

July 14, 2016

Securities Act of 1933:
Section 3(a)(10) and Rule 144

United States Securities and Exchange Commission
Division of Corporation Finance
Office of International Corporate Finance
100 F Street, N.E.
Washington, D.C. 20549

Re: Flamel Technologies S.A. and Avadel Pharmaceuticals plc

Ladies and Gentlemen:

We write as legal counsel to Flamel Technologies S.A., a corporation (*société anonyme*) incorporated in France (“Flamel”), and Avadel Pharmaceuticals Limited, an Irish private corporation (“Avadel Limited”) and a wholly owned subsidiary of Flamel, with respect to a proposed redomestication transaction whereby Flamel will merge with and into Avadel Limited for the purpose of changing Flamel’s domicile from France to Ireland, as more particularly set forth below. Prior to the effectiveness of the merger, Avadel Limited will re-register as an Irish public limited company, or plc, and will thereafter be named Avadel Pharmaceuticals plc (“Avadel plc”). Flamel and Avadel Limited have authorized us to make the factual representations set forth in this letter on their behalf.

As discussed below, Flamel and Avadel Limited request that the staff (the “Staff”) of the Office of International Corporate Finance, Division of Corporation Finance (the “Division”) of the U.S. Securities and Exchange Commission (the “Commission”) (1) confirm that, based on the facts and circumstances set forth in this letter, the Staff will not recommend any enforcement action to the Commission if Avadel plc issues, pursuant to the merger described above, its ordinary shares and American Depositary Shares (“ADSs”), including the Avadel plc ordinary shares underlying such ADSs, without registration under the Securities Act of 1933 (the “Securities Act”) in reliance on the exemption from the registration requirements thereunder provided by Section 3(a)(10) thereof, and (2) concur with our view as to certain resales of Avadel plc ordinary shares and ADSs, including the Avadel plc ordinary shares underlying such ADSs, in reliance on Rule 144 as described in this letter.

I. Background.

A. Information about Flamel. Flamel is a specialty pharmaceutical company that operates directly in France and through wholly owned subsidiaries in Ireland and the United States. Flamel’s 2015 revenues were approximately \$170 million, compared with 2014 revenues

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of approximately \$15 million. Pursuant to a sponsored American Depositary Shares program, ADSs representing Flamel's ordinary shares are listed for trading on The Nasdaq Global Market ("Nasdaq") under the trading symbol "FLML." Over 97% of Flamel's outstanding ordinary shares are represented by ADSs.

Flamel has been a reporting company under the Securities Exchange Act of 1934 (the "Exchange Act") since 1996, when it filed a Form F-1 to register its ADSs for sale in its initial public offering. As a result of the Form F-1 being declared effective by the Commission, Flamel's ADSs were registered under Section 12(g) of the Exchange Act, and in August 2006, when Nasdaq began operating as a national securities exchange, all Nasdaq-listed securities registered under Section 12(g), including Flamel's ADSs, automatically became registered under Section 12(b) pursuant to Nasdaq's arrangements with the Commission. Flamel is current in its reporting obligations under the Exchange Act. The Flamel ADSs and the underlying ordinary shares registered under Section 12(b) constitute the only class of securities with respect to which Flamel has a reporting obligation under the Exchange Act. No Flamel securities are listed for trading on any exchange in France or anywhere else other than the ADSs listed for trading on Nasdaq.

Flamel was a foreign private issuer until 2016. At the end of Flamel's second fiscal quarter during its fiscal year ended December 31, 2015, Flamel determined that it no longer qualified as a foreign private issuer. Therefore, beginning January 1, 2016 Flamel began to file with the Commission its periodic reports on Forms 8-K, 10-Q and 10-K. Also, as of June 30, 2015, Flamel determined that it would be a large accelerated filer for 2016 based on its public market float as of that date.

Flamel prepares its consolidated financial statements in accordance with U.S. generally accepted accounting principles (GAAP). Flamel's annual report on Form 10-K for the fiscal year ended December 31, 2015, filed on March 15, 2016, included Flamel's consolidated financial statements for such fiscal year which were prepared in accordance with GAAP and accompanied by the unqualified opinion thereon by Flamel's independent registered public accounting firm.

Flamel maintains the following effective registration statements on Form S-8 with respect to its ordinary shares, ADSs and other employee benefit plan interests: nos. 333-137844, 333-134638, 333-111725, 333-109693, 333-12542, and 333-177591.

B. Summary of the Proposed Redomestication. For business and regulatory reasons, Flamel's board of directors has determined that it is in the best interest of Flamel and its shareholders to change Flamel's jurisdiction of incorporation from France to Ireland,¹ by

¹ The factors Flamel's board of directors deemed relevant in determining to pursue the Redomestication included: (a) to better ensure Flamel's ongoing compliance with certain SEC rules and Nasdaq listing requirements, (b) to

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merging into its wholly-owned Irish subsidiary Avadel plc (the “Redomestication”). The sole purpose and effect of the Redomestication is to change Flamel’s corporate domicile from France to Ireland; the Redomestication will not involve the acquisition or disposition of any business, assets or securities of any other person or entity. Thus, from the point of view of Flamel shareholders, their underlying economic interests will not be altered by the receipt of shares of Avadel plc in lieu of shares of Flamel as a result of the Redomestication. Diagrams of Flamel’s ownership structure before and after the Redomestication are provided on Exhibits A-1 and A-2 to this letter, respectively.

obtain certain benefits the board perceived in terms of corporate governance matters, and (c) to obtain certain benefits the board perceived in terms of operational effectiveness.

Regarding factor (a), the board noted that prior to January 1, 2016, Flamel relied on a foreign private issuer exception to certain SEC and Nasdaq requirements applicable to the registration of its ADSs for public sale in the U.S. and for listing on Nasdaq. However, upon becoming a “domestic issuer” for SEC reporting purposes on January 1, 2016, Flamel must now comply with these requirements. In certain cases, in particular with respect to corporate governance matters, the board believed that these requirements are not fully consistent with principles of French law applicable to *sociétés anonymes* such as Flamel, which, among other things, limit the ability of a board of directors of a French *sociétés anonymes* to delegate authority to committees and other persons in the manner contemplated by certain of such requirements. Therefore, in the view of Flamel’s board of directors, by becoming an Irish corporation (the boards of which may fully delegate authority in the manner contemplated by such SEC rules and Nasdaq listing requirements), Flamel will reduce concerns in this regard about the continued and long-term compliance with these SEC and Nasdaq requirements; and there will be greater assurance of the continued and long-term listing of Flamel’s equity securities on Nasdaq so that its shareholders can continue to participate in a liquid market.

Regarding factor (b), the board noted that the legal system of Ireland is more similar to the legal system of the United States than to the legal system of France. The Irish legal system which will apply to Avadel as a public company following consummation of the Redomestication, like the U.S. legal system, is a common law system rather than a civil law system. Therefore Flamel’s board believes that, by redomesticating to Ireland, its investors (the majority of whom are U.S. persons) will be more likely to understand the legal system that governs the company in which they have invested (*i.e.*, the legal system of Ireland) as compared to the legal system of France. In addition, Flamel’s board also believes that certain corporate governance procedures under Irish law will provide Flamel’s management with increased flexibility in completing transactions that involve the issuance of Avadel’s ordinary shares.

Regarding factor (c), the board noted that, in 2014, Flamel transferred substantially all of the intellectual property of its consolidated group to Flamel Ireland Limited, Flamel’s wholly-owned operational subsidiary, which is now a 100% subsidiary of Avadel Limited. The board believes that, in addition to the attractive nature of the business environment in Ireland and the presence of Flamel’s IP and related functions in Ireland, having its legal domicile in Ireland will allow additional synergies within Flamel’s consolidated group of companies, improve the efficiency of its management and supporting services, help unify the company’s consolidated decision-making process, thereby helping to ensure the company’s customers receive safe and effective products, and generally place the company within the fast-growing international community of global health care companies in Ireland (with, among other things, potential synergies from access to a growing local talent pool and proximity to potential joint venture partners).

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The principal features of the proposed Redomestication are as follows:

(i) Flamel will merge with and into Avadel plc, with Avadel plc continuing as the surviving entity and Flamel ceasing to exist as a separate entity; as a result of the Redomestication, all of the assets and liabilities of Flamel will be acquired and assumed by Avadel plc by operation of law (such merger, the “Merger”).

(ii) Avadel Limited is Flamel’s directly owned holding company in Ireland. Avadel Limited was formed by Flamel’s Irish attorneys on December 1, 2015 for use by Flamel for corporate reorganization purposes; the initial name of the entity was “Fccml Limited.” Avadel Limited was formed with *de minimis* capitalization and no operations.

(iii) Prior to March 2016, Flamel’s directly owned holding company in Ireland was Flamel Irish Holdings Limited (“FIHL”), and FIHL’s principal assets were 100% of the shares of Flamel Ireland Ltd., which is Flamel’s second-tier Irish subsidiary (the “Irish IP Company”) and which owns a substantial part of Flamel’s worldwide intellectual property rights, consisting primarily of patents (both registered and being applied for). In March 2016, Flamel reorganized its Irish corporate structure by merging FIHL into FIHL’s wholly owned subsidiary, Fccml Limited, with Fccml Limited surviving the merger and thereby acquiring ownership of the Irish IP Company. In May 2016, Fccml Limited changed its name to Avadel Pharmaceuticals Limited. Shortly before consummating the Merger, to give effect to the Redomestication, Avadel Limited will re-register as an Irish public limited company and will thereupon change its name to Avadel Pharmaceuticals plc.

(iv) Because the jurisdictions of incorporation of Flamel and Avadel Limited are part of the European Union, it will be necessary to effect the Merger in accordance with the provisions of “Directive 2005/56/EC of the European Parliament and of the Council of 26 October 2005 on cross-border mergers of limited liability companies” (“Directive 56”). Directive 56 establishes a uniform framework to facilitate cross-border mergers by companies formed in any jurisdiction of the European Economic Area (“EEA”). Since it was enacted in 2005, both France and Ireland have adopted enabling legislation to implement Directive 56. A copy of Directive 56 is attached to this request as Exhibit B. The Dublin, Ireland-based law firm Arthur Cox, Flamel’s Irish legal counsel, has prepared a letter containing its opinions and confirmations in respect of certain matters in relation to the Merger and relevant to this request, which letter is annexed hereto as Exhibit C (the “Arthur Cox Legal Opinion”); in addition, attached to the Arthur Cox Legal Opinion is a summary, prepared by Arthur Cox, which sets forth certain additional information about Directive 56 relevant to this request (the “Directive 56 Summary”). As contemplated by Directive 56, Flamel and Avadel Limited have

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entered into an agreement to be known as the “common draft terms of cross-border merger” (the “Common Draft Terms”).

