Deerfield Management is the manager of the selling shareholder. James E. Flynn has the power to exercise Deerfield Management's voting and dispositive power over the shares held by the selling shareholder. Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. are members of the selling shareholder. Deerfield Mgmt is the general partner of Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P.
- (2) Comprised of ordinary shares issuable upon exercise of the Warrants.
- (3) Under the terms of the Warrants held by the selling shareholder, the number of ordinary shares that may be acquired by the selling shareholder upon any exercise of the Warrants is generally limited to the extent necessary to ensure that, following such exercise, the total number of ordinary shares then owned by the selling shareholder, together with its affiliates and any others persons or entities whose beneficial ownership of ordinary shares would be aggregated with those of the selling shareholder for purposes of Section 13(d) of the Exchange Act and the applicable regulations of the SEC, would not exceed 19.985% of the total number of ordinary shares then issued and outstanding. The 19.985% limitation is disregarded for purposes of this table, and the numbers of ordinary shares beneficially owned do not reflect this limitation.
- (4) We do not know when or in what amounts the selling shareholder may offer shares for sale. The selling shareholder may choose not to sell any of the shares offered by this prospectus. This table assumes the sale by the selling shareholder of all of the shares available for resale under this prospectus.

#### DESCRIPTION OF SHARE CAPITAL

Set forth below is certain information concerning Flamel's share capital. Related summary information is provided in "Item 10 - Additional Information" of our Annual Report on Form 20-F for the year ended December 31, 2011, which is incorporated by reference into this prospectus.

## General

The share capital of Flamel consists of ordinary shares, nominal value 0.122 euros per share. Flamel has authorized 34,012,490 ordinary shares, 25,157,250 of which were issued and outstanding as of August 31, 2012. All of the shares, including the shares to be sold in this offering, are or will be fully paid.

Flamel does not hold any shares in its treasury.

#### **Capital Authorized but Unissued**

At the Combined Ordinary and Extraordinary Meeting of Shareholders of Flamel held on June 22, 2012, our shareholders authorized the Board of Directors to increase the share capital of the Company to, among other things, allocate stock options and free shares to employees and provide for sufficient share capital underlying the Warrants issued to the selling shareholder.

The following table shows all the current authorizations granted by the shareholders to the board of directors in respect of capital increases, and the usage made of these powers through August 31, 2012:

Maximum

Nature of Authorized Operation	Valid Through	Amount of Capital Increase (par value) (in euros)	Use of delegation since June 22, 2012	Balance
Authorization for the Issuance of 1,000,00 Stock Options	August 21, 2015	121,960	Yes	121,960
Authorization for the Issuance of 200,000 shares at no cost ('free shares')	August 21, 2015	24,392	No	24,392
Issuance of 2,200,000 stock warrants	March 13, 2018	268,312	No	268,312
Issuance of 1,100,000 stock warrants	March 13, 2018	134,156	No	134,156
Reconciliation of the Number of Shares Outstanding at the Beginning ar	nd End of the Year			
Number of Ordinary Shares as of the opening date of the fiscal year 2011				24,962,250
Issuance of Ordinary Shares on March 8, 2012				195,000
Number of Ordinary Shares as of August 31, 2012				25.157.250

## **Options Outstanding**

Stock options outstanding at June 30, 2012, which expire from 2012 to 2021, had exercise prices ranging from € 3.28 to 25.39. The weighted average remaining contractual life of all options is 4.86 years. As of June 30, 2012, there were 3,087,990 outstanding options at a weighted average exercise price of € 11.52, of which 2,250,490 were exercisable at a weighted average price of €14.07.

# **History of the Share Capital**

The table below shows the evolution of Flamel's share capital over the last three fiscal years through August 31, 2012:

Date	Operation	Number of Shares Issued/Warrants Subscribed	Par Value (0.122 euros nominal value per share issued)	Premium (in euros)	Value of Share Increase Capital (in euros)	Cumulative number of shares outstanding
April 2009	Exercise of employee stock options	20,000	2,439	19,301	21,740	24,225,350
July 2009	Subscription for Warrants by Directors	250,000	-	185,000	185,000	24,225,350
December 2009	Definitive acquisition of Free Shares	117,250	14,300			24,342,600
April 2010	Exercise of employee stock options	40,000	4,878	298,442	303,320	24,382,600
April 2010	Definitive acquisition of Free Shares	40,000	4,878	-	-	24,422,600
June 2010	Subscription for Warrants by Directors	250,000	-	175,000	175,000	24,422,600
November 2010	Exercise of employee stock options	3,000	366	2,904	3,270	24,425,600
December 2010	Definitive acquisition of Free Shares	200,050	24,398	-	-	24,625,650
December 2010	Exercise of employee stock options	20,000	2,439	53,161	55,600	24,645,650
July 2011	Subscription for Warrants by Directors	300,000	_	141,000	141,000	24,645,650
September 2011	Exercise of employee stock options	30,000	3,659	28,951	32,610	24,675,650
December 2011	Definitive acquisition of Free Shares	272,400	33,222	-	-	24,948,050
December 2011	Exercise of employee stock options	14,200	1,732	37,673	39,405	24,962,250
March 2012	Exercise of employee stock options	195,000	23,782	430,568	454,350	25,157,250
			16			

