



Avadel Pharmaceuticals plc
10 Earlsfort Terrace
Dublin 2, Ireland

November 24, 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 comments 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 October 29, 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. You state that the sterile injectable drugs (the “Products”) do not represent a product line, and therefore are not a distinguishable component of the company. Please tell us if you believe that the Products meet the definition of a component of an entity as defined in ASC 205-20. If not, please explain. In your response, please address your presentation of the unaudited pro forma financial information you presented in exhibit 99.2 of Form 8-K dated July 2, 2020, which gives effect to the sale of the Products. Based on this presentation, it appears that, at a minimum, the operations of the Products can be clearly distinguished, operationally and for financial reporting purposes, from the rest of the entity.

Response to Comment No. 1.

ASC 205-20-20 defines a component as:

“A component of an entity comprises operations and cash flows that can be clearly distinguished, operationally and for financial reporting purposes, from the rest of the entity. A component of an entity may be a reportable segment or an operating segment, a reporting unit, a subsidiary, or an asset group.”

The Products do not meet the definition of a component because the operations and cashflows related to the Products are not clearly distinguishable from the rest of the Company. We have always managed the Company as one operating segment, one reporting unit, and one asset group and therefore one component. We do not separately report the expenses related to the Products due to the small, centralized nature of our operations involved in developing, marketing, distributing, and selling drugs. Avadel has one leased office and approximately 30 employees, the same as both prior to and subsequent to the sale of the Products. All of our employees supported both the Products and the development of FT218. No positions were eliminated and none of our employees were terminated upon the sale of the Products, and we did not reduce the size of our facilities as a result of the sale.

The pro forma financial information included in the Form 8-K filed on July 2, 2020 was based on Regulation S-X, Article 11, Rule 11-01 requirements which focuses on the quantitative aspect of the disposition and not the qualitative. The Company provided this information in the interest of providing our shareholders with timely information about the transaction. The Company had to prepare this information for the Form 8-K, as the Company does not operate or financially report the business in this manner. In our Form 10-Q for the quarter ended June 30, 2020, we added a reference to this Form 8-K if our investors wanted additional information related to the transaction. EY's *Financial reporting development: Pro Forma*, states "Article 11 pro forma financial information also may be necessary if the disposition is material, even if the disposed operations do not meet the criteria in ASC 205-20, Discontinued Operations." Therefore, we believe it is inappropriate to draw the conclusion from our presentation of pro forma financial information that the Products represent a component.

The financial information that was disclosed within the Form 8-K was primarily based on either contractual or regulatory obligations that the Company is required to comply with, rather than because the financial information was distinguishable within the Company's operations. In our previous letter on October 14, 2020, we discussed that only gross profit and certain operating expenses are truly distinguishable for the Products. The significant majority of the other costs and expenses to support the Products were not clearly distinguishable. The adjustments reflected in Exhibit 99.2 of the Form 8-K were identified through our accounting records in order to prepare the information provided but is not representative of how the Company operated.

We note that the significant majority of the Company's centralized operating expenses that also supported the Products were not adjusted for in the Form 8-K as they are not distinguishable from the rest of the entity. Although the pro forma adjustments included nearly 100% of our product sales and cost of products sold, less than 5% of our combined Research and Development and Selling, General and Administrative expenses were adjusted, clearly indicating the significance of the indistinguishable costs related to the Products in those line items. For example, we do not maintain separate personnel, departments, functions, or for that matter operating divisions for the Products for activities such as procurement, marketing, distribution, and selling. Therefore, we believe that the fact that we comply with the Form 8-K disclosure requirements does not imply that the Products were distinguishable for operational purposes from the rest of the entity in applying ASC 205-20.

Our facts are comparable to the interpretive examples in the *KPMG Handbook: Discontinued Operations, Example 3.3.10* and *Question 3.3.50* (refer to Appendix A). In those examples, 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. Since the Products represent all of our revenue-generating assets, and therefore all of our revenue and costs of product sold, 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.

