

ICU Medical, Inc.
951 Calle Amanecer
San Clemente, California 92673

November 27, 2023

VIA EDGAR

United States Securities and Exchange Commission
Division of Corporation Finance
Office of Industrial Applications and Services
100 F. Street, N.E.
Washington, D.C. 20549
Attention: Michael Fay, Brian Cascio

Re: ICU Medical, Inc.

Form 10-K for the fiscal year ended December 31, 2022

Form 10-Q for the quarterly period ended June 30, 2023

Form 8-K dated February 27, 2023

File No. 001-34634

To the addressees set forth above:

This letter is submitted on behalf of ICU Medical, Inc., a Delaware corporation (the “Company”), with respect to the comments of the Staff (the “Staff”) of the Securities and Exchange Commission contained in the Staff’s letter dated October 25, 2023.

For ease of review, we have set forth below, in italics, the numbered comments in the Staff’s letter, followed by the Company’s response thereto. Unless otherwise indicated, capitalized terms used herein have the meanings assigned to them in the applicable filing and all references to page numbers in such responses are to page numbers in such filing.

Staff Comment No. 1

Form 10-K for the fiscal year ended December 31, 2022

Consolidated Financial Statements

Note 1. Revenue Recognition, page 73

We note you estimate variable consideration related to rebates, chargebacks and product returns. Please provide in future filings the qualitative and quantitative information about the significant judgments and changes in judgments that significantly affect the determination of your transaction price, as set forth in ASC 606-10-50-1(b), 50-17(b), and 50-20(a). Please provide us any intended revisions and the calculations used to determine variable consideration for the periods presented.

Response: The Company respectfully acknowledges the Staff’s comment and in response the Company, in future filings, will provide the following revisions (added language as underlined and deleted language as strikethrough) which include additional quantitative and qualitative information related to the calculations used and significant judgments applied that affect the estimation of variable consideration related to wholesaler chargebacks:

Payment is typically due in full within 30 days of delivery or the start of the contract term. Revenue is recorded in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. We offer certain volume-based rebates to both our distribution and end customers, which we record as variable consideration when calculating the transaction price. Rebates are offered on both a fixed and tiered/variable basis. In both cases, we use information available at the time, including ~~and~~ current contractual requirements, our historical experience with each customer and forecasted customer purchasing patterns, to estimate the most likely rebate amount. We also provide chargebacks to distributors that sell to end customers at prices determined under a contract between us and the end customer. Chargebacks are the difference between the prices we charge our distribution customers and the contracted prices we have with the end customer which are processed as credits to our distribution customers.

Individual chargeback rates can vary significantly depending on the product and contracted prices with distributors and end customers. In estimating the expected value of chargeback amounts in order to ~~when determine~~ determining the transaction price, we generally use a combination of the following information available at the time, ~~including our historical experience~~:

- (i) Actual recent history of chargebacks paid to each distributor determined at either a product or product-family level; and
- (ii) Inventory balances at distributors for which a chargeback claim is expected to be paid upon future sale to an end customer.

On a periodic basis, the Company also uses metrics to evaluate the adequacy of the chargeback reserve including movements in inventory on hand at distributors, trends in accrued versus paid chargebacks and impacts from price changes and similar metrics.

The chargeback reserve reflects our best estimate of the amount of consideration using the expected value method and is recorded as a reduction of accounts receivable, net on the consolidated balance sheets along with rebates and product return reserves which are less significant. The value of the chargeback reserve generally represents approximately two months of obligation due to the timing difference between the initial sale to a distributor and the processing of a chargeback claim which occurs after the product is sold to the end customer.

Staff Comment No. 2

Form 10-Q for the quarterly period ended June 30, 2023

Liquidity and Capital Resources, page 49

You set forth in your disclosure "during the six months ended June 30, 2023, our cash and cash equivalents and short-term investment securities increased by \$15.3 million from \$213.0 million at December 31, 2022 to \$197.7 million at June 30, 2023. This increase was primarily due to cash generated from operations." We note, however, you experienced a decrease during that time frame. Please correct your discussion in future filings.

Response: The Company respectfully acknowledges the Staff's comment and recognizes that the cited discussion reflects a decrease in cash and cash equivalents and short-term investment securities during the relevant period. The discussion in the Company's most recent Form 10-Q for the quarterly period ended September 30, 2023, filed on November 6, 2023 (the "Q3 Form 10-Q") correctly reflects this, and the Company will continue to do so in future filings, as applicable.

