

The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell nor are we seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Filed pursuant to Rule 424(b)(5)  
Registration No. 333-193898

**SUBJECT TO COMPLETION, DATED MARCH 6, 2014**

**PRELIMINARY PROSPECTUS SUPPLEMENT**  
(to Prospectus dated February 28, 2014)

## American Depositary Shares



# FLAMEL TECHNOLOGIES, S.A.

## Representing Ordinary Shares

We are offering American Depositary Shares, or ADSs, representing ordinary shares of Flamel Technologies, S.A., a French company. Each ADS will represent one ordinary share, nominal value €0.122 per share. Our ordinary shares, in the form of ADSs, are traded under the symbol “FLML” on the NASDAQ Global Market. On March 5, 2014, the last reported sale price for the ADSs on the NASDAQ Global Market was \$10.58 per ADS.

Before buying the ADSs, you should carefully consider the risk factors described in “Risk Factors” beginning on page S-10 of this prospectus supplement and those contained in the documents incorporated by reference in this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved of anyone’s investment in these securities, or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per ADS	Total
Price to public	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) We have agreed to reimburse the underwriters for certain of their expenses as described under “Underwriting” on page S-35 of this prospectus supplement.

We have granted the underwriters an option exercisable for up to 30 days from the date of this prospectus supplement to purchase up to additional ADSs at the public offering price less underwriting discounts and commissions to cover over-allotments. If this option were exercised in full, we would receive approximately \$ million of additional proceeds, before expenses.

The underwriters expect to deliver the ordinary shares to the purchasers on or about March , 2014.

*Sole Book-Running Manager*

## JMP Securities

*Co-Managers*

**SunTrust Robinson Humphrey**  
Roth Capital Partners

**Ladenburg Thalmann & Co. Inc.**  
Summer Street Research Partners

The date of this prospectus supplement is March , 2014.

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You should rely only on the information we have provided or incorporated by reference in this prospectus supplement or in the accompanying prospectus. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus supplement or in the accompanying prospectus. This prospectus supplement is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information contained in this prospectus supplement and in the accompanying prospectus is accurate only as of their respective dates and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus supplement or the accompanying prospectus or any sale of securities.

## ABOUT THIS PROSPECTUS SUPPLEMENT

Unless the context otherwise requires, “Flamel,” the “Company,” “we,” “us” and “our” refer to Flamel Technologies, S.A. and its subsidiaries, on a consolidated bases, unless otherwise indicated, “\$”, “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.

This document is in two parts. The first part is this prospectus supplement, which describes the terms of the offering and also adds to and updates information contained in the accompanying prospectus. The second part is the accompanying prospectus, which provides more general information. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus, on the other hand, you should rely on the information in this prospectus supplement. It is also important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents we have referred you to in the section entitled “Where You Can Find More Information” below in this prospectus supplement. The information incorporated by reference is considered part of this prospectus supplement, and information we file later with the Securities and Exchange Commission, or SEC, may automatically update and supersede this information.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

You should rely only on the information contained in this prospectus supplement or the accompanying prospectus, or incorporated by reference herein. We have not authorized, and the underwriters have not authorized, anyone to provide you with information that is different. The information contained in this prospectus supplement or the accompanying prospectus or incorporated by reference herein or therein is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of the ADSs. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you in the sections entitled “Where You Can Find More Information” and “Incorporation of Documents by Reference” in this prospectus supplement and in the accompanying prospectus.

This prospectus supplement, the accompanying prospectus and the information incorporated herein by reference include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement, the accompanying prospectus or any related free writing prospectus are the property of their respective owners.

We are offering to sell, and seeking offers to buy, ADSs only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the ADSs in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the ADSs and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

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This prospectus supplement and the accompanying prospectus 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 supplement and the accompanying prospectus have not been and will not be submitted to the *Autorité des Marchés Financiers* for approval in France nor that of any equivalent stock market authority of any member State of the European Economic Area.

The securities specified in this prospectus supplement and the accompanying prospectus are not intended for distribution in France except to (i) persons providing asset management services for the account of third parties and (ii) qualified investors (*investisseurs qualifiés*) to the exclusion of individuals all as defined in, and in accordance with, Articles L. 411-1, L. 411-2, D. 411-1 *et seq.* of the French Monetary and Financial Code (*Code monétaire et financier*). The prospectus supplement and the accompanying prospectus have not been and are not to be distributed or reproduced (in whole or in part) in France. This prospectus supplement and the accompanying prospectus 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*).

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus 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 supplement as well as the information contained in our 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 in connection with our acquisition of Éclat Pharmaceuticals, LLC (“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;
- products that we bring to market, including Bloxiverz<sup>TM</sup>, may not be as successful as anticipated;
- 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 our debt agreements, and our failure to do so could adversely affect our ability to operate our business, develop our product portfolio or pursue certain opportunities;
- 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;

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- 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 cause 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;
- the price of our ordinary shares, in the form of ADSs, 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; and
- 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. Except as required by law, we undertake no

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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.

## SUMMARY

*The following summary is qualified in its entirety by, and should be read together with, the more detailed information and financial statements and related notes thereto appearing elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. Before you decide to invest in the ADSs, you should read the entire prospectus supplement and the accompanying prospectus carefully, including the risk factors and the financial statements and related notes included or incorporated by reference in this prospectus supplement and the accompanying prospectus.*

### Company Overview

We are a specialty pharmaceutical company with a business model focused on blending high-value internally developed products with our leading drug delivery capabilities. We have a proprietary pipeline of niche specialty pharmaceutical products, while our drug delivery platforms are being used to target safer, more efficacious formulations of pharmaceuticals to address unmet medical needs. Our pipeline includes biological and chemical drugs formulated with our Medusa™ and Micropump® proprietary drug delivery platforms. Several Medusa-based products have been successfully tested in clinical trials. We have developed products and manufacture Micropump-based microparticles under FDA-audited GMP guidelines. We have collaborations with a number of leading pharmaceutical/biotech companies including GlaxoSmithKline (“GSK”).

We have developed and own outstanding drug delivery platforms that are able to tackle key challenges in the formulation of drugs:

- for injectable formulations, Medusa™; and
- for oral formulations, Micropump® (and its applications LiquiTime® and Trigger-Lock™).

Drug delivery platforms are of particular interest for managing the life cycle of medicines, as they offer many advantages: i.e., improvement of drug characteristics such as bioavailability, pharmacokinetics, efficacy, compliance, and side effects; protection of market position through patent extension or differentiation; and extension of market to new indications thanks to improvement of the drug’s characteristics. The drug delivery industry landscape has dramatically changed over the past decade and even more so during the past five years, largely as a function of the growing importance of generic drugs. Generics — especially in the small molecule space — have accelerated the demand for drug delivery solutions while, at the same time, reducing the overall market for drug-delivery formulations due to reduced pricing power.

#### *Medusa Platform*

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). The hydrogels, which are easy and cost effective to produce under European Medicine Agency (“EMA”) and United States Food and Drug Administration (“FDA”) current Good Manufacturing Practices (“cGMP”) requirements, have been proven to be safe and biodegradable. An ADME and regulatory toxicology package has been completed; a type IV Drug Master File has been filed with the FDA (assigned number 024634) in February 2011 and recently updated in February 2013. Medusa enables the controlled delivery from one day up to 14 days of non-denatured or non-modified drugs that remain fully active (as distinguished from protein engineering or chemical modification approaches). It is used to develop biobetters with potentially improved efficacy and reduced toxicity, as well as greater patient convenience.

The Medusa drug delivery platform is patented in the United States Europe and Japan. It is being utilized in collaborations with our partners, as well as in our proprietary pipeline.

#### *Micropump Drug Delivery Platform*

The Micropump controlled-release drug delivery platform is designed to increase the absorption time of drugs, particularly for drugs only absorbed in the small intestine. Micropump enables the achievement of precise pharmacokinetics. Micropump can be presented in various dosage forms such as capsules, tablets, sachets or oral suspensions (LiquiTime®) without modifying the release rate. We have also developed another drug delivery platform for oral drugs, Trigger Lock™, for the controlled release of narcotic and opioid



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analgesics defeating the most commonly employed methods of drug tampering. This technology has successfully transitioned to commercial stage with Coreg CR®, a Micropump-based controlled-release formulation of carvedilol phosphate, sold in the US since 2007 by GSK.

The Micropump drug delivery platform is patented in the United States, Europe and Japan. In addition, the Coreg CR formulation has been patented in the U.S. and listed at the FDA Orange Book by our partner GSK. The Micropump drug delivery platform is being utilized in collaborations with leading pharmaceutical and biotechnology companies.

### *Recent Developments in the Products Portfolio*

On May 31, 2013, the FDA approved the company's New Drug Application ("NDA") for Bloxiverz™ (neostigmine methylsulfate), a drug used intravenously in the operating room for the reversal of the effects of non-depolarizing neuromuscular blocking agents after surgery. Our subsidiary, Éclat Pharmaceuticals ("Éclat"), is working to place product into the marketplace and informing clinical staff, hospital risk managers and Group Purchasing Organizations to make them aware of availability of the first FDA-approved version of neostigmine methylsulfate.

In September 2013, the FDA accepted for review our second NDA. We have received a Prescription Drug User Fee Act date, the target date for the FDA to complete its review of the NDA, of April 28, 2014. For competitive reasons, we have decided not to identify the product at this time, but we intend to provide additional information at a later date.

As a part of our research and development program, we have completed preclinical studies with our proprietary extended release Medusa hGH XL product which utilizes our Medusa® technology applied to recombinant human growth hormone. Our study data provided significant evidence to move this proprietary drug forward into a human clinical trial in 2014 with once weekly dosing.

We will continue to push forward on additional NDA filings out of the Éclat portfolio and on development of additional, innovative drugs that employ our proprietary platform of technologies. Greater research and development spending on these new product efforts is designed to build our near-term and mid-term pipeline and potential revenues. We currently have six products in development using our four drug delivery platforms and expect to make six to eight regulatory filings through 2017 (including two NDA filings in 2014). In addition, we continue to explore development, supply and licensing opportunities for our four drug delivery platforms with third parties, but will not rely completely on those partnerships to create revenue and profit opportunities.

### *Company Information*

Our principal executive offices are located at 33 Avenue du Docteur Georges Levy, 69693 Vénissieux Cedex, France, and our telephone number at that location is +33 472 783 434. In addition, we have operations in St. Louis, Missouri, USA, and manufacturing facilities in Pessac, France. For more information regarding our business, please refer to our Annual Report on Form 20-F for the year ended December 31, 2012, which is incorporated herein by reference. Our website address is [www.flamel.com](http://www.flamel.com). Information contained on our website is not part of this prospectus.

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We are in the process of finalizing our financial statements for the year ended December 31, 2013. The following presents selected preliminary unaudited financial results for the quarters and full fiscal years ended December 31, 2013 and 2012. Because we have not yet issued our audited consolidated financial statements for the year ended December 31, 2013 and have not yet filed our Annual Report on Form 20-F for 2013, we caution you that the selected financial data shown below does not represent comprehensive financial statements prepared in accordance with Regulation S-X. As such, these preliminary results for the periods indicated are subject to risks and uncertainties and may change.

Based on our current expectations with respect to the sales of products and the anticipated timeline for receipt of regulatory approvals for products under development, we anticipate being cash flow positive by the end of 2014.

	Three months ended December 31,		Year ended December 31,	
	2012	2013	2012	2013
<i>(Unaudited; amounts in thousands, except per share data)</i>				
<b>Revenue:</b>				
License and research revenue	\$ 3,450	\$ 2,434	\$ 9,324	\$ 6,549
Product sales and services	2,163	2,149	9,657	8,951
Other revenues	1,697	1,595	7,120	6,942
Total revenue	<u>7,310</u>	<u>6,177</u>	<u>26,101</u>	<u>22,442</u>
<b>Costs and expenses:</b>				
Cost of goods and services sold	(1,495)	(335)	(5,860)	(4,349)
Research and development	(6,162)	(4,173)	(26,115)	(26,686)
Selling, general and administrative	(2,950)	(5,184)	(14,153)	(13,306)
Fair value remeasurement of acquisition liabilities	14,871	4,507	18,834	(28,135)
Impairment of assets	(7,170)		(7,170)	
Total	<u>(2,906)</u>	<u>(5,185)</u>	<u>(34,464)</u>	<u>(72,476)</u>
Profit (loss) from operations	<u>4,404</u>	<u>992</u>	<u>(8,363)</u>	<u>(50,034)</u>
Interest income (loss), net	98	(599)	511	(2,356)
Interest expense on the debt related to the Royalty agreement	—	38	—	(1,990)
Foreign exchange gain (loss)	(108)	(118)	(180)	(288)
Other Income (loss)	11	41	102	573
Income (loss) before income taxes	<u>4,405</u>	<u>354</u>	<u>(7,930)</u>	<u>(54,095)</u>
Income tax benefit (expense)	<u>4,697</u>	<u>4,772</u>	<u>4,702</u>	<u>11,170</u>
Net income (loss)	<u>\$ 9,102</u>	<u>\$ 5,126</u>	<u>\$ (3,228)</u>	<u>\$ (42,925)</u>
<b>Earnings (loss) per share:</b>				
Basic	\$ 0.36	\$ 0.20	\$ (0.13)	\$ (1.69)
Diluted	\$ 0.36	\$ 0.20	\$ (0.13)	\$ (1.69)
<b>Weighted average number of shares outstanding:</b>				
Basic	25,213	25,496	25,135	25,449
Diluted	25,314	25,824	25,135	25,449

The preliminary financial data included in this prospectus supplement has been prepared by, and is the responsibility of, Flamel's management. PricewaterhouseCoopers Audit has not audited, reviewed, compiled or performed any procedures with respect to the accompanying preliminary financial data. Accordingly, PricewaterhouseCoopers Audit does not express an opinion or any other form of assurance with respect thereto.

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**The Offering**

ADSs offered	ADSs representing    ordinary shares.
ADSs to be outstanding after the offering (assuming no exercise of the underwriters’ over-allotment option)	ADSs representing    ordinary shares <sup>(1)</sup> , assuming the deposit of all outstanding shares into the ADS deposit facility.
Over-allotment Option	We have granted the underwriters an option to purchase up to an additional ADSs, representing    ordinary shares. This option is exercisable, in whole or in part, for a period of 30 days from the date of this prospectus supplement.
The ADSs	Each ADS will represent one ordinary share, nominal value €0.122 per share. You will have the rights of an ADS holder as provided in the deposit agreement among us, The Bank of New York Mellon, the depository, and holders and beneficial owners of ADSs from time to time. To better understand the terms of the ADSs, you should carefully read the section entitled “Description of American Depositary Shares” in the accompanying prospectus.
Use of Proceeds	We intend to use approximately \$    of the proceeds from this offering for the repayment of outstanding indebtedness. We will use the remaining net proceeds to continue the development of our product pipeline, and for general corporate purposes, including working capital. See “Use of Proceeds” on page S-27.
Risk Factors	See “Risk Factors” beginning on page S-10 for a discussion of factors you should carefully consider before deciding to invest in the ADSs.
NASDAQ Global Market symbol	FLML.
Income Tax Considerations	See “Certain Income Tax Considerations” in this prospectus supplement for a discussion of certain material income tax considerations of an investment in the ADSs.

