

Arcutis Biotherapeutics, Inc.
3027 Townsgate Road, Suite 300
Westlake Village, CA 91361

October 10, 2025

**CONFIDENTIAL AND PROPRIETARY
DELIVERY VIA SECURE FILE TRANSFER**

U.S. Securities & Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549
Division of Corporation Finance
Attention: Bonnie Baynes & Angela Connell

**Re: Arcutis Biotherapeutics, Inc.
Annual Report on Form 10-K for the Fiscal Year Ended December 31, 2024
Filed February 25, 2025
File No. 001-39186**

To the addressees set forth above:

This letter sets forth the response of Arcutis Biotherapeutics, Inc. (the “*Company*,” “*we*,” “*our*” and “*us*”) to the comments provided by the staff (the “*Staff*”) of the Division of Corporation Finance of the Securities and Exchange Commission (the “*Commission*”) in its letter dated September 15, 2025 (the “*Comment Letter*”) with respect to the Company’s Annual Report on Form 10-K for the year ended December 31, 2024 filed with the Commission on February 25, 2025 (the “*10-K*”).

For your convenience, we have reproduced the Staff’s comments exactly as set forth in the Comment Letter in bold below, and set forth below each such comment is the Company’s response. Page numbers and captions referenced in the responses refer to the 10-K unless otherwise stated. Capitalized terms used but not otherwise defined herein have the meanings ascribed to such terms in the 10-K. We have enclosed with this response a FOIA Confidential Treatment Letter.

* * * * *

*****] Certain confidential information contained in this document, marked by bracketed asterisks, has been omitted and filed separately with the SEC pursuant to 17 C.F.R. § 200.83**

Confidential Treatment Requested by Arcutis Biotherapeutics, Inc.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations; Results of Operations – Product Revenue, Net, page 103

1. We note your disclosure on page 103 that the \$55.9 million, or over 100% increase to ZORYVE cream 0.3% net product revenue at December 31, 2024 was primarily due to higher end customer demand and improving gross-to-net discounts for ZORYVE cream 0.3%. We also note your disclosures in the financial statements that you recorded accrued sales deductions of \$38.4 million & \$11.6 million at December 31, 2024 and December 31, 2023. Given the significant increase in product revenues and the existence of chargebacks, rebates, returns, prompt pay discounts, and other deductions, please provide the following with a view toward future disclosure:
- Given your product sales in Canada since 2023, quantify for us how much of product sales are non-U.S. for all periods and if you expect the future trend to change.
 - Provide us a roll forward of the accrual for each estimate for the year ended December 31, 2024 showing the following:
 - Beginning balance,
 - Current provision related to sales made in current period,
 - Current provision related to sales made in prior periods,
 - Actual returns or credits in current period related to sales made in current period,
 - Actual returns or credits in current period related to sales made in prior periods, and
 - Ending balance.
 - Separately tell us:
 - The effect that could result from using other reasonably likely assumptions than what you used to arrive at each accrual such as a range of reasonably likely amounts or other type of sensitivity analysis.
 - Please provide us a discussion of the amount of and reason for fluctuations for each type of reduction of gross revenue (i.e. product returns, chargebacks, customer rebates and other discounts and allowances) including the effect that changes in your estimates of these items had on your revenues and operations.

Response: The Company respectfully acknowledges the Staff's comment and advises the Staff that product revenue, net outside the United States represented less than 10% of the Company's consolidated product revenue, net for the years ended December 31, 2023 and 2024. The Company currently expects this to continue and, based on the relatively small amount of non-U.S. product revenue, net that it generates, does not believe that supplemental

[***] Certain confidential information contained in this document, marked by bracketed asterisks, has been omitted and filed separately with the SEC pursuant to 17 C.F.R. § 200.83

Confidential Treatment Requested by Arcutis Biotherapeutics, Inc.

quantitative disclosure of such non-U.S. product revenue, net is required or would enhance an investor's understanding of the Company's financial condition or results of operations. The Company respectfully advises the Staff that the Company will continue to monitor the extent of its non-U.S. product revenue, net, and if such information becomes meaningful and material to an investor's understanding of the Company's overall business and its financial condition and results of operations, the Company will consider additional disclosure regarding such non-U.S. product revenue, net in future filings.