#### **Memorandum and Articles of Association**

In this section, we summarize material provisions of applicable French law and our *statuts*. This description is not complete and is qualified, in its entirety, by reference to our *statuts*, an English translation of which was filed as an exhibit to our Annual Report on Form 20-F for the year ended December 31, 2011, which is incorporated by reference into this prospectus. You may obtain copies of our *statuts* in French from the Registry of Commerce and Companies in Lyons, France, under registration number 379001530.

Flamel's corporate affairs are governed by our *statuts* and applicable laws and regulations (in particular, Chapter V of Title II of the Second Book of the French Commercial Code).

## **Corporate Purposes**

Article 3 of our *statuts* provides that the purposes of the Company, in France and abroad, are:

- design and realization of new materials for the chemical industry as well as other industries, in the fields of pharmacy, health, automotive, aerospace, telecommunications, turbines, and packing and conditioning, among others;
- · research and development of polymer and ceramic materials corresponding to identified needs;
- · filing, study, acquisition, operation and concession of patents, licenses, processes, trademarks and specialized knowledge related to the above mentioned technical fields;
- · production and sale of designed materials;
- · design, development, fabrication, distribution, import, export of medicines, pharmaceutical products and other health materials as well as the operation of pharmaceutical products, medicines and other health materials; and
- · more generally, any operations directly or indirectly related to the above.

#### **Board of Directors**

Transactions in which Directors are Materially Interested. Under French law, any agreement entered into (directly or through an intermediary) between Flamel and any one of the members of the Board of Directors that is not entered into (i) in the ordinary course of our business and (ii) under normal conditions is subject to the prior authorization of the disinterested members of the Board of Directors. The same provision applies to agreements between Flamel and another company if one of the members of the Board of Directors is the Chief Executive Officer (directeur général), one of his delegates (directeurs généraux délégués), or one of the members of the Board of Directors (administrateurs) of the Company is the owner, general partner (associé indéfiniment responsable), manager (gérant), member of the Board of Directors, member of the Supervisory Board (membre du Conseil de surveillance) or, more generally, manager (dirigeant) of the other company. The same provision also applies to agreements in which one of the members of the Board of Directors has an indirect interest.

Compensation. The aggregate amount of attendance fees (*jetons de présence*) of the Board of Directors is determined by the shareholders at an ordinary general meeting. The Board of Directors then divides this aggregate amount among its members by a simple majority vote. In addition, the Board of Directors may grant exceptional compensation (*rémunérations exceptionnelles*) to individual directors on a case-by-case basis for special assignments following the procedures described above at "— Transactions in which Directors are Materially Interested." The Board of Directors may also authorize the reimbursement of travel and accommodation expenses, as well as other expenses incurred by Directors in the corporate interest.

Borrowing Power. Under French corporate law, the CEO ("directeur général") has the power to represent the Company and execute any agreements on its behalf. The articles of association or decisions of the Board may limit this power by, for example, requiring prior authorization of the Board if borrowing exceeds a specified threshold. There are currently no limits imposed by the shareholders on the borrowing powers exercisable by the CEO ("directeur général"). However, there are limits on the Company's borrowing power under the Note Agreement executed in connection with the acquisition of Éclat.

Age Limits and Share Ownership Requirements. Flamel's statuts provide that at no time may the number of Directors over the age of 70 exceed one-third of the total number of Directors in office. The statuts also require that each member of the Board of Directors must own at least one share during the whole term of his or her office as a Director.

## Changes in Share Capital

Except as set forth below, the share capital of Flamel may be increased only with the approval of the shareholders at an extraordinary general meeting. Increases in share capital may be effected either by the issuance of additional shares, by an increase in the nominal value of existing shares or by the creation of a new class of shares. Additional shares may be issued for cash, in satisfaction of indebtedness incurred by Flamel by way of set-off, for assets contributed in kind, upon the conversion, exchange or redemption of debt securities previously issued by Flamel, upon the exercise of stock options, warrants or other similar securities comprising rights to subscribe for shares, or by capitalization of reserves. Share dividends may be distributed in lieu of payment of cash dividends, as described under " – Dividend and Liquidation Rights."