Our facts are also similar to *Illustration 2-1: Component of an entity* from EY's *Financial reporting developments: Discontinued Operations* (refer to Appendix B). Since the brands in this example 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. As discussed above, none of our products had or have separately identifiable and distinct cash flows due to the small size of our workforce and centralized costs involved at a company our size, and therefore were part of the larger cash-flow-generating group that is the whole Company and are not a component of the entity on their own.

2. We note from your response to comment 1 that you do not believe the sale of the sterile injectable drugs represented a strategic shift as contemplated by ASC 205-20-45. We continue to believe that the disposal may have represented a strategic shift. Please help us better understand your conclusion. In your response, please address the statements made in the press release announcing the sale of the Products on July 1, 2020. We note that in that press release, the company articulated that the sale of the sterile injectable drug portfolio was a significant milestone for the company, as it further reflected your commitment to strategically focus on advancing FT218 through the regulatory review process and, if approved, bringing your formulation of sodium oxybate to patients. We also note the statement made by Mr. Greg Divis, your Chief Executive Officer, in which he stated, "By divesting our portfolio of sterile injectable drugs, we are now singularly focused on supporting the regulatory approval process, market planning and maximizing shareholder value for FT218." Please also tell us how you considered the fact that the Products sold and FT218 are based on different technologies.

Response to Comment No. 2.

A strategic shift did not occur because our strategy both prior to and subsequent to the sale of the Products remains unchanged. The Company was founded in France in 1990 as Flamel Technologies as an organization focused on drug development and commercialization. Over the past 30 years, the Company has evaluated numerous products. The Company has not focused on a particular indication or technology, nor has it focused on curing specific diseases. Our products, whether internally developed or acquired from a third party, have represented improved medical applications of already existing drugs, including increasing the bioavailability, stability, ease of use or safety of a drug, among other things. Our strategy can be trifurcated into three primary stages: 1) identification, assessment and development of targeted drug candidates; 2) creation and execution of a plan to successfully formulate, develop and obtain FDA approval for the drug candidate; and 3) maximize the value of those drugs for our shareholders through either strategic partnerships, licensing arrangements, commercialization, or outright asset sales. This has been the Company's strategy since inception and is the strategy both before and after the sale of the Products.

The Products represented improved medical applications of already existing, unapproved drugs for which the Company was able to obtain FDA approval. The same is true for FT218 if it is approved. FT218 is an investigational, once-nightly formulation of sodium oxybate designed to treat excessive daytime sleepiness and cataplexy in patients with narcolepsy. If approved, we believe once-nightly FT218 has the potential to offer a meaningful treatment alternative for patients to switch from twice-nightly sodium oxybate, a product that has been on the market for nearly 20 years.

Throughout our history, we have had several drug candidates in different stages of our strategy. Prior to June 30, 2020, we had three drugs in the third stage (Bloxiverz®, Vazculep®, and Akovaz™), one that had completed the second stage (Nouress™), and one at the completion of the first stage (FT218) of our strategy. The history of the development of FT218 is contemporary with the 2013 acquisition of the drug candidates that became Bloxiverz, Vazculep, and Akovaz. The Company has been investigating the development of FT218 for many years and pre-dates the Company's 2014 announcement of positive results from two clinical studies for the treatment of narcolepsy. Our current, primary focus on the development of FT218 is not new and is consistent with the long-standing strategy of the Company.

In considering technology, we are agnostic to the drug-delivery technology used to deliver the medicine in our products and drug candidates. The Company does not sell drug-delivery technologies, we develop and sell drug products that sometimes utilize our internally developed patented delivery technologies, formulations, and processes. We own four different drug-delivery technologies that we evaluate for use in potential additional drug candidates (Micropump®, LiquiTime®, Medusa™, and Trigger Lock™). While FT218 uses the Micropump drug-delivery technology and the Products do not, it was not a consideration in our determination that the sale did not represent a strategic shift. As demonstrated in the Company's history in Appendix C, each of our drug candidates is different from the last. We have developed drug candidates using a variety of drug-delivery technologies or using none at all. Due to the competitive and innovative nature of the pharmaceutical industry, we continuously evaluate opportunities for additional drug candidates to add to our pipeline or product portfolio. However, alternative drug-delivery technologies can also be obtained through strategic partnerships, license arrangements or outright acquisition. Additionally, we have developed drugs that do not use a drug-delivery technology as was the case with the Products.

