

November 16, 2017

**VIA EDGAR**

Mr. Perry J. Hindin  
Special Counsel  
Office of Mergers and Acquisitions  
U.S. Securities and Exchange Commission  
Division of Corporation Finance  
100 F Street, N.E.  
Washington, D.C. 20549

Re: **Ocera Therapeutics, Inc.**  
**Schedule TO-T**  
**Filed November 9, 2017 by Mallinckrodt Public Limited Company et. al**  
**File No. 5-86177**

Dear Mr. Hindin:

On behalf of our clients, Mallinckrodt plc ("**Mallinckrodt**") and its wholly-owned subsidiaries MAK LLC ("**Parent**") and MEH Acquisition Co. ("**Purchaser**") and together with Mallinckrodt and Parent, the "**Filing Parties**", set forth below are the responses of the Filing Parties to the comment letter from the staff (the "**Staff**") of the Securities and Exchange Commission (the "**SEC**"), dated November 14, 2017 (the "**Comment Letter**"), concerning the Schedule TO-T (File No. 005-86177) (the "**Schedule TO**") filed on November 9, 2017, under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), by the Filing Parties. Concurrently with our submission of this letter, we are filing an amendment to the Schedule TO setting forth the changes described herein (the "**TO Amendment**").

We are delivering one courtesy copy of the TO Amendment and one courtesy copy of this letter to Mr. Hindin of the SEC's Division of Corporation Finance, Office of Mergers and Acquisitions.

The headings and numbered paragraphs of this letter correspond to the headings and paragraph numbers contained in the Comment Letter, and to facilitate your review, we have reproduced the text of the Staff's comments in bold. Capitalized terms used herein and otherwise not defined herein shall have the meanings assigned to such terms in the Schedule TO and the Offer to Purchase filed as Exhibit (a)(1)(A) thereto (the "**Offer to Purchase**").

**Offer to Purchase**

**General**

- 1. Please provide us with a legal analysis as to whether the contingent value rights are securities, the offer and sale of which should be registered under the Securities Act of 1933. In preparing your response, it may be helpful to provide your analysis of prior staff no-action letters on this topic in support of your position.**

We believe that the contingent value rights (the “*CVRs*”) described in the Offer to Purchase are not “securities” that would require registration under the Securities Act of 1933, as amended (the “*Securities Act*”), but instead represent a non-transferable contractual right to receive one or more cash payments upon the achievement of certain specified milestones as further described below. In prior Staff no-action letters, the Staff has not recommended enforcement action in connection with the issuance without registration under the Securities Act of contractual contingent payment rights possessing the same key characteristics as the CVRs. The Staff has consistently granted such no-action relief in connection with contractual contingent payment rights in a proposed tender offer or merger if the following factors (which are applicable to the CVRs in this transaction) apply:

- (i) the rights are an integral part of the consideration to be received in the merger or tender offer and will be granted pro-rata;
- (ii) the rights do not represent any ownership or equity interest and do not carry voting or dividend rights or bear a stated rate of interest;
- (iii) the rights are non-transferable, except by operation of law or by will or intestacy;
- (iv) the rights will not be evidenced by any form of certificate or instrument; and
- (v) any amount ultimately paid to the selling stockholders does not depend on the operating results of the surviving company or any constituent company to the merger.

See, e.g., the following no-action letters: Lorimar, Inc. (November 4, 1985); Essex Communications Corp. (June 28, 1988); Slater Development Corp. (April 7, 1988); Minnesota Mining and Manufacturing Company (October 13, 1988); First Boston, Inc. (December 2, 1988); GID/TL, Inc. (March 21, 1989); Genentech Clinical Partners III (April 28, 1989); Quanex Corporation (July 28, 1989); Marriott Residence Inn Limited Partnership (February 20, 2002) and Marriott Residence Inn II Limited Partnership (May 8, 2002).

### ***Staff No-Action Letter Precedents***

The Staff has established its position for not requiring registration of contractual contingent payment rights as “securities” in the precedents listed above and described in further detail below.

For example, in Minnesota Mining and Manufacturing Company, *supra*, the Staff did not require contingent payment rights given as partial consideration for a company acquired in a stock for stock merger to be registered under the Securities Act. These rights were to be paid in shares of the company’s stock equivalent to fixed monetary amounts the value of which was dependent upon whether the acquired company was able to meet certain revenue targets in the future, and upon the amount of future revenues generated by sales of products developed by the acquired company. The Staff cited the following facts as being particularly relevant to its decision: the rights were an integral part of the consideration to be received in the merger; the holders of the rights were to have no rights common to stockholders such as voting and dividend rights; the rights bore no stated rate of interest; the rights were not assignable or transferable except by operation of law; and the rights were not represented by any form of certificate or instrument.

A particularly relevant precedent is Genentech Clinical Partners, *supra*, where in partial consideration for an acquisition, the purchaser proposed to make certain contingent payments calculated as a percentage of the net revenue from future sales in the United States of products containing a certain ingredient. The Staff took a no-action position with respect to Genentech’s decision not to register the Genentech contingent payment rights under the Securities Act. The SEC stated that, in arriving at its position, it “particularly noted that the rights are an integral part of the consideration to be received by selling securityholders in the proposed transaction; any amount ultimately payable pursuant to the rights is not dependent on the operating results of Genentech, Inc.; the rights will not be transferable except by operation of law; the rights carry no voting or dividend rights and do not bear a stated rate of interest; the rights will not be represented by any form of certificate or instrument; and the rights will not represent any equity or ownership interest in Genentech, Inc. or the Partnership.” These same characteristics apply to the CVRs proposed to be established in favor of Ocera Therapeutics, Inc. (“*Ocera*”) security holders, as described in more detail below.