French law requires that the net assets of a corporation as calculated under French statutory accounting (*capitaux propres*) be equal to at least one-half of its issued nominal capital (*capital social*). The board of directors of any such French corporation must, within four months from the approval by the shareholders of the audited accounts showing such a deficiency in the net asset position, convene an extraordinary meeting of shareholders in order to decide whether the corporation ought to be dissolved before its statutory term or whether to continue the business activity of the corporation. If the dissolution is not declared, the net asset position must then be restored at the latest at the end of the second fiscal year following the fiscal year during which the insufficient net asset position was legally established by the shareholders.

#### **Preemptive Subscription Rights**

Unless previously waived or cancelled, holders of shares have preemptive rights to subscribe for additional shares issued by Flamel on a pro rata basis. Shareholders may individually waive such preemptive subscription rights or cancel all of them at an extraordinary general meeting under certain circumstances. Preemptive subscription rights, if not previously cancelled by an extraordinary general meeting or individually waived by each shareholder, are transferable during the subscription period relating to a particular offering of shares, unless otherwise decided by the extraordinary general meeting.

#### Attendance and Voting at Shareholders' Meetings

In accordance with French law, there are two types of shareholders' general meetings, ordinary and extraordinary. Ordinary general meetings of shareholders are required for matters such as the election of directors, the appointment of statutory auditors, the approval of the annual report prepared by the Board of Directors and the annual accounts and the declaration of dividends.

Extraordinary general meetings of shareholders are required for approval of matters such as amendments to Flamel's *statuts*, modification of shareholders' rights, approval of mergers, increases or decreases in share capital, the creation of a new class of capital stock and the authorization of the issuance of securities convertible or exchangeable into shares. In particular, shareholder approval will be required for any and all mergers in which (i) the Company is not wholly owned by the absorbing company or (ii) the Company does not wholly own the absorbed company.

The Board of Directors is required to convene an annual ordinary general meeting of shareholders, which must be held within six months of the end of Flamel's fiscal year, which is December 31. Under the Company's statuts, all directors stand for re-election at each annual ordinary general meeting of shareholders. Other ordinary or extraordinary meetings may be convened at any time during the year. Meetings of shareholders may be convened by the Board of Directors or, if the Board of Directors fails to call such a meeting, by Flamel's designated statutory auditors, currently PricewaterhouseCoopers Audit or by an agent appointed by the court. The court may be requested to appoint such an agent either by shareholder(s) holding at least 5% of Flamel's share capital, a shareholder's association meeting the requirements of Article L.225-120 of the French Commercial Code, or in cases of urgency, by the works council or an interested party. Following a successful takeover bid or the acquisition of control of the Company, the new majority shareholders may call a shareholders' ordinary or extraordinary general meeting, depending on matters to be considered in such meeting. The notice calling such meeting must state the matters to be considered.

French law provides that, at least 15 days before the date set for any general meeting on first notice, and at least six days before the date set for any general meeting on second notice, notice of the meeting must be sent by mail to all holders of properly registered shares who have held such shares prior to the date of the notice. A preliminary written notice (*avis de reunion*) must be sent to each shareholder who has requested to be notified in writing before the date set for any ordinary or extraordinary general meeting. Shareholders holding a defined percentage of the share capital of the Company, which varies depending on the absolute amount of the share capital, may propose resolutions to be submitted for approval by the shareholders at the meeting. The defined percentage referred to in the preceding sentence will never be higher than five percent. Holders of ADSs will receive notice of shareholders meetings and other reports and communications that are made generally available to shareholders from the Depositary if we furnish sufficient copies of the documents and ask the Depositary to mail them to ADR holders. See "Description of American Depositary Shares – Voting of the Underlying Shares" for the contents and time periods for notices of shareholder meetings to be given to the holders of ADSs.

Attendance and exercise of voting rights at ordinary general meetings and extraordinary general meetings of shareholders are subject to certain conditions. Pursuant to the Company's *statuts*, holders of shares deciding to exercise their voting rights must have their Shares registered in their names in the shareholder registry maintained by or on behalf of Flamel one day prior to the meeting at the latest. Certain procedures to effect such requirements will apply to a holder of ADSs desiring to exercise the voting rights relating to the shares corresponding to such ADSs. See "Description of American Depository Shares – Voting of the Underlying Shares."

