

Confidential Treatment Requested by Arrowhead Pharmaceuticals, Inc.
FOIA Confidential Treatment Request
Pursuant to 17 C.F.R. § 200.83
For Portions of This Letter Described Below

March 3, 2023

Via EDGAR

Securities and Exchange Commission Division of Corporation Finance Office of Life Sciences 100 F. Street, N.E. Washington, D.C. 20549

Attn: Frank Wyman Angela Connell

Re: Arrowhead Pharmaceuticals, Inc.

Form 10-K for the Fiscal Year Ended September 30, 2022

Filed November 28, 2022 File No. 001-39896

### Ladies and Gentlemen:

This letter sets forth the response of Arrowhead Pharmaceuticals, Inc. (the "Company," "we," "our" and "us") to the comment provided by the staff of the Division of Corporation Finance (the "Staff") of the Securities and Exchange Commission (the "Commission") in its comment letter dated February 10, 2023 (the "Comment Letter") with respect to the Company's Form 10-K for the Fiscal Year Ended September 30, 2022 filed with the Commission on November 28, 2022.

Pursuant to 17 C.F.R. § 200.83 ("Rule 83"), the Company requests confidential treatment for a portion of its response to Staff comment 2. Specifically, the Company requests that a portion of its response to Staff comment 2 that has been redacted from the version of this letter filed via the Commission's EDGAR system and marked by bracketed asterisks "[\*]" be maintained in confidence, not be made part of any public record and not be disclosed to any person, including in response to any request under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), as such response contains confidential information. An unredacted version of this letter is being provided to the Commission under separate cover along with the request for confidential treatment under Rule 83.

For your convenience, we have reproduced the comment of the Staff exactly as given in the Comment Letter in bold and italics below and set forth below the comment the Company's response.

Form 10-K for the fiscal year ended September 30, 2022 Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations, page 60

Given the multiple collaboration and license agreements to which you are a party and the fact that to-date
your revenues have been limited to upfront and milestone payments related to these agreements, please
consider revising your future filings to provide a tabular summary which disaggregates your revenue by
collaborative partner.

## Response:

The Company acknowledges the Staff's comment and agrees that, in future periodic filings with the Commission, the Company will revise its disclosures to provide a tabular summary which disaggregates our revenue by each collaborative partner.



Notes to Consolidated Financial Statements
Note 2. Collaboration and License Agreements
Joint Venture and License Agreement with Visirna Therapeutics, Inc., page F-18

- 2. Please provide us with the following as it relates to your Joint Venture and License Agreement with Visirna Therapeutics:
  - Provide your analysis under ASC 810 supporting your conclusions that (a) Visirna meets the
    definition of a variable interest entity and (b) that you are the primary beneficiary.
  - Explain the factors that you considered in concluding that Visirna meets the definition of a business.
  - Provide us with more details as to how this joint venture was capitalized. In this regard, you disclose that you entered into a Share Purchase Agreement whereby you acquired a majority stake in Visirna as partial consideration for the License Agreement. You also disclose that Vivo Capital acquired a minority stake in exchange for \$60 million in initial capital. Clarify how this ties into your Statement of Stockholders' Equity on page F-7, whereby it appears that the \$60 million investment provided by Vivo was allocated between APIC (\$39.8 million) and Non-controlling Interest (\$20.2 million).
  - Provide us with copies of both the Visirna License Agreement and Share Purchase Agreement to
    assist us with our analysis. In addition, explain your consideration of filing these agreements as
    exhibits.

### Responses:

Provide your analysis under ASC 810 supporting your conclusions that (a) Visirna meets the definition of a variable interest entity and (b) that you are the primary beneficiary.

### Variable Interest Entity:

The Company respectfully acknowledges the Staff's comment and advises the Staff that Visirna and the Company entered into a license agreement pursuant to which Visirna received an exclusive license to develop, manufacture, and commercialize four of the Company's RNAi-based investigational medicines in Greater China ("Licensed Products"). In exchange for the license of the rights to the License Products, the Company received a [\*]% equity interest in Visirna. Vivo Capital contributed \$60 million in cash for a [\*]% equity interest in Visirna. There is no other equity or debt interest in Visirna as of September 30, 2022. Visirna is expected to incur approximately \$[\*] in losses over the next three years to develop and commercialize the Licensed Products and the current operating plan contemplates additional capital calls to fund these losses beyond the capital contributed by Vivo. As a result, the amount of equity investment at risk is not sufficient to permit the Visirna to fund its activities without additional subordinated financial support. Accordingly, Visirna meets the definition of a variable interest entity pursuant to ASC 810-10-15-14(a).