Our drug-delivery technologies are not a prerequisite for determining our next drug candidates. The fact that one of our drug delivery technologies is used in FT218 does not make it an inherent part of our strategy going forward. Nor does it dictate that a strategic shift occurs every time a different drug-delivery technology (whether it is one we own or not) is used or not used in our past, present or future drug candidates. To suggest otherwise is to suggest that the Company potentially undergoes a strategic shift every time an additional product is developed, which is unreasonable. Additionally, as noted in Appendix C, we have divested several drugs in our history. If each divestiture of a drug was to be considered a strategic shift, we would have presented discontinued operations in each of the last three years (2018-2020) with the divestitures of AcipHex® Sprinkle™, Karbinal™, Cefaclor for Oral Suspension, Flexichamber™, Noctiva, and the Products.

We plan to continue to develop and obtain FDA approval for FT218, and then elect a method of monetization that maximizes value to our shareholders. Depending on the method of monetization, as we continue to develop additional drugs, we could potentially enter a cycle of presenting substantially all of the Company as discontinued operations every few years with each divestiture. Per ASU 2014-08, the FASB issued updates to the discontinued operations guidance in Subtopic 205-20 for this reason. Too many disposals of groups of assets qualified for discontinued operations presentation, which resulted in financial statements that were "less decision useful" for users. We agree with the FASB that such a cycle of financial statement presentation would not provide value to the users of the financial statements and believe that it instead has the potential to mislead.

Regarding our CEO's statements you reference, the statement is absolutely affirmative of the Company's strategy and not at all indicative of a strategic shift. The fact that Mr. Divis describes the transaction in this way is evidence that our strategy continues, unchanged, after the sale of the Products. The sale was significant in that it accelerated the future cash flows from mature drugs in the amount of \$42 million, a material amount to shareholders of a company our size. Mr. Divis is simply communicating the fact that accelerating \$42 million of cash flow from the Products is a significant event to support the continued development of FT218, which has been ongoing for over six years and is now approaching submission to the FDA following our just-completed Phase 3 trials. The Company has communicated in past press releases that we have historically used the cash flow from the Products to fund the development of FT218. Additionally, the word "milestone" is commonly used by many companies in shareholder communications when describing significant events, as was the case in this instance. For the Products, the disposal represented the completion of the third stage to our strategy of developing and maximizing the value of these Products to our shareholders, which was part of our strategic plan, and as such marked a milestone. We further note that in the same press release, that the Company's strategy is not limited to FT218 in the statement "The Company's *primary* focus is the development and potential FDA approval of FT218, which has completed a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy." The use of the word "primary" is intentional as it refers to on-going efforts to identify other drug candidates and drug development activities.

The Company has experienced changes in the available capital resources over its history and the number of drug candidates the Company has in its pipeline is, in part, a function of the level of capital resources available at any given time. The level of available capital resources does not change our strategy, only how, when, and the pace at which we implement it. For the past several years, FT218 has been our lead drug candidate. Until the recent \$190 million of capital raises was completed in the first half of 2020, the Company lacked sufficient capital resources to expand our drug candidate pipeline. Assuming an approval by the FDA of FT218 and subsequent successful commercialization, we will evaluate other opportunities to expand our drug development pipeline or add products. Now that the Company is appropriately capitalized, our opportunity to expand our pipeline and evaluate other drug candidates is significantly enhanced.