(iv) As required by Directive 56, Flamel and Avadel Limited have each obtained a report of an independent third party expert stating, among other things, the expert’s view as to whether the securities exchange ratio in the Merger is fair and reasonable. Directive 56 requires that the expert report must be made available to the shareholders of each merging company at least one month prior to the meeting at which they will vote upon the Merger.

(v) Flamel’s shareholders will consider the Merger at an extraordinary general meeting (the “Extraordinary Meeting”) to be held in conjunction with Flamel’s annual general meeting of shareholders. Shareholder approval of the Merger requires a two-thirds majority of Flamel shares represented in person or by proxy at the Extraordinary Meeting. The proxy statement provided to Flamel shareholders in connection with the Extraordinary Meeting sets forth the material terms of the Merger, and provides a comparison of the material differences between the corporate laws of France and Ireland and the governance provisions under the organizational documents applicable to Flamel and Avadel plc.

(vi) After the shareholders of Flamel and Avadel Limited approve the Merger, Directive 56 requires each merging company to obtain a pre-merger certificate from the competent authority designated by its country to review cross-border mergers involving companies organized in an EEA Country. Directive 56 requires that, prior to issuing a pre-merger certificate, the competent authority must scrutinize the legality of the cross-border merger as regards that part of the procedure concerning the merging company subject to its national law.

(vii) In addition to the initial reviews described above required for issuance of the pre-merger certificates, Directive 56 requires that the pre-merger certificates be submitted to an authority designated by the EEA member state of the entity surviving or resulting from the merger (such member state being Ireland for purposes of the Redomestication) for a second-step review of the merger, and final approval thereof. For this purpose, Ireland has designated the Irish High Court (the “Court”), and accordingly the parties to the Merger will petition the Court to make a determination as to whether the terms and conditions of the Merger are fair (both procedurally and substantively) to the shareholders of each of the merging companies (including Flamel) and to authorize the completion of the Merger. The Court will make its fairness determination after holding a hearing on the matter (the “Hearing”). The Hearing will be held in open court and all shareholders and creditors of each of the merging companies will have an opportunity to appear at the Hearing. Shareholders of the merging companies will be given public notice of the Hearing by means of newspaper advertisements in the Irish Companies Registration

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Office Gazette, two National Irish daily newspapers and the international editions of The Financial Times and The Wall Street Journal. The Court will be advised, prior to the Hearing, that its approval and finding of fairness as to the Merger will be the basis for qualifying for the exemption from the registration requirements of the Securities Act provided by Section 3(a)(10) with respect to the shares of Avadel plc to be issued pursuant to the Common Draft Terms upon consummation of the Merger.

C. Effect of the Redomestication.

(i) In the Redomestication, the outstanding ordinary shares of Flamel (including the ordinary shares represented by ADSs) will be exchanged for newly issued ordinary shares of Avadel plc, on a one-for-one basis. No cash, property or securities of any kind will be paid to Flamel shareholders other than the newly issued ordinary shares of Avadel plc, on a one-for-one basis.

(ii) As a result of the Redomestication:

(1) Each shareholder of Flamel will cease to own ordinary shares of Flamel and will instead own the same number of ordinary shares of Avadel plc that they owned in Flamel immediately prior to the Redomestication, and such ownership will be in the same form as the ownership of Flamel ordinary shares immediately before the Redomestication – either direct ownership of ordinary shares or ADSs representing ordinary shares. Pursuant to the Common Draft Terms, the ordinary shares of Avadel plc held by Flamel will be cancelled after the Merger. As a result, the shareholders of Flamel immediately before the Redomestication will own 100% of the outstanding ordinary shares of Avadel plc immediately after the Redomestication.²

² To qualify as an Irish plc, Avadel plc must have outstanding share capital with a value of at least €25,000. Therefore, prior to re-registering as a plc, Avadel Limited will create a new class of 25,000 ordinary shares to be referred to as “deferred ordinary shares,” with each deferred ordinary share having a nominal value of €1.00. Avadel plc will issue all 25,000 of these deferred ordinary shares to Flamel’s wholly owned U.S. subsidiary, Flamel US Holdings, Inc., a Delaware corporation. While these 25,000 deferred ordinary shares of Avadel plc will continue to be outstanding after the consummation of the Redomestication, such shares will continue to be owned by Flamel US Holdings, Inc.; and thus Avadel plc, as the ultimate parent of Flamel US Holdings, Inc., will be the indirect beneficial owner of the Avadel plc deferred ordinary shares.

The deferred ordinary shares will be non-voting, will not have the right to receive any dividend or distribution or any return of capital or other participation in the assets of Avadel plc except that, upon a winding up or return of capital of Avadel plc (other than on a redemption of any class of the shares of Avadel plc), the holders of the deferred ordinary shares will be entitled to participate in such return of capital or winding up of Avadel plc, with such entitlement limited to the repayment of the amount paid up or credited as paid up on such deferred ordinary

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(2) All stock options, warrants and other rights to acquire ordinary shares (or ADSs, as applicable) of Flamel, including rights under any and all of Flamel's benefit plans for directors, officers and employees (the "Assumed Benefit Plans"), will be assumed by Avadel plc and after the Redomestication will continue to represent rights to acquire ordinary shares (or ADSs) of Avadel plc on the same terms and conditions.

(3) The assets, liabilities, business, operations, shareholders, directors, officers and employees of Avadel plc and its consolidated group of companies immediately after the Redomestication will be the same as the assets, liabilities, business, operations, shareholders, directors, officers and employees of Flamel and its consolidated group of companies immediately before the Redomestication.

(4) The consolidated financial statements of Avadel plc will continue to be prepared in accordance with GAAP and in all material respects will present the same financial information as has been presented by Flamel in its consolidated financial statements (with certain possible adjustments (not anticipated to be material) in the equity section of the balance sheet, such as to reflect possible differences in the nominal capital requirements applicable to the French and Irish corporations).

(iii) With respect to the Nasdaq listing status of the ADSs issued by Flamel and Avadel:

(1) Upon completion of the Redomestication, Flamel intends to cause Nasdaq to file with the Commission a Form 25 to delist and deregister the Flamel ADSs under Section 12(b) of the Exchange Act.

(2) Upon the effectiveness of the Form 25, Flamel intends to file a Form 15 with the Commission to immediately terminate its reporting obligations under Section 12(g) of the Exchange Act and suspend its reporting obligations under Section 15(d) of the Exchange Act with respect to the ADSs and the related Flamel ordinary shares.

shares and shall be paid only after the holders of ordinary shares shall have received payment in respect of such amount as is paid up or credited as paid up on those ordinary shares held by them at that time, plus the payment in cash of €100,000,000 on each such ordinary share. Thus, the deferred ordinary shares will have no economic value, and will have no dilutive effect on the Flamel shareholders' ownership interests in Avadel plc after the Redomestication.

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(3) Flamel confirms that it will comply with its Exchange Act reporting obligations until the filing of such Form 15.

(4) Upon completion of the Redomestication, Avadel plc will file post-effective amendments to each of Flamel's registration statements on Form S-8 and Form S-3 (if any) expressly adopting each such registration statements as its own registration statement as contemplated by Rule 414 under the Securities Act.

(5) Pursuant to Nasdaq Listing Rule 5250(e)(4), the Redomestication will be treated as a substitution listing event and the ADSs representing Avadel plc ordinary shares will, upon issuance in connection with the Merger, be listed for trading on Nasdaq under the trading symbol "AVDL."

C. Transaction-Related Form 8-K. No later than four business days after consummation of the Merger, Avadel plc will file a Form 8-K reporting that the Merger has been consummated, and making all other required disclosures, including, among other relevant matters, disclosure of Avadel plc's reliance upon the exemption provided under Section 3(a)(10) and that, pursuant to Rule 12g-3(a) promulgated under the Exchange Act, Avadel plc will be deemed to be Flamel's successor under Section 12(g) and as a result the ADSs representing ordinary shares of Avadel plc will be deemed registered under Section 12(b) of the Exchange Act.

D. Certain Alternatives Considered. Flamel considered certain alternative arrangements instead of the arrangements described above, including:

(i) Flamel considered merging into an entity that would be a wholly owned shell company at the time of the Redomestication. However, for certain regulatory purposes, it was determined that Flamel would prefer to merge into its direct wholly owned Irish holding company. In addition, Flamel was advised that, for certain financial and accounting reasons, the successor in its reincorporation transaction should be a recently formed entity. Therefore, during February and March 2016 Flamel caused its Irish holdings to be reorganized as described in item I.B.(iii) above.

(ii) Rather than issue its ordinary shares directly, Flamel has determined that Avadel plc will continue to maintain a sponsored ADS program with respect to its ordinary shares upon and after completion of the Merger, pursuant to terms and conditions substantially similar to the terms and conditions applicable to the ADS program currently in effect with respect to Flamel's ordinary shares, with the understanding that Avadel plc may consider whether to terminate such ADS program at an appropriate time after the Merger.

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II. Discussion and Analysis – Reliance on 3(a)(10) Exemption.

Section 3(a)(10) of the Securities Act provides an exemption from the registration requirements of the Securities Act for securities “issued in exchange for one or more bona fide outstanding securities . . . where the terms and conditions of such issuance and exchange are approved, after a hearing upon the fairness of such terms and conditions at which all persons to whom it is proposed to issue securities in such exchange shall have the right to appear, by any court.”

The key requirements of a section 3(a)(10) exemption therefore are (1) an exchange of a security for another security, claim or property interest, (2) court approval of the terms and conditions of such issuance and exchange and (3) prior to such approval, a court hearing on the fairness of such terms and conditions open to all persons exchanging securities. In addition, in the view of the Staff as expressed in Staff Legal Bulletin 3A (“Bulletin 3A”), the court should be informed that its approval will be the basis for the Section 3(a)(10) exemption. This Part II considers the Redomestication in the context of these key requirements of the Section 3(a)(10) exemption.

(1) *Securities for securities.* Under the Common Draft Terms, upon consummation of the Merger, the ordinary shares of Flamel will be exchanged solely for ordinary shares of Avadel plc on a one-for-one basis. Flamel ADSs will be exchanged solely for ADSs of Avadel plc, on a one-for-one basis. No cash, securities, property or other consideration of any kind would be issued to the Flamel shareholders other than the ordinary shares of Avadel plc. Thus, as required under Section 3(a)(10), there is an exchange solely of securities for securities.

