



Avadel Pharmaceuticals plc  
10 Earlsfort Terrace  
Dublin 2, Ireland

October 14, 2020

Ms. Nudrat Salik  
Mr. Ameen Hamady  
Office of Life Sciences  
Division of Corporation Finance  
Securities and Exchange Commission  
100 F Street, N.E.  
Washington, D.C. 20549

**Re: Avadel Pharmaceuticals plc**

**Form 10-Q for the Period Ended June 30, 2020**  
**Filed August 10, 2020**  
**File No. 001-37977**

Dear Ms. Salik and Mr. Hamady:

Avadel Pharmaceuticals plc (the “**Company**,” “**we**” or “**us**”) is submitting this letter in response to a comment of the staff of the Division of Corporation Finance (the “**Staff**”) of the U.S. Securities and Exchange Commission (the “**Commission**”) with respect to our quarterly report on Form 10-Q filed on August 10, 2020 (the “**10-Q**”), as set forth in the Staff’s letter dated September 21, 2020 to Thomas McHugh, Senior Vice President and Chief Financial Officer (the “**Comment Letter**”).

For reference purposes, the text of the Comment Letter has been reproduced and italicized herein with responses below each numbered comment. All capitalized terms used and not otherwise defined herein shall have the meanings set forth in the 10-Q.

Form 10-Q for the Period Ended June 30, 2020

Note 4. Disposition of the Hospital Business, page 13

*1. We note your response to comment 1. Pursuant to ASC 205-20-45-1B, the sale of the sterile injectable drugs portfolio business appears to represent a strategic shift that has had a major effect on your operations and financial results and correspondingly it would appear that this business, which also represents a component of an entity, should be reported as discontinued operations. In this regard, we note that this business appears to be a different product line than your current lead drug candidate, FT218, which you note is management’s primary focus. In addition, the pro forma financial information provided indicates that the strategic shift had a major effect on your operations and financial results in terms of revenues, net income/loss and net income/loss per share amounts. Please also refer to Example 1 of the Implementation Guidance in ASC 205-20-55-82 through 55- 101. Please revise your financial statements to reflect the sterile drugs portfolio business as discontinued operations.*

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#### Response to Comment No. 1.

We refer to our telephonic discussion with the Staff on October 2, 2020, which clarified our understanding of your comment. As discussed, the Staff would like to further understand the Company's strategy and products in relation to the Company's judgment that there was not a strategic shift as defined in ASC 205-20 with the sale of the sterile injectable products.

Since it was originally founded in France in 1990 as Flamel Technologies ("Flamel"), the Company's strategy has been to develop and obtain Food and Drug Administration ("FDA") approval for new drugs, and to maximize the value of those drugs for our shareholders. In our public filings, we describe the Company as "...an emerging biopharmaceutical company... We are primarily focused on the development and potential United States ("U.S.") Food and Drug Administration ("FDA") approval of FT218. Outside of our lead product candidate, we continue to evaluate opportunities to expand our product portfolio." We reiterated our strategy of maximizing the value of our drugs for our shareholders in a recent press release dated September 14, 2020 with respect to our current lead product candidate, FT218, in which we state "...we will continue to evaluate all strategic options, including sale, merger, out-licensing or commercialization to maximize shareholder value."

We identify drug candidates using criteria that include the ability to apply our patented drug delivery technologies and the potential commercial opportunity. The Company's current drug-delivery technologies include Micropump®, LiquiTime®, Medusa™, and Trigger Lock™. In addition to our drug-delivery technologies, the Company uses our internal resources and processes to develop a strategy for FDA approval. Once we receive FDA approval of a given drug, we evaluate the best means to maximize its value through either strategic partnerships, licensing arrangements, commercialization, or outright asset sales.

Examples of our strategy include:

- the sterile injectable drugs (the "Products"), which were originally acquired as undeveloped drugs in the acquisition of Eclat Pharmaceuticals in 2012. Using our internal resources and processes, the Company developed these drugs, obtained FDA approval and commercialized the Products over the years 2013-2016. On June 30, 2020, the Company decided to maximize the remaining value of those drugs by selling them to Exela. The sale of the Products did not change or shift our strategy. Instead, the sale of the Products simply represented a mechanism to maximize value to our shareholders.
  - the internal development of Nouress (cysteine hydrochloride), which was approved by the FDA on December 13, 2019 and received patent approval on December 16, 2019. Using our internal resources and processes, the Company developed the drug and obtained FDA approval, which resulted in the issuance of patents on the drug. While we never launched Nouress, the value of Nouress was maximized by including it in the transaction with Exela rather than marketing and selling it ourselves.
  - the internal development of FT218 (once-nightly formulation of sodium oxybate), which is still in the development stage and has not been approved by the FDA. We completed our Phase 3 clinical trial in April 2020. FT218 was not included in the transaction with Exela as we are still developing and seeking FDA approval for the drug.
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- we continue to identify and select new candidates for drug development. The same internal resources and processes used to develop and seek FDA approval for the “Products,” Nouress, and FT218, will be used to develop and seek FDA approval for newly identified drug candidates. With each of our products and drug candidates, the Company will seek to maximize the value to our shareholders through the use of strategic partnerships, licensing arrangements, commercialization, or outright asset sales, consistent with the strategy we have used with the other drugs we have developed.