All shareholders who have properly registered their shares have the right to participate in general meetings, either in person, by proxy, or by mail, and to vote according to the number of shares they hold. Each share confers on the shareholder the right to one vote. Our *statuts* do not provide for cumulative voting rights. Under French law, shares held by entities controlled directly or indirectly by Flamel shall not be entitled to any voting rights. A proxy may be granted by a shareholder whose name is reflected on the Company's share registry to his or her spouse, to his or her partner under civil partnership (*pacte civil de solidarité*), to another shareholder or to a legal representative, in the case of a legal entity, or by sending a proxy in blank to the Company without nominating any representative. In the latter case, the chairman of the meeting of shareholders will vote the Shares with respect to which such blank proxy has been given in favor of all resolutions proposed by the Board of Directors and against all others.

The presence in person or by proxy of shareholders holding not less than 20% (in the case of an ordinary meeting) or 25% (in the case of an extraordinary meeting) of the shares entitled to vote is necessary for a quorum. If a quorum is not present at an initial meeting, then the meeting must be adjourned. An adjourned meeting may be reconvened upon 10 days' notice. Upon recommencement of an adjourned meeting, no quorum is required in the case of an ordinary general meeting but, in the case of an extraordinary meeting, the presence in person or by proxy of shareholders holding not less than 20% of the shares entitled to vote is required for a quorum.

At an ordinary meeting, a simple majority of the votes cast is required to pass a resolution. At an extraordinary general meeting, a two-thirds majority of the votes cast is required. However, a unanimous vote is required to increase liabilities of shareholders. Abstention by those present or represented by proxy is deemed a vote against the resolution submitted to a vote.

In addition to rights to certain information regarding Flamel, any shareholder may, during a period no more than 15 days preceding a shareholders' meeting and no later than four business days preceding a shareholders' meeting, submit written questions to the Board of Directors relating to the agenda for the meeting. The Board of Directors is required to respond to such questions during the meeting.

As set forth in the *statuts*, shareholders' meetings are held at the registered office of the Company or at any other location specified in the written notice.

## **Dividend and Liquidation Rights**

If the financial results show the existence of a distributable profit, Flamel's *statuts* permit a general shareholders' meeting to allocate such profits to one or several reserve accounts, to carry the amount forward or to distribute it to shareholders. As provided under French law, net income in each fiscal year (after deduction for legal reserve), as increased or reduced, as the case may be, by any net income or loss of any French corporation carried forward from prior years, is available for distribution to the shareholders of such corporation as dividends, all as determined in accordance with French statutory accounting. Dividends may also be distributed from available reserves of any French corporation, subject to approval by the shareholders and certain limitations.

Under French law, a corporation is legally required to establish and maintain a legal reserve by making a minimum transfer of 5% of its net income in each year to such legal reserve as may be necessary to maintain it at a level equal to 10% of the aggregate nominal value of its share capital, as increased or reduced from time to time. The legal reserve is distributable only upon liquidation. The payment of dividends, if any, is fixed by the ordinary general meeting of shareholders at which the annual accounts are approved following recommendation of the Board of Directors. Dividends are payable pro rata to holders of shares outstanding on the date of the shareholder meeting approving the distribution of dividends or, in the case of interim dividends, on the date of the meeting of the Board of Directors approving the distribution of interim dividends. The actual dividend payment date is determined by the shareholders at the ordinary general meeting approving the declaration of the dividends or by the Board of Directors in the absence of such determination by the shareholders. The payment of the dividends must occur within nine months of the end of a French company's fiscal year. Dividends not claimed within five years of the date of payment revert to the French state. The *statuts* of the Company authorize the shareholders, in an ordinary general meeting, to authorize the grant to each shareholder of an option to receive all or part of any annual or interim dividends in either cash or shares.

If net income (as shown on an interim income statement certified by Flamel's statutory auditors) is sufficient, the Board of Directors has the authority, subject to French law and regulations, without the approval of shareholders, to distribute interim dividends.

In the event that Flamel is liquidated, the assets of Flamel remaining after payment of its debts, liquidation expenses and all of its remaining obligations will be distributed first to repay in full the capital of the shares, and the surplus, if any, will then be distributed pro rata among the holders of shares in proportion to the nominal value of their shareholdings and subject to any special rights granted to holders of priority or preference shares, if any. Shareholders are liable for corporate liabilities only up to the par value of the shares they hold and are not liable to further capital calls of the Company.