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(1) The number of our ordinary shares to be outstanding after this offering is based on 25,617,550 ordinary shares outstanding as of February 28, 2014. This number excludes:

- an aggregate of 18,014,550 shares reserved for future issuance under our currently outstanding equity plans;
- 4,079,990 shares issuable upon the exercise of outstanding stock options, directors warrants and warrants granted pursuant to our currently outstanding equity plans at a weighted average exercise price of \$10.77 per share;
- 3,300,000 shares issuable upon the exercise of outstanding warrants issued in connection with our acquisition of Éclat at a weighted average exercise price of \$8.63 per share; and
- 367,600 shares issuable at the end of the vesting period pursuant to our currently outstanding Employee free share awards.

## RISK FACTORS

*Investing in the ADSs involves a high degree of risk. You should carefully consider the following risks and other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus, including our historical financial statements and related notes, before deciding whether to purchase the ADSs. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks occurs, our business, business prospects, cash flow, results of operations or financial condition could be harmed. In this case, the trading price of the ADSs could decline, and you might lose all or part of your investment.*

### **Risks Related to Our Business**

***We depend on a small number of customers for the majority of the revenues related to our drug delivery platforms, and the loss of any one of these customers could reduce our revenues significantly.***

We depend on a small number of customers for the majority of our revenues from our drug delivery platforms. Revenue from GlaxoSmithKline plc (GSK) generated 69% of total revenues in the nine months ended September 30, 2013. The termination of our relationship with GSK and our failure to broaden our customer base could cause our revenues to decrease significantly and result in losses from our operations. Further, we may be unable to negotiate favorable business terms with customers and partners that represent a significant portion of our revenues. If so, our revenues and gross profits, if any, may not grow as expected or may not grow at a rate sufficient to make us profitable.

***Our focusing on (i) the development and licensing of four versatile, proprietary drug delivery platforms, (ii) the development of novel, high-value products based on our drug delivery platforms and (iii) as a result of our acquisition of Éclat, the development, approval, and commercialization of niche branded and generic pharmaceutical products in the U.S., rather than primarily on collaborative agreements with pharmaceutical and biotechnology companies, may not be successful.***

We have relied primarily over recent years on our collaborative agreements and relationships with pharmaceutical and biotechnology companies as partners with respect to our drug delivery platforms and our change in focus to the development of novel, high-value products based on our drug delivery platforms and as a result of our acquisition of Éclat, the development, approval, and commercialization of niche branded and generic pharmaceutical products in the US may not be successful in the near or long term and negatively impact our business, financial condition, and results of operations, and further increase our research and development expenses.

***Our current revenues from our drug delivery business primarily depend on third party pharmaceutical and biotechnology companies successfully developing products that incorporate our drug delivery platforms.***

We market and sell our technologies to third parties who incorporate our technologies into their products. We depend upon collaborative agreements with pharmaceutical and biotechnology companies to develop, test, obtain regulatory approval for and commercialize products that incorporate our drug delivery technologies. We currently have collaborative agreements or relationships with GSK and other pharmaceutical and biotechnology companies whose identities remain confidential.

The number of products that our partners successfully develop under these collaborative agreements will affect our revenues. We cannot control the timing or other aspects of the development or marketing by our partners of their products that incorporate our technologies and may not be informed by our partners concerning the timing and other aspects of their development or marketing efforts. The failure of one or more of our partners to develop successful products that incorporate our technologies or to perform as we expect under our agreements with them could have a material adverse effect on our business, financial condition and results of operations. We face risks relating to our collaborative agreements, including risks that:

- our collaborative agreements may not result in any new commercial products;
- the existing commercial products developed under our collaborative agreements may not be successful;
- our pharmaceutical and biotechnology company partners may not successfully obtain regulatory approval in a timely manner, or at all, and may not market any commercial products;

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- we cannot control the amount and timing of resources that our pharmaceutical and biotechnology company partners devote to the development or commercialization of products using our technologies or to the marketing and distribution of those products;
- we may not be able to meet the milestones established in current or future collaborative agreements;
- we may not be able to successfully develop new drug delivery platforms that would be attractive to potential pharmaceutical or biotechnology company partners;
- our collaborative partners may terminate their relationships with us; and
- our collaborative partners may enter bankruptcy or otherwise dissolve.

***Although products that incorporate our drug delivery platforms and products in development may appear promising at their early stages of development and in clinical trials, none of these potential platforms or products may reach the commercial market for a number of reasons.***

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Successful research and development of pharmaceutical products is difficult, expensive and time consuming. Many product candidates fail to reach the market. We intend to continue to enhance our current technologies and pursue additional proprietary drug delivery platforms. Our success will depend on the discovery and the successful commercialization of products that can utilize our drug delivery platforms and development products from Éclat. If products incorporating our drug delivery platforms or our development products fail to reach the commercial market, our future revenues would be adversely affected.

Even if our products and technologies appear promising during various stages of development, there may not be successful commercial applications developed for them for a number of reasons, including:

- the FDA, the EMA, the competent authority of an EU Member State or an institutional review board (“IRB”), or an Ethics Committee (EU equivalent to IRB), or our pharmaceutical or biotechnology partners may delay or halt applicable clinical trials;
- we or our pharmaceutical or biotechnology partners may face slower than expected rate of patient recruitment and enrollment in clinical trials, or may devote insufficient funding to the clinical trials;
- we or our products and technologies or our pharmaceutical and biotechnology company partners’ products may be found to be ineffective or cause harmful side effects, or may fail during any stage of pre-clinical testing or clinical trials;
- we may not find additional pharmaceutical or biotechnology companies to adopt our technologies or, if partnered, the business strategy of our partners may change;
- we or our pharmaceutical and biotechnology company partners may find certain products using our technologies cannot be manufactured on a commercial scale and, therefore, may not be economical to produce;
- we or our partners may determine that managed care providers are unwilling or unable to reimburse patients at an economically attractive level for products under development; or
- products that use our technologies and products in development acquired from Éclat could fail to obtain regulatory approval or, if approved, fail to achieve market acceptance, fail to be included within the pricing and reimbursement schemes of the U.S. or EU Member States, or be precluded from commercialization by proprietary rights of third parties.

***We must invest substantial sums in research and development in order to remain competitive, and we may not fully recover these investments.***

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop technologies and new products. In 2012 and the first nine months of 2013, we spent \$26.1 million and \$22.5 million, respectively, on research and development. Our ongoing investments in research and development for future products could result in higher costs without a proportionate increase, or any increase, in revenues. The research and development process is

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lengthy and carries a substantial risk of failure. If our research and development does not yield sufficient new technologies and products that achieve commercial success, our future operating results will be adversely affected.

***We must comply with various covenants and obligations under our debt agreements and our failure to do so could adversely affect our ability to operate our business, develop our product portfolio or pursue certain opportunities.***

We and our subsidiaries are subject to financial and non-financial restrictive covenants under (A) the Note Agreement dated March 13, 2012 (the “Éclat Note Purchase Agreement”), among Flamel, Flamel US Holdings, Inc. and Breaking Stick LLC, formerly Éclat Holdings, LLC, (B) the Facility Agreement dated December 31, 2012 (the “Deerfield Credit Facility”), among Flamel US Holdings, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P.; and (C) the Facility Agreement dated December 3, 2013 (the “Broadfin Credit Facility”) among Flamel US Holdings Inc., Flamel Technologies, Inc., Éclat Pharmaceuticals, LLC and Talec Pharma LLC and Broadfin Healthcare Master Fund, Ltd. The debt agreements may impair our ability and reduce our flexibility to operate and finance our business, plan for or react to changes in our business, the economy or the markets, or limit our ability to engage in activities that may be in our long term best interest. These covenants include, restrictive covenants with respect to (1) establishment of new subsidiaries, (2) liquidation, dissolution, mergers, consolidations or other corporate reorganizations, (3) prior to March 13, 2015, engaging someone other than Mr. Anderson to manage a substantial part of our business, unless Mr. Anderson’s employment agreement is terminated before such date other than as a result of our breach, (4) making restricted payments (such as dividends or distributions) to any shareholder, (5) creating or incurring any lien on our assets or those of our subsidiaries, subject to certain permitted exceptions; and (6) creating, incurring, assuming or guaranteeing any indebtedness, subject to certain permitted exceptions. If we were to default under the one or more of these debt agreements by violating covenants or otherwise, the lenders’ remedies would include the ability to, among other things, accelerate payment of all or a substantial portion of the amounts payable under the note and seize outstanding receivables. Defaults under the note or facility agreement, if not cured or waived, could have a material adverse effect on our business, financial condition, and results of operations. In addition, our largest shareholder, Deerfield Capital, has a controlling interest, and our Chief Executive Officer, Mr. Anderson, has a minority interest in Breaking Stick LLC. As a result, their interest may differ from those of our other shareholders.

***We depend upon a single site for the manufacture of each our current products, and any interruption of operations could have a material adverse effect on our business.***

Each of our current products is manufactured at a single facility. A significant interruption of operations at the facility for such product for any reason, such as fire, flood, labor disruptions or other manmade or natural disaster or a failure to obtain or maintain required regulatory approvals, could have a material adverse effect on our business, financial condition and results of operations. In case of a disruption, we may need to establish alternative manufacturing sources for the effected products, and this would likely lead to substantial production delays as we build or locate replacement facilities and seek to satisfy necessary regulatory obligations, including undergoing a successful inspection by the FDA, EMA, the competent authorities of EU Member States or our clients and obtaining the required regulatory approvals with respect to our drug delivery products. If this occurs, we may be unable to demonstrate compliance with applicable regulatory requirements governing manufacturing and to satisfy contractual obligations related to the effected products with our pharmaceutical or biotechnology partners in a timely manner.

***We depend on a limited number of suppliers for certain raw materials used in our drug delivery platforms and for the manufacture of certain products in development, and any failure of such suppliers to deliver sufficient quantities of these raw materials or product could interrupt our production process and could have a material adverse effect on our business.***

We purchase a number of raw materials used in our drug delivery platforms and products in development from a limited number of suppliers, including a single supplier for certain key ingredients. These raw materials include excipients such as cephers and cellets and active ingredients such as carvedilol phosphate

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used for the production of Coreg CR® microparticles and polyglutamate used in the production of our Medusa polymers. We use a contract manufacturing organization for the supply of our products in development. We generally have contracts in place with these suppliers, which are reviewed based on future forecast requirements. We determine minimum inventory levels based on our goal of holding at least three months of future requirements in inventory. If the supplies of these materials were interrupted for any reason, our manufacturing and marketing of certain products could be delayed. These delays could be extensive and expensive, especially in situations where a substitution was not readily available or required variations of existing regulatory approvals and certifications or additional regulatory approval. For example, an alternative supplier may be required to pass an inspection by the FDA, EMA or the competent authorities of EU Member States for compliance with current cGMP requirements before we may incorporate that supplier's ingredients into our manufacturing. We expect to continue relying on our current suppliers for the foreseeable future, but failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

***We depend on key personnel to execute our business plan. If we cannot attract and retain key personnel, we may not be able to successfully implement our business plan.***

Our success depends in large part upon our ability to attract and retain highly qualified personnel. During our operating history, we have assigned many key responsibilities within our Company to a relatively small number of individuals, each of whom has played key roles in executing various important components of our business. We do not maintain material key person life insurance for any of our key personnel. If we lose the services of Michael S. Anderson, our Chief Executive Officer, we may have difficulty executing our business plan in the manner we currently anticipate. Further, because each of our key personnel is involved in numerous roles in various components of our business, the loss of any one or more of such individuals could have an adverse effect on our business.

***If our competitors develop and market technologies or products that are safer or more effective than ours, or obtain regulatory approval and market such technologies or products before we do, our commercial opportunity will be diminished or eliminated.***

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures and other pharmaceutical and biotechnology companies, including other companies developing drug delivery platforms. Some of these competitors are also our business partners. Our Medusa technology competes with technologies from companies such as Ambrx, Enzon, Polytherics and Prolor Biotech, among others. Numerous companies, such as Acusphere, Supernus, Depomed and Alkermes, develop oral drug delivery platform that can compete with our Micropump technology. LiquiTime (liquid oral controlled-delivery platform) competes with technologies such as those developed Tris Pharma. With our Trigger Lock technology, we compete with companies seeking to develop abuse-deterrent formulations of scheduled drugs such as Pain Therapeutics or Acura Pharmaceuticals. The Éclat products compete with products of companies such as Covidien and Hi-Tech, among others. If we are successful in expanding our marketed products, we will encounter more competitors.

Many of these competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do. Furthermore, acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance our competitors' resources. Accordingly, our competitors may succeed in developing competing technologies and products, obtaining regulatory approval and gaining market share for these products more rapidly than we do.

Additionally, new chemical entities could be developed that, if successful, could compete against our technologies or products. Among the many experimental therapies being tested in the U.S. and in the EU, there may be some that we do not now know of that may compete with our drug delivery platforms or products in the future. These chemical entities and new products may be safer or may work better than our technologies or products. Our collaborators could choose a competing drug delivery platform to use with their drugs instead of one of our drug delivery platforms.

***We may fail to realize the anticipated benefits expected from the acquisition of Éclat and its portfolio of pipeline products.***

With the acquisition of Éclat, a new part of our business strategy is to develop, obtain FDA approval and commercialize its portfolio of potential niche brand and generic specialty pharmaceutical products. We also are aiming to transition to a more vertically integrated business model that adds increased commercial capabilities in the US to our existing drug delivery platforms. There can be no assurance that this strategy will be successful or that we will be able to successfully integrate and grow these two businesses, which could negatively impact our business and operating results.

***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 success depends in part on our ability to continually enhance and broaden our product offerings in response to market demands, competitive pressures and evolving technologies. Accordingly, we may in the future pursue the acquisition of complementary businesses, products or technologies instead of developing them ourselves. We do not know if we would be able to successfully complete any acquisitions, or whether we would be able to successfully integrate any acquired business, product or technology or retain any key employees. Integrating any business, product or technology we acquire could be expensive and time consuming, disrupt our ongoing business and distract our management. If we were to be unable to integrate any acquired businesses, products or technologies effectively, our business would suffer. In addition, any amortization or charges resulting from the costs of acquisitions could negatively impact our operating results.

