



Avadel Pharmaceuticals plc  
10 Earlsfort Terrace  
Dublin 2, Ireland

August 26, 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-K for the Fiscal Year Ended December 31, 2019  
Filed March 16, 2020  
Form 8-K  
Filed July 2, 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 annual report on Form 10-K for the Fiscal Year Ended December 31, 2019 (the “**10-K**”) and with respect to our current report on Form 8-K filed on July 2, 2020 (the “**8-K**”), as set forth in the Staff’s letter dated August 12, 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 8-K.

Form 8-K Filed July 2, 2020

Exhibit 99.2, page 1

*1. We note you sold your portfolio of sterile injectable drugs on June 30, 2020. Your pro forma financial information indicates that this business represents all of your revenues recorded during the year ended December 31, 2019 and the three months ended March 31, 2020. We also note on page 14 of your Form 10-Q for the period ended June 30, 2020 that you determined that this business did not meet the criteria for presentation as discontinued*

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operations. Please help us understand how you made this determination pursuant to ASC 205-20.

Response to Comment No. 1.

The Company used guidance provided in ASC 205-20 to determine that the sale of the sterile injectable drugs portfolio business (the “Hospital Products”) did not meet the criteria for presentation as discontinued operations. Our assessment initially focused on the following guidance:

**ASC 205-20-45-1A: A discontinued operation may include a component of an entity or a group of components of an entity, or a business or nonprofit activity.**

**ASC 205-20-45-1B: A disposal of a component of an entity or a group of components of an entity shall be reported in discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity’s operations and financial results when any of the following occurs:**

- a. The component of an entity or group of components of an entity meets the criteria in paragraph 205-20-45-1E to be classified as held for sale**
- b. The component of an entity or group of components of an entity is disposed of by sale**
- c. The component of an entity or group of components of an entity is disposed of other than by sale in accordance with paragraph 360-10-45-15 (for example, by abandonment or in a distribution to owners in a spinoff)**

The Company determined that it should assess whether or not the sale of Hospital Products met the criteria for presentation as discontinued operations as we considered it a business (ASC 205-20-45-1A). Accordingly, we assessed whether the disposal constituted a strategic shift that would have a major effect on the entity’s operations and financial results. For this assessment, we reviewed all relevant facts and circumstances surrounding the transaction and compared those facts and circumstances to the guidance provided in ASC 205-20-45-1C:

**ASC 205-20-45-1C: Examples of a strategic shift that has (or will have) a major effect on an entity’s operations and financial results could include a disposal of a major geographical area, a major line of business, a major equity method investment, or other major parts of an entity (see paragraphs 205-20-55-83 through 55-101) for Examples.**

Based on the examples provided in ASC 205-20-55-83 through 55-101 and an in-depth analysis of the relevant quantitative and qualitative facts, the Company first considered the following qualitative factors in determining that the sale of Hospital Products did not represent a strategic shift:

- The strategy of the Company has always been to develop, commercialize and maximize the value of drugs approved by the United States Food and Drug





Administration (“FDA”) and the sale of the Hospital Products does not represent a change in this strategy. The Company continues to operate in the same industry using the same strategy which is the development and commercialization of FDA approved drugs.

- Over the past several years, the cash flows from the Hospital Products have been used primarily to partially fund the research and development of our current lead drug candidate, FT218. The sale of the Hospital Products accelerated these cash flows and mitigated the risk as the Hospital Products’ value has continued to decline with the significant revenue decreases realized over the past several years. Additional competitors in the hospital sterile injectables marketplace have resulted in substantial declines in historical and forecasted year-over-year revenues from the Hospital Products. The sale transaction represents a mechanism to accelerate and maximize the expected future cash flow and allows for focus of the Company’s resources on FT218.
  - The Company is planning to use the proceeds to focus on the development of FT218. The Company does not believe that cash flow from the Hospital Products alone would be sufficient to fully fund the complete development costs of FT218 and that the primary source of cash to fund the development of FT218 would most likely be in the form of a capital raise. To this point, during the first half of 2020, Avadel completed two separate capital raises totaling \$190 million of gross proceeds.
  - There were no employees who were 100% dedicated to the operations associated with the Hospital Products and Avadel did not eliminate any employee positions directly as a result of this disposition.
  - The Company believes that the primary reason for shareholders investment is the continued development and future potential of its lead drug candidate, FT218. The Company’s earnings releases and earning calls over the past eighteen months have been primarily focused on the progress of the development of FT218. The amount of interest and types of questions Avadel receives from our analysts when it is on quarterly earnings calls and other investor interactions is focused on FT218. While the Company has disclosed information about revenue from the Hospital Products, it has communicated that the focus is to maximize cash flow generated by these products to fund the development of FT218. We believe, as further evidence of shareholders being primarily focused on FT218 is that, after the sale of the Hospital Products was announced, there was no noticeable change in the share price, share volume or market value of the Company in the trading days following the announcement compared to the trading days prior to the announcement. We believe that this further evidences continuation of our strategy to pursue development and commercialization of FT218 and the absence of a strategic change that would have a major effect on the Company.
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In making the determination that the sale of the Hospital Products did not represent a strategic shift, the Company also evaluated quantitative measures. The Company believes that the quantitative assessment of revenue, on a stand-alone analysis, does not represent a meaningful measure of the value of the Company nor a true indicator of discontinued operations given the historical trend of significantly declining revenue. Instead, the focus for management and the Company's shareholders is the development and potential of FT218 and that revenue from the Hospital Products is not a meaningful or key financial metric used to assess the value of the Company.