The Company has had numerous other drug candidates at various stages of the FDA drug approval process and commercialization throughout our history (including those using our other patented drug-delivery technologies and our internal processes). Prior to the aforementioned sale to Exela, as of June 30, 2020, our portfolio of drugs and drug candidates included Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection), Akovaz™ (ephedrine sulfate injection), Nouress™ (cysteine hydrochloride injection), and FT218 (development phase, once-nightly formulation of sodium oxybate). Bloxiverz, Vazculep, Akovaz, and Nouress were included in the sale to Exela on June 30, 2020. Each of our drugs and drug candidates are for a different indication. We do not believe any of our development phase drugs qualify as products, and therefore we do not consider FT218 to be a product.

The Products were described as “the hospital business” or “the hospital products” in prior filings for ease of communication. The Products are for different indications and can be administered in hospitals, outpatient facilities, or in doctor offices. Nouress is primarily used in neonatal facilities and is not specific to any surgical procedures. We have never categorized these, or any of our commercialized products as separate product lines. In our quarterly and annual financial statement filings, we have provided product sales by the individual name of the drug versus as “hospital products.”

We referred to Example 1 in ASC 205-20-55-84 through 55-86 and do not believe the fact pattern is analogous to the Company. The Products do not represent a separate product line and as such could not be a separately identifiable component of the Company. Per the interpretive examples in the *KPMG Handbook: Discontinued Operations, Example 3.3.10 and Question 3.3.50* (refer to Appendix A), it is not appropriate to present all or almost all of an entity’s assets or activities as discontinued operations, as they would not be clearly distinguishable from the rest of the entity. We believe that presenting the disposition of the Products as a discontinued operation would not provide meaningful information to the users of the financial statements and instead could be confusing.

Additionally, *Illustration 2-1: Component of an entity* from EY’s *Financial reporting developments: Discontinued Operations* (refer to Appendix B), provides an example of an entity disposing of certain brands in a group of products. As the brands are part of a larger cash-flow-generating group, the disposed brands do not represent a group that on its own is a component of the entity. None of our products had or have separately identifiable and distinct cash flows (other than gross profit) due to the centralized costs involved in developing, marketing, distribution, and selling the drugs at a company our size. We are a small company with approximately 30 employees, without separate operating divisions or sales forces. The resources that supported the Products are the same resources that support the development of FT218. As such, the Products cannot be viewed as a distinguishable component of the Company.

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In summary, we believe in our professional judgment that the sale of the sterile injectable drugs does not represent a strategic shift, and therefore, should not be reported as a discontinued operation. The sale of the Products and the continued development of FT218 is consistent with our strategy of developing and obtaining FDA approval for new drugs and maximizing the value of those drugs to our shareholders. In addition, the Products do not represent a product line, and therefore are not a distinguishable component of the Company. However, we appreciate that the disposition of the Products had a major effect on certain financial statement line items such as revenues, net income/loss and net income/loss per share amounts that may be relevant to investors. In the interest of transparency, we propose including additional disclosures in our third quarter Form 10-Q consistent with the pro-forma financial information disclosed in our Form 8-K filed on July 2, 2020.

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Should you have any further comments or questions with regard to the foregoing, please contact the undersigned at (636) 449-1843 or by email at [tmchugh@avadel.com](mailto:tmchugh@avadel.com).

Sincerely,

/s/ Thomas McHugh

Thomas McHugh

cc:

Gregory Divis, *Chief Executive Officer, Avadel Pharmaceuticals plc*  
Jerad G. Seurer, *VP, Deputy General Counsel & Corporate Secretary, Avadel Pharmaceuticals plc*  
Robert E. Puopolo, *Goodwin Procter LLP*

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## Appendix A

### KPMG Handbook: Discontinued Operations

#### *Example 3.3.10: Disposal of single asset in a 'single-asset' company*

ABC Corp. is a 'single-asset' company formed to own, develop, operate, maintain and lease one commercial office building. Other insignificant assets include trade receivables and cash. Tenant's lease contains an option to purchase the building, which Tenant exercises before year-end. Closing is expected to occur within two months of the year-end.

Because the building is ABC's sole asset, the operations (the building) to be disposed of cannot be distinguished from the rest of the entity. Therefore, the disposal of ABC's only asset does not meet the definition of a component of an entity as contemplated in Subtopic 205-20, and cannot be reported in discontinued operations in ABC's financial statements.

However, ABC needs to apply the measurement requirements in Subtopic 360-10 (see Question 4.2.20).

**Question 3.3.50:** Is the disposal of all or almost all of an entity's operations reported in discontinued operations?

**Interpretive response:** No. We do not believe that an entity should report the disposal of all or almost all its activities in discontinued operations. In this instance, the operations disposed of generally do not meet the definition of a component of an entity in Subtopic 205-20 because they are not clearly distinguishable from the rest of the entity.

For further discussion of how the requirements in Subtopic 360-10 apply in this circumstance, see Question 4.2.20.

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## Appendix B

### EY Financial Reporting Developments: Discontinued Operations

#### *Illustration 2-1: Component of an entity*

An entity that manufactures and sells consumer products has several product groups, each with different product lines and brands. For that entity, a product group is the lowest level at which the operations and cash flows can be clearly distinguished, operationally and for financial reporting purposes, from the rest of the entity. Therefore, each product group is a component of the entity.

The entity has experienced losses associated with certain brands in its beauty care products group. The entity decides to remain in the beauty care business but will discontinue the brands with which the losses are associated. Because the brands are part of a larger cash-flow-generating product group, the disposed brands do not represent a group that on its own is a component of the entity.

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