***If we cannot keep pace with the rapid technological change in our industry, we may lose business, and our drug delivery platforms could become obsolete or noncompetitive.***

Our success also depends, in part, on maintaining a competitive position in the development of products and technologies in a rapidly evolving field. Major technological changes can happen quickly in the biotechnology and pharmaceutical industries. If we cannot maintain competitive products and technologies, our current and potential pharmaceutical and biotechnology company partners may choose to adopt the drug delivery platforms of our competitors. Our competitors may succeed in developing competing technologies or obtaining regulatory approval for products before us, and the products of our competitors may gain market acceptance more rapidly than our products. Such rapid technological change, or the development by our competitors of technologically improved or different products, could render our drug delivery platforms obsolete or noncompetitive.

***If we cannot adequately protect our intellectual property and proprietary information, we may be unable to sustain a competitive advantage.***

Our success depends, in part, on our ability to obtain and enforce patents for our products, processes and technologies and to preserve our trade secrets and other proprietary information. If we cannot do so, our competitors may exploit our innovations and deprive us of the ability to realize revenues and profits from our developments.

Any patent applications that we may have made or may make relating to our potential products, processes and technologies may not result in patents being issued. Patent law relating to the scope of claims in the pharmaceutical field in which we operate is continually evolving and can be the subject of some uncertainty. The laws providing patent protection may change in a way that would limit protection. Our current patents may not be exclusive, valid or enforceable. They may not protect us against competitors that challenge our patents, such as companies that submit drug marketing applications to the FDA, the EMA, or the competent authorities of EU Member States that rely, at least in part, on safety and efficacy data from our products or our business partners' products (e.g., abbreviated new drug applications), obtain patents that may have an adverse effect on our ability to conduct business or are able to circumvent our patents. The scope of any patent protection may not be sufficiently broad to cover our products or to exclude competing products. Our collaborations with third parties expose us to risks that they will claim intellectual property rights on our inventions or fail to keep our unpatented technology confidential.

We may not have the necessary financial resources to enforce our patents. Further, patent protection once obtained is limited in time, after which competitors may use the covered technology without obtaining a



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license from us. Because of the time required to obtain regulatory marketing approval, the period of effective patent protection for a marketed product is frequently substantially shortened.

We also rely on trademarks, copyrights, trade secrets and know-how to develop, maintain and strengthen our competitive position. To protect our trade secrets and proprietary technologies and processes, we rely, in part, on confidentiality agreements with our employees, consultants, advisors and partners. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully develop the information. If these agreements are breached, we cannot be certain that we will have adequate remedies. Further, we cannot guarantee that third parties will not know, discover or independently develop equivalent proprietary information or techniques, or that they will not gain access to our trade secrets or disclose our trade secrets to the public. Therefore, we cannot guarantee that we can maintain and protect unpatented proprietary information and trade secrets. Misappropriation or other loss of our intellectual property would adversely affect our competitive position and may cause us to incur substantial litigation or other costs.

### ***The implementation of the Leahy-Smith America Invents Act of 2011 may adversely affect our business.***

The Leahy-Smith America Invents Act of 2011 (“AIA”), which was signed into law on September 16, 2011, includes several provisions that may impact our business and patent protection in the United States. The AIA changes the current U.S. “first-to-invent” system to a system that awards a patent to the “first-inventor-to-file” for an application for a patentable invention. This change alters the pool of available materials that can be used to challenge patents in the U.S. and eliminates the ability to rely on prior research to lay claim to patent rights. Disputes will be resolved through new derivation proceedings and the AIA creates mechanisms to allow challenges to newly issued patents in reexamination proceedings. Although many of the changes bring U.S. law into closer harmony with EU and other national patent laws, the new bases and procedures may make it easier for competitors to challenge our patents, which could result in increased competition and have a material adverse effect on our business and results of operations. The changes may also make it harder to challenge third-party patents and place greater importance on being the first inventor to file a patent application on an invention. The AIA amendments to patent filing and litigation procedures in the U.S., may result in litigation being more complex and expensive and divert the efforts of our technical and management personnel.

### ***Even if we and our partners obtain necessary regulatory approvals, their and our products and our technologies may not gain market acceptance.***

Even if we and our pharmaceutical and biotechnology company partners obtain the necessary regulatory approval to market products or products that incorporate our technologies, such products, technologies and product candidates may not gain market acceptance among physicians, patients, healthcare payers and medical communities. The degree of market acceptance of any product, technology or product candidate will depend on a number of factors, including:

- the scope of regulatory approvals, including limitations or warnings in a product’s regulatory-approved labeling;
- demonstration of the clinical efficacy and safety of the product or technology;
- the absence of evidence of undesirable side effects that delay or extend trials;
- the lack of regulatory delays or other regulatory actions;
- its cost-effectiveness;
- its potential advantage over alternative treatment methods;
- the availability of third-party reimbursement; and
- the marketing and distribution support it receives.

If any of our products or technologies or our partners’ products fail to achieve market acceptance, our ability to generate revenue will be limited, which would have a material adverse effect on our business.

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***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.***

Our business continues to be dependent on our ability to work with customers and partners in collaborative relationships to develop products using our technologies, although we have products in development that are not dependent on these collaborative relationships. We have in the past and expect that in the future we will enter into collaborative arrangements, some of which not evidenced by formal or executed definitive agreements, but rather by memoranda of understanding, material transfer agreements, options or feasibility agreements. If the collaborative relationships give rise to disputes regarding the relative rights, obligations and revenues of the parties, including the ownership of intellectual property and associated rights and obligations, such disputes may delay collaborative research, development or commercialization of potential products and may lead to lengthy and expensive litigation or arbitration. The terms of collaborative arrangements may also limit or preclude us from fully developing our products or technologies developed pursuant to such collaborations. Additionally, the collaborators under these arrangements may breach the terms of their respective agreements or fail to prevent infringement of the licensed patents by third parties. Moreover, negotiating collaborative arrangements often takes considerably longer to conclude than the parties initially anticipate, which could cause us to agree to less favorable agreement terms that delay or defer recovery of our development costs and reduce the funding available to support key programs or the development of our products and technologies.

We may be unable to enter into future collaborative arrangements on acceptable terms, which could also adversely affect our ability to develop and commercialize our current and potential future products. Further, even if we do enter into acceptable collaboration arrangements, it is possible that our collaborative partners may not choose to develop and commercialize products using our technologies or may not devote sufficient resources to the development and commercial sales of products using our technologies. Our collaborative arrangements may also limit or preclude us with respect to the development of our products or technologies that may compete with those of our collaborators, but may not necessarily restrict our collaborative partners from competing with us or restrict their ability to market or sell competitive products. Our current and any future collaborative partners may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with us or may terminate their relationships with us or otherwise decide not to proceed with development and commercialization of products containing our drug delivery platform.

***If we or our collaborative partners are required to obtain licenses from third parties, our revenues and royalties on any commercialized products could be reduced.***

The development of some of our products may require the use of technology developed by third parties. The extent to which efforts by other researchers have resulted or will result in patents and the extent to which we or our collaborative partners are forced to obtain licenses from others, if available, on commercially reasonable terms is currently unknown. If we or our collaborative partners must obtain licenses from third parties, fees must be paid for such licenses, which would reduce the revenues and royalties we may receive on commercialized products that incorporate our technologies.

***Third parties may claim that our technologies, or the products in which they are used, or our products infringe on their rights, and we may incur significant costs resolving these claims.***

Third parties may claim, that the manufacture, use, import, offer for sale or sale of our drug delivery platforms or our products infringes on their patent rights. In response to such claims, we may have to seek licenses, defend infringement actions or challenge the validity of those patent rights in court. If we cannot obtain required licenses, are found liable for infringement or are not able to have such patent rights declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from the manufacture, use, import, offer for sale or sale of products or methods of drug delivery covered by the patents of others. We may not have identified, or be able to identify in the future, U.S. or foreign patents that pose a risk of potential infringement claims.

Any claims that our products or technologies infringe or may infringe proprietary rights of third parties, with or without merit, could be time-consuming, result in costly litigation or divert the efforts of our technical

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and management personnel, any of which could disrupt our relationships with our partners and could significantly harm our operating results.

We enter into collaborative agreements with pharmaceutical and biotechnology companies to apply our drug delivery platforms to drugs developed by others. Ultimately, we receive license revenues and product development fees, as well as revenues from royalties and the sale of products incorporating our technology. The drugs to which our drug delivery platforms are applied are generally the property of our pharmaceutical and biotechnology company partners. Those drugs may be the subject of patents or patent applications and other forms of protection owned by such companies or third parties. If those patents or other forms of protection expire, are challenged or become ineffective, sales of the drugs by such companies may be restricted or may cease and adversely affect our revenues.

***If our third party collaborative partners face generic competition for their products, our revenues and royalties from such products may be adversely affected.***

Some of our third party collaborative partners may utilize our drug delivery platforms in products with exclusive rights secured by patents or other means. These rights are limited in time and do not always provide effective protection for their products. If our collaborative partners are unable to protect their products' exclusivity or patent rights, generic competition may erode their market share, undermine the profitability of their products and limit the royalties we could collect from product sales. The expiration of the Hatch Waxman exclusivity for Coreg CR in April 2010 opened Coreg CR to potential generic competition, which may negatively affect the royalties we could collect in the future. Abbreviated New Drug Applications have been submitted to the FDA by Mutual Pharmaceuticals, Lupin Pharmaceuticals and Impax Laboratories requesting marketing approval of generic formulations of Coreg CR and by Anchen Pharmaceuticals regarding only 40 mg dosage strength. Should the FDA grant approval to any or all of these applications, our royalty income from sales of Coreg CR would be negatively affected. Through September 30, 2013, we have generated \$54.7 million in royalty revenue from Coreg CR, the only product sold using our drug delivery platform.

***Healthcare reform and restrictions on reimbursements may limit our financial returns.***

Our ability to successfully commercialize our products and technologies may depend on the extent to which the government health administration authorities, the health insurance funds in the EU Member States, private health insurers and other third party payers in the U.S. will reimburse consumers for the cost of these products, which would affect the volume of drug products sold by pharmaceutical and biotechnology companies that incorporate our technology into their products. Third party payers are increasingly challenging both the need for, and the price of, novel therapeutic drugs and uncertainty exists as to the reimbursement status of newly approved therapeutics. The commercial success of our products depends in part on the conditions under which products incorporating our technology are reimbursed. Adequate third party reimbursement may not be available for such drug products to enable us to maintain price levels sufficient to realize an appropriate return on our investments in research and product development, which could materially and adversely affect our business. We cannot predict the effect that changes in the healthcare system, especially cost containment efforts, may have on our business. In particular, it is difficult to predict the effect of health care reform legislation enacted in the U.S. in 2010, certain provisions of which are still subject to regulatory implementation, further legislative change and ongoing judicial review. Any such changes or changes due to future legislation governing the pricing and reimbursement of healthcare products in the EU Member States may adversely affect our business.

***Security breaches and other disruptions could compromise confidential information and expose us to liability and cause our business and reputation to suffer.***

In the ordinary course of our business, we collect and store proprietary data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, on our networks. The secure maintenance and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information systems and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or

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stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, investigations by regulatory authorities in the U.S. and EU Member States, disruption to our operations and damage to our reputation, any of which could adversely affect our business.

### ***Failure to comply with domestic and international privacy and security laws could result in the imposition of significant civil and criminal penalties.***

The costs of compliance with these laws, including protecting electronically stored information from cyber attacks, and potential liability associated with failure to do so could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA.

### ***Fluctuations in foreign currency exchange rates and the impact of the European sovereign debt crisis may cause fluctuations in our financial results.***

For the year ended December 31, 2012, we derived 42% of our total revenues from transactions in U.S. dollars, but have 34% of our cash and cash equivalents, all of our marketable securities, and the majority of our expenses denominated in Euros. Our functional currency is the Euro and our reporting currency is the U.S. Dollar. As a result, both our actual and reported financial results could be significantly affected by fluctuations of the Euro relative to the U.S. dollar. We do not engage in substantial hedging activities with respect to the risk of exchange rate fluctuations, although we do, from time to time, purchase Euros against invoiced Dollar receivables.

Recent developments in the EU have created uncertainty about the ability of certain EU Member States to continue to service their sovereign debt obligations. This debt crisis and the related financial restructuring efforts may cause the value of the Euro to deteriorate, reducing the value of the Euro relative to the U.S. Dollar. Any strengthening in the U.S. Dollar relative to the Euro would have a negative effect on our balance sheet while a weakening in the U.S. Dollar relative to the Euro would have a positive effect. In addition, the sovereign debt crisis affecting some EU Member States is contributing to instability in global credit markets. If global economic and market conditions, or economic conditions in the European Union, the U.S. or other key markets, remain uncertain, persist or deteriorate further, our business, financial condition, results of operations and cash flows may be adversely affected.

## **Risks Relating to Regulatory and Legal Matters**

### ***Products that incorporate our drug delivery platforms and our development products acquired from Éclat and other products we may develop are subject to regulatory approval. If we or our pharmaceutical and biotechnology company partners do not obtain such approvals, or if such approvals are delayed, our revenues may be adversely affected.***

In the U.S., federal state and local government agencies, primarily the FDA, regulate all pharmaceutical products, including existing products and those under development. We or our pharmaceutical and biotechnology company partners may experience significant delays in expected product releases while attempting to obtain regulatory approval for products incorporating our technologies. If we or our partners are not successful, our revenues and profitability may decline. We cannot control, and our pharmaceutical and biotechnology company partners cannot control, the timing of regulatory approval for any of these products, or if approval is obtained at all.

Applicants for FDA approval often must submit to the FDA extensive clinical and pre-clinical data as well as information about product manufacturing processes and facilities and other supporting information. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. The FDA also may require us or our partners to conduct additional pre-clinical studies or clinical trials. For instance, we do not anticipate the necessity to conduct individual

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toxicity and carcinogenicity tests for each product that we develop using the Medusa nano-particulate technology. Due to their special properties, however, nanoparticle formulations may pose different issues of safety or effectiveness than non-nanoscale products. With that in mind, the FDA may require additional toxicology tests and clinical trials to confirm the safety and effectiveness of product candidates using the Medusa technology, which would impact development plans for product candidates. Similarly, although we anticipate submitting applications for approval for the development products acquired from Éclat that rely on existing data to demonstrate safety and effectiveness, FDA may determine that additional studies particular to our products are necessary. If FDA requires such additional data, it would impact development plans for those products.

Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted new product application, also may delay an approval or result in rejection of an application. For instance, under the Food and Drug Administration Amendments Act of 2007 (“FDAAA”), we or our partners may be required to develop risk evaluations and mitigation strategies, or REMS, to ensure the safe use of their product candidates. If the FDA disagrees with our or our partners’ REMS proposals, it may be more difficult and costly for us or our partners to obtain regulatory approval for product candidates. Similarly, FDAAA provisions may make it more likely that the FDA will refer a marketing application for a new product to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. This review may add to the wait time for approval, and, although the FDA is not bound by the recommendation of an advisory committee, objections or concerns expressed by an advisory committee may cause the FDA to delay or deny approval.

The FDA has substantial discretion in the approval process and may disagree with our or our partners’ interpretations of data and information submitted in an application, which also could cause delays of an approval or rejection of an application. Even if the FDA approves a product, the approval may limit the uses or indications for which a product may be marketed, restrict distribution of the product or require further studies.

The FDA may also withdraw product clearances and approvals for failure to comply with regulatory requirements or if problems follow initial marketing. In the same way, medicinal products for supply on the EU market are subject to marketing authorization by either the European Commission, following an opinion by the EMA, or by the competent authorities of EU Member States. Applicants for marketing authorization must submit extensive technical and clinical data essentially in the form of the ICH Common Technical Document. The data is subject to extensive review by the competent authorities and may be considered inappropriate or insufficient. If applications for marketing authorization by pharmaceutical and biotechnology company partners are delayed, or rejected, if the therapeutic indications for which the product is approved are limited, or if conditional marketing authorization imposing post-marketing clinical trials or surveillance is imposed, our revenues may decline and earnings may be negatively impacted.

Manufacturers of drugs, including the active pharmaceutical ingredients, also must comply with applicable cGMP requirements, both as a condition of approval and for continued authority to manufacture and distribute products. Our manufacturing facilities and those of our pharmaceutical and biotechnology company partners may be required to pass a pre-approval inspection by the FDA, the EMA, the competent authorities of EU Member States or our customers, and will be subject to periodic inspection after that, all intended to ensure compliance with cGMP. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures, and we and our pharmaceutical and biotechnology company partners will need to ensure that all of our processes, methods and equipment are compliant with cGMP. We will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we, our pharmaceutical and biotechnology company partners or suppliers of key ingredients cannot comply with these practices, the sale of our products or products developed by our partners that incorporate our technologies may be suspended. This would reduce our revenues and gross profits.

If our products or products that incorporate our technologies are marketed in other jurisdictions, we and the partners with whom we are developing our technologies must obtain required regulatory approvals from foreign regulatory agencies and comply with extensive regulations regarding safety, quality and efficacy.

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These related obligations are frequently as demanding as those imposed by the FDA, the EMA or the competent authorities of EU Member States. If approvals to market our products or our partners' products are delayed, or if we or our partners fail to receive these approvals or previously received approvals are withdrawn, our revenues would be reduced. We may be required to incur significant costs to obtain or maintain foreign regulatory approvals.

***Commercial products are subject to continuing regulation, and we on our own, and in conjunction with our pharmaceutical and biotechnology company partners, may be subject to adverse consequences if we or they fail to comply with applicable regulations.***

We on our own and in conjunction with our pharmaceutical and biotechnology company partners will be subject to extensive regulatory requirements for our and their products and product candidates that incorporate our technologies, even if the products receive regulatory approval. These regulations are wide-ranging and govern, among other things:

- adverse drug experiences and other reporting requirements;
- product promotion and marketing;
- product manufacturing, including cGMP compliance;
- record keeping;
- distribution of drug samples;
- required post-marketing studies or clinical trials;
- authorization renewal procedures;
- authorization variation procedures;
- compliance with any required REMS;
- updating safety and efficacy information;
- processing of personal data;
- use of electronic records and signatures; and
- changes to product manufacturing or labeling.

If we or our partners, including any contract manufacturers that we use, fail to comply with these laws and regulations, the FDA, the European Commission, competent authorities of EU Member States, or other regulatory organizations, may take actions that could significantly restrict or prohibit commercial distribution of our products and products that incorporate our technologies. If the FDA, the European Commission or competent authorities of EU Member States determine that we are not in compliance with these laws and regulations, they could, among other things:

- issue warning letters;
- impose fines;
- seize products or request or order recalls;
- issue injunctions to stop future sales of products;
- refuse to permit products to be imported into, or exported out of, the United States or the European Union;
- suspend or limit our production;
- withdraw or vary approval of marketing applications;
- order the competent authorities of EU Member States to withdraw or vary national authorization; and
- initiate criminal prosecutions.

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***We are subject to U.S. 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.***

We are subject to extensive and complex U.S. federal and state and international laws and regulations, including but not limited to, health care “fraud and abuse” laws, such as anti-kickback and false claims laws and regulations pertaining to government benefit program reimbursement, price reporting and regulations, and sales and marketing practices. These laws and regulations are broad in scope and they are subject to evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our revenues, profitability, and financial condition. In the current environment, there appears to be a greater risk of investigations of possible violations of these laws and regulations. This is reflected by recent enforcement activity and pronouncements by the US Office of Inspector General of the Department of Health and Human Services that it intends to continue to vigorously pursue fraud and abuse violations by pharmaceutical companies, including through the potential to impose criminal penalties on pharmaceutical company executives. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

***Regulatory reforms may adversely affect our ability to sell our products or technologies profitably.***

From time to time, the U.S. Congress, the Council of the European Union and the European Parliament, as well as the legislators of the EU Member States, adopt changes to the statutes that the FDA, the European Commission and the competent authorities of the EU Member States enforce in ways that could significantly affect our business. In addition, the FDA, the European Commission and the competent authorities of the EU Member States often issue new regulations or guidance, or revise or reinterpret their current regulations and guidance in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA, EU or EU Member State’s regulations, guidance or interpretations changed, and what the impact of any such changes may be.

It is possible, however, that such changes could have a significant impact on the path to approval of products incorporating our technologies, our products or of competing products, and to our obligations and those of our pharmaceutical and biotechnology company partners. For example, the FDAAA contains a number of provisions that strengthen the FDA’s regulatory authority in various areas, including clinical trial registration and results reporting, pharmacovigilance, quality and other safety-related issues and post-approval clinical study requirements. As another example, with adoption of the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”), enacted in March, 2010 as a subtitle of the Patient Protection and Affordable Care Act, biological products incorporating our technologies may face competition from “biosimilar” products that are approved via an abbreviated process on the basis of a showing that the product is highly similar to the approved product. This abbreviated approval pathway is intended to permit a biosimilar product to come to market more quickly and less expensively than if a “full” biologics license application (“BLA”) were submitted, by relying to some extent on FDA’s previous review and approval of the reference product to which the proposed product is similar. The BPCIA provides periods of exclusivity during which abbreviated applications may not be submitted to, or approved by, FDA, but the statute then allows approval by an abbreviated pathway and, if certain standards are met, a finding by FDA that the biosimilar product is interchangeable with the reference product. If competitors are able to obtain marketing approval for biosimilars under an abbreviated regulatory approval process in the U.S. or the EU, certain products incorporating our technologies may become subject to additional competition with the attendant pricing pressure. Because the BPCIA is a highly complicated statute that has only recently been enacted, there is uncertainty as to how many important components of the new law will be implemented. Some issues may be resolved by three draft guidances that FDA issued in February 2012 or by issuance of regulations or other guidances, but other positions may develop on an ad hoc basis as FDA confronts them in the context of specific applications. The recent modifications to the provisions of the Community Code on medicinal product governing pharmacovigilance also impose further reporting and surveillance obligations on our partner

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pharmaceutical and biotechnology companies and grant greater supervisory powers to the European Commission and the competent authorities of EU Member States.

***We and companies to which we have licensed our technology and subcontractors we engage for services related to our in development products are subject to extensive regulation by the FDA and other regulatory authorities. Our and their failure to meet strict regulatory requirements could adversely affect our business.***

We and companies to which we license our technology as well as companies acting as subcontractors for our products are subject to extensive regulation by the FDA, other domestic regulatory authorities and equivalent foreign regulatory authorities, particularly the European Commission and the competent authorities of EU Member States. Those regulatory authorities may conduct periodic audits or inspections of the applicable facilities to monitor compliance with regulatory standards and we remain responsible for the compliance of our subcontractors. If the FDA or another regulatory authority finds failure to comply with applicable regulations, the authority may institute a wide variety of enforcement actions, including: warning letters or untitled letters; fines and civil penalties; delays in clearing or approving, or refusal to clear or approve, products; withdrawal, suspension or variation of approval of products; product recall or seizure; orders to the competent authorities of EU Member States to withdraw or vary national authorization; orders for physician notification or device repair, replacement or refund; interruption of production; operating restrictions; injunctions; and criminal prosecution. Any adverse action by a competent regulatory agency could lead to unanticipated expenditures to address or defend such action and may impair the ability to produce and market applicable products, which could significantly impact our revenues and royalties that we receive from our customers.

***We may face product liability claims related to clinical trials we may sponsor or for which we provide investigational products or technologies or the use or misuse of our products or products that incorporate our technologies.***

The testing, including through clinical trials, manufacturing and marketing of our products or products that incorporate our drug delivery platforms may expose us to potential product liability and other claims resulting from their use. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from contract research organizations or pharmaceutical and biotechnology companies or hospitals conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Insurance coverage is expensive and difficult to obtain, and we may be unable to obtain coverage in the future on acceptable terms, if at all. Although we currently maintain general liability insurance with a limit of €8 million and product liability and recall insurance with a limit of €10 million for products incorporating our technology, and coverage of \$5 million for products marketed by Éclat. We believe the amounts to be commercially reasonable, we cannot be certain that the coverage limits of our insurance policies or those of our strategic partners will be adequate. If we are unable to obtain sufficient insurance at an acceptable cost, a product liability claim or recall could adversely affect our financial condition. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical and biotechnology companies with whom we are developing our drug delivery platforms may not protect us from product liability claims from the consumers of those products or from the costs of related litigation. If we are subject to a product liability claim, our product liability insurance may not reimburse us, or be sufficient to reimburse us, for any expenses or losses we may suffer. A successful product liability claim against us, if not covered by, or if in excess of, our product liability insurance, may require us to make significant compensation payments. These payments would be reflected as expenses on our statement of operations and reduce our earnings.

***If we use biological and hazardous materials in a manner that causes injury, we may be liable for significant damages.***

Our research and development activities involve the controlled use of potentially harmful biological materials, hazardous materials and chemicals, and are subject to U.S., state, EU, national and local laws and regulations governing the use, storage, handling and disposal of those materials and specified waste products. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials, including fires and/or explosions, storage tank leaks and ruptures and discharges



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or releases of toxic or hazardous substances. These operating risks can cause personal injury, property damage and environmental contamination, and may result in the shutdown of affected facilities and the imposition of civil or criminal penalties. The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results.

We currently maintain environmental liability, property, business interruption and casualty insurance with aggregate maximum limits of €115 million, which are limits that we believe to be commercially reasonable, but may be inadequate to cover any actual liability or damages. If we fail to comply with environmental regulations, we could be subject to criminal sanctions and/or substantial liability for any damages that result, and any such liability could be significant.

### **Risks Relating to Ownership of Our Securities**

#### ***Our share price has been volatile and may continue to be volatile.***

The trading price of our shares has been, and is likely to continue to be, highly volatile. The market value of an investment in our shares may fall sharply at any time due to this volatility. During the year ended December 31, 2013, the closing price of the ADSs as reported on the NASDAQ National Market ranged from \$2.99 to \$8.21. During the year ended December 31, 2012, the closing sale price of the ADSs as reported on the NASDAQ National Market ranged from \$2.99 to \$7.67. The market prices for securities of drug delivery, biotechnology and pharmaceutical companies historically have been highly volatile. Factors that could adversely affect our share price include, among others:

- fluctuations in our operating results;
- announcements of technological collaborations, innovations or new products by us or our competitors;
- actions with respect to the acquisition of new or complementary businesses;
- governmental regulations;
- developments in patent or other proprietary rights owned by us or others;
- public concern as to the safety of drug delivery platforms developed by us or drugs developed by others using our platform;
- the results of pre-clinical testing and clinical studies or trials by us or our competitors;
- adverse events related to our products or products developed by pharmaceutical and biotechnology company partners that use our drug delivery platforms;
- lack of efficacy of our products;
- litigation;
- decisions by our pharmaceutical and biotechnology company partners relating to the products incorporating our technologies;
- actions by the FDA, the EMA or national authorities of EU Member States in connection with submissions related to the products incorporating our technologies;
- the perception by the market of biotechnology and high technology companies generally; and
- general market conditions, including the impact of the current financial environment.

#### ***Because we have limited commercial sales, evaluating our prospects may be difficult.***

We recorded the first commercial sales of products using one of our polymer technologies through our partner, Corning, in 1999. Our first commercial sales of a pharmaceutical compound incorporating our Micropump technology occurred in March 2007 with the launch of Coreg CR. We have had no commercial sales to date of products incorporating our Medusa technology. Accordingly, we have only a limited history of commercial sales, which may make it difficult to evaluate our prospects. The difficulty in evaluating our prospects may cause volatile fluctuations in the market price of our shares as investors and holders react to

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information about our prospects. Since 1995, we have generated revenues from product development fees and licensing arrangements and royalties. Our business and prospects must be evaluated in light of the risks and uncertainties of a company with limited commercial sales of products and only one currently marketed product.

### ***If we are not profitable in the future, the value of our shares may fall.***

We have a history of operating losses and have accumulated aggregate net loss from inception of approximately \$241 million through September 30, 2013. If we are unable to earn a profit in future periods, the market price of our stock may fall. The costs for research and product development of our drug delivery platforms and general and administrative expenses have been the principal causes of our net losses in recent years. Our ability to operate profitably depends upon a number of factors, many of which are beyond our direct control. These factors include:

- the demand for our technologies and products;
- the level of product and price competition;
- our ability to develop new collaborative partnerships and additional commercial applications for our products;
- our ability to control our costs;
- our ability to broaden our customer base;
- the effectiveness of our marketing strategy;
- the effectiveness of our partners' marketing strategy for products that use our technology; and
- general economic conditions.

### ***We may require additional financing, which may not be available on favorable terms or at all, and which may result in dilution of our shareholders' equity interest.***

We may require additional financing to fund the development and possible acquisition of new drug products and delivery platforms and to increase our production capacity beyond what is currently anticipated. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. If we cannot obtain financing when needed, or obtain it on favorable terms, we may be required to curtail our plans to continue to develop drug delivery platforms. We also may elect to pursue additional financing at any time to more aggressively pursue development of new drug delivery platforms. Other factors that will affect future capital requirements and may require us to seek additional financing include:

- the development and acquisition of new products and technologies;
- the progress of our research and product development programs;
- results of our collaborative efforts with current and potential pharmaceutical and biotechnology company partners; and
- the timing of, and amounts received from, future product sales, product development fees and licensing revenue and royalties.