As disclosed in the Company's 10-K for the year ended December 31, 2024, the Company records revenue from product sales at the net sales price, which includes estimates of variable consideration that result from invoice discounts for prompt payment and distribution service fees, government and private payer rebates, chargebacks, discounts and fees, product returns and costs of co-pay assistance programs for patients, as well as other incentives. Reserves are established for the estimates of variable consideration based on the amounts earned or to be claimed on the related sales, and the Company records accrued sales deductions related to such considerations based on data received from its customers, current contractual arrangements, market events and trends, external historical data, and forecasted customer buying patterns and patient utilization. The table below presents information regarding the Company's total accrued sales deductions for the year ended December 31, 2024 (in thousands):

	Total Accrued Sales Deductions
Balance, January 1, 2024	\$ 11,578
Amounts charged against product revenues	[***]
Payments and credits	[***]
Balance, December 31, 2024	<u>\$ 38,430</u>

With respect to the Staff's comment regarding returns and credits, the Company respectfully advises the Staff that it recorded returns and related return credits of \$0.7 million for the year ended December 31, 2024. As disclosed in the Company's 10-K for the year ended December 31, 2024, the Company commenced commercialization of ZORYVE in August 2022 and, in the early product launch period, the Company estimated its provision for returns based on industry data to estimate its provision for returns for the years ended December 31, 2022 and 2023. As the Company continued to commercialize ZORYVE, it collected additional data regarding actual product-specific returns. In the fourth quarter of 2024, with the benefit of two years of commercialization experience and data, the Company determined to utilize such product-specific information to estimate its provision for returns for the year ended December 31, 2024. This revision to the input used to estimate its returns resulted in a lower estimated returns rate. As a result of this lower estimated return rate, the Company

[*] Certain confidential information contained in this document, marked by bracketed asterisks, has been omitted and filed separately with the SEC pursuant to 17 C.F.R. § 200.83**

Confidential Treatment Requested by Arcutis Biotherapeutics, Inc.

recorded a \$4.1 million reduction in the Company's accrued sales deductions as of December 31, 2024 and a favorable true-up impact to product revenue, net in the fourth quarter of 2024. The amount of the favorable true-up related to sales made in the years ended December 31, 2023 and 2022 was \$2.0 million in aggregate, which we consider to be immaterial for separate disclosure.

The Company respectfully advises the Staff that it does not consider the change in the return rate or resulting reduction in accrued sales deductions or favorable true-up impact to product revenue, net, to be significant to the Company's financial condition or results of operations or material to an investor's understanding of the Company's overall business and its financial condition and results of operations. The Company further advises the Staff that the Company has not made, and does not anticipate making, any significant changes to the methodologies used to measure provisions for variable consideration. However, the Company notes that the balances within these reserves can fluctuate significantly through the consistent application of the Company's methodologies, in part due to the Company's rapid commercialization and growth. For the year ended December 31, 2024, no material adjustments were recorded due to changes in estimates for amounts related to product revenue from previous years. The Company advises the Staff that a change of 5% would have an effect on our consolidated total accrual balance of approximately \$1.9 million. Further, the Company notes that the increase in total accrued sales deductions as of December 31, 2024, as compared to December 31, 2023, was primarily driven by higher gross product revenue due to increased product sales and demand, as well as improved coverage.

Finally, the Company respectfully advises the Staff that it believes its existing presentation of product revenue, net and accrued sales deductions in its disclosures and financial statements, including qualitative disclosure regarding the estimates of variable considerations and developments in gross-to-net discounts, is currently appropriate for the Company's stage of commercialization and operations, and its limited number of products available for sale (ZORYVE cream and foam formulations), and presents information that is material to an investor's understanding of the Company's overall business and its financial condition and results of operations.

Note 8. Commitments and Contingencies, page F-24

2. **We note your disclosure in Item 3 on page 96 of the patent infringement complaints filed against you by Teva Pharmaceutical Industries Ltd. on August 13, 2024 and September 20, 2024 with the European Patent Office. We also note that you did not include disclosure of your estimate of potential exposure to loss contingencies in Note 8, Commitments and Contingencies, on page F-24. Please tell us how you applied ASC 450-20-25 in assessing the likelihood of the loss or impairment of an asset or the incurrence of a liability as a result of the litigation, and your consideration of providing the disclosures required by ASC 450-20-50-3 through 50-5 as it relates to this potential loss contingency, including the amount or range of reasonably possible losses in excess of recorded amounts.**

[*] Certain confidential information contained in this document, marked by bracketed asterisks, has been omitted and filed separately with the SEC pursuant to 17 C.F.R. § 200.83**

Confidential Treatment Requested by Arcutis Biotherapeutics, Inc.