#### Repurchase of Shares

Pursuant to French law, Flamel may not acquire its shares except in certain limited circumstances not presently applicable to it.

#### Form and Holding of Shares

Form of Shares. Flamel's statuts provide that shares may be held only in registered form.

Holding of Shares. Shares are registered in the name of the respective owners thereof in the registry maintained by or on behalf of Flamel. Stock certificates evidencing shares, in a manner comparable to that in the United States, are not issued by French companies, but the Company may issue or cause to be issued confirmations as to holdings of shares registered in such registry to the persons in whose name such shares are registered. Such confirmations do not constitute documents of title and are not negotiable instruments.

## **DESCRIPTION OF AMERICAN DEPOSITARY SHARES**

Our ordinary shares are traded on the NASDAQ Global Market in the form of ADSs delivered by The Bank of New York Mellon pursuant to the Deposit Agreement dated as of June 6, 1996, as amended and restated as of August 10, 2001, among Flamel, The Bank of New York Mellon, as depositary (the "Depositary"), and all owners and holders from time to time of ADSs issued thereunder (the "Deposit Agreement"). The Depositary's principal executive office is located at One Wall Street, New York, New York 10286.

The following is a summary of the material provisions of the Deposit Agreement, which is qualified in its entirety by reference to the Deposit Agreement filed as an exhibit to the Registration Statement on Form F-6 filed on-September 30, 2003 (File No. 333-109281). Copies of the Deposit Agreement are available for inspection at the Corporate Trust Office of the Depositary, which is presently located at 101 Barclay Street, New York, New York 10286. Capitalized terms used but not defined herein shall have meanings assigned to them in the Deposit Agreement.

#### **American Depositary Receipts**

Each American Depositary Receipt ("ADR") is a certificate evidencing a specific number of ADSs. The Depositary will execute and deliver the ADRs. Each ADS represents one Ordinary Share (or a right to receive one Ordinary Share) deposited with the Depositary or the Paris office of CACEIS Bank, as custodian for the Depositary (the "Custodian"), presently located at 1-3, Place Valhubert, 75206 Paris Cedex 13, FRANCE. Each ADS will also represent any other securities, cash or other property that may be held by the Depositary. As used herein, the term "ADR holder" shall mean a person in whose name an ADR is registered on the books of the Depositary maintained for such purpose.

You may hold ADSs either directly (by having an ADR registered in your name) or indirectly through your broker or other financial institution. If you hold ADSs directly, you are an ADR holder. This description assumes you hold your ADSs directly. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADR holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

As an ADR holder, we will not treat you as one of our shareholders, and you will not have shareholder rights. French law governs shareholder rights. The Depositary will be the holder of the Ordinary Shares underlying your ADSs. As a holder of ADRs, you will have ADR holder rights. The Deposit Agreement sets forth ADR holder rights as well as the rights and obligations of the Depositary. New York law governs the Deposit Agreement and the ADRs.

We refer to the Ordinary Shares that are at any time deposited or deemed deposited under the Deposit Agreement and any and all other securities, cash and property received by the Depositary or the Custodian in respect thereof and at such time held under the Deposit Agreement as "Deposited Securities."

## **Dividends and Other Distributions**

The Depositary has agreed to pay to you the cash dividends or other distributions it or the Custodian receives on the Ordinary Shares or other deposited securities, after deducting its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

· *Cash.* The Depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the Deposit Agreement allows the Depositary to distribute the foreign currency only to those ADR holders to whom such distribution is possible. The Depositary will hold the foreign currency it cannot convert for the account of the ADR holders who have not been paid but will not invest the foreign currency and will not be liable for any interest.

Before making a distribution, the Depositary will deduct any withholding taxes that must be paid. The Depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when the Depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.

- · *Shares.* The Depositary may distribute additional ADRs representing any shares we distribute as a dividend or free distribution. The Depositary will only distribute whole ADRs and will sell shares that would require it to deliver fractional ADRs and distribute the net proceeds in the same way that it does with cash. If the Depositary does not distribute additional ADRs, the outstanding ADRs will also represent the new shares.
- **Rights to purchase additional shares.** If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the Depositary may make these rights available to you. If the Depositary decides it is not legal and feasible to make the rights available but that it is feasible to sell the rights, the Depositary will use reasonable efforts to sell the rights and distribute the proceeds in the same way as it does with cash. The Depositary will allow rights that are not distributed or sold to lapse. *In that case, you will receive no value for them.*

If the Depositary makes rights available to you, it will exercise the rights and purchase the shares on your behalf. The Depositary will then deposit the shares and deliver ADRs to you. It will only exercise rights if you pay it the exercise price and any other charges the rights require you to pay.