If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in loss of sales, increased costs and reduced revenues.

### ***Our operating results may fluctuate, which may adversely affect our share price.***

Fluctuations in our operating results may lead to fluctuations, including declines, in our share price. Our operating results may fluctuate from period to period due to a variety of factors, including:

- demand by consumers for the products we and our partners produce;
- new product introductions;

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- pharmaceutical and biotechnology company ordering patterns;
- the number of new collaborative agreements into which we enter;
- the number and timing of product development milestones that we achieve under collaborative agreements;
- the level of our development activity conducted for, and at the direction of, pharmaceutical and biotechnology companies under collaborative agreements; and
- the level of our spending on new drug delivery platform development and technology acquisition, and internal product development.

Variations in the timing of our revenue and expenses also could cause significant fluctuations in our operating results from period to period and may result in greater than expected losses or more difficulty achieving earnings.

***We are subject to different corporate disclosure standards that may limit the information available to holders of the ADSs.***

As a foreign private issuer, we are not required to comply with the notice and disclosure requirements under the Exchange Act, relating to the solicitation of proxies for shareholder meetings. Although we are subject to the periodic reporting requirements of the Exchange Act, the periodic disclosure required of non-U.S. issuers under the Exchange Act is more limited than the periodic disclosure required of U.S. issuers. Therefore, there may be less publicly available information about us than is regularly published by or about other public companies in the United States.

***We currently do not intend to pay dividends and cannot assure shareholders that we will make dividend payments in the future.***

We have never declared or paid a cash dividend on any of our capital stock and do not anticipate declaring cash dividends in the foreseeable future. Declaration of dividends on our shares will depend upon, among other things, future earnings, if any, the operating and financial condition of our business, our capital requirements, general business conditions and such other factors as our Board of Directors deems relevant.

***Judgments of United States courts, including those predicated on the civil liability provisions of the federal securities laws of the United States, may not be enforceable in French courts.***

An investor in the U.S. may find it difficult to:

- effect service of process within the U.S. against us and our non-U.S. resident directors and officers;
- enforce United States court judgments based upon the civil liability provisions of the United States federal securities laws against us and our non-U.S. resident directors and officers in France; or
- bring an original action in a French court to enforce liabilities based upon the U.S. federal securities laws against us and our non-U.S. resident directors and officers.

***Holders of ADSs have fewer rights than shareholders and have to act through the Depositary to exercise those rights.***

Holders of ADSs do not have the same rights as shareholders and, accordingly, cannot exercise rights of shareholders against us. The Bank of New York Mellon, as depositary, or the “Depositary”, is the registered shareholder of the deposited shares underlying the ADSs. Therefore, holders of ADSs will generally have to exercise the rights attached to those shares through the Depositary. We will use reasonable efforts to request that the Depositary notify the holders of ADSs of upcoming votes and ask for voting instructions from them. If a holder fails to return a voting instruction card to the Depositary by the date established by the Depositary for receipt of such voting instructions, or if the Depositary receives an improperly completed or blank voting instruction card, or if the voting instructions included in the voting instruction card are illegible or unclear, then such holder will be deemed to have instructed the Depositary to vote its shares, and the Depositary shall vote such shares in favor of any resolution proposed or approved by our Board of Directors and against any resolution not so proposed or approved.

***Preferential subscription rights may not be available for U.S. persons.***

Under French law, shareholders have preferential rights to subscribe for cash issuances of new shares or other securities giving rights to acquire additional shares on a pro rata basis. U.S. holders of our securities (which might not be shares but ADSs) may not be able to exercise preferential subscription rights for their securities unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirements imposed by the Securities Act is available. We may, from time to time, issue new shares or other securities giving rights to acquire additional shares (such as warrants) at a time when no registration statement is in effect and no Securities Act exemption is available. If so, United States holders of our securities will be unable to exercise any preferential rights and their interests will be diluted. We are under no obligation to file any registration statement in connection with any issuance of new shares or other securities.

For holders of our shares in the form of ADSs, the Depositary may make these rights or other distributions available to holders in the United States if we instruct it to do so. If we fail to issue such instruction and the Depositary determines that it is impractical to sell the rights, it may allow these rights to lapse. In that case, the holders will receive no value for them.

***Our largest shareholders own a significant percentage of the share capital and voting rights of the Company.***

At December 31, 2013, Deerfield Capital and certain of its affiliates beneficially owned approximately 17.7% of our ordinary shares, Broadfin Capital and certain of its affiliates beneficially owned approximately 15.4% of our ordinary shares. To the extent these shareholders continue to hold a large percentage of our share capital and voting rights, they will remain in a position to exert heightened influence in the election of the directors of the Company and in other corporate actions that require shareholder approval, including change of control transactions.

***Purchasers in this offering will experience immediate dilution in the net tangible book value of their investment.***

Purchasers of the ADSs in this offering will experience an immediate dilution in the net tangible book value of the ADSs purchased in this offering because the price per share of ADSs in this offering is substantially higher than the net tangible book value of each share outstanding immediately after this offering. The net tangible book value of our ordinary shares as of September 30, 2013 was approximately (\$56.5) million, or approximately (\$2.2) per ADS. See “Dilution” in this prospectus supplement for a more detailed discussion of the dilution you will incur if you purchase ADSs in this offering.

***Our management will have broad discretion over the use of the proceeds we receive in this offering and might not apply the proceeds in ways that increase the value of your investment.***

Our management will have broad discretion to use our net proceeds from this offering and you will be relying on the judgment of our management regarding the application of these proceeds. Our management might not apply our net proceeds of this offering in ways that increase the value of your investment. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

## USE OF PROCEEDS

We estimate that the net proceeds from our sale of the ADSs in this offering will be approximately \$ million (or approximately \$ million if the underwriters' over-allotment option is exercised in full), after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use a portion of the net proceeds from the sale of the securities offered pursuant to this prospectus supplement to repay all amounts outstanding under the Deerfield Credit Facility, which matures on February 4, 2017, and the Broadfin Credit Facility, which matures on January 31, 2017. As of December 31, 2013, \$15.0 million principal amount was outstanding under the Deerfield Credit Facility, which bears interest at a rate of 12.5% per annum; and \$5.0 million principal amount was outstanding under the Broadfin Credit Facility, which bears interest at a rate of 12.5% per annum. Each of the Deerfield Credit Facility and the Broadfin Credit Facility were entered into to provide us with additional working capital.

We currently intend to use the remaining net proceeds from the sale of the securities offered hereby to continue the development of our product pipeline, including possible clinical trials, and for general corporate purposes, including working capital.

Management's plans for the use of the proceeds of this offering are subject to change due to unforeseen events and opportunities, and the amounts and timing of our actual expenditures depend on several factors. Accordingly, our management team will have broad discretion in using the net proceeds of this offering. Pending the use of the net proceeds, we intend to invest the net proceeds in short-term, investment-grade, interest-bearing instruments.

## MARKET PRICE AND DIVIDEND INFORMATION

Our ordinary shares, in the form of ADSs, are currently listed on the NASDAQ Global Market under the symbol "FLML." As of February 28, 2014, we had 25,617,550 ordinary shares outstanding, held by approximately 258 holders of record.

The following table sets forth the quarterly high and low sales prices of the ADSs on the NASDAQ Global Market for the periods indicated:

	Per ADS	
	High	Low
<b>2014:</b>		
First Quarter (through March 5, 2014)	\$ 11.48	\$ 7.95
<b>2013:</b>		
First Quarter	\$ 4.69	\$ 2.99
Second Quarter	\$ 6.40	\$ 3.93
Third Quarter	\$ 6.90	\$ 5.55
Fourth Quarter	\$ 8.21	\$ 5.30
<b>2012:</b>		
First Quarter	\$ 7.70	\$ 4.92
Second Quarter	\$ 5.75	\$ 3.96
Third Quarter	\$ 5.62	\$ 4.00
Fourth Quarter	\$ 4.38	\$ 2.85

We have never declared or paid a cash dividend on any of our capital stock and do not anticipate declaring cash dividends in the foreseeable future. Declaration of dividends on our shares will depend upon, among other things, future earnings, if any, the operating and financial condition of our business, our capital requirements, general business conditions and such other factors as our Board of Directors deems relevant.

## DILUTION

Our net tangible book value on September 30, 2013 was approximately (\$56.5) million, or (\$2.20) per share based on 25,465,400 ordinary shares outstanding as of that date. "Net tangible book value" is our total assets minus the sum of liabilities and intangible assets. "Net tangible book value per share" is net tangible book value divided by the total number of shares outstanding. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of ADSs in this offering and the net tangible book value per share of our ordinary shares immediately afterwards. After giving effect to the sale by us of 7,561,430 ADSs in this offering at an assumed public offering prices of \$10.58 per ADS (the last reported sale price of the ADSs on the NASDAQ Global Market on March 5, 2014) and after deducting the underwriting discount and estimated offering expenses payable by us, our net tangible book value as of September 30, 2013 would have been approximately \$18.1 million, or \$0.55 per share. This represents an immediate increase in net tangible book value of \$2.75 per share to existing shareholders and an immediate dilution of \$10.03 per ADS to new investors purchasing ADSs in this offering. The following table illustrates this dilution:

Assumed public offering price per ADS	\$10.58
Net tangible book value per ADS as of September 30, 2013	\$(2.20)
Increase per ADS attributable to new investors after giving effect to the offering	\$ 2.75
Net tangible book value per ADS after giving effect to the offering	\$ 0.55
Dilution per ADS to new investors	\$10.03

If the underwriters' over-allotment option is exercised in full to purchase 1,134,214 additional ADSs in this offering, based upon an assumed public offering price of \$10.58 (the last reported sale price of the ADSs on the NASDAQ Global Market on March 5, 2014), the net tangible book value per share after giving effect to the offering would be \$0.86 per ADS, the increase in the net tangible book value per share to existing shareholders would be \$3.06 per share and the dilution to the new investors would be \$9.72 per ADS.

The foregoing table does not take into effect further dilution to new investors that could occur upon the exercise of outstanding stock options and warrants having a per share exercise price less than the offering price per ADS in this offering.

## CAPITALIZATION

The following table sets forth capitalization as of September 30, 2013:

- on an actual basis; and
- on an as adjusted basis to give effect to material changes since September 30, 2013, excluding any material changes in the fair value remeasurement.

You should read this table in conjunction with other sections of this prospectus supplement, the accompanying prospectus and any documents that they incorporate by reference, including our consolidated financial statements and the related notes.

	As of September 30, 2013	
	Actual	As Adjusted
	(\$ in thousands, unaudited)	
Cash and cash equivalents	\$ 7,807	\$ 3,689 <sup>(4)</sup>
Liabilities:		
Long-term debt, less current portion <sup>(1)</sup>	\$ 65,398	\$ 69,392 <sup>(5)</sup>
Capital lease obligations, less current portion	122	122
Deferred revenue, less current portion	136	136
Deferred tax liabilities	7,670	7,670
Other long-term liabilities <sup>(2)</sup>	24,986	22,111
Total long-term liabilities	98,313	99,431
Shareholders' equity:		
Ordinary shares at nominal value of 0.122 euro (34,329,690 shares authorized and 25,612,550 shares issued) <sup>(3)</sup>	3,722	3,722
Additional paid-in capital	211,002	211,002
Accumulated deficit	(240,668)	(240,745)
Accumulated other comprehensive income	10,539	10,539
Total shareholders' equity	(15,405)	(15,482)
Total capitalization	\$ 82,908	\$ 83,949

(1) Long-term debt, less current portion includes:

Government loans for R&D projects	\$ 2,151	\$ 2,151
Acquisition liability contingent consideration	34,418	34,418
Acquisition liability note	8,531	8,531
Acquisition liability warrant consideration	7,457	7,457
Deerfield Facility Agreement	9,322	9,322
Deerfield Royalty Agreement	3,519	3,519
Broadfin Facility agreement	—	2,344
Broadfin Royalty Agreement	—	1,650
Total long-term debt, less current portion	\$65,398	\$69,392

(2) Other long-term liabilities includes:

Funding from partner GSK long-term	\$ 5,979	\$ 5,979
Provision for retirement indemnity	3,145	3,145
R&D tax credit financing long-term	12,959	12,959
Employee service award provision long-term	2,875	—
Other	28	28
Total Other Long-term Liabilities	\$24,986	\$22,111

(3) At an extraordinary shareholders' meeting held on February 11, 2014, our shareholders approved resolutions authorizing the Board of Directors, subject to certain limitations, to increase in our authorized capital by up to an additional 17,000,000 ordinary shares.

(4) As of February 28, 2014.

(5) Reflects facility agreement and royalty agreement entered into on December 3, 2013 with Broadfin Healthcare Masterfund Ltd on which initial funding of \$5.0 million was received.

## CERTAIN INCOME TAX CONSIDERATIONS

*The following summary of the material U.S. federal and French tax consequences of an investment in the ADSs and the ordinary shares they represent is based upon laws and relevant interpretations thereof in effect as of the date of this prospectus supplement, all of which are subject to change. This summary does not deal with all possible tax consequences relating to an investment in the ADSs or ordinary shares, such as the tax consequences under U.S. state, local and other tax laws.*

### U.S. Federal Income Taxation

The following discussion describes the material U.S. federal income tax consequences to U.S. Holders (defined below) under present law of an investment in the ADSs. This summary applies only to investors that hold the ADSs as capital assets. This discussion is based on the tax laws of the United States as in effect on the date of this prospectus supplement and on U.S. Treasury regulations in effect or in some cases, proposed, as of the date of this prospectus supplement, as well as judicial and administrative interpretations thereof available on or before such date. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below.

The following discussion does not deal with the tax consequences to any particular investor or to persons in special tax situations such as:

- certain financial institutions;
- insurance companies;
- broker dealers;
- U.S. expatriates;
- traders that elect to mark-to-market their securities holdings;
- tax-exempt entities;
- persons liable for alternative minimum tax;
- persons whose functional currency is not the U.S. dollar;
- persons holding an ADS as part of a straddle, hedging, conversion or integrated transaction; or
- persons that actually or constructively own 10% or more of our voting stock.

### **PROSPECTIVE PURCHASERS ARE URGED TO CONSULT THEIR TAX ADVISORS ABOUT THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE, LOCAL AND FOREIGN TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF ADSs.**

The discussion below of the U.S. federal income tax consequences to “U.S. Holders” will apply if you are a beneficial owner of ADSs and you are, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) organized under the laws of the United States, any state in the United States or the District of Columbia;
- an estate whose income is subject to U.S. federal income taxation regardless of its source; or
- a trust that (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) was in existence on August 20, 1996, was treated as a U.S. person under the U.S. Internal Revenue Code of 1986, as amended, on the previous day and has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.