### Primary Beneficiary:

The Company respectfully acknowledges the Staff's comment and advises the Staff that it meets the requirements of ASC 810-10-25-38A to be the primary beneficiary of Visirna, as further described below.

### Power criterion:

Visirna was formed to enter into the exclusive license with the Company and thereafter to develop, have made, use, sell, offer for sale, import, export or otherwise commercialize the Licensed Products in Greater China. Risks associated with Visirna include research and development risk (i.e., the risk that the Licensed Products may not be successfully developed and ultimately yield an approved product) and commercialization risk (i.e., the risk that, to the extent the Licensed Products are approved, Visirna is unable to successfully market them). The entity is designed to pass along the risks and rewards of the development, manufacturing, and commercialization of the Licensed Products to its shareholders.

The completion of clinical development of a new drug, followed by successful commercialization is highly uncertain and depends on numerous judgments that will need to be made over the next several years. During this



time, Visirna's key business activities will consist of the following: pre-clinical studies, human clinical trials, regulatory filings and interactions, intellectual property strategies and enforcement, manufacturing and ultimately commercialization. Within these key business activities, the Company has control via a tie-breaking vote over certain of the most critical and sensitive decisions, including the following: changing the patient dosing schedule in clinical trials, expanding the product label to include a new indication, whether to pursue a high-dose study, development of a new drug formulation or a new method of drug administration, or any other decision that, in Arrowhead's judgment, will be detrimental to the development, commercialization, or manufacturing of the Licensed Products (collectively, the "Significant Activities").

The decisions made in regard to the development and commercialization of the Licensed Products are governed by the Joint Steering, Development, and Commercialization Committees (collectively, the "Committees"). Each of Visirna and Arrowhead appoint 3 representatives to the Committees. However, pursuant to the Licensing Agreement Arrowhead has final decision-making authority (i.e. the tie-breaker vote) over Significant Activities.

Moreover, Visirna's board of directors ("Board") is comprised of the following members:

- --Arrowhead [\*]
- --Vivo Capital [\*]
- -- Company CEO (jointly appointed by the Company and Vivo Capital)

Decisions made by the board of directors require a vote of the directors appointed by the holders of two-thirds of the outstanding shares. Approval of the annual budget also requires the separate affirmative vote of the majority of the Vivo Capital directors. However, within the board-approved budget, Arrowhead retains the ability to direct the Significant Activities (i.e., there is only a single line item for R&D; nothing related to specific R&D activities or specific costs of such activities). Additionally, the budget is approved annually and there are no approval requirements for budget variances or overruns, nor is there a requirement to provide period budget results to Vivo Capital (i.e. budget vs. actual). As a result, the Company does not believe that the requirement for Vivo Capital to also approve the annual operating budget constrains Arrowhead's power to direct the most Significant Activities.

### **Economics assessment:**

The Company has the obligation to absorb losses and the right to receive benefits of Visirna that could potentially be significant to Visirna through its [\*]% equity interest in Visirna.

As the Company meets both the power and economics criteria enumerated in ASC 810-10-25-38A, it is the primary beneficiary of Visirna.

# Explain the factors that you considered in concluding that Visirna meets the definition of a business.

The Company respectfully acknowledges the Staff's comment and observes that the statement as to Visirna being a business is unnecessary and neither impacts the consolidation assessment (i.e., the Company participated in the design of the entity and is unable to apply the business scope exception) or the cost-basis accounting for the transaction given the Company's consolidation of Visirna. The Company will remove the referenced sentence in future filings.

Provide us with more details as to how this joint venture was capitalized. In this regard, you disclose that you entered into a Share Purchase Agreement whereby you acquired a majority stake in Visirna as partial consideration for the License Agreement. You also disclose that Vivo Capital acquired a minority stake in exchange for \$60 million in initial capital. Clarify how this ties into your Statement of Stockholders' Equity on page F-7, whereby it appears that the \$60 million investment provided by Vivo was allocated between APIC (\$39.8 million) and Non-controlling Interest (\$20.2 million).