U.S. securities laws may restrict transfers and cancellation of the ADRs represented by shares purchased upon exercise of rights. For example, you may not be able to trade these ADRs freely in the United States. In this case, the Depositary may deliver restricted ADRs that have the same terms as the ADRs described in this section except for changes needed to put the necessary restrictions in place.

• Other Distributions. The Depositary will send to you anything else we distribute on Deposited Securities by any means it believes are legal, fair and practical. If it cannot make the distribution in such a manner, the Depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the Depositary is not required to distribute any securities (other than ADSs) to you unless it receives satisfactory evidence from us that it is legal to make that distribution.

The Depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADR holder. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADRs, ADSs, shares, rights or anything else to ADR holders. This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.

## **Deposit, Withdrawal and Cancellation**

The Depositary will deliver ADRs if you or your broker deposits shares or evidence of rights to receive shares with the Custodian or the Depository. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the Depositary will register the appropriate number of ADSs in the names you request and will deliver the ADRs at its office to the persons you request.

You may turn in your ADRs at the Depositary's office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the Depositary will transfer the shares and any other Deposited Securities underlying the ADR to you, or a person you designate, at the office of the Custodian. Alternatively, at your request, risk and expense, the Depositary will deliver the Deposited Securities at its office, if feasible.

## **Voting of the Underlying Shares**

You may instruct the Depositary to vote the Ordinary Shares underlying your ADRs, but only if we ask the Depositary to ask for your instructions. *Otherwise, you will not be able to exercise your right to vote unless you withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares.* 

If we ask for your instructions, the Depositary will notify you of the upcoming vote and arrange to deliver our voting materials to you. The materials will (1) describe the matters to be voted on and (2) explain how you may instruct the Depositary to vote the Ordinary Shares or other deposited securities underlying your ADSs as you direct. For instructions to be valid, the Depositary must receive them on or before the date specified. The Depositary will try, as far as practical, subject to French law and the provisions of our *statuts*, to vote or to have its agents vote the shares or other deposited securities as you instruct.

If the Depositary does not receive voting instructions from you by the specified date, it will consider you to have authorized and directed it to vote the number of deposited securities represented by your ADSs in accordance with the recommendations of our management. However, the Depositary will not vote under the preceding sentence if we notify the Depositary that:

- · we do not wish it to do so;
- $\cdot$  we think there is substantial shareholder opposition to the particular question; or
- · we think the particular question would have an adverse impact on our shareholders.

The Depositary will only vote, or attempt to vote, as you instruct, or as described in this paragraph.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the Depositary to vote your Ordinary Shares. In addition, the Depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise your right to vote and there may be nothing you can do if your shares are not voted as you requested.

#### Fees and Expenses

# Persons depositing shares or ADR holders must pay:

- 1. \$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)
- 2. \$0.02 (or less) per ADS
- 3. A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs

#### For:

- · Execution and delivery of ADRs, including issuances resulting from a distribution of shares or rights or other property
- Cancellation of ADRs for the purpose of withdrawal, including if the Deposit Agreement terminates
- · Any cash distribution to you
- Distribution of securities distributed to holders of deposited securities which are distributed by the Depositary to ADR holders

- 4. \$1.50 or less per certificate
- 5. Registration or transfer fees
- 6. Expenses of the Depositary
- Taxes and other governmental charges the Depositary or the custodian has to pay on any ADR or share underlying an ADR, for example, stock transfer taxes, stamp duty or withholding taxes
- 8. Expenses of the Depositary in converting foreign currency to U.S. dollars

· Registration of transfer of ADRs

- Transfer and registration of shares on our share register to or from the name of the Depositary or its agent when you deposit or withdraw shares
- Cable, telex and facsimile transmissions (when expressly provided in the Deposit Agreement)

The Depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The Depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The Depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The Depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the Depositary may make payments to us to reimburse and/or share revenue from the fees collected from ADS holders, or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the ADS program. In performing its duties under the deposit agreement, the Depositary may use brokers, dealers or other service providers that are affiliates of the Depositary and that may earn or share fees or commissions.

#### **Payment of Taxes**

The Depositary may deduct the amount of any taxes owed from any payments to you and may also sell deposited securities, by public or private sale, to pay any taxes owed. You will remain liable if the proceeds of the sale are not enough to pay the taxes. If the Depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to you any proceeds, or send to you any property, remaining after it has paid the taxes.