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If you are a partner in a partnership or other entity taxable as a partnership for U.S. federal income tax purposes that holds ADSs, your tax treatment generally will depend on your status and the activities of the partnership. If you are a partner or partnership holding ADSs, you should consult your own tax advisors.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. If you hold ADSs, you generally will be treated as the holder of the underlying ordinary shares represented by those ADSs for U.S. federal income tax purposes.

### *Taxation of Dividends and Other Distributions on the ADSs*

Subject to the passive foreign investment company, or PFIC, rules discussed below, the gross amount of any distribution (including constructive dividends) to you with respect to the ADSs generally will be included in your gross income as dividend income on the date of actual or constructive receipt by the depository, but only to the extent that the distribution is paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). We do not currently intend to calculate our earnings and profits under U.S. federal income tax principles. Therefore, you should expect that any distribution we make generally will be treated as a dividend. The dividends will not be eligible for the dividends-received deduction allowed to corporations in respect of dividends received from other U.S. corporations.

With respect to certain non-corporate U.S. Holders, including individual U.S. Holders, dividends may constitute “qualified dividend income” and be taxed at the lower applicable capital gains rate, provided that (1) the ADSs with respect to which the dividends are paid are readily tradable on an established securities market in the United States, or we are eligible for one of certain income tax treaties with the United States, including the current income tax treaty between the United States and France, (2) we are not a passive foreign investment company (as discussed below) for either our taxable year in which the dividend was paid or the preceding taxable year, and (3) certain holding period requirements are met. Under U.S. Internal Revenue Service authority, ADSs are considered for the purpose of clause (1) above to be readily tradable on an established securities market in the United States if they are listed on the Nasdaq Global Select Market, as the ADSs are. You should consult your tax advisors regarding the availability of the lower rate for dividends paid with respect to the ADSs.

Dividends will constitute foreign source income for U.S. foreign tax credit limitation purposes and generally will constitute “passive category income” but could, in the case of certain U.S. Holders, constitute “general category income.”

Subject to certain conditions and limitations, French withholding taxes on dividends at a rate not exceeding the rate per the U.S. Treaty (defined below) may be treated as foreign taxes eligible for credit against your U.S. federal income tax. You should consult your own tax advisors regarding the creditability of any French tax.

### *Taxation of Disposition of ADSs*

Subject to the PFIC rules discussed below, you will recognize taxable gain or loss on any sale, exchange or other taxable disposition of an ADS equal to the difference between the amount realized for the ADS and your tax basis in the ADS. The gain or loss generally will be capital gain or loss. If you are a non-corporate U.S. Holder, including an individual U.S. Holder, who has held the ADS or ordinary share for more than one year at the time of disposition, you will be eligible for reduced tax rates. The deductibility of capital losses is subject to limitations. Any such gain or loss that you recognize generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes. You generally would only be able to claim a foreign tax credit for any foreign taxes to the extent that you have foreign source income.

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### *Passive Foreign Investment Company Status*

We do not currently expect to be a PFIC for U.S. federal income tax purposes for our current taxable year or the foreseeable future. Our actual PFIC status for the current taxable year, however, will not be determinable until the close of the current taxable year ending December 31, 2014, and accordingly, there is no guarantee that we will not be a PFIC for the current taxable year or any future taxable year. A non-U.S. corporation is considered to be a PFIC for any taxable year if either:

- at least 75% of its gross income is passive income; or
- at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income.

For this purpose, passive income generally includes dividends, interest, royalties and rents (other than royalties and rents derived in the active conduct of a trade or business and not derived from a related person). We will be treated as owning our proportionate share of the assets and receiving our proportionate share of the income of any other corporation in which we own, directly or indirectly, more than 25% (by value) of the stock.

We must make a separate determination each year as to whether we are a PFIC. As a result, our PFIC status may change. If we are a PFIC for any year during which you hold ADSs, unless you make a “mark-to-market” election as discussed below, we generally will continue to be treated as a PFIC for all succeeding years during which you hold ADSs.

If we are a PFIC for any taxable year during which you hold ADSs, you will be subject to special tax rules with respect to any “excess distribution” that you receive and any gain you realize from a sale or other disposition (including a pledge) of the ADSs, unless you make a “mark-to-market” election as discussed below. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period for the ADSs will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over your holding period for the ADSs;
- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or “excess distribution” cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the ADSs cannot be treated as capital, even if you hold the ADSs as capital assets.

Alternatively, a U.S. Holder of “marketable stock” (as defined below) in a PFIC may make a mark-to-market election for such stock of a PFIC to elect out of the tax treatment under the excess distribution regime described above. If you make a mark-to-market election for the ADSs, you will include in income each year an amount equal to the excess, if any, of the fair market value of the ADSs as of the close of your taxable year over your adjusted basis in such ADSs. You are allowed a deduction for the excess, if any, of the adjusted basis of the ADSs over their fair market value as of the close of the taxable year. However, deductions are allowable only to the extent of any net mark-to-market gains on the ADSs included in your income for prior taxable years. Amounts included in your income under a mark-to-market election, as well as gain on the actual sale or other disposition of the ADSs, are treated as ordinary income. Ordinary loss treatment also applies to the deductible portion of any mark-to-market loss on the ADSs, as well as to any loss realized on the actual sale or disposition of the ADSs, to the extent that the amount of such loss does not exceed the net mark-to-market gains previously included for such ADSs. Your basis in the ADSs will be adjusted to reflect any such income or loss amounts.

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The mark-to-market election is available only for “marketable stock,” which is stock that is regularly traded in other than *de minimis* quantities on at least 15 days during each calendar quarter on a qualified exchange, including the Nasdaq Global Select Market, or other market, as defined in applicable U.S. Treasury regulations. The ADSs are listed on the Nasdaq Global Select Market, and we expect that they will continue to be regularly traded on the Nasdaq Global Select Market. Consequently, if you are a holder of ADSs, the mark-to-market election should be available to you were we to be or become a PFIC.

If you hold ADSs in any year in which we are a PFIC, you will be required to file U.S. Internal Revenue Service Form 8621 regarding distributions received on the ADSs and any gain realized on the disposition of the ADSs (as well as any other information specified by the U.S. Department of the Treasury).

In addition, if we are a PFIC, we do not intend to prepare or provide you with the information necessary to make a “qualified electing fund” election.

You are urged to consult your tax advisor regarding the application of the PFIC rules to your investment in ADSs.

### *Information Reporting and Backup Withholding*

Dividend payments with respect to ADSs and proceeds from the sale, exchange or redemption of ADSs may be subject to information reporting to the U.S. Internal Revenue Service and possible U.S. backup withholding. Backup withholding will not apply, however, if you are a corporation or a U.S. Holder who furnishes a correct taxpayer identification number and makes any other required certification or if you are otherwise exempt from backup withholding. If you are a U.S. Holder who is required to establish exempt status, you generally must provide such certification on U.S. Internal Revenue Service Form W-9. You should consult your tax advisor regarding the application of the U.S. information reporting and backup withholding rules.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against your U.S. federal income tax liability, and you may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the U.S. Internal Revenue Service and furnishing any required information in a timely manner.

Certain U.S. Holders who are individuals that hold certain foreign financial assets (which may include the ADSs) are required to report information relating to such assets, subject to certain exceptions. You should consult your tax advisor regarding the effect, if any, of these rules on your ownership and disposition of the ADSs.

### **French Material Tax Consequences**

The following is a description of the material French tax consequences of the acquisition, ownership and disposition of the ADSs by a U.S. Holder. This description is based on applicable tax laws, regulations and judicial decisions as of the date of this annual report, and, where applicable, the Convention between the United States of America and France for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital, dated of August 31, 1994, as amended from time to time (the “U.S. Treaty”).

This description is based in part upon the representation of the custodian and the assumption that each obligation in the Depositary Agreement with the depository relating to your ADSs and any related agreement will be performed in accordance with their terms.

The following is a description of the principal tax effect on U.S. Holders for the purposes of French tax if, all of the following points apply:

- the U.S. Holder owns, directly, indirectly or constructively, less than 10% of the Company capital and dividend rights;
- the U.S. Holder is entitled to the benefits of the U.S. Treaty (including under the “limitations on benefits” article of the U.S. Treaty);
- the U.S. Holder does not hold the ADSs through a permanent or a fixed base in France;

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- the U.S. Holder is not multi-resident;
- the U.S. Holder does not hold the ADSs through a non-U.S. based pass-through entity; and
- the U.S. Holder does not receive dividend, capital gains or other payments on the ADSs on an account located in a Non-cooperative State as defined in Article 238-0 A of the French General Tax Code and as mentioned in a list published by the French tax authorities as amended from time to time (on January 1<sup>st</sup> of each year).

A U.S. Holder to whom all the above requirements apply will be hereafter defined as a Qualifying U.S. Holder.

This description is relevant only to holders of ADSs who are Qualifying U.S. Holders.

For purposes of the U.S. Treaty Qualifying U.S. Holders of ADSs will be treated as the owners of Company's ordinary shares represented by such ADSs.

Special rules apply to U.S. expatriates, insurance companies, pass-through entities and investors in such entities, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax and securities broker-dealers, among others. Those special rules are not discussed in this annual report.

Holders of Company ADSs are encouraged to consult their own tax advisors as to the particular tax consequences to them of owning the ADS, including their eligibility for benefits under the U.S. Treaty, the application and effect of state, local, foreign and other tax laws and possible changes in tax laws or in their interpretation.

### ***Taxation of Dividends***

Dividends paid by a French company to non-French holders are generally subject to a 30% withholding tax (or 21% if the holder is an individual resident of the EU, Norway, Iceland or Liechtenstein). Such 30% withholding tax rate can be increased to 75% if the dividend is paid towards non-cooperative States or territories (as mentioned above) irrespective of the tax residence of the beneficiary of the dividends. Such withholding tax rates may, however, be reduced by application of a tax treaty with France.

Dividends paid to a Qualifying U.S. Holder by French companies are immediately subject to a reduced rate of 15%, provided that such Qualifying U.S. Holder establishes before the date of payment of the dividend that he or she is a U.S. resident under the U.S. Treaty by completing and delivering the depositary with a simplified certificate (Form 5000-FR) (the "Certificate") in accordance with French tax guidelines (BOI-INT-DG-20-20-20-20). Dividends paid to a Qualifying U.S. Holder that has not filed and delivered to the paying agent the Certificate before the dividend payment date, will be subject to French withholding tax at the rate of 30%. The tax withheld in excess of 15% can be refunded by the French tax authorities provided that such Qualifying U.S. Holder duly completes and provides the French tax authorities with the Certificate and Form 5001-FR (the "Forms") before December 31 of the second calendar year following the year during which the dividend is paid. U.S. pension funds and other tax exempt entities are subject to the same general filing requirement as the U.S. Holders, except that they may be required to supply additional documentation evidencing their entitlement to these benefits.

### ***Taxation of Capital Gains***

A Qualifying U.S. Holder will not be subject to any French income or withholding tax on any capital gain realized upon the sale or exchange of ADSs of the Company.

### ***Estate and Gift Taxes***

Under the Convention Between the United States of America and the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritance and Gifts dated November 24, 1978 (as amended from time to time), if a U.S. Holder transfers his or her shares by gift or by reason of the U.S. Holder's death, that transfer will not be subject to French gift or inheritance tax unless the U.S. Holder is domiciled in France at the time of making the gift or at the time of his or her death or if the shares are held for use in the conduct of a business or profession through a permanent establishment or a fixed base in France.

### ***Wealth Tax***

Qualifying U.S. Holders will not be subject to French wealth tax.

## UNDERWRITING

Under the terms and subject to the conditions set forth in an underwriting agreement dated the date of this prospectus supplement, the underwriters named below, for whom JMP Securities LLC is acting as representative, have severally agreed to purchase, and we have agreed to sell to them, the number of ADSs indicated below:

Name	Number of ADSs
JMP Securities LLC	
SunTrust Robinson Humphrey, Inc.	
Ladenburg Thalmann & Co. Inc.	
Roth Capital Partners	
Summer Street Research Partners	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to various conditions, including approval of legal matters by counsel. The nature of the underwriters' obligations commits them to purchase and pay for all of the ADSs listed above if any are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

The underwriters are offering the ADSs, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

The representative expects to deliver the ADSs to purchasers on or about March , 2014.

### Commissions and Discounts

The underwriters initially propose to offer the ADSs directly to the public at the offering price listed on the cover page of this prospectus supplement. After the initial offering of the ADSs, the offering price and other selling terms may from time to time be varied by the representative.

The following table shows the per ADS and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us.

	Per ADS	Total No Exercise	Full Exercise
Price to public	\$	\$	\$
Underwriting discounts and commissions	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$550,000, which amount includes up to \$50,000 that we have agreed to reimburse the underwriters for their fees and expenses, including the fees and expenses of their counsel. In addition, upon the closing of this offering, we will pay to Leerink Swann LLC a financial advisory fee equal to \$ , which amount will reduce the total underwriting commission payable to the underwriters. Leerink Swann LLC is not acting as an underwriter in connection with this offering.

### Indemnification of Underwriters

We will indemnify the underwriters against some civil liabilities, including liabilities under the Securities Act. If we are unable to provide this indemnification, we will contribute to payments the underwriters may be required to make in respect of those liabilities.

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### **Electronic Offer, Sale and Distribution of ADSs**

A prospectus in electronic format may be made available on the web sites maintained by the underwriters, or selling group members, if any, participating in this offering and the underwriter participating in this offering may distribute prospectuses electronically. The underwriter may agree to allocate a number of ADSs to selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriter and selling group members that will make internet distributions on the same basis as other allocations.

### **Selling Restrictions**

No action has been taken in any jurisdiction (except in the United States) that would permit a public offering of the ADSs, or the possession, circulation or distribution of this prospectus or any other material relating to us or the ADSs in any jurisdiction where action for that purpose is required. Accordingly, the ADSs may not be offered or sold, directly or indirectly, and neither this prospectus nor any other material or advertisements in connection with the ADSs may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable laws, rules and regulations of any such country or jurisdiction.

*Canada.* The ADSs may not be offered, sold or distributed, directly or indirectly, in any province or territory of Canada or to or for the benefit of any resident of any province or territory of Canada, except pursuant to an exemption from the requirement to file a prospectus in the province or territory of Canada in which such offer, sale or distribution is made, and only through a dealer duly registered under the applicable securities laws of that province or territory or in accordance with an exemption from the applicable registered dealer requirements.