(2) *Court approval.*

(a) *Approval.* Pursuant to Directive 56, the Court will approve the Merger at the Hearing. In addition, the Common Draft Terms will require, as a condition precedent to the Merger, that the Court must both approve the Merger and include in its order of approval a determination that the Merger is fair (both procedurally and substantively) to the shareholders of both of the merging companies (including Flamel).

(b) *Non-U.S. Court.* The Staff has stated its view, in Section 4.B.4 of Bulletin 3A, that “any court” as used in Section 3(a)(10) includes a foreign court. The Staff has granted numerous prior Section 3(a)(10) no-action requests in circumstances where the judicial proceeding on the applicable transaction will be conducted by a court of a country other than the United States. See, e.g., *Weatherford International Ltd.* (available January 14, 2009) (Supreme Court of Bermuda) (“Weatherford”); *Shire Pharmaceuticals Group Plc and Shire Plc* (available November 17, 2005) (High Court of Justice of England and Wales) (“Shire”); *SanDisk Corporation* (available September 21, 2006) (Israeli District Court) (“SanDisk”); *Constellation Brands, Inc.* (available January 29, 2003) (Supreme Court of South Australia) (“Constellation Brands”); *AngloGold Limited* (available January 15, 2004) (High Court of Ghana)

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(“*AngloGold*”); *ForBio Inc.* (available September 23, 1998) (Supreme Court of Queensland, Australia) (“*ForBio*”); *StaffMark, Inc.* (available September 3, 1998) (High Court of Justice, England); *China Light & Power Company, Limited* (available January 2, 1998) (High Court of the Hong Kong Special Administrative Region). Specifically, such no-action requests have been granted by the Division where Irish courts were to conduct the judicial proceedings. *See, e.g., Galen Holdings PLC*, 2000 SEC No-Act. LEXIS 831 (available Aug. 7, 2000); *ADC Telecommunications, Inc.*, 1999 SEC No-Act. LEXIS 657 (available July 30, 1999).

(c) *Irish High Court.* In the proposed Redomestication, the Court will conduct the judicial proceeding to determine the fairness of the Redomestication to the shareholders of both merging companies, including Flamel, which is a French corporation. Flamel notes that a judicial proceeding to approve a merger might typically be expected to be conducted by a court established by the jurisdiction of the merging company (*i.e.*, the company not surviving the merger and whose shareholders are receiving the new securities being issued in reliance upon the 3(a)(10) exemption). Flamel also acknowledges that a court of the merging company’s jurisdiction may have an interest in ensuring that the transaction is fair to the shareholders of the merging company. Consistent with this expectation, we are not aware of a no-action request to the Staff in circumstances where the court jurisdiction and the merging company jurisdiction were not the same. However, Flamel believes that in the context of its proposed Redomestication, the Court should satisfy the “court” requirement of the 3(a)(10) exemption for the reasons described below.

As noted in the Directive 56 Summary, Directive 56 requires that only the courts of the EEA member state where the entity resulting from a merger will have its seat have jurisdiction to scrutinize the legality of the merger, including ruling on the fairness of a cross-border merger. Thus, courts of other EEA member states are not empowered to conduct a hearing for such purpose, even where the shareholders of their companies will have their shares converted into shares of the resulting or surviving entity. This arrangement is consistent with the political, legal and economic partnership of the European Union, under which EEA member states have, in effect, limited their sovereign rights within certain fields, including cross-border mergers. In this sense, the EU member states may be said to have “pooled” their sovereignty and allocated the responsibility to review the terms and procedures for, and sanction, a merger to the courts of the jurisdiction where the resulting entity will reside. Accordingly, EEA member states may be thought to consider themselves as one single, expansive jurisdiction for these purposes, with the courts of all EEA member states having an interest in ensuring the fairness of the transaction for the shareholders of each of the merging companies. Moreover, there is no other court empowered to review and authorize an EEA cross-border merger.

Therefore we believe that, in a cross-border merger between corporations formed in different EEA member states in accordance with the requirements of Directive 56, such as in the Redomestication, a court of the relevant EEA member state that conducts the second-step hearing pursuant to Directive 56 (*i.e.*, the hearing by the single national authority to give final

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approval to the transaction, following the initial hearings at which the pre-merger certificates are issued), in this case, the Court, should be deemed to be a “court” as such term is used in Section 3(a)(10) and Bulletin 3A.

(d) *Irish Legal Opinion.* In respect of the Merger, the Arthur Cox Legal Opinion concludes that:

(i) in accordance with Article 11 of the Directive [*i.e.*, Directive 56] and regulation 14(1) of the European Communities (Mergers) Regulations 2008 of Ireland (the “Regulations”), the Court is the competent authority in the European Economic Area in connection with the Merger to make an order confirming the scrutiny of the legality of the Merger as regards that part of the procedure which concerns the completion of the Merger and the Merger cannot become effective without such order having been given by the Court; and

(ii) the Court retains the right to hear submissions from interested parties to the Merger, which includes the registered holders of Flamel shares (the “Flamel Shareholders”), at the hearing of the Court at which the Court scrutinizes the legality of the Merger and all Flamel shareholders will have the right to attend such hearing.

In addition, the Arthur Cox Legal Opinion confirms certain factual matters, including: (w) in accordance with an order of the Court dated 25 April 2016 (the “Court Order”), the Court will conduct the Hearing as to the fairness (procedurally and substantively) of the terms and conditions of the Merger to all persons to whom it is proposed to issue shares of Avadel, being the Flamel shareholders, pursuant to the Merger, and an affirmative finding of such fairness by the Court at the Fairness Hearing is a prerequisite to the Merger; (x) pursuant to the terms of the Common Draft Terms, it is a condition to the Merger becoming effective that the Court will rule on the fairness (procedurally and substantively) of the terms and conditions of the Merger; (y) the Flamel shareholders will receive notice of the Hearing by way of advertisements placed in the Irish Companies Registration Office Gazette, two National Irish daily newspapers and the international editions of The Financial Times and The Wall Street Journal; and (z) pursuant to the terms of the Common Draft Terms, Flamel and Avadel Limited will advise the Court in advance of the Fairness Hearing that, on the basis of the Court ordering and confirming the: (i) scrutiny of the legality of the Merger as regards that part of the procedure concerning the completion of the Merger; and, (ii) fairness (procedurally and substantively) of the terms and conditions of the Merger, Avadel plc will rely on the Section 3(a)(10) Exemption and that it will not register the ordinary shares it issues pursuant to such merger under the Securities Act.

(3) *Fairness Hearing.*

(a) *Condition Precedent.* Under the Common Draft Terms, it is a condition to the consummation of the Merger that the Court issue an order determining the fairness (both procedural and substantive) of the Merger to the shareholders of the merging companies. Flamel

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confirms to the Staff that the Court will be advised, prior to the Hearing, that the Court's approval of the Merger will be the basis for qualifying for the exemption from the registration requirements of the Securities Act provided by Section 3(a)(10) with respect to the ordinary shares of Avadel plc to be issued pursuant to the Common Draft Terms upon consummation of the Merger.

(b) Hearing in Open Court, Etc. Flamel understands that, according to the procedural rules of the Court, (i) the Hearing will be held in open court, (ii) all persons to whom Avadel plc will issue its ordinary shares upon consummation of the Merger will have the right to appear at the Hearing, and (iii) such hearing will be held prior to the Court issuing its determination as to the fairness of the Merger. Moreover, in a preliminary order issued by the Court on April 27, 2016, the Court confirmed that all persons to whom Avadel plc shares are proposed to be issued will have the right to appear at the Hearing.

(c) Hearing After Shareholder Votes. As noted above, the sequence of events required by Directive 56 for cross-border mergers requires that the votes of the shareholders of Flamel and Avadel Limited must occur before the Court holds the second-step hearing (*i.e.*, the Hearing) to consider whether to approve the Redomestication. The Court will conduct the Hearing as part of the substantive application to approve the Redomestication, and such application can only be made after the pre-merger certificates have been issued in France and Ireland. In turn, the shareholder vote of approval at Flamel's Extraordinary Meeting is necessary to obtain its pre-merger certificate. Thus, it would not be feasible to schedule the Hearing before the Flamel shareholders vote on whether to approve the Redomestication. The Division has expressed the view in Bulletin 3A that it does not object to a security holders' vote before the fairness hearing, provided the issuer submits to the court the disclosure materials offering the securities before it mails them to the offerees. Prior to mailing its definitive proxy statement with respect to the shareholders meeting at which the Redomestication will be considered, Flamel submitted such proxy statement to the Court.

(d) Adequate Notice. Flamel and Avadel Limited will give shareholders of the merging companies notice of the Hearing by means of newspaper advertisements in the Irish Companies Registration Office Gazette, two National Irish daily newspapers and the international editions of The Financial Times and The Wall Street Journal. These advertisements, which will be placed at least two weeks before the Hearing, will inform the Flamel shareholders of the Hearing, including its date, time and place, and of each shareholder's right to appear at the Hearing. In addition, Flamel's proxy statement will disclose, among other matters relating to the Redomestication, the right of the shareholders to appear at the Hearing.

(e) No Improper Impediments. Flamel confirms to the Staff that the Hearing will be public and open to all Flamel shareholders, and there will be no improper impediments for its shareholders to appear at the Hearing. To this end, Flamel confirms that there will be no prerequisites to appearance that would prevent any of its shareholders from having an opportunity to appear at the Hearing. Flamel understands that the Court could require any

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Flamel shareholder to notify the Court of an intent to appear one or two days prior to the Hearing. If the Court requires such notice, the notice to be published in newspapers would set forth all pertinent details of how to comply with this requirement. As noted in footnote 22 of Bulletin 3A, the Division of Corporation Finance has not objected to a requirement to provide written notice of an intention to appear at a court hearing. As noted above, in the preliminary order issued by the Court on April 27, 2016, the Court confirmed that all persons to whom Avadel plc shares are proposed to be issued will have the right to appear at the Hearing; such preliminary order did not indicate there would be any such notice requirement for attendance at the Hearing.