#### Reclassifications, Recapitalizations and Mergers

If we (i) change the nominal value of our shares; (ii) reclassify, split up or consolidate any of the Deposited Securities; (iii) distribute securities on the shares that are not distributed to you; or (iv) recapitalize, reorganize, merge, liquidate, sell all or substantially all of our assets, or take any similar action, then:

- the cash, shares or other securities received by the Depositary will become Deposited Securities, and each ADS will automatically represent its equal share of the new Deposited Securities; and
- the Depositary may, and upon our request will, distribute some or all of the cash, shares or other securities it received. The Depositary may also deliver new ADRs or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new Deposited Securities.

## **Reports and Other Communications**

The Depositary will make available for inspection by owners of ADRs at its Corporate Trust Office any reports and communications, including proxy solicitation materials, received from us which are both (a) received by the Depositary as the holder of the Deposited Securities and (b) made generally available by us to the holders of such Deposited Securities. The Depositary will also send to the owners of ADRs copies of Company notices of shareholder meetings or the adjournment thereof, actions related to any cash or other distributions and the offering of any rights and copies of annual reports, quarterly reports, summaries of notices of shareholders' meetings and other communications made generally available to owners of Deposited Securities. If instructed in writing by Flamel, the Depositary will arrange for copies of such reports and communications to be mailed to all owners of ADRs at Flamel's expense. Any such reports and communications, including any proxy solicitation materials, will be furnished to the Depositary in English.

#### **Amendment and Termination**

We may agree with the Depositary to amend the Deposit Agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the Depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADR holders, it will not become effective for outstanding ADRs until 60 days after the Depositary notifies ADR holders of the amendment. At the time an amendment becomes effective, you are considered, by continuing to hold your ADR, to agree to the amendment and to be bound by the ADRs and the Deposit Agreement as amended.

The Depositary will terminate the Deposit Agreement if we ask it to do so. The Depositary may also terminate the Deposit Agreement if the Depositary has told us that it would like to resign and we have not appointed a successor Depositary within 90 days. In either case, the Depositary must notify you at least 90 days before termination.

After termination, the Depositary and its agents will do the following under the Deposit Agreement but nothing else: (1) advise you that the Deposit Agreement is terminated, (2) collect distributions on the Deposited Securities, (3) sell rights and other property and (4) deliver shares and other Deposited Securities upon cancellation of ADRs. One year after termination, the Depositary may sell any remaining Deposited Securities by public or private sale. After that, the Depositary will hold the money it received on the sale, as well as any other cash it is holding under the Deposit Agreement, for the pro rata benefit of the ADR holders that have not surrendered their ADRs. It will not invest the money and has no liability for interest. The Depositary's only obligations will be to account for the money and other cash. After termination, our only obligations will be to indemnify the Depositary and to pay fees and expenses of the Depositary that we have agreed to pay.

#### **Limitations on Obligations and Liability**

The Deposit Agreement expressly limits our obligations and the obligations of the Depositary. It also limits our liability and the liability of the Depositary. The Depositary and we:

- · are only obligated to take the actions specifically set forth in the Deposit Agreement without negligence or bad faith;
- · are not liable if either of us is prevented or delayed by law or circumstances beyond our control from performing our obligations under the Deposit Agreement;
- · are not liable if either of us exercises discretion permitted under the Deposit Agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADRs or the Deposit Agreement on your behalf or on behalf of
  any other party; and
- · may rely upon any documents we believe in good faith to be genuine and to have been signed or presented by the proper party.

In the Deposit Agreement, we agree to indemnify the Depositary for acting as Depositary, except for losses caused by the Depositary's own negligence or bad faith.

#### **Requirements for Depositary Actions**

Before the Depositary will deliver or register a transfer of an ADR, make a distribution on an ADR, or permit withdrawal of shares, the Depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- · satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- · compliance with regulations it may establish, from time to time, consistent with the Deposit Agreement, including presentation of transfer documents.

The Depositary may refuse to deliver ADRs or register transfers of ADRs generally when the transfer books of the Depositary or our transfer books are closed or at any time if the Depositary or we think it advisable.

## Your Right to Receive the Shares Underlying your ADRs

You have the right to cancel your ADRs and withdraw the underlying shares at any time except:

- when temporary delays arise because (i) the Depositary has closed its transfer books or we have closed our transfer books, (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting or (iii) we are paying a dividend on our shares;
- · when you or other ADR holders seeking to withdraw shares owe money to pay fees, taxes and similar charges; and
- · when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADRs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the Deposit Agreement.