Response: The Company respectfully acknowledges the Staff’s comment and advises the Staff that it evaluates the status of all of its legal proceedings in each reporting period, including the patent infringement complaint filed against the Company by Teva Pharmaceutical Industries (“Teva Complaint”), to assess whether accruals are appropriate under ASC 450-20-25-2 and to determine whether an estimate of possible loss or a range of possible losses can be made under ASC 450-20-50.

During this evaluation, the Company’s management considers all existing and new matters, including, but not limited to, (i) the nature and status of each matter; (ii) the advice of legal counsel and other advisors related to each matter; (iii) the Company’s experience or that of other entities in similar matters; (iv) the Company’s belief in whether it has meritorious and valid substantive defenses against the allegations made by the parties; (v) the damages or awards sought, and associated impact on the business; (vi) substantive rulings by a court on similar matters; (vii) information gleaned through settlement discussions, if any; (viii) whether there is uncertainty as to the outcome of pending appeals or motions; (ix) whether there are significant factual issues to be resolved; and (x) whether the matters involve novel issues or unsettled legal theories.

Under ASC 450, loss contingency accruals are recognized for probable and estimable losses. In accordance with ASC 450-20-25-2, at the time of the filing of the 10-K, the Company evaluated potential loss contingencies as discussed above, and specifically reviewed the facts surrounding the Teva Complaint, and determined that a loss resulting from the Teva Complaint was not reasonably possible, as defined in ASC 450-20-20. For example, the patents subject to the Teva Complaint are European patents for which there are no long-lived assets or historical product revenue, net, and the Company respectfully submits that the outcome of such complaint would not have a material impact on the Company’s current business. The Company also respectfully notes that it believes it has meritorious and valid substantive defenses against the allegations made in the Teva Complaint. Accordingly, as of December 31, 2024, the Company did not accrue any amount related to loss contingencies under ASC 450 and the Company respectfully submits that disclosure per ASC 450-20-50-3 through 50-5 is not necessary.

Notwithstanding the foregoing paragraph, the Company determined to include a brief summary of the Teva Complaint in Item 3 and in the risk factors set forth in Item 1A of the 10-K in order to provide investors with an understanding of the current status of this matter. The Company respectfully submits to the Staff that it will clarify its consideration of ASC 450 in future filings by including the following language, or something similar thereto, in the Commitments and Contingencies note to the financial statements:

[*] Certain confidential information contained in this document, marked by bracketed asterisks, has been omitted and filed separately with the SEC pursuant to 17 C.F.R. § 200.83**

Confidential Treatment Requested by Arcutis Biotherapeutics, Inc.

Contingencies

From time to time, the Company may be involved in legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of business or otherwise. The ultimate outcome of any litigation is uncertain and unfavorable outcomes could have a negative impact on the results of operations and financial condition. Regardless of outcome, litigation can have an adverse impact on the Company because of the defense costs, diversion of management resources and other factors.

As of December 31, 2024 and 2023, the Company determined that no loss contingencies from legal proceedings, including the patent infringement complaint filed against the Company by Teva Pharmaceutical Industries, met the threshold of reasonably possible as defined in ASC 450, and accordingly, no material amounts were accrued related to loss contingencies under ASC 450.

* * * * *

Please direct any questions or comments regarding this correspondence to our counsel, Ross McAloon of Latham & Watkins LLP, at (714) 755-8051.

Very truly yours,

Arcutis Biotherapeutics, Inc.

By: /s/ Latha Vairavan

Name: Latha Vairavan

Title: Chief Financial Officer

cc: Masaru Matsuda, Arcutis Biotherapeutics, Inc.
Ross McAloon, Latham & Watkins LLP
FOIA Office, Attn: FOIA/Privacy Act Branch Chief,
United States Securities and Exchange Commission (without enclosures)

*****] Certain confidential information contained in this document, marked by bracketed asterisks, has been omitted and filed separately with the SEC pursuant to 17 C.F.R. § 200.83**

Confidential Treatment Requested by Arcutis Biotherapeutics, Inc.