In summary, the Products do not represent a component of the Company and therefore are not a discontinued operation. However, even if one were to argue that the Products represented a component, we believe the sale of the Products does not represent a strategic shift. The sale of the Products and the continued development of FT218 is consistent with our historical strategy of identifying, developing, and obtaining FDA approval for improved medical applications of already existing drugs and maximizing the value of those drugs to our shareholders. However, as indicated in our letter dated October 14, 2020, we appreciate that the disposition of the Products impacts several financial statement line items such as revenues, net income/loss and net income/loss per share amounts that may be relevant to investors. Therefore, we have included additional disclosures in Footnote 4 to our third quarter Form 10-Q filed on November 9, 2020, consistent with the pro forma financial information disclosed in our Form 8-K filed on July 2, 2020.

* * * * *

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.

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*

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.

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.

Appendix C

Brief highlights of Avadel Pharmaceutical's¹ history and its focus on drug development:

1990 – Founded in France with the Micropump and Medusa technologies. The Company later develops LiquiTime and Trigger Lock technologies.

1996 – Completed its initial public offering on NASDAQ.

2003-2007 – Developed, obtained FDA approval for, and launched Coreg CR, the first successful product utilizing Micropump. Coreg CR was subsequently commercialized by GlaxoSmithKline.

2012 – Acquired Eclat Pharmaceuticals for Bloxiverz, Vazculep, and Akovaz drug candidates.

2012 – Completed the development of Bloxiverz, received FDA approval, and successfully launched and commercialized the drug. This drug did not use the Company's drug-delivery technologies.

2013 – Completed development for Vazculep, received FDA approval, and successfully launched and commercialized the drug. This drug did not use the Company's drug-delivery technologies.

2014 – Announced positive results for two clinical studies of Micropump sodium oxybate (FT218) for the treatment of narcolepsy.

2016 – Acquired FSC Pediatrics, Inc. and added four additional FDA approved products to its product portfolio, AcipHex® SprinkleTM, KarbinalTM, Cefaclor for Oral Suspension, and FlexichamberTM. These drugs did not use the Company's drug-delivery technologies.

2016 – Completed the development of Akovaz, received FDA approval, and successfully launched and commercialized the drug. This drug did not use the Company's drug-delivery technologies.

2016 – Initiated a Phase 3 trial of Micropump sodium oxybate (FT218) for the treatment of narcolepsy.

2017 – Acquired the rights to Noctiva, an already FDA-approved drug from Serenity Pharmaceuticals. The Company launched and commercialized the drug in 2018, and subsequently discontinued sales in 2019. This drug did not use the Company's drug-delivery technologies.

2018 – Divested AcipHex® SprinkleTM, KarbinalTM, Cefaclor for Oral Suspension, and FlexichamberTM by sale.

December 2019 – Announced the completion of enrollment in its Phase 3 trial of Micropump sodium oxybate (FT218) for the treatment of narcolepsy.

December 2019 – Completed development of Nouress and obtained FDA approval. This drug did not use the Company's drug-delivery technologies.

March 2020 – Successfully raised gross proceeds of \$65M through a PIPE offering.

April 2020 – Announced positive top line results following the completion of the Phase 3 trial of Micropump sodium oxybate (FT218) for the treatment of narcolepsy.

May 2020 – Successfully raised gross proceeds of \$125M through a secondary offering.

June 2020 – Announced the sale of its sterile injectable drugs, including Bloxiverz, Vazculep, Akovaz, and Nouress for \$42M.

Current – Primarily focused on completing the steps necessary to submit its New Drug Application (NDA) to the FDA to seek approval of FT218 and also evaluating opportunities to expand its product pipeline.

¹ The Company was named Flamel Technologies prior to 2017.

Select other drug candidates and products from our history of numerous drug candidates:

Asacard® (1997) with Micropump
Basulin™ (1999) with Medusa
ColCys® Biomaterials (1999)
Genvir™ (2000) with Micropump
Metformin XL (2002) with Micropump
Lansoprazole (2004)
Interferon (2004) with Medusa
Interleukin (2004) with Medusa
Hycet® (2012)
hGH XL (2013) with Medusa
Ibuprofen (2014) with LiquiTime
Guaifenesin (2014) with LiquiTime
Exenatide (2014) with Medusa
Hydromorphone (2016) with Trigger Lock