The Company respectfully advises the Staff that Visirna and the Company entered into a license agreement in exchange for a [\*]% equity interest in Class A convertible preferred shares. Vivo Capital contributed \$60 million in



cash for a [\*]% equity interest in Class A convertible preferred shares. There is no other equity or debt interest in Visirna as of September 30, 2022.

The Company accounted for the formation of the joint venture as a common control transaction. The Company accounted for the change in ownership percentage from the Vivo Capital contribution pursuant to ASC 810-10-45-23 and 24 and ASC 220-10-45-14. To properly account for the change in ownership percentage of Visirna, the Company performed the following steps illustrated in the interpretive guidance from section 7.1.2 of the Deloitte Roadmap to Noncontrolling Interests as follows:

Step 1 – Adjust the net assets of the subsidiary to reflect any consideration paid directly to or received directly from the subsidiary.

The net assets of Visirna consist of the Licensed Products, which has no historical carrying value, and \$60 million in cash contributed by Vivo Capital.

<u>Step 2 – Determine the new ownership percentages of the controlling and noncontrolling interests.</u>

The ownership percentages are [\*]% and [\*]% for the Company and Vivo Capital, respectively.

Step 3 – Adjust the carrying amount of the noncontrolling interest by multiplying the adjusted net assets of the subsidiary (step 1) by the noncontrolling interest's new ownership percentage after the transaction (step 2).

The Company adjusted the net assets of Visirna by multiplying \$60 million, representing the net assets of Visirna per step 1, by the noncontrolling interest's ownership percentage of [\*]% (step 2), equal to \$20.2 million.

Step 4 – Recognize any difference between the consideration paid (received) by the consolidated reporting entity and the adjustment to the noncontrolling interest (step 3) as an adjustment to the consolidated reporting entity's APIC.

The Company recorded \$39.8 million to APIC representing the difference between the net assets of Visirna of \$60 million and the adjustment to the noncontrolling interest of \$20.2 million per step 3.

Step 5 – To the extent necessary, adjust the consolidated reporting entity's AOCI balance to reflect the parent's adjusted interest in the subsidiary's AOCI (by using the percentages determined in step 2), and record an offsetting adjustment to the consolidated reporting entity's APIC.

Step 5 is not applicable as Visirna does not have an AOCI balance.

Provide us with copies of both the Visirna License Agreement and Share Purchase Agreement to assist us with our analysis. In addition, explain your consideration of filing these agreements as exhibits.

We are concurrently transmitting to the Staff copies of the Visirna License Agreement and Share Purchase Agreement.

With respect to the Staff's question about the filing of these agreements as exhibits, at the time that these agreements were entered into, the Company calculated the total value of Visirna Therapeutics by comparing the percentage of ownership that Vivo Capital took into the joint venture and the amount that was paid in cash for that ownership. Given that the Visirna joint venture has no reasonably foreseeable potential to provide the Company with revenue in the near-term, and that the license is geographically limited to Greater China in scope, the Company determined that Visirna Therapeutics and the agreements related thereto were immaterial considering the Company's current enterprise value and the scope of our pipeline.

Moreover, we note that Item 601(b)(10)(ii) of Regulation S-K provides that contracts of the type that ordinarily accompany a registrant's business will be deemed to be made in the ordinary course unless certain exceptions apply (most notable, that the Company is "substantially dependent" on such contract). In the case of the Visirna License Agreement and Share Purchase Agreement, these are similar in scope and nature to other out-license transactions



previously completed by the Company and often implemented by other registrants in the biopharmaceutical sector, which creates a presumption that it was entered into in the ordinary course. Further, none of the exceptions Item 601(b)(10)(ii) apply to these contracts. Accordingly, we respectfully submit that neither the Visirna License Agreement nor Share Purchase Agreement are required to be filed as exhibits under Item 601 of Regulation S-K, even if they are deemed material.

If you have any questions or further comments about this response, please contact me by email at [\*] or by phone at [\*].

Sincerely,

# Arrowhead Pharmaceuticals, Inc.

By: /s/ Ken Myszkowski

Name: Kenneth Myszkowski Title: Chief Financial Officer

Cc:

Ryan A. Murr, Gibson, Dunn & Crutcher LLP Aaron Briggs, Gibson, Dunn & Crutcher LLP