To complement its analysis of the qualitative factors noted above, the Company evaluated other quantitative factors with respect to the Hospital Products, including:

- The assets that were sold related to the Hospital Products represent less than 5% of total assets on the Company's balance sheet as of December 31, 2019, March 31, 2020 and June 30, 2020.
- The \$42 million transaction price represents approximately 9.0% of the market capitalization at the time of the sale.
- Operating expenses attributable to the Hospital Products represents less than 5% of the combined research and development and selling, general and administrative expenses for each of the year ended December 31, 2019 and the three months ended March 31, 2020 and the three and six months ended June 30, 2020. The Company does not anticipate a material decrease in operating expenditures as a result of this sale.

Given the analysis of both qualitative and quantitative factors, the Company determined that the sale of the Hospital Products did not represent a strategic shift and did not meet the criteria in ASC 205-20 for presentation as discontinued operations.

*2. In regards to adjustment (d), please help us better understand how you determined the amount of goodwill to eliminate pursuant to ASC 350-20-40-1 through 40-7. In this regard, we note that the goodwill recorded appears to be related to your acquisition of Eclat Pharmaceuticals LC in 2012. It also appears that the earn-out payments addressed in adjustment (g) which the buyer will be assuming after the close of the acquisition are associated with your acquisition of Eclat Pharmaceuticals based on page 77 of your Form 10-K.*

Response to Comment No. 2.

The Company applied guidance provided in ASC 350-20-40-1 through 40-7 to determine the amount of goodwill to dispose as part of the sale of Hospital Products on June 30, 2020. The guidance specifically states the following:

***ASC 350-20-40-2: When a portion of a reporting unit that constitutes a business (see Section 805-10-55) or nonprofit activity is to be disposed of, goodwill associated with***

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***that business or nonprofit activity shall be included in determining the gain or loss on disposal.***

***ASC 350-20-40-3: The amount of goodwill to be included in that carrying amount shall be based on the relative fair values of the business or nonprofit activity to be disposed of and the portion of the reporting unit that will be retained. For example, if a reporting unit with a fair value of \$400 is selling a business or nonprofit activity for \$100 and the fair value of the reporting unit excluding the business or nonprofit activity being sold is \$300, 25% of the goodwill residing in the reporting unit would be included in the carrying amount of the business or nonprofit activity to be sold.***

The Hospital Products associated with Eclat Pharmaceuticals LLC (“Eclat”) acquisition was fully integrated within the Company. The Company has historically operated as a single operating segment with a single reporting unit. The Company does not maintain the specific identification of goodwill as initially recognized in connection with the acquisition of Eclat in 2012 and therefore it believes that the goodwill associated with the Eclat acquisition has lost its identity as the Company integrated the acquired business and performed the goodwill impairment test for the single reporting unit. We determined the disposition of the Hospital Products represented a business which was part of the Company’s single reporting unit. The Company believes that it was appropriate to calculate the goodwill to be allocated on the disposal of Hospital Products based on ASC 350-20-40-3 (relative fair value), which requires us to take the fair value of Hospital Products as a percentage of the fair value of the entire reporting unit.

When the Company acquired Eclat in 2012, the Hospital Products business was integrated with the Company’s existing operations related to the development and commercialization of pharmaceutical products. There is no delineation in the way the Company allocates resources to its components within its one operating segment. The integration of the Hospital Products over the past eight years has resulted in the commingling of assets as part of the single reporting unit which has rendered the goodwill indistinguishable. This is consistent with FASB Standard 142, *Goodwill and Other Intangible Assets*, in the Basis for Conclusions paragraphs B164-166 which discusses goodwill from acquisition to disposition. Paragraph B166 indicates that goodwill typically loses its identity as part of integration, and states “Board members noted that those situations (such as when the acquired business is operated as a stand-alone entity) would be infrequent because some amount of integration generally occurs after an acquisition.” The Company believes that an allocation of 100% of the goodwill to the Hospital Products sale would be inappropriate given the fact that the disposed business had been fully integrated into our existing operations.

Further, we have historically performed our annual goodwill impairment analysis by comparing the fair value of our one reporting unit to its carrying amount. We do this test by comparing the overall market capitalization of the Company to the carrying amount of goodwill, making no separate breakout or distinction between assets. In performing our analysis, we use ASC 350-20-25-22 which states that “...quoted market prices in active markets are the best evidence of fair value and shall be used as the basis for the measurement, if available...”

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Based on the above analysis and the guidance in ASC 350-20-40-4 through 40-6, the Company concluded that it was appropriate to determine the amount of goodwill to be derecognized as part of the disposal transaction based on a relative fair value basis approach pursuant to ASC 350-20-40-3.

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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 S. McHugh  
Thomas S. McHugh

Senior Vice President and Chief Financial Officer

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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