#### Pre-release of ADRs

The Deposit Agreement permits the Depositary to deliver ADRs before deposit of the underlying shares. This is called a pre-release of ADRs. The Depositary may also deliver shares upon cancellation of pre-released ADRs (even if the ADRs are canceled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the Depositary. The Depositary may receive ADRs instead of shares to close out a pre-release.

The Depositary may pre-release ADRs only under the following conditions:

- before or at the time of the pre-release, the person to whom the pre-release is being made represents to the Depositary in writing that it or its customer owns the shares or ADRs to be deposited;
- · the pre-release is fully collateralized with cash or other collateral that the Depositary considers appropriate; and
- the Depositary must be able to close out the pre-release on not more than five business days' notice. In addition, the Depositary will limit the number of ADSs that may be outstanding at any time as a result of pre-release to thirty percent (30%) of the Ordinary Shares deposited, although the Depositary may disregard the limit from time to time, if it thinks it is appropriate.

## **Shareholder Communications: Inspection Rights**

The Depositary will make available for your inspection at its office all communications that it receives from us as a holder of Deposited Securities that we make generally available to holders of Deposited Securities. The Depositary will send you copies of those communications if we ask it to. The Depositary will keep books for the registration and transfer of ADRs, which will be open for inspection by the owners of ADRs and the Company at all reasonable times, provided that such inspection shall be limited to business of the Company or a matter related to the Deposit Agreement or the ADRs and not for the purpose of communicating with ADR owners for another business. At any time and from time to time, the Depositary may close the transfer books in connection with the performance of its duties under the Deposit Agreement or upon the Company's request.

#### **EXPENSES**

We will incur the following expenses in connection with the registration of the ordinary shares offered by the selling shareholder:

Legal Fees and Expenses	\$ 60,000
Accounting Fees and Expenses	\$ 35,000
ADR Conversion Fees	\$ 2,000
SEC Registration Fee	\$ 3,263
Printing Expenses	\$ 1,500
TOTAL	\$ 101,763

All amounts shown are estimates, except for the amount of the SEC registration fee. Any selling commissions, brokerage fees, applicable transfer taxes, and fees and disbursements of counsel for the selling shareholder are payable by the selling shareholder.

#### **LEGAL MATTERS**

Hogan Lovells (Paris) LLP, Paris, France, will provide the Company with an opinion as to French legal matters and the validity of the ordinary shares.

#### **EXPERTS**

The financial statements and management's assessment of the effectiveness of internal control over financial reporting (which is included in Management's Report on Internal Control over Financial Reporting) incorporated in this Prospectus by reference to the Annual Report on Form 20-F for the year ended December 31, 2011 have been so incorporated in reliance on the report of PricewaterhouseCoopers Audit, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The financial statements of Eclat Holdings, LLC incorporated in this prospectus by reference to Exhibit 99.2 have been so incorporated in reliance on the report of Swink, Fiehler & Company P.C., an independent public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## ENFORCEABILITY OF CIVIL LIABILITIES

We are a limited liability company (*société anonyme*) organized under the laws of France, and many of our directors and officers reside outside the United States. In addition, a substantial portion of our assets are located in France. As a result, it may be difficult for investors to effect service of process within the United States on such persons. It may also be difficult to enforce against them, either inside or outside the United States, judgments obtained against them in U.S. courts, or to enforce in U.S. courts, judgments obtained against them in courts in jurisdictions outside the United States, in any action based on civil liabilities under the U.S. federal securities laws. There is doubt as to the enforceability against such persons in France, whether in original actions or in actions to enforce judgments of U.S. courts, of liabilities based solely on the U.S. federal securities laws. Actions for enforcement of foreign judgments against such persons would require such persons who are of French nationality to waive their right under Article 15 of the French Civil Code to be sued only in France. We believe that no such French persons have waived such right with respect to actions predicated solely upon U.S. federal securities laws. In addition, actions in the United States under the U.S. federal securities laws could be affected under certain circumstances by the French law of July 26, 1968, as amended, which may preclude or restrict the obtaining of evidence in France or from French persons in connection with such actions. Additionally, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France.

# DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Under French law, a company may purchase directors and officers' insurance for all or part of the members of its management. A French corporation is responsible to third parties for the consequences of the decisions of its board of directors. However, if those decisions qualify as mismanagement under Article L. 225-251 of the French Commercial Code (*Code de commerce*), the relevant member of the board of directors may have to fully or partly indemnify the company. The Registrant maintains liability insurance for its directors and principal executive officers, including insurance against liabilities under the Securities Act.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable.