

2401 4th Avenue Suite 1050 Seattle, Washington 98121

July 7, 2016

## VIA EDGAR SUBMISSION

Securities and Exchange Commission Division of Corporation Finance 100 F Street, NE, Mail Stop 4720 Washington, DC 20549

Attention: Ms. Suzanne Hayes Assistant Director

Re: Aptevo Therapeutics Inc. Amendment No. 2 to Registration Statement on Form 10 Filed June 29, 2016 <u>File No. 001-37746</u>

Ladies and Gentlemen:

We are submitting this letter in response to comments contained in a letter dated July 5, 2016 from Suzanne Hayes, Assistant Director, of the Staff (the "Staff") of the Securities and Exchange Commission to Aptevo Therapeutics Inc. The responses to these comments are set forth below and are keyed to the numbering of the comments and the headings used in the Staff's letter.

## Exhibit 99, Information Statement

## Management's Discussion and Analysis of Financial Condition and Results of Operations IXINITY, page 109

- 1. Please refer to your response to our prior comment 3. You indicate in the last sentence of the second paragraph that, since April 2015, you have incurred approximately \$9 million in research and development expense related to IXINITY, primarily for clinical trial activities and process development and qualification activities. Provide us an analysis under ASC 730-10 supporting your classification of these expenses incurred after FDA approval as research and development expense. In addition, provide further disclosure explaining:
  - how much related to clinical trial activities and why you incurred these expenses after FDA approval; and
  - how much related to process development and qualification activities and a more robust description explaining these activities. Distinguish between "manufacturing process development" and "fill/finish process development and qualification" activities, which are terms you use to describe increases/decreases on page 112.



Securities and Exchange Commission July 7, 2016 Page 2

**Response:** In response to the Staff's comment, upon further review we have determined the \$9 million in IXINITY post-approval research and development expense we disclosed in amendment #2 was incorrect. The corrected amount of IXINITY spend for the period was \$8 million. We have updated our disclosure to reflect the correction. In addition, we have expanded the related disclosure with respect to clinical trial activities and process development and qualification activities. Please find below the Company's analysis supporting classification of the approximately \$8 million in post–licensure research and development expense in accordance with ASC 730-10:

- Clinical trial activities:
  - Ø Approximately \$1 million for activities associated with obtaining licensure of IXINITY for pediatric use (children under the age of 12).
    Pediatric use is currently not approved by the FDA. These costs are appropriately classified as research and development in accordance with ASC 730-10-55-1(d) as "testing in search for or evaluation of product or process alternatives"; and
  - Ø Approximately \$2 million for continued treatment of clinical subjects as part of a post-licensure extension clinical study required by the FDA. These costs are appropriately classified as research and development in accordance with ASC 730-10-55-1(d).
- Process development and qualification activities:
  - Ø Approximately \$2 million for activities associated with ongoing non-clinical process development studies related to the optimization of the manufacturing of bulk drug substance. These costs are appropriately classified as research and development in accordance with ASC 730-10-55-1(e) as "modification of the formulation or design of a product or process" and ASC 730-10-55-1(c) as "conceptual formulation and design of possible product or process alternatives", primarily due to the significant level of uncertainty to successfully complete these activities;
  - Ø Approximately \$1 million for the continuation of pre-licensure stability study commitments as required by the FDA to demonstrate that IXINITY maintains stability up to and beyond the product's expiry dating. These costs are appropriately classified as research and development in accordance with ASC 730-10-55-1(d) as "testing in search for or evaluation of product or process alternatives" as they are a continuation of development activities from our pre-licensure data package submitted to the FDA; and
  - Ø Approximately \$1 million for non-routine process development and qualification costs related to a new fill/finish facility at Emergent's Baltimore, Maryland site. The qualification of the facility requires us to develop a new fill/finish process



Securities and Exchange Commission July 7, 2016 Page 3

that will also require inspection and approval by the FDA as a supplement to our Biologics License for IXINITY. The development and qualification of a new fill/finish facility is the equivalent of designing a new process to produce IXINITY and therefore, in accordance with ASC 730-10-55-1(e), "modification of the formulation or design of a product or process", is appropriately classified as research and development expense.

In response to the Staff's comment to *distinguish between "manufacturing process development" and "fill/finish process development and qualification" activities, which are terms you use to describe increases/decreases on page 112, we have described above the fill/finish process development and qualification which relates to a new fill/finish facility that is the equivalent of designing a new process to produce IXINITY. During the year ended December 31, 2014, we incurred manufacturing process development costs associated with responses to FDA complete response letters received which noted deficiencies in the manufacturing section of our license application. We determined that these costs incurred are appropriately classified as research and development in accordance with ASC 730-10. In addition, during 2014 and through April 2015 (prior to FDA approval), we incurred approximately \$13 million in expenditures associated with pre-approval inventory that we expensed as research and development expense and was characterized in the filling as "manufacturing process development". These costs were expensed because the FDA review process had not progressed to a point where regulatory approval was probable. We determined that the costs incurred are appropriately classified as research and development in accordance with ASC 730-10.* 

## Notes to Combined Financial Statements

1. Nature of Business and Basis of Presentation, pages F-7 and F-27

- 2. Please refer to your response to our prior comment 5 and address the following:
  - Disclose the number of authorized shares and the dollar amount capitalized of Aptevo Therapeutics, Inc., the company that will serve as the registrant; and
  - Disclose, as you have in your response, the names of the legal entities and the assets, liabilities and operations of certain businesses that are included in the combined financial statements.

**Response:** In response to the Staff's comment, we have disclosed the number of authorized shares and the dollar amount capitalized of Aptevo Therapeutics Inc. and the names of the legal entities and the assets, liabilities and operations of the certain businesses that are included in the combined financial statements. This disclosure has been updated in both the Audited Combined Financial Statements on page F-7 and in the Unaudited Condensed Combined Financial Statements on page F-28.



Securities and Exchange Commission July 7, 2016 Page 4

If you have any questions, or require any additional information, please contact Eric M. Burt, Vice President and Associate General Counsel, Emergent BioSolutions Inc., at (240) 631-3241.

By: /s/ Robert G. Kramer

Robert G. Kramer President

cc: Bonnie Baynes, Staff Accountant James Rosenberg, SACA Josh Samples, Staff Attorney