(f) ADS Holders. Although Flamel understands that the Court has general discretion as to whom it allows to appear and be heard at the Hearing, holders of Flamel's ADSs will not be entitled by the terms of the Depositary Agreement governing Flamel's sponsored ADS facility, or by applicable law, to attend the Extraordinary Meeting or the Hearing in the capacity as an ADS holder. The Hearing, however, will be held in open court. In addition, the depositary, as record holder of Flamel shares underlying the Flamel ADSs (the "Depositary"), will be entitled to attend Flamel's Extraordinary Meeting and appear at the Hearing. The Depositary will make timely delivery of the proxy materials to the holders of Flamel ADSs. As noted above, the proxy materials include the proxy statement and forms of instruction to the Depositary for voting the Flamel ADSs at the Extraordinary Meeting. The proxy statement includes instructions to the holders of Flamel ADSs who wish to attend the Extraordinary Meeting or the Hearing the procedures to follow in order to present their Flamel ADSs to the Depositary for cancellation and delivery of Flamel ordinary shares so as to become record holders of Flamel ordinary shares prior to the Extraordinary Meeting or Hearing, as the case may be. Following these procedures will allow any holder of Flamel ADSs to become entitled under the documents governing Flamel's sponsored ADS program and applicable law to attend the Extraordinary Meeting and the Hearing. To facilitate the use of these procedures, the Depositary will provide a telephone number so that holders of Flamel ADSs may receive guidance or initiate the process of converting their ADSs to ordinary shares. Flamel believes that the conversion process should normally take approximately five French business days to complete.

Thus, although the holders of Flamel ADSs will not have the right to attend the Extraordinary Meeting, they will be given the opportunity to instruct the Depositary of the ordinary shares underlying their Flamel ADSs regarding how to vote at the Extraordinary Meeting.

Because the Hearing will be held in open court, the Court can use its general discretion to allow any person to be heard at the Hearing and the Flamel ADS holders may convert their Flamel ADSs to Flamel ordinary shares in order to attend the Extraordinary Meeting and Hearing, the fact that ADS holders may not be entitled to attend the Extraordinary Meeting or appear at the Hearing in their capacity as ADS holders should not affect the availability of the Section 3(a)(10) exemption. The Staff has granted no-action requests in

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comparable circumstances. *See The Rank Organisation Plc* (available August 6, 1996); and *Shire*. Thus, Flamel believes that the requirements of Section 3(a)(10) that the fairness hearing be open to all persons to whom securities will be issued in the exchange, and that there be no improper impediments to shareholders appearing at the Hearing, will be fulfilled in connection with the Redomestication.

Based on the foregoing analysis, we respectfully submit that, under the facts and circumstances of the Redomestication, Avadel plc may issue its ordinary shares and ADSs, including the Avadel plc ordinary shares underlying such ADSs, in the Merger without registration under the Securities Act in reliance on the exemption from the registration requirements thereunder provided by Section 3(a)(10) thereof.

III. Discussion and Analysis – Resales Under Rule 144.

In Bulletin 3A, the Staff expressed the view that securities received in a business combination transaction not involving a shell company, other than a business combination shell company, that was exempt under Section 3(a)(10) may generally be resold without regard to Rule 144 if the sellers are not affiliates of the issuer of the Section 3(a)(10) securities and have not been affiliates within 90 days of the transaction, as such securities would not constitute “restricted securities” within the meaning of Rule 144(a)(3). As described above, Avadel Limited currently has substantial assets consisting principally of the shares of the Irish IP Company, which in turn owns patent rights and other intellectual property, and at the time of the Redomestication Avadel plc will continue to hold such assets. We also note that, from its formation in December 2015 until its participation in the business combination with FIHL described above in part I.B.(iii) of this letter, Avadel Limited had no operations and nominal assets. However, because Avadel Limited was formed for Flamel’s use for corporate reorganization purposes, we believe Avadel Limited is a “business combination shell company” as contemplated by Rule 405. Under these circumstances we believe that the Redomestication would not involve a shell company for purposes of the foregoing staff view as to Rule 144 resales of securities of Avadel plc.

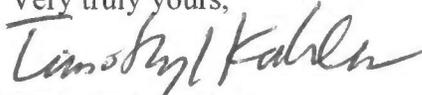
Therefore, it is our view that (a) the Avadel plc ordinary shares and ADSs, including the Avadel plc ordinary shares underlying such ADSs, received in the Merger will not constitute “restricted securities” within the meaning of Rule 144(a)(3) under the Securities Act; (b) persons may resell their Avadel plc ordinary shares and ADSs, including the Avadel plc ordinary shares underlying such ADSs, without regard to Rule 144 if they are not affiliates of either Flamel or Avadel plc within 90 days prior to the Merger and are not affiliates of Avadel plc after the Merger; and (c) persons may resell their Avadel plc ordinary shares and ADSs, including the Avadel plc ordinary shares underlying such ADSs, in the manner permitted by Rule 144 if they are affiliates of either Flamel or Avadel plc before the Merger and are affiliates of Avadel plc after the Merger.

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For the reasons set forth above, we respectfully request that the Division (1) confirm that, based on the facts and circumstances set forth in this letter, the Staff will not recommend any enforcement action to the Commission if Avadel plc issues, pursuant to the Merger as described above, its ordinary shares and ADSs, including the Avadel plc ordinary shares underlying such ADSs, without registration under the Securities Act in reliance on the exemption from the registration requirements thereunder provided by Section 3(a)(10) thereof, and (2) concur with our view as to certain resales of Avadel plc ordinary shares and ADSs, including the Avadel plc ordinary shares underlying such ADSs, in reliance on Rule 144 as described above.

If the Division contemplates issuing a response that differs from any of our requests, we respectfully request the opportunity for a conference to discuss and clarify our views. If you require additional information or would like to discuss any of the foregoing matters, please do not hesitate to contact the undersigned at (212) 704-6169.

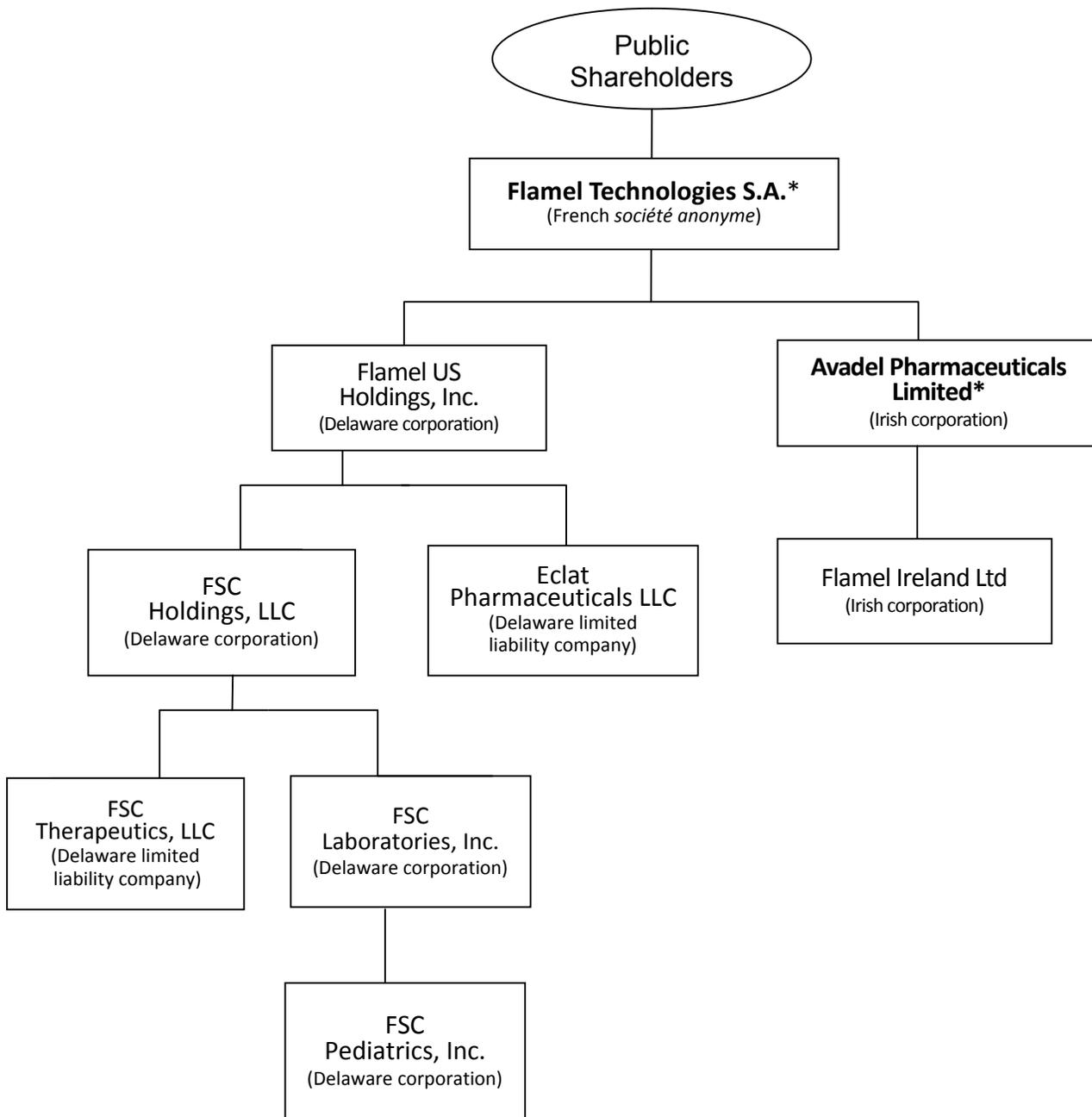
Very truly yours,



Timothy I. Kahler

cc: Phillandas T. Thompson, Esq.
Senior Vice President, General Counsel
and Corporate Secretary
Flamel Technologies S.A.