*European Economic Area.* In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or the Relevant Implementation Date, the ADSs may not be offered to the public in that Relevant Member State prior to the publication of a prospectus in relation to the ADSs which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that the ADSs may, with effect from and including the Relevant Implementation Date, be offered to the public in that Relevant Member State at any time:

- (a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year, (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- (c) to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the underwriter for any such offer; or
- (d) in any other circumstances falling within Article 3(2) of the Prospectus Directive.

For the purposes of this provision, the expression an “offer of ADSs to the public” in relation to any of the ADSs in any Relevant Member States means the communication in any form and by any means of sufficient information on the terms of the offer and the ADSs to be offered so as to enable an investor to decide to purchase or subscribe for the ADSs, as the same may be varied in that Member State, by any measure implementing the Prospectus Directive in that Member State, and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

*United Kingdom.* An offer of the ADSs may not be made to the public in the United Kingdom within the meaning of Section 102B of the Financial Services and Markets Act 2000, as amended, or the FSMA, except to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities or otherwise in circumstances that do not require the publication by the company of a prospectus pursuant to the Prospectus Rules of the Financial Services Authority, or the FSA.

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An invitation or inducement to engage in investment activity (within the meaning of Section 21 of FSMA) may only be communicated to persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or in circumstances in which Section 21 of FSMA does not apply to the company.

All applicable provisions of the FSMA with respect to anything done by the underwriter in relation to the ADSs must be complied with in, from or otherwise involving the United Kingdom.

### **Lock-up Agreements**

We, our executive officers and directors have agreed, subject to limited exceptions, for a period of 90 days after the date of the underwriting agreement, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, enter into any swap, hedge or similar agreement or arrangement that transfers in whole or in part, the economic risk of ownership of, or engage in any short selling of, any ordinary shares or ADSs or any securities convertible into or exchangeable for our ordinary shares or ADSs either owned as of the date of the underwriting agreement or thereafter acquired, without the prior written consent of the underwriter. This 90-day period may be extended if (1) during the last 17 days of the 90-day period, we issue an earnings release or material news or a material event regarding us occurs or (2) prior to the expiration of the 90-day period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 90-day period, then the period of such extension will be 18 days, beginning on the issuance of the earnings release or the occurrence of the material news or material event, subject to limited exceptions. Pursuant to the underwriting agreement, we may issue free shares to our employees and directors, ordinary shares or ADSs or stock options under our existing equity compensation plans and ordinary shares or ADSs upon conversion of stock options or warrants outstanding as of the date of this offering. The underwriter may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

### **NASDAQ Global Market Listing**

Our ordinary shares, in the form of ADSs, are listed on The NASDAQ Global Market under the trading symbol "FLML".

### **Passive Market-Making**

In connection with the offering, the underwriters may engage in passive market-making transactions in the ADSs on The NASDAQ Capital Market in accordance with Rule 103 of Regulation M under the Exchange Act during the period before the commencement of offers or sales of ADSs and extending through the completion and distribution. A passive market-maker must display its bids at a price not in excess of the highest independent bid of the security. However, if all independent bids are lowered below the passive market-maker's bid, that bid must be lowered when specified purchase limits are exceeded.

### **Short Sales, Stabilizing Transactions, and Penalty Bids**

In order to facilitate the offering of the ADSs, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the ADSs on the NASDAQ Global Market. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under their option to purchase additional shares described above. The underwriters can close out a covered short sale by exercising the option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the option. The underwriters may also sell shares in excess of the option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, ADSs in the open market to stabilize the price of the ADSs. These activities may raise or maintain the market price of the ADSs above independent market levels or prevent or retard a decline in the market price of the ADSs. The underwriters are not required to engage in these activities and may end any of these activities at any time.

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The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the ADSs, including the imposition of penalty bids. This means that if the representative of the underwriters purchases ADSs in the open market in stabilizing transactions or to cover short sales, the representative can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

### **Other Relationships**

The underwriters and their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have in the past performed and may in the future perform various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

### **LEGAL MATTERS**

Fidal Law Firm, 12 boulevard du General Leclerc 92200 Neuilly-sur-Seine France, will pass upon certain matters of French law for the Company, including the validity of the ordinary shares. Troutman Sanders LLP, will pass upon certain matters of U.S. laws for the Company. Goodwin Procter LLP, New York, New York and Taylor Wessing, Paris, France, are acting as counsel for the underwriters.

### **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 supplement by reference to the Annual Report on Form 20-F for the year ended December 31, 2012 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.

### **WHERE YOU CAN FIND MORE INFORMATION**

We are subject to the reporting requirements of the Exchange Act, and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the SEC's public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference facilities. SEC filings are also available at the SEC's web site at <http://www.sec.gov>.

This prospectus supplement and the accompany prospectus are only part of a registration statement on Form F-3 that we have filed with the SEC under the Securities Act, and therefore omit certain information contained in the registration statement. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus supplement and the accompanying prospectus, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the public reference room or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.



## INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to “incorporate by reference” information that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus supplement and accompanying prospectus. To the extent that any statement that we make in this prospectus supplement is inconsistent with the statements made in the accompanying prospectus or the information incorporated by reference, the statements made in the accompanying prospectus are deemed modified or superseded by the statements made in this prospectus supplement, while information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference into this prospectus supplement the documents listed below and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus supplement but prior to the termination of the offering of the shares covered by this prospectus supplement and accompanying prospectus (other than current reports furnished pursuant to Items 2.02 and 7.01 of Form 8-K). The documents we are incorporating by reference are:

- our Annual Report on Form 20-F for the fiscal year ended December 31, 2012;
- our Reports of Foreign Private Issuer on Form 6-K pursuant to Rules 13a-16 and 15d-16 filed with the Commission on February 12, 2013, March 1, 2013, April 2, 2013, May 16, 2013, May 28, 2013, June 7, 2013, July 15, 2013, August 2, 2013, September 19, 2013, December 6, 2013, December 10, 2013, January 15, 2014, January 31, 2014 and February 14, 2014;
- all documents we subsequently file under Sections 13(a), 13(c) or 15(d) of the Exchange Act after the date of the initial registration statement of which this prospectus forms a part (and prior to effectiveness) 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
- 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, +33 472 783 434.

PROSPECTUS

Up to 17,000,000 Ordinary Shares



**FLAMEL TECHNOLOGIES, S.A.**

Ordinary Shares in the Form of American Depositary Shares

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We may offer and sell from time to time an aggregate of up to 17,000,000 ordinary shares of Flamel Technologies, S.A., or Flamel, which may be represented by American Depositary Shares, or ADSs. Each ADS represents one ordinary share or the right to receive one ordinary share.

We may offer the securities for sale in amounts, at prices, and on terms determined at the time of the offering. We may sell the securities directly to you, through agents we select or through underwriters and dealers we select. If we use agents, underwriters or dealers, we will name them and describe their compensation in a prospectus supplement. This prospectus describes some of the general terms that may apply to an offering of the securities. The specific terms of any offering will be described in a supplement to this prospectus that contains specific information about the offering. You should read this prospectus and the accompanying prospectus supplement carefully before you invest.

ADSs, representing ordinary shares of Flamel, approximately €0.122 nominal value, referred to as ordinary shares, are traded under the symbol “FLML” on the NASDAQ Global Market. On February 11, 2014, the last reported sale price for our ADSs on the NASDAQ Global Market was \$9.52 per ADS.

**Investing in our securities involves risks that are described in the “Risk Factors” section beginning on page 4 of this prospectus and included in any prospectus supplement.**

The date of this prospectus is February 28, 2014

**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.**

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## ABOUT THIS PROSPECTUS

In this prospectus, “Flamel,” “the Company,” “we,” “us” and “our” refer to Flamel Technologies, S.A. and its subsidiaries, on a consolidated bases, unless otherwise indicated, “\$”, “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.

This prospectus is part of a registration statement on Form F-3 that we filed with the Securities and Exchange Commission, or the SEC, using the “shelf” registration process. Under this registration statement, we may from time to time, in one or more offerings, sell the ordinary shares, which may be represented by ADSs, as described in the prospectus. Each time we sell securities in primary offerings, we will provide a supplement to this prospectus that contains specific information about the terms of such offering. The supplement may also add, update or change information contained in this prospectus. Before purchasing any securities, you should carefully read both this prospectus and any supplement, together with the additional information incorporated by reference into this prospectus or any supplement.

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 nor that of any equivalent stock market authority of any member State of the European Economic Area.

The securities specified in this prospectus and any prospectus supplement are not intended for distribution in France except to (i) persons providing asset management services for the account of third parties and (ii) qualified investors (*investisseurs qualifiés*) to the exclusion of individuals all as defined in, and in accordance with, Articles L. 411-1, L. 411-2, D. 411-1 *et seq.* of the French Monetary and Financial Code (*Code monétaire et financier*). The prospectus and any prospectus supplement have not been and are not to be distributed or reproduced (in whole or in part) in France. 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*).

## 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, 2012, 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 in connection with our acquisition of Éclat Pharmaceuticals, LLC (“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 our debt agreements, and our failure to do so could adversely affect our ability to operate our business, develop our product portfolio or pursue certain opportunities;
- 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;

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- 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 cause 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;
- the price of our ADSs 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; and
- 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. Except as required by law, 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.

## THE COMPANY

### General

We are a specialty pharmaceutical company with a business model focused on blending high-value internally developed products with our leading drug delivery capabilities. We have a proprietary pipeline of niche specialty pharmaceutical products, while our drug delivery platforms are being used to target safer, more efficacious formulations of pharmaceuticals to address unmet medical needs. Our partnered pipeline includes biological and chemical drugs formulated with our Medusa® and Micropump® proprietary drug delivery platforms. Several Medusa-based products have been successfully tested in clinical trials. We have developed products and manufacture Micropump-based microparticles under FDA-audited GMP guidelines. We have a collaboration with GlaxoSmithKline (Coreg CR®, carvedilol phosphate) as well as other pharmaceutical and biotechnology companies which have not yet been disclosed.

### Recent Developments in the Products Portfolio

On May 31, 2013, the U.S. Food and Drug Administration (“FDA”) approved the company’s New Drug Application (NDA) for Bloxiverz™ (neostigmine methylsulfate), a drug used intravenously in the operating room for the reversal of the effects of non-depolarizing neuromuscular blocking agents after surgery. Our subsidiary, Éclat Pharmaceuticals is working to place product into the marketplace and informing clinical staff, hospital risk managers and Group Purchasing Organizations (“GPOs”) to make them aware of availability of the first FDA-approved version of neostigmine sulfate.

On September 2013, FDA accepted for review our second new drug application (“NDA”). We have received a Prescription Drug User Fee Act (“PDUFA”) date, the target date for the FDA to complete its review of the NDA, of April 28, 2014. For competitive reasons, we have decided not to identify the product at this time, but we intend to provide additional information at a later date.

As a part of our research and development program, we have completed preclinical studies with our proprietary extended release Medusa hGH XL product which utilizes our Medusa® technology applied to recombinant human growth hormone (rhGH). Our study data provided significant evidence to move this proprietary drug forward into a human clinical trial in 2014 with once weekly dosing.

We will continue to push forward on additional NDA filings out of the Éclat portfolio and on development of additional, innovative drugs that employ our proprietary platform of technologies. Greater research and development spending on these new product efforts is designed to build our near-term and mid-term pipeline and potential revenues. In addition, we continue to explore development, supply and licensing opportunities for our five drug delivery platforms with third parties, but will not rely completely on those partnerships to create revenue and profit opportunities.

### Company Information

Our principal executive offices are located at 33 Avenue du Docteur Georges Levy, 69693 Vénissieux Cedex, France, and our telephone number at that location is +33 472 783 434. In addition, we have operations in St. Louis, Missouri, USA, and manufacturing facilities in Pessac, France. For more information regarding our business, please refer to our Annual Report on Form 20-F for the year ended December 31, 2012, which is incorporated herein by reference. Our website address is [www.flamel.com](http://www.flamel.com). Information contained on our website is not part of this prospectus.

## RISK FACTORS

Investing in the ADSs involves a high degree of risk. Before making an investment decision, you should carefully consider 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, 2012, which are incorporated herein by reference, and any risk factors that may be set forth in any applicable prospectus supplement, together with all of the other information contained or incorporated by reference into this prospectus or any applicable prospectus supplement. 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.

## USE OF PROCEEDS

Unless we otherwise specify in the applicable prospectus supplement, we intend to use the net proceeds from the sale of securities under this prospectus for general corporate purposes, including working capital and repayment of outstanding debt. We will include additional information about any indebtedness to be repaid with net proceeds from the sale of the shares in an applicable prospectus supplement. Accordingly, we will retain broad discretion over the use of the proceeds. Until we use the net proceeds from the sale of the securities for these purposes, we may place the net proceeds in temporary investments.

## 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.

<b>Year Ended December 31, Euro to U.S. Dollar:</b>	<b>High</b>	<b>Low</b>	<b>Average Rate*</b>
2013	1.3814	1.2768	1.3282
2012	1.3454	1.2089	1.2856
2011	1.4882	1.2889	1.3917
2010	1.4563	1.1942	1.3268
2009	1.512	1.2555	1.3933
<b>Previous Six Months, Euro to U.S. Dollar:</b>	<b>High</b>	<b>Low</b>	<b>Average Rate*</b>
January 2014	1.3687	1.3526	1.3610
December 2013	1.3814	1.3536	1.3704
November 2013	1.3611	1.3365	1.3493
October 2013	1.3805	1.3493	1.3635
September 2013	1.3545	1.3117	1.3348
August 2013	1.3392	1.3203	1.3310

\* 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 February 11, 2014, was \$1.3676 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.



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The following table sets forth our unaudited consolidated indebtedness and capitalization as of September 30, 2013 in accordance with U.S. GAAP. The information in this table should be read in conjunction with and is qualified by reference to the financial statements and notes thereto and other financial information included in our Report of Foreign Private Issuer on Form 6-K filed on January 15, 2014 and incorporated by reference in this prospectus.