Staff Comment No. 3

You disclose that "net income plus adjustments for non-cash net expenses contributed \$151.7 million." Please tell us whether you consider this reference a non-GAAP measure and how you arrived at this determination. Please provide us any intended revisions to your disclosure, as applicable. Refer to Item 10(e) of Regulation S-K.

Response: The Company respectfully acknowledges the Staff's comment and advises the Staff that the intention of this disclosure was to quantify the impact on operating cash flows resulting from non-cash expenses as compared to changes in operating assets and working capital as these categories tend to be different in nature. However, to avoid misinterpretation, the Company removed the disclosure of net income plus adjustments for non-cash expenses in its Q3 Form 10-Q and advises the Staff that it will not include such disclosure in future filings.

Staff Comment No. 4

Form 8-K dated February 27, 2023

Exhibit 99.1

Use of Non-GAAP Financial Information, page 6

Please describe for us in further detail the "quality system and product-related remediation" costs and the "quality and regulatory initiatives and remediation" costs incurred during 2022 and 2023, and explain to us how you have considered Non-GAAP Financial Measures Compliance & Disclosure Interpretations 100.01 as part of making an adjustment for these costs in determining your non-GAAP measures.

Response: The Company respectfully acknowledges the Staff's comment and provides the following response. The 2023 quality and regulatory initiatives and remediation costs included (i) incremental costs, primarily product certification, labor, contractor and third-party costs, to develop processes and systems to comply with the European Union Medical Device Regulations ("EU MDR") and (ii) costs related to quality system remediation and product field corrective actions incurred in response to observations noted in an FDA Warning Letter received by Smiths Medical prior to the Company's acquisition of Smiths Medical in January 2022. The 2022 quality system and product-related remediation costs were substantially similar to the 2023 costs described in clauses (i) and (ii) in the preceding sentence; however, the Company refined the description in 2023 to more accurately reflect the nature of the costs.

When adjusting for costs in determining the Company's non-GAAP financial measures, the Company evaluates the nature and effect of the excluded costs, specifically how those costs correlate to the Company's operations, revenue generating activities, business strategy, industry and regulatory environment. Based on those evaluations, the Company considers whether a cost could be viewed as recurring and the exclusion thus misleading. The Company considered the updates in the EU MDR regulations to be a significant change to the existing regulatory framework and believed that the costs of initial compliance for previously registered products were duplicative and not reflective of the Company's normal operating expenses associated with core operations. For example, requirements of the new regulations included new labeling requirements, new classification rules, new safety and performance requirements, the requirement to have sufficient clinical evidence demonstrating compliance and new requirements for a post-market surveillance system. The Company incurred significant one-time charges in 2023 and 2022 related to the initial implementation of all such requirements. Similarly, the remediation costs incurred for corrective actions as a result of the FDA Warning Letter inherited as part of an acquired business were not considered to be costs which would recur on an ongoing basis. Although the FDA may conduct inspections or audits of the Company facilities at any time, the Company's normal operations are

subject to a high-standard quality control process. The charges related to the development of enhanced quality management systems and processes of Smiths Medical were incurred to bring the acquired business in compliance with the required minimum standards of the Company and the product field corrective actions addressed historical deficiencies resulting from Smiths Medical's sub-standard quality management system and processes which were outside of the Company's control prior to acquisition. The Company expects these charges to cease once the EU MDR certification requirements have been met prior to the effective date and when the FDA Warning Letter observations have been fully remediated.

The Company reviews the non-GAAP measures regularly to determine whether there warrants a change in characterization of adjustments based on the frequency of the charges incurred.

* * *

We hope that the foregoing has been responsive to the Staff's comments and look forward to resolving any outstanding issues as quickly as possible. Please do not hesitate to contact our counsel, Latham & Watkins LLP, by calling Daniel Rees at (714) 755-2244 with any questions or further comments you may have or if you wish to discuss the above.

Sincerely,

/s/ Brian M. Bonnell

Brian M. Bonnell
Chief Financial Officer
ICU Medical Inc.

cc: Virginia Sanzone, ICU Medical, Inc.
Daniel Rees, Latham & Watkins LLP