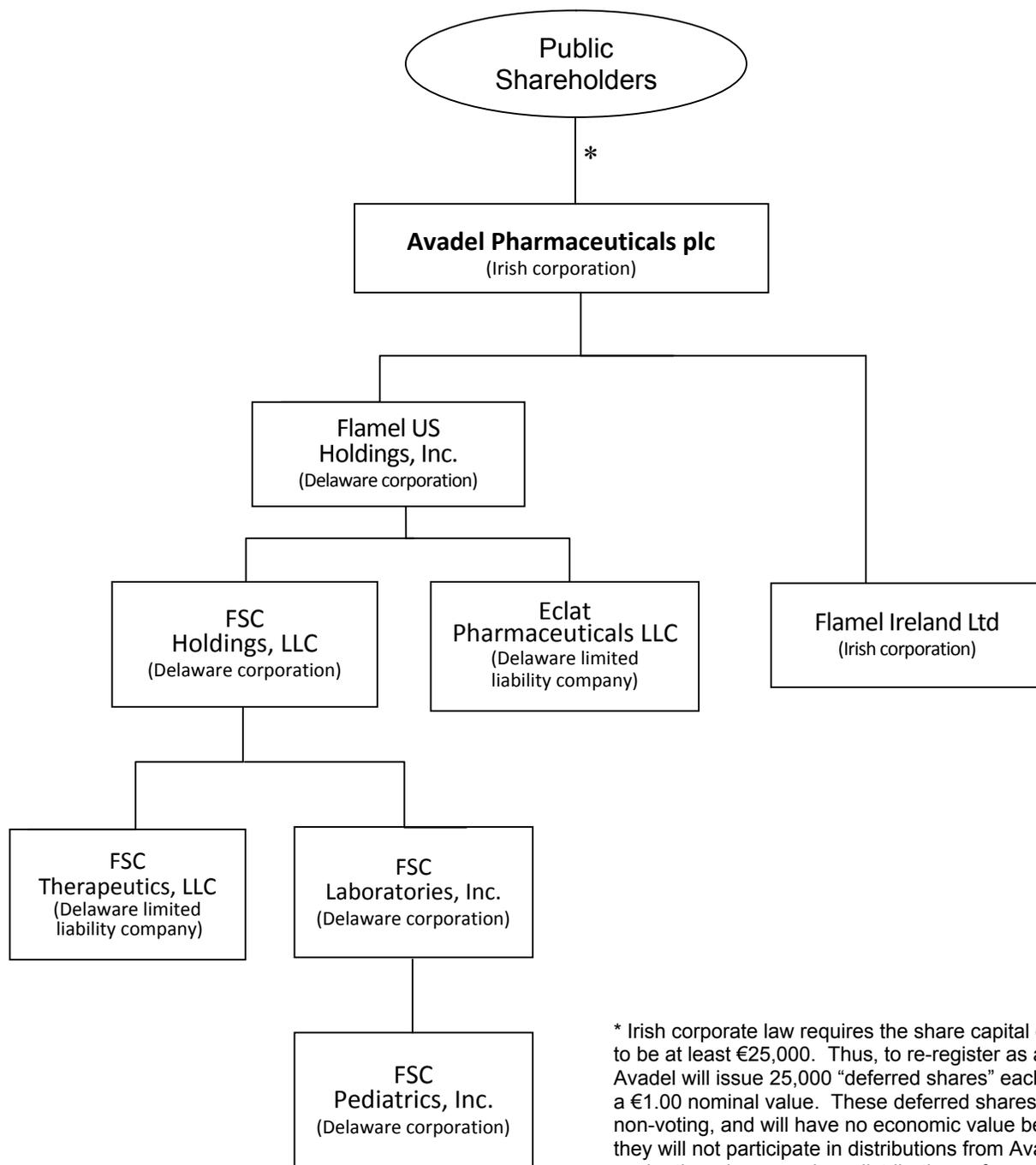
**Group Structure Chart Prior to the
Consummation of the Redomestication**



*Entities in the Scope of the Merger

All subsidiary companies are owned 100%.

**Group Structure Chart After the
Consummation of the Redomestication**



* Irish corporate law requires the share capital of a plc to be at least €25,000. Thus, to re-register as a plc, Avadel will issue 25,000 “deferred shares” each having a €1.00 nominal value. These deferred shares will be non-voting, and will have no economic value because they will not participate in distributions from Avadel until each other share receives distributions of €100,000,000.

All subsidiary companies are owned 100%.

**DIRECTIVE 2005/56/EC OF THE EUROPEAN PARLIAMENT AND OF
THE COUNCIL**

of 26 October 2005

on cross-border mergers of limited liability companies
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN
UNION,

Having regard to the Treaty establishing the European Community, and in particular
Article 44 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (1),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (2),

Whereas:

- (1) There is a need for cooperation and consolidation between limited liability companies from different Member States. However, as regards cross-border mergers of limited liability companies, they encounter many legislative and administrative difficulties in the Community. It is therefore necessary, with a view to the completion and functioning of the single market, to lay down Community provisions to facilitate the carrying-out of cross-border mergers between various types of limited liability company governed by the laws of different Member States.
- (2) This Directive facilitates the cross-border merger of limited liability companies as defined herein. The laws of the Member States are to allow the cross-border merger of a national limited liability company with a limited liability company from another Member State if the national law of the relevant Member States permits mergers between such types of company.
- (3) In order to facilitate cross-border merger operations, it should be laid down that, unless this Directive provides otherwise, each company taking part in a cross-border merger, and each third party concerned, remains subject to the provisions and formalities of the national law which would be applicable in the case of a national merger. None of the provisions and formalities of national law, to which reference is made in this Directive, should introduce restrictions on freedom of establishment or on the free movement of capital save where these can be justified in accordance with the case-law of the Court of Justice and in particular by requirements of the general interest and are both necessary for, and proportionate to, the attainment of such overriding requirements.

- (4) The common draft terms of the cross-border merger are to be drawn up in the same terms for each of the companies concerned in the various Member States. The minimum content of such common draft terms should therefore be specified, while leaving the companies free to agree on other items.
- (5) In order to protect the interests of members and others, both the common draft terms of cross-border mergers and the completion of the cross-border merger are to be publicised for each merging company via an entry in the appropriate public register.
- (6) The laws of all the Member States should provide for the drawing-up at national level of a report on the common draft terms of the cross-border merger by one or more experts on behalf of each of the companies that are merging. In order to limit experts' costs connected with cross-border mergers, provision should be made for the possibility of drawing up a single report intended for all members of companies taking part in a cross-border merger operation. The common draft terms of the cross-border merger are to be approved by the general meeting of each of those companies.
- (7) In order to facilitate cross-border merger operations, it should be provided that monitoring of the completion and legality of the decision-making process in each merging company should be carried out by the national authority having jurisdiction over each of those companies, whereas monitoring of the completion and legality of the cross-border merger should be carried out by the national authority having jurisdiction over the company resulting from the cross-border merger. The national authority in question may be a court, a notary or any other competent authority appointed by the Member State concerned. The national law determining the date on which the cross-border merger takes effect, this being the law to which the company resulting from the cross-border merger is subject, should also be specified.
- (8) In order to protect the interests of members and others, the legal effects of the cross-border merger, distinguishing as to whether the company resulting from the cross-border merger is an acquiring company or a new company, should be specified. In the interests of legal certainty, it should no longer be possible, after the date on which a cross-border merger takes effect, to declare the merger null and void.
- (9) This Directive is without prejudice to the application of the legislation on the control of concentrations between undertakings, both at Community level, by Regulation (EC) No 139/2004 (3), and at the level of Member States.
- (10) This Directive does not affect Community legislation regulating credit intermediaries and other financial undertakings and national rules made or introduced pursuant to such Community legislation.
- (11) This Directive is without prejudice to a Member State's legislation demanding information on the place of central administration or the principal place of business proposed for the company resulting from the cross-border merger.
- (12) Employees' rights other than rights of participation should remain subject to the national provisions referred to in Council Directive 98/59/EC of 20 July 1998 on collective redundancies (4), Council Directive 2001/23/EC of 12 March 2001 on the safeguarding of employees' rights in the event of transfers of undertakings, businesses or parts of undertakings or businesses (5), Directive 2002/14/EC of the European Parliament and of

the Council of 11 March 2002 establishing a general framework for informing and consulting employees in the European Community (6) and Council Directive 94/45/EC of 22 September 1994 on the establishment of a European Works Council or a procedure in Community-scale undertakings and Community-scale groups of undertakings for the purposes of informing and consulting employees (7).

- (13) If employees have participation rights in one of the merging companies under the circumstances set out in this Directive and, if the national law of the Member State in which the company resulting from the cross-border merger has its registered office does not provide for the same level of participation as operated in the relevant merging companies, including in committees of the supervisory board that have decision-making powers, or does not provide for the same entitlement to exercise rights for employees of establishments resulting from the cross-border merger, the participation of employees in the company resulting from the cross-border merger and their involvement in the definition of such rights are to be regulated. To that end, the principles and procedures provided for in Council Regulation (EC) No 2157/2001 of 8 October 2001 on the Statute for a European company (SE) (8) and in Council Directive 2001/86/EC of 8 October 2001 supplementing the Statute for a European company with regard to the involvement of employees (9), are to be taken as a basis, subject, however, to modifications that are deemed necessary because the resulting company will be subject to the national laws of the Member State where it has its registered office. A prompt start to negotiations under Article 16 of this Directive, with a view to not unnecessarily delaying mergers, may be ensured by Member States in accordance with Article 3(2)(b) of Directive 2001/86/EC.
- (14) For the purpose of determining the level of employee participation operated in the relevant merging companies, account should also be taken of the proportion of employee representatives amongst the members of the management group, which covers the profit units of the companies, subject to employee participation.
- (15) Since the objective of the proposed action, namely laying down rules with common features applicable at transnational level, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and impact of the proposed action, be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary to achieve that objective.
- (16) In accordance with paragraph 34 of the Interinstitutional Agreement on better law-making (10), Member States should be encouraged to draw up, for themselves and in the interest of the Community, their own tables which will, as far as possible, illustrate the correlation between this Directive and the transposition measures and to make them public,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Scope

This Directive shall apply to mergers of limited liability companies formed in accordance with the law of a Member State and having their registered office, central administration or principal place of business within the Community, provided at least two of them are governed by the laws of different Member States (hereinafter referred to as cross-border mergers).

Article 2

Definitions

For the purposes of this Directive:

- 1) 'limited liability company', hereinafter referred to as 'company', means:
 - (a) a company as referred to in Article 1 of Directive 68/151/EEC (11), or
 - (b) a company with share capital and having legal personality, possessing separate assets which alone serve to cover its debts and subject under the national law governing it to conditions concerning guarantees such as are provided for by Directive 68/151/EEC for the protection of the interests of members and others;
2. 'merger' means an operation whereby:
 - (a) one or more companies, on being dissolved without going into liquidation, transfer all their assets and liabilities to another existing company, the acquiring company, in exchange for the issue to their members of securities or shares representing the capital of that other company and, if applicable, a cash payment not exceeding 10 % of the nominal value, or, in the absence of a nominal value, of the accounting par value of those securities or shares; or
 - (b) two or more companies, on being dissolved without going into liquidation, transfer all their assets and liabilities to a company that they form, the new company, in exchange for the issue to their members of securities or shares representing the capital of that new company and, if applicable, a cash payment not exceeding 10 % of the nominal value, or in the absence of a nominal value, of the accounting par value of those securities or shares; or
 - (c) a company, on being dissolved without going into liquidation, transfers all its assets and liabilities to the company holding all the securities or shares representing its capital.

Article 3

Further provisions concerning the scope

1. Notwithstanding Article 2(2), this Directive shall also apply to cross-border mergers where the law of at least one of the Member States concerned allows the cash payment referred to in points (a) and (b) of Article 2(2) to exceed 10 % of the nominal value, or, in the absence of a nominal value, of the accounting par value of the securities or shares representing the capital of the company resulting from the cross-border merger.
2. Member States may decide not to apply this Directive to cross-border mergers involving a cooperative society even in the cases where the latter would fall within the definition of

‘limited liability company’ as laid down in Article 2(1).

3. This Directive shall not apply to cross-border mergers involving a company the object of which is the collective investment of capital provided by the public, which operates on the principle of risk-spreading and the units of which are, at the holders’ request, repurchased or redeemed, directly or indirectly, out of the assets of that company. Action taken by such a company to ensure that the stock exchange value of its units does not vary significantly from its net asset value shall be regarded as equivalent to such repurchase or redemption.

Article 4

Conditions relating to cross-border mergers

1. Save as otherwise provided in this Directive,
 - (a) cross-border mergers shall only be possible between types of companies which may merge under the national law of the relevant Member States, and
 - (b) a company taking part in a cross-border merger shall comply with the provisions and formalities of the national law to which it is subject. The laws of a Member State enabling its national authorities to oppose a given internal merger on grounds of public interest shall also be applicable to a cross-border merger where at least one of the merging companies is subject to the law of that Member State. This provision shall not apply to the extent that Article 21 of Regulation (EC) No 139/2004 is applicable.
2. The provisions and formalities referred to in paragraph 1(b) shall, in particular, include those concerning the decision-making process relating to the merger and, taking into account the cross-border nature of the merger, the protection of creditors of the merging companies, debenture holders and the holders of securities or shares, as well as of employees as regards rights other than those governed by Article 16. A Member State may, in the case of companies participating in a cross-border merger and governed by its law, adopt provisions designed to ensure appropriate protection for minority members who have opposed the cross-border merger.

Article 5

Common draft terms of cross-border mergers

The management or administrative organ of each of the merging companies shall draw up the common draft terms of cross-border merger. The common draft terms of cross-border merger shall include at least the following particulars:

- (a) the form, name and registered office of the merging companies and those proposed for the company resulting from the cross-border merger;
- (b) the ratio applicable to the exchange of securities or shares representing the company capital and the amount of any cash payment;
- (c) the terms for the allotment of securities or shares representing the capital of the company resulting from the cross-border merger;

- (d) the likely repercussions of the cross-border merger on employment;
- (e) the date from which the holding of such securities or shares representing the company capital will entitle the holders to share in profits and any special conditions affecting that entitlement;
- (f) the date from which the transactions of the merging companies will be treated for accounting purposes as being those of the company resulting from the cross-border merger;
- (g) the rights conferred by the company resulting from the cross-border merger on members enjoying special rights or on holders of securities other than shares representing the company capital, or the measures proposed concerning them;
- (h) any special advantages granted to the experts who examine the draft terms of the cross-border merger or to members of the administrative, management, supervisory or controlling organs of the merging companies;
- (i) the statutes of the company resulting from the cross-border merger;
- (j) where appropriate, information on the procedures by which arrangements for the involvement of employees in the definition of their rights to participation in the company resulting from the cross-border merger are determined pursuant to Article 16;
- (k) information on the evaluation of the assets and liabilities which are transferred to the company resulting from the cross-border merger;
- (l) dates of the merging companies' accounts used to establish the conditions of the cross-border merger.

Article 6

Publication

1. The common draft terms of the cross-border merger shall be published in the manner prescribed by the laws of each Member State in accordance with Article 3 of Directive 68/151/EEC for each of the merging companies at least one month before the date of the general meeting which is to decide thereon.
2. For each of the merging companies and subject to the additional requirements imposed by the Member State to which the company concerned is subject, the following particulars shall be published in the national gazette of that Member State:
 - (a) the type, name and registered office of every merging company;
 - (b) the register in which the documents referred to in Article 3(2) of Directive 68/151/EEC are filed in respect of each merging company, and the number of the entry in that register;
 - (c) an indication, for each of the merging companies, of the arrangements made for the exercise of the rights of creditors and of any minority members of the merging companies and the address at which complete information on those arrangements may be obtained free of charge.

Article 7

Report of the management or administrative organ

The management or administrative organ of each of the merging companies shall draw up a report intended for the members explaining and justifying the legal and economic aspects of the cross-border merger and explaining the implications of the cross-border merger for members, creditors and employees.

The report shall be made available to the members and to the representatives of the employees or, where there are no such representatives, to the employees themselves, not less than one month before the date of the general meeting referred to in Article 9.

Where the management or administrative organ of any of the merging companies receives, in good time, an opinion from the representatives of their employees, as provided for under national law, that opinion shall be appended to the report.

Article 8

Independent expert report

1. An independent expert report intended for members and made available not less than one month before the date of the general meeting referred to in Article 9 shall be drawn up for each merging company. Depending on the law of each Member State, such experts may be natural persons or legal persons.
2. As an alternative to experts operating on behalf of each of the merging companies, one or more independent experts, appointed for that purpose at the joint request of the companies by a judicial or administrative authority in the Member State of one of the merging companies or of the company resulting from the cross-border merger or approved by such an authority, may examine the common draft terms of cross-border merger and draw up a single written report to all the members.
3. The expert report shall include at least the particulars provided for by Article 10(2) of Council Directive 78/855/EEC of 9 October 1978 concerning mergers of public limited liability companies (12). The experts shall be entitled to secure from each of the merging companies all information they consider necessary for the discharge of their duties.
4. Neither an examination of the common draft terms of cross-border merger by independent experts nor an expert report shall be required if all the members of each of the companies involved in the cross-border merger have so agreed.

Article 9

Approval by the general meeting

1. After taking note of the reports referred to in Articles 7 and 8, the general meeting of each of the merging companies shall decide on the approval of the common draft terms of cross-border merger.
2. The general meeting of each of the merging companies may reserve the right to make implementation of the cross-border merger conditional on express ratification by it of the

arrangements decided on with respect to the participation of employees in the company resulting from the cross-border merger.

3. The laws of a Member State need not require approval of the merger by the general meeting of the acquiring company if the conditions laid down in Article 8 of Directive 78/855/EEC are fulfilled.

Article 10

Pre-merger certificate

1. Each Member State shall designate the court, notary or other authority competent to scrutinise the legality of the cross-border merger as regards that part of the procedure which concerns each merging company subject to its national law.
2. In each Member State concerned the authority referred to in paragraph 1 shall issue, without delay to each merging company subject to that State's national law, a certificate conclusively attesting to the proper completion of the pre-merger acts and formalities.
3. If the law of a Member State to which a merging company is subject provides for a procedure to scrutinise and amend the ratio applicable to the exchange of securities or shares, or a procedure to compensate minority members, without preventing the registration of the cross-border merger, such procedure shall only apply if the other merging companies situated in Member States which do not provide for such procedure explicitly accept, when approving the draft terms of the cross-border merger in accordance with Article 9(1), the possibility for the members of that merging company to have recourse to such procedure, to be initiated before the court having jurisdiction over that merging company. In such cases, the authority referred to in paragraph 1 may issue the certificate referred to in paragraph 2 even if such procedure has commenced. The certificate must, however, indicate that the procedure is pending. The decision in the procedure shall be binding on the company resulting from the cross-border merger and all its members.

Article 11

Scrutiny of the legality of the cross-border merger

1. Each Member State shall designate the court, notary or other authority competent to scrutinise the legality of the cross-border merger as regards that part of the procedure which concerns the completion of the cross-border merger and, where appropriate, the formation of a new company resulting from the cross-border merger where the company created by the cross-border merger is subject to its national law. The said authority shall in particular ensure that the merging companies have approved the common draft terms of cross-border merger in the same terms and, where appropriate, that arrangements for employee participation have been determined in accordance with Article 16.
2. To that end each merging company shall submit to the authority referred to in paragraph 1 the certificate referred to in Article 10(2) within six months of its issue together with the common draft terms of cross-border merger approved by the general meeting referred to in Article 9.

Article 12

Entry into effect of the cross-border merger

The law of the Member State to whose jurisdiction the company resulting from the cross-border merger is subject shall determine the date on which the cross-border merger takes effect. That date must be after the scrutiny referred to in Article 11 has been carried out.

Article 13

Registration

The law of each of the Member States to whose jurisdiction the merging companies were subject shall determine, with respect to the territory of that State, the arrangements, in accordance with Article 3 of Directive 68/151/EEC, for publicising completion of the cross-border merger in the public register in which each of the companies is required to file documents.

The registry for the registration of the company resulting from the cross-border merger shall notify, without delay, the registry in which each of the companies was required to file documents that the cross-border merger has taken effect. Deletion of the old registration, if applicable, shall be effected on receipt of that notification, but not before.

Article 14

Consequences of the cross-border merger

1. A cross-border merger carried out as laid down in points (a) and (c) of Article 2(2) shall, from the date referred to in Article 12, have the following consequences:
 - (a) all the assets and liabilities of the company being acquired shall be transferred to the acquiring company;
 - (b) the members of the company being acquired shall become members of the acquiring company;
 - (c) the company being acquired shall cease to exist.
2. A cross-border merger carried out as laid down in point (b) of Article 2(2) shall, from the date referred to in Article 12, have the following consequences:
 - (a) all the assets and liabilities of the merging companies shall be transferred to the new company;
 - (b) the members of the merging companies shall become members of the new company;
 - (c) the merging companies shall cease to exist.
3. Where, in the case of a cross-border merger of companies covered by this Directive, the laws of the Member States require the completion of special formalities before the transfer of certain assets, rights and obligations by the merging companies becomes

effective against third parties, those formalities shall be carried out by the company resulting from the cross-border merger.

4. The rights and obligations of the merging companies arising from contracts of employment or from employment relationships and existing at the date on which the cross-border merger takes effect shall, by reason of that cross-border merger taking effect, be transferred to the company resulting from the cross-border merger on the date on which the cross-border merger takes effect.
5. No shares in the acquiring company shall be exchanged for shares in the company being acquired held either:
 - (a) by the acquiring company itself or through a person acting in his or her own name but on its behalf;
 - (b) by the company being acquired itself or through a person acting in his or her own name but on its behalf.

Article 15

Simplified formalities

1. Where a cross-border merger by acquisition is carried out by a company which holds all the shares and other securities conferring the right to vote at general meetings of the company or companies being acquired:
 - Articles 5, points (b), (c) and (e), 8 and 14(1), point (b) shall not apply,
 - Article 9(1) shall not apply to the company or companies being acquired.
2. Where a cross-border merger by acquisition is carried out by a company which holds 90 % or more but not all of the shares and other securities conferring the right to vote at general meetings of the company or companies being acquired, reports by an independent expert or experts and the documents necessary for scrutiny shall be required only to the extent that the national law governing either the acquiring company or the company being acquired so requires.