	As of September 30, 2013 <u>(\$ in thousands)</u> (unaudited)
Cash and cash equivalents	\$ 7,807
<b>Liabilities:</b>	
Long-term debt, less current portion <sup>(1)(2)</sup>	\$ 65,398
Capital lease obligations, less current portion	122
Deferred revenue, less current portion	136
Deferred tax liabilities	7,670
Other long-term liabilities <sup>(3)</sup>	24,986
<b>Total long-term liabilities</b>	<b>98,313</b>
<b>Shareholders' equity:</b>	
Ordinary shares at nominal value of 0.122 euro (34,329,690 shares authorized and 25,612,550 shares issued) <sup>(4)</sup>	3,722
Additional paid-in capital	211,002
Accumulated deficit	(240,668)
Accumulated other comprehensive income	10,539
<b>Total shareholders' equity</b>	<b>(15,405)</b>
<b>Total capitalization</b>	<b>\$ 82,908</b>

- (1) Long-term debt, less current portion includes:
- |   |                 |
|---|-----------------|
| Government loans for R&D projects                 | \$ 2,151        |
| Acquisition liability contingent consideration    | 34,418          |
| Acquisition liability note                        | 8,531           |
| Acquisition liability warrant consideration       | 7,457           |
| Deerfield Facility agreement                      | 9,322           |
| Deerfield Royalty Agreement                       | 3,519           |
| <b>Total long-term debt, less current portion</b> | <b>\$65,398</b> |
- (2) Does not reflect \$5.0 million outstanding under our new loan agreement entered into in December 2013.
- (3) Other long-term liabilities includes:
- |  |                 |
|--|-----------------|
| Funding from partner GSK long-term         | \$ 5,979        |
| Provision for retirement indemnity         | 3,145           |
| R&D tax credit financing long-term         | 12,959          |
| Employee service award provision long-term | 2,875           |
| Other                                      | 28              |
| <b>Total Other Long-term Liabilities</b>   | <b>\$24,986</b> |
- (4) At an extraordinary shareholders' meeting held on February 11, 2014, our shareholders approved resolutions authorizing the Board of Directors, subject to certain limitations, to increase in our authorized capital by up to an additional 17,000,000 ordinary shares.

### MARKET PRICE INFORMATION

There is currently no public trading market for our ordinary shares. The ADSs have been traded on the Nasdaq Global Market under the symbol “FLML” since 1996. The following table shows the high and low sales prices of the ADSs on the NASDAQ Global Market for the periods indicated.

	Per ADS	
	High	Low
<b>2014:</b>		
First Quarter (through February 11, 2014)	\$ 11.48	\$ 7.95
<b>2013:</b>		
First Quarter	\$ 4.69	\$ 2.99
Second Quarter	\$ 6.40	\$ 3.93
Third Quarter	\$ 6.90	\$ 5.55
Fourth Quarter	\$ 8.21	\$ 5.30
<b>2012:</b>		
First Quarter	\$ 7.70	\$ 4.92
Second Quarter	\$ 5.75	\$ 3.96
Third Quarter	\$ 5.62	\$ 4.00
Fourth Quarter	\$ 4.38	\$ 2.85

### PLAN OF DISTRIBUTION

We may sell the securities covered by this prospectus in any one of more of the following ways from time to time:

- to or through underwriters;
- to or through dealers;
- directly to one or more purchasers;
- through agents; or
- through a combination of any of the above.

The prospectus supplement with respect to any offering of our securities will set forth the terms of the offering, including:

- the name or names of any underwriters, dealers or agents;
- the purchase price of the securities and the proceeds to us from the sale;
- any underwriting discounts and commissions or agency fees and other items constituting underwriters’ or agents’ compensation; and
- any delayed delivery arrangements.

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.

If underwriters are used in the sale of any securities, the securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions described above. The securities may be either offered to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters. Generally, the underwriters’ obligations to purchase the securities will be subject to conditions precedent and the underwriters will be obligated to purchase all of the securities if they purchase any of the securities. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

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We may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase the securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject to conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we pay for solicitation of these contracts.

Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time. Pursuant to a requirement by the Financial Industry Regulatory Authority, or FINRA, the maximum commission or discount to be received by any FINRA member or independent broker/dealer may not be greater than 8% of the gross proceeds received by us for the sale of any securities being registered pursuant to SEC Rule 415 under the Securities Act.

We may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of securities, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of securities. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement or in a post-effective amendment.

Underwriters, dealers and agents may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments made by the underwriters, dealers or agents, under agreements between us and the underwriters, dealers and agents.

We may grant underwriters who participate in the distribution of securities an option to purchase additional securities to cover over-allotments, if any, in connection with the distribution.

Underwriters, dealers or agents may receive compensation in the form of discounts, concessions or commissions from us or our purchasers, as their agents in connection with the sale of securities. These underwriters, dealers or agents may be considered to be underwriters under the Securities Act. As a result, discounts, commissions or profits on resale received by the underwriters, dealers or agents may be treated as underwriting discounts and commissions. The prospectus supplement will identify any such underwriter, dealer or agent and describe any compensation received by them from us. Any initial public offering price and any discounts or concessions allowed or re-allowed or paid to dealers may be changed from time to time.

Any underwriter may engage in over-allotment transactions, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time. We make no representation or prediction as to the direction or magnitude of any effect that such transactions may have on the price of the securities. For a description of these activities, see the information under the heading "Underwriting" or "Plan of Distribution" in the applicable prospectus supplement.

Underwriters, broker-dealers or agents who may become involved in the sale of the securities may engage in transactions with and perform other services for us in the ordinary course of their business for which they receive compensation.

**DESCRIPTION OF SHARE CAPITAL**

Set forth below is certain information concerning our 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, 2012, which is incorporated by reference into this prospectus.

**General**

Our share capital consists of ordinary shares, nominal value 0.122 euros per share. We have authorized 51,329,690 ordinary shares, 25,612,550 of which were issued and outstanding as of February 11, 2014. All of the shares, including the shares to be sold in any subsequent offering, are or will be fully paid.

We do not hold any shares in our treasury.

**Capital Authorized but Unissued**

At our Combined Ordinary and Extraordinary Meeting of Shareholders held on June 20, 2013, our shareholders authorized the Board of Directors to increase our share capital to, among other things, allocate stock options and free shares to employees. In addition, at a subsequent Extraordinary Meeting of Shareholders held on February 11, 2014, our shareholders authorized the Board of Directors to increase the share capital of the Company in connection with potential offerings by the Company that meet the criteria specified by the shareholders.

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 February 11, 2014:

<b>Nature of Authorized Operation</b>	<b>Valid Through</b>	<b>Maximum Amount of Capital Increase (par value) (in euros)</b>	<b>Use of delegation since June 20, 2013</b>	<b>Balance</b>
Authorization of the Issuance of 15,000,000 Ordinary Shares	August 11, 2015	1,829,400	No	1,829,400
Authorization of the Issuance of 2,000,000 Ordinary Shares	August 11, 2015	243,920	No	243,920
Authorization for the Issuance of 1,000,00 Stock Options	August 21, 2015	121,960	Yes	3,415
Authorization for the Issuance of 200,000 shares at no cost (“Free Shares”)	August 21, 2015	24,392	Yes	—
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
Authorization for Issuance of 600,000 Stock Options	August 20, 2016	73,176	No	73,176
Authorization for the Issuance of 200,000 Free Shares	August 20, 2016	24,392	Yes	10,556
Authorization of 300,000 stock warrants	December 20, 2014	36,588	Yes	12,196
Authorization for Issuance of 200,000 Ordinary Shares	December 20, 2014	24,392	No	24,392
Authorization for Issuance of 3,000,000 Ordinary Shares	April 11, 2016	365,880	No	365,880
Authorization for Issuance of 15,000,000 Ordinary Shares	August 11, 2015	1,829,400	No	1,829,400
Authorization for Issuance of 2,000,000 Ordinary Shares	August 11, 2015	243,920	No	243,920

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### **Reconciliation of the Number of Shares Outstanding**

Number of Ordinary Shares as of the opening date of the fiscal year 2013	25,415,400
Issuance of Ordinary Shares on June 20, 2013	50,000
Issuance of Ordinary Shares on December 12, 2013	147,150
Number of Ordinary Shares as of December 31, 2013	25,612,550

### **Options Outstanding**

Stock options outstanding at September 30, 2013, which expire from 2013 to 2023, had exercise prices ranging from €3.00 to €25.39. The weighted average remaining contractual life of all options is 3.81 years. As of September 30, 2013, there were 3,133,990 outstanding options at a weighted average exercise price of €10.41, of which 2,251,240 were exercisable at a weighted average price of €12.95.

### **History of the Share Capital**

The table below shows the evolution of our share capital over the last three fiscal years through February 11, 2014:

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
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
December, 2012	Definitive acquisition of Free Shares	258,150	31,484	—	—	25,415,400
June, 2013	Exercise of warrants	50,000	6,098	218,902	225,000	25,465,400
August, 2013	Subscription for warrants by Directors	180,000	—	77,400	77,400	25,465,400
December 2013	Definitive acquisition of Free Shares	147,150	17,946	—	—	25,612,550

### **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, 2012, 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 Lyon, France, under registration number 379001530.

Our 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).

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### **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 (1) in the ordinary course of our business and (2) 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.* Our *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, our share capital 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 us by way of set-off, for

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assets contributed in kind, upon the conversion, exchange or redemption of debt securities previously issued by us, 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 us 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 our *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 (1) we are not wholly owned by the absorbing company or (2) we do 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 our fiscal year, which is December 31. Under our *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 our 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 our 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 ten 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 our share capital, 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

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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 our *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 Depositary 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 our 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 us 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 our registered office 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, our *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



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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 our 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 we are liquidated, our assets remaining after payment of our debts, liquidation expenses and all of our 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, we may not acquire our shares except in certain limited circumstances not presently applicable to it.

### ***Form and Holding of Shares***

*Form of Shares.* Our *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 we 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 and further amended and restated as of February 28, 2014, among Flamel, The Bank of New York Mellon (formerly, “The Bank of New York”), 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 February 12, 2014. 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 Vallhubert, 75206 Paris Cedex 13, FRANCE. Each ADS will also represent any other securities, cash or other property that may be held by the Depositary.

You may hold ADSs either (A) directly (i) by having an ADR registered in your name, or (ii) by having ADSs registered in your name in the Direct Registration System or (B) indirectly through your broker or other financial institution. If you hold ADSs directly, you are a registered ADS 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 used herein, the term “ADR holder” shall mean a person holding ADSs directly.

The Direct Registration System, also referred to as “DRS,” is a system administered by The Depositary Trust Company, also referred to as “DTC,” under which the Depositary may register the ownership of uncertificated ADSs, which ownership is confirmed by periodic statements sent by the Depositary to the registered holders of uncertificated ADSs.

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 ordinary 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

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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 ADR holders, it will exercise the rights and purchase the shares on your behalf. The Depositary will then deposit the shares and deliver ADRs to the persons entitled to them. 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. 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 to or upon the order of the person or persons that made the deposit.

You may surrender your ADRs at the Depositary's Corporate Trust 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 Corporate Trust 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

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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;
- 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. \$0.05 (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
4. \$1.50 or less per certificate
5. \$0.05 (or less) per ADS per calendar year
6. Registration or transfer fees
7. Expenses of the Depositary
8. 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
9. Expenses of the Depositary in converting foreign currency to U.S. dollars
10. Any charges incurred by the Depositary or its agents for servicing the deposited securities.

#### **For:**

Issuance 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  
Registration or transfer of ADRs  
Depositary services  
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)

As necessary

As necessary

As necessary

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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 (1) change the nominal value of our shares; (2) reclassify, split up or consolidate any of the Deposited Securities; (3) distribute securities on the shares that are not distributed to you; or (4) 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 distribute new ADSs representing new Deposited Securities 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 (1) received by the Depositary as the holder of the Deposited Securities and (2) 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 us, the Depositary will arrange for copies of such reports and communications to be mailed to all owners of ADRs at our 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.*

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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 (1) the Depositary has closed its transfer books or we have closed our transfer books, (2) the transfer of shares is blocked to permit voting at a shareholders' meeting or (3) we are paying a dividend on our shares;

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- 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 Depository to deliver ADRs before deposit of the underlying shares. This is called a pre-release of ADRs. The Depository 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 Depository. The Depository may receive ADRs instead of shares to close out a pre-release.

The Depository 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 Depository 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 Depository considers appropriate; and
- the Depository must be able to close out the pre-release on not more than five business days' notice. In addition, the Depository 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 Depository may disregard the limit from time to time, if it thinks it is appropriate.

### **Direct Registration System**

In the Deposit Agreement, all parties to the Deposit Agreement acknowledge that the DRS and Profile Modification System, or Profile, will apply to uncertificated ADSs upon acceptance thereof to DRS by DTC. DRS is the system administered by DTC under which the Depository may register the ownership of uncertificated ADSs, which ownership will be evidenced by periodic statements sent by the Depository to the registered holders of uncertificated ADSs. Profile is a required feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of ADSs, to direct the Depository to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the Depository of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the Deposit Agreement understand that the Depository will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the Deposit Agreement, the parties agree that the Depository's reliance on and compliance with instructions received by the Depository through the DRS/Profile System and in accordance with the Deposit Agreement will not constitute negligence or bad faith on the part of the Depository.

### **Shareholder Communications: Inspection Rights**

The Depository 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 Depository will send you copies of those communications if we ask it to. The Depository 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 Depository may close the transfer books in connection with the performance of its duties under the Deposit Agreement or upon the Company's request.

## WHERE YOU CAN FIND MORE INFORMATION

We file 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](http://www.flamel.com). We are not incorporating the contents of our or the SEC’s websites or the website of any other person into this prospectus.

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 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, 2012;
- our Reports of Foreign Private Issuer on Form 6-K pursuant to Rules 13a-16 and 15d-16 filed with the Commission on February 12, 2013, March 1, 2013, April 2, 2013, May 16, 2013, May 28, 2013, June 7, 2013, July 15, 2013, August 2, 2013, September 19, 2013, December 6, 2013, December 10, 2013, January 15, 2014 and January 31, 2014;
- all documents we subsequently file under Sections 13(a), 13(c) or 15(d) of the Exchange Act after the date of the initial registration statement of which this prospectus forms a part (and prior to effectiveness) 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
- 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, +33 472 783 434.

## 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	\$ 40,000
Accounting Fees and Expenses	\$ 35,000
SEC Registration Fee	\$ 20,583
Printing Expenses	\$ 5,000
Miscellaneous Expenses	\$ 5,000
<b>TOTAL</b>	<b><u>\$105,583</u></b>

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

Fidal Law Firm, 12 boulevard du Général Leclerc 92200 Neuilly-sur-Seine France, will pass upon certain matters of French law for the Company, including the validity of the ordinary shares. Troutman Sanders LLP, will pass upon certain matters of U.S. laws for the Company.

## 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, 2012 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.

## 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.

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**American Depositary Shares**



**FLAMEL TECHNOLOGIES, S.A.**

**Representing Ordinary Shares**

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**PROSPECTUS SUPPLEMENT**

**March , 2014**

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*Sole Book-Running Manager*

**JMP Securities**

*Co-Managers*

**SunTrust Robinson Humphrey  
Ladenburg Thalmann & Co. Inc.  
Roth Capital Partners  
Summer Street Research Partners**

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