Article 16

Employee participation

1. Without prejudice to paragraph 2, the company resulting from the cross-border merger shall be subject to the rules in force concerning employee participation, if any, in the Member State where it has its registered office.
2. However, the rules in force concerning employee participation, if any, in the Member State where the company resulting from the cross-border merger has its registered office shall not apply, where at least one of the merging companies has, in the six months before the publication of the draft terms of the cross-border merger as referred to in Article 6, an average number of employees that exceeds 500 and is operating under an employee participation system within the meaning of Article 2(k) of Directive 2001/86/EC, or where the national law applicable to the company resulting from the cross-border merger does not

- (a) provide for at least the same level of employee participation as operated in the relevant merging companies, measured by reference to the proportion of employee representatives amongst the members of the administrative or supervisory organ or their committees or of the management group which covers the profit units of the company, subject to employee representation, or
 - (b) provide for employees of establishments of the company resulting from the cross-border merger that are situated in other Member States the same entitlement to exercise participation rights as is enjoyed by those employees employed in the Member State where the company resulting from the cross-border merger has its registered office.
- 3. In the cases referred to in paragraph 2, the participation of employees in the company resulting from the cross-border merger and their involvement in the definition of such rights shall be regulated by the Member States, *mutatis mutandis* and subject to paragraphs 4 to 7 below, in accordance with the principles and procedures laid down in Article 12(2), (3) and (4) of Regulation (EC) No 2157/2001 and the following provisions of Directive 2001/86/EC:
 - (a) Article 3(1), (2) and (3), (4) first subparagraph, first indent, and second subparagraph, (5) and (7);
 - (b) Article 4(1), (2), points (a), (g) and (h), and (3);
 - (c) Article 5;
 - (d) Article 6;
 - (e) Article 7(1), (2) first subparagraph, point (b), and second subparagraph, and (3). However, for the purposes of this Directive, the percentages required by Article 7(2), first subparagraph, point (b) of Directive 2001/86/EC for the application of the standard rules contained in part 3 of the Annex to that Directive shall be raised from 25 to 33 1/3 %;
 - (f) Articles 8, 10 and 12;
 - (g) Article 13(4);
 - (h) part 3 of the Annex, point (b).
- 4. When regulating the principles and procedures referred to in paragraph 3, Member States:
 - (a) shall confer on the relevant organs of the merging companies the right to choose without any prior negotiation to be directly subject to the standard rules for participation referred to in paragraph 3(h), as laid down by the legislation of the Member State in which the company resulting from the cross-border merger is to have its registered office, and to abide by those rules from the date of registration;
 - (b) shall confer on the special negotiating body the right to decide, by a majority of two thirds of its members representing at least two thirds of the employees, including the votes of members representing employees in at least two different Member States, not to open negotiations or to terminate negotiations already opened and to rely on the rules on participation in force in the Member State where the registered office of the company resulting from the cross-border merger

will be situated;

- (c) may, in the case where, following prior negotiations, standard rules for participation apply and notwithstanding these rules, determine to limit the proportion of employee representatives in the administrative organ of the company resulting from the cross-border merger. However, if in one of the merging companies employee representatives constituted at least one third of the administrative or supervisory board, the limitation may never result in a lower proportion of employee representatives in the administrative organ than one third.
- 5. The extension of participation rights to employees of the company resulting from the cross-border merger employed in other Member States, referred to in paragraph 2(b), shall not entail any obligation for Member States which choose to do so to take those employees into account when calculating the size of workforce thresholds giving rise to participation rights under national law.
- 6. When at least one of the merging companies is operating under an employee participation system and the company resulting from the cross-border merger is to be governed by such a system in accordance with the rules referred to in paragraph 2, that company shall be obliged to take a legal form allowing for the exercise of participation rights.
- 7. When the company resulting from the cross-border merger is operating under an employee participation system, that company shall be obliged to take measures to ensure that employees' participation rights are protected in the event of subsequent domestic mergers for a period of three years after the cross-border merger has taken effect, by applying *mutatis mutandis* the rules laid down in this Article.

Article 17

Validity

A cross-border merger which has taken effect as provided for in Article 12 may not be declared null and void.

Article 18

Review

Five years after the date laid down in the first paragraph of Article 19, the Commission shall review this Directive in the light of the experience acquired in applying it and, if necessary, propose its amendment.

Article 19

Transposition

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 15 December 2007.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Article 20

Entry into force

This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Union.

Article 21

Addressees

This Directive is addressed to the Member States.
Done at Strasbourg, 26 October 2005.

For the European Parliament
The President
J. BORRELL FONTELLES

For the Council
The President
D. ALEXANDER

-
- (1) OJ C 117, 30.4.2004, p. 43.
 - (2) Opinion of the European Parliament of 10 May 2005 (not yet published in the Official Journal) and Council Decision of 19 September 2005.
 - (3) Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EC Merger Regulation) (OJ L 24, 29.1.2004, p. 1).
 - (4) OJ L 225, 12.8.1998, p. 16.
 - (5) OJ L 82, 22.3.2001, p. 16.
 - (6) OJ L 80, 23.3.2002, p. 29.
 - (7) OJ L 254, 30.9.1994, p. 64. Directive as amended by Directive 97/74/EC (OJ L 10, 16.1.1998, p. 22).
 - (8) OJ L 294, 10.11.2001, p. 1. Regulation as amended by Regulation (EC) No 885/2004 (OJ L 168, 1.5.2004, p. 1).
 - (9) OJ L 294, 10.11.2001, p. 22.
 - (10) OJ C 321, 31.12.2003, p. 1.
 - (11) First Council Directive 68/151/EEC of 9 March 1968 on coordination of safeguards which, for the protection of the interests of members and others, are required by Member States of companies within the meaning of the second paragraph of Article 58 of the Treaty, with a view to making such safeguards equivalent throughout the Community (OJ L 65, 14.3.1968, p. 8). Directive as last amended by the 2003 Act of Accession.
 - (12) OJ L 295, 20.10.1978, p. 36. Directive as last amended by the 2003 Act of Accession.

ARTHUR COX

14 July 2016

Troutman Sanders LLP
875 Third Avenue
New York
NY 10022
USA

Re: Cross-border merger between Flamel Technologies S.A. (“Flamel”) and Avadel Pharmaceuticals Limited (“Avadel”) (the “Merger”)

Dear Sirs,

1. Basis of Opinion and Confirmations

- 1.1 We act as legal adviser in Ireland to Flamel and Avadel. You have asked for our legal opinion (the “**Opinion**”) and/or confirmations of fact (the “**Confirmations**”) as to certain matters of Irish law concerning the Merger to be effected pursuant to *Directive 2005/56/EC of the European Parliament and of the Council of 26 October 2005 on cross-border mergers of limited liability companies* (the “**Directive**”) (a summary of the relevant principal aspects of which is set out in the appendix to this letter) in support of your submission to be dated on or about the date of this letter (the “**Troutman Sanders Letter**”) to the United States Securities and Exchange Commission (the “**SEC**”) in which you ask the SEC to concur with your views that the Merger satisfies all the elements for reliance upon the exemption afforded under Section 3(a)(10) (the “**Section 3(a)(10) Exemption**”) of the United States Securities Act of 1933, as amended (the “**Securities Act**”).
- 1.2 As set out in the Troutman Sanders Letter, upon effectiveness of the Merger it is proposed that:
 - (a) the outstanding ordinary shares of Flamel will be exchanged for newly issued ordinary shares of Avadel on a one-for-one basis (the “**Shares**”); and
 - (b) the ordinary shares of Avadel held by Flamel will be cancelled.

1.3 The Opinion and Confirmations in this letter are also strictly confined to:

Donogh Crowley, John S Walsh, Michael Meghen, William Johnston, Eugene McCague, Nicholas G Moore, David O'Donohoe, Colm Duggan, Isabel Foley, John Meade, Conor McDonnell, Patrick McGovern, Grainne Hennessy, Séamus Given, Caroline Devlin, Ciarán Bolger (Chairman), Gregory Glynn, Stephen Hegarty, Sarah Cunniff, Kathleen Garrett, Pádraig Ó Ríordáin, Elizabeth Bothwell, William Day, Andrew Lenny, John Menton, Orla O'Connor, Brian O'Gorman (Managing Partner), Mark Saunders, Mark Barr, John Matson, Deborah Spence, Kevin Murphy, Cormac Kissane, Raymond Hurley, Kevin Langford, Eve Mulconry, Philip Smith, Kenneth Egan, Conor Hurley, Alex McLean, Glenn Butt, Niav O'Higgins, Fintan Clancy, Rob Corbet, Rachel Niall, Siobhán Hayes, Pearse Ryan, Uítan Shannon, Dr Thomas B Courtney, Orla Keane, Aaron Boyle, Rachel Hussey, Colin Kavanagh, Kevin Lynch, Garrett Monaghan, Geoff Moore, Fiona McKeever, Chris McLaughlin, Maura McLaughlin, Joanelle O'Cleirigh, Paul Robinson, Richard Willis, Deirdre Barrett, Cian Beecher, Ailish Finnerty, Robert Cain, Connor Manning, Keith Smith, John Donald, Dara Harrington, David Molloy, Stephen Ranalow, Gavin Woods, Simon Hannigan, Claire McGrade, Colin Monaghan, Niamh Quinn, Colin Rooney, Catherine Austin, Hilary Callanan, Jennifer McCarthy, Aiden Small, Adrian Mulryan, John Barrett, Phil Cody, Karen Killoran, Richard Ryan

FL079/003/AC#20726810.8

- (a) the matters expressly stated herein and are not to be read as extending by implication or otherwise to any other matter; and
- (b) the documents we have examined in connection with this opinion (the “**Documents**”) (as listed in the Schedule).

We have not reviewed any documents referred to in the Documents (other than the Documents) for the purposes of giving our Opinion and Confirmations and we express no legal opinion or confirmation of fact on them.

- 1.4 The Opinion and Confirmations set out below speak only as of the date of this letter and are confined to and given in all respects on the basis of the laws of Ireland in force at the date of this letter as currently applied by the courts of Ireland. We have made no investigations and we express no opinion as to the laws of any other jurisdiction or the effect thereof. In particular, we express no opinion on the laws of the European Union as they affect any jurisdiction other than Ireland.

2. **Opinion**

Subject to the assumptions in this letter and to any matters not disclosed to us, we are of the opinion that:

- 2.1 in accordance with Article 11 of the Directive and regulation 14(1) of the European Communities (Cross-Border Mergers) Regulations 2008 of Ireland (the “**Regulations**”), the Irish High Court (the “**Court**”) is the competent authority in the European Economic Area in connection with the Merger to make an order confirming the scrutiny of the legality of the Merger as regards that part of the procedure which concerns the completion of the Merger and the Merger cannot become effective without such order having been given by the Court; and
- 2.2 the Court retains the right to hear submissions from interested parties to the Merger, which includes the registered holders of Flamel shares (the “**Flamel Shareholders**”), at the hearing of the Court at which the Court scrutinises the legality of the Merger and all Flamel shareholders will have the right to attend such hearing.

3. **Confirmations**

Subject to the assumptions in this letter and to any matters not disclosed to us, we confirm the following statements of fact:

- 3.1 in accordance with an order of the Court dated 25 April 2016 (the “**Court Order**”), the Court will conduct a hearing as to the fairness (procedurally and substantively) (the “**Fairness Hearing**”) of the terms and conditions of the Merger to all persons to whom it is proposed to issue shares of Avadel, being the Flamel Shareholders, pursuant to the Merger, and an affirmative finding of such fairness by the Court at the Fairness Hearing is a prerequisite to the Merger;
- 3.2 pursuant to the terms of the common draft terms of the Merger dated 27 May 2016 (as subsequently amended and restated on 29 June 2016), entered into by Flamel and Avadel (the “**Common Draft Terms**”), it is a condition to the Merger becoming effective that the Court will rule on the fairness (procedurally and substantively) of the terms and conditions of the Merger;
- 3.3 the Flamel Shareholders will receive notice of the Fairness Hearing by way of advertisements placed in the Irish Companies Registration Office Gazette, two

national Irish daily newspapers and the international editions of The Financial Times and The Wall Street Journal; and

- 3.4 pursuant to the term of the Common Draft Terms, Flamel and Avadel will advise the Court in advance of the Fairness Hearing that, on the basis of the Court ordering and confirming the: (i) scrutiny of the legality of the Merger as regards that part of the procedure concerning the completion of the Merger; and, (ii) fairness (procedurally and substantively) of the terms and conditions of the Merger, Avadel will rely on the Section 3(a)(10) Exemption and that it will not register the Shares under the Securities Act pursuant to the Merger.

4. Assumptions

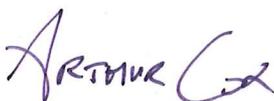
For the purpose of giving this Opinion and the Confirmations, we assume the following without any responsibility on our part if any assumption proves to be untrue as we have not verified independently any assumption:

- 4.1 that Flamel and Avadel will jointly make an application to the Court to make an order confirming scrutiny of the legality of the Merger as regards that part of the procedure which concerns the completion of the Merger;
- 4.2 that neither the Directive or the Regulations will be amended or modified;
- 4.3 that the Court will not amend or modify the Court Order;
- 4.4 that neither Flamel nor Avadel will amend the conditions to the Merger becoming effective to the Merger as contained in the Common Draft Terms;
- 4.5 the completeness and authenticity of all Documents submitted to us as originals or copies of originals and (in the case of copies) conformity to the originals of copy documents and the genuineness of all signatories, stamps and seals thereon;
- 4.6 where incomplete Documents have been submitted to us or signature pages only have been supplied to us for the purposes of issuing the Opinion and Confirmations, that the originals of such documents correspond in all respects with the last draft of the complete Documents submitted to us; and
- 4.7 that the Documents will be signed or executed in a form and content having no material difference to the drafts provided to us, will be delivered by the parties thereto, and that the terms thereof will be observed and performed by the parties thereto.

5. Disclosure

The Opinion and the Confirmations in this letter are addressed to you and may not be relied upon by any person except yourselves, although we agree that this letter may be attached to the Troutman Sanders Letter, in the form of the draft letter attached hereto, to the SEC for the purposes of the no-action letter concerning the issue of the Shares.

Yours faithfully



ARTHUR COX

Schedule

The Documents

1. Troutman Sanders Letter
2. Common Draft Terms
3. Court Order

Appendix

Summary of the relevant principal aspects of the Directive

French courts or other French national authorities do not have jurisdiction to opine on the fairness of a cross-border merger between a French company and an Irish company, when the merged company will have its seat in Ireland (i.e. formed under Irish law), as is the case here. This flows from the application of relevant EU law, as follows:

1. **General principles of EU law**

First, the European Union, of which both France and Ireland are Member States, constitutes, in the words of the Court of Justice of the European Union, “*a new legal order of international law for the benefit of which the States have limited their sovereign rights, albeit within limited fields*”.¹ In those fields, the Union has the competences attributed to it under the relevant Treaties, in particular the Treaty on the Functioning of the European Union (“**TFEU**”) and these competences may be exclusive or shared with the Member States. Under the TFEU, the matter of cross-border merger transactions between limited companies established in different Member States of the European Union is a shared competence between the European Union and its Member States. Accordingly, it is an area in which Member States (including France and Ireland) have effectively transferred their sovereign rights to the European Union.

According to article 2(2) of the TFEU, in the case of shared competences, the European Union and the Member States may legislate and adopt legally binding acts in that area, but Member States can exercise their competences only to the extent that the Union has not exercised its competence. Insofar as intra-EU cross-border mergers are concerned, the Union has intervened by way of Directive 2005/56/EC of the European Parliament and of the Council of 26 October 2005 on cross-border mergers of limited liability companies (“**the Cross-Border Merger Directive**”).

A directive is one of the legal instruments at the disposal of the European Union institutions when exercising the Union’s competences. A directive is a legal instrument that is binding, as to the result to be achieved, upon each Member State to which it is addressed but it leaves to the national authorities the choice of form and methods of its implementation. While Member States have discretion as to how a directive will be implemented or transposed in their legal systems, the ends which must be met will be set out in considerable detail in a directive. As such directives are often used by the European Union institutions when harmonising the laws of the Member States within a certain area. In concrete terms, each Member State is required to adopt legal instruments within their own legal system to make provisions to achieve the ends set out in the Directive. The Cross-Border Merger Directive was transposed into Irish law by the European Communities (Cross Border Mergers) Regulations 2008 as amended by the European Communities (Mergers and Divisions of Companies) (Amendment) Regulations 2011 (the “**Regulations**”) and in France, by the Law of 3 July 2008².

Although the Directive has been implemented in each jurisdiction under its own legal processes, the uniform application of EU law is ensured by a number of mechanisms, including the following:

¹ Case 26/62, *Van Gend en Loos*, [1963] ECR 1.

² Section IV – articles L236-25 to L236-32 and R236-13 to R236-20 of the French Commercial code; articles L2371-1 et seq. of the French Labour Code.

- Under Article 258 TFEU, the European Commission (one of the institutions of the European Union) may take infringement proceedings against Member States which fail to transpose a directive correctly or within the prescribed timeframe;
- Under Article 267 TFEU, when issues arise before a Court of a Member State as to the proper interpretation of the Treaties or the validity and interpretation of acts of the institutions of the Union (including a directive), such a court may (and if it is the court of last jurisdiction in respect of the matter before it is obliged to) request the CJEU to give a preliminary ruling on the issue to clarify the points of EU law raised.
- Under the principle of the primacy of EU law and the obligation of cooperation under the Treaties, all the authorities of Member States, including their Courts, must not apply national law when it is inconsistent with a provision of EU law.

Thus, for cross border mergers under the Directive, there is a single unified jurisdiction: the EU.

2. **Approval process under the Cross-Border Merger Directive**

The purpose of the Cross-Border Merger Directive is to facilitate the carrying out of cross-border mergers between various types of limited liability companies governed by the laws of different Member States. Prior to the introduction of the Directive, cross-border mergers of limited liability companies encountered many legislative and administrative difficulties in the European Community. The European Union considered that it was necessary, with a view to the completion and functioning of the single European market, to enact provisions to facilitate the carrying out of cross-border mergers between various types of limited liability companies governed by the laws of different Member States. This was achieved by the introduction under the Directive of a single common merger procedure ensuring the uniformity of applicable requirements in the Member States.

A cross-border merger under the Directive results in each transferor company being dissolved without going into liquidation, thus avoiding the publicity, delay and expense of a liquidation. Furthermore, all of the assets and liabilities (including legal proceedings, employment contracts and other contracts, agreements or instruments) of the transferor companies are transferred to the surviving company by operation of law.

The proposed cross-border merger between Flamel Technologies SA and Avadel Pharmaceuticals Limited (the “**Merger**”) is a cross-border merger pursuant to the Directive of limited liability companies that are governed by the laws of different Member States. Accordingly, it is governed by and occurs under the single common merger approval procedure established by the Directive.

The Directive provides for a two-step approval process whereby the ultimate approval of the cross-border merger is to be granted by a single national authority, namely the competent authority in the jurisdiction of the surviving company:

- (i) Under the first step, each of the merging companies must comply with a number of procedural and administrative requirements, which include, inter alia, the provision to members of the merging companies of a report (the common draft terms) explaining and justifying the legal and economic aspects of the cross-border merger and explaining the implications of the cross-border merger for members, creditors and employees. In addition an independent expert report (the expert report) must be provided and must, among other things, state the methods used to calculate the proposed exchange ratio and provide an opinion on whether the proposed exchange ratio is fair and reasonable.

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Once all such requirements have been complied with, an application must be made by each of the merging companies to their respective national authority which will, on being satisfied that all relevant administrative matters have been complied with, issue a pre-merger certificate. This certificate conclusively attests to the proper completion of the pre-merger procedural requirements for each merging company in their respective Member State.

- (ii) Under the second step, the cross-border merger is approved by a single national authority, namely the competent national authority in the Member State which laws will govern the company resulting from the cross-border merger which will scrutinise the legality of the cross-border merger to determine whether it should proceed and the terms on which it should proceed. In order to enable the authority to complete this task, each of the merging companies must submit to it the pre-merger certificate issued by its relevant national authority and the authority must ensure that the merging companies have approved the common draft terms in the same terms and, where appropriate, that arrangements for employee participation have been determined in accordance with the Directive.

Insofar as the Merger is concerned, the relevant authority granting approval of the cross-border merger will be the Irish High Court, to the exclusion of any French courts, but relying, inter alia, on the pre-merger certificate issued by the relevant French authority to Flamel Technologies SA. Under the Regulations, approval may only be granted by the Irish High Court once it is satisfied that all procedural requirements have been satisfied and that there is no reason why the cross-border merger should not be implemented. In this respect, the High Court has exclusive jurisdiction at this stage of the process to opine on the fairness or otherwise of a cross-border merger and when doing so, will consider the cross-border merger from the perspective of the shareholders of all companies involved in the merger and creditors of the merging companies, not only Irish shareholders. By contrast, the Courts or authorities of other Member States (i.e. in our case, France) have no jurisdiction to consider and/or rule on the cross-border merger and would, if doing so, be acting contrary to the provisions of the Directive and in breach of EU law.