### ***Recent Transactions***

The criteria established in the Genentech no-action letter and in the subsequent no-action letters noted above that followed Genentech are well-established and have been relied on in recent transactions involving contractual contingent payment rights that were not registered under the Securities Act, including contingent payment rights payable upon achievement of developmental, regulatory and commercial milestones similar to those that determine payment under the CVRs. Such recent transactions include, among others:

- Sientra, Inc.'s 2017 acquisition of Miramar Labs, Inc., in which Sientra agreed to pay Miramar Labs shareholders \$0.3149 per share in cash, plus a non-transferable contractual contingent value right for each share, which entitled the holder to receive up to an additional \$0.7058 per share upon the achievement of certain sales milestones relating to Miramar's miraDry® System.
- Allergan plc's 2016 acquisition of Tobira Therapeutics, in which Allergan agreed to pay Tobira shareholders \$28.35 per share in cash, plus one non-transferable contractual contingent value right for each share, which represented the right to receive contingent payments of up to \$49.84 in cash in the aggregate per share, upon the achievement of certain product development, regulatory and commercial milestones relating to Tobira's product, such as enrollment of patients in a clinical trial, achievement of FDA approval and commercial sales of the product.
- Grupo Ferrer Internacional, S.A.'s 2016 acquisition of Alexza Pharmaceuticals, Inc., in which Grupo Ferrer agreed to pay Alexza shareholders \$0.90 per share in cash, plus one non-transferable contractual contingent value right for each share, which represented the right to receive a pro rata share of contingent payments of up to approximately \$32.8 million in the aggregate, upon the achievement of certain licensing payments and revenue milestones relating to Alexza's product.
- Echo Pharma Acquisition Limited's 2013 acquisition of Elan Corporation, plc, in which Echo Pharma agreed to pay Elan Corporation shareholders \$13.00 per share in cash plus one non-transferable contingent value right, which entitled the holder to receive up to an additional \$2.50 per share, payable upon the achievement of certain regulatory and commercial milestones. The first contingent payment was payable upon FDA approval of certain additions to the label for Elan Corporation's Tysabri product. The second and third contingent payments were payable if the worldwide net sales of Tysabri for certain periods were in excess of certain net sales thresholds.
- Forest Laboratories' 2014 acquisition of Furiex Pharmaceuticals, Inc., in which Forest agreed to pay Furiex Pharmaceuticals shareholders \$95.00 per share in cash plus one non-transferable contingent value right to receive up to an additional \$30 per share, payable upon the achievement of certain regulatory milestones related to FDA approval of new drug applications.
- Daiichi Sankyo Company, Limited's 2014 acquisition of Ambit Biosciences Corporation, in which Daiichi Sankyo agreed to pay Ambit Biosciences shareholders \$15.00 per share in cash plus one non-transferrable contingent value right to receive up to \$4.50 per share upon the achievement of certain commercialization milestones related to the launch in the United States of products approved to treat certain conditions.

- Cubist Pharmaceuticals, Inc.'s September 2013 acquisition of Trius Therapeutics, in which Cubist agreed to pay Trius shareholders \$13.50 per share in cash plus one non-transferrable contingent value right for each share which represented the contractual right to receive up to \$2.00 per share upon the achievement of certain milestones. A holder of a contingent value right was entitled to a cash payment of \$1.00 if net sales of certain products in 2016 were greater than \$125 million plus an additional amount for each \$1 million of net sales of certain products in 2016 that were in excess of \$125 million, up to a maximum payment of \$2.00 for each contingent value right then held by such holder.

### ***The Contingent Value Rights***

Each of the five factors listed above are applicable to the CVRs in this transaction. The Filing Parties intentionally structured the CVRs to comply with the Staff's criteria.

As described in more detail in the Offer to Purchase, for each Share tendered in the Offer, a tendering security holder will receive a CVR which grants the right to receive one or more payments in cash, currently estimated to be up to \$2.58 per CVR, contingent upon the achievement of certain milestones as described below, in each case without interest thereon and subject to any required tax withholdings.

The potential aggregate payments to the holders of all CVRs issuable under the Merger Agreement (which includes CVRs issuable to holders of certain stock options, warrants and restricted stock units of Ocera) and holders of certain Ocera stock options whose holders may be entitled to receive payments concurrently with the holders of CVRs equals \$75 million, subject to reduction, under certain circumstances, to the extent Ocera's cash and cash equivalents on hand are not sufficient to pay and fully discharge all of its transaction expenses and indebtedness at closing or December 31, 2017, whichever occurs earlier. Each payment is conditioned upon the achievement of the applicable milestones and calculated as follows (each such aggregate milestone payment, as may be adjusted, a "**Milestone Payment**"):

- (i) Parent will be obligated to pay an aggregate amount equal to \$10 million upon the enrollment of the first patient in a Phase 3 clinical trial of an intravenous formulation of a product containing as an active pharmaceutical ingredient L-ornithine phenylacetate, a combination of L-ornithine and phenylacetate, or a derivative of such ingredients (any such product, the "**Product**") by Parent, any of its affiliates or their respective licensee or sublicensee with respect to rights to develop or commercialize the Product (the "**IV Milestone**"),

- (ii) Parent will be obligated to pay an aggregate amount equal to \$15 million upon the enrollment of the first patient in a Phase 3 clinical trial of an oral formulation of the Product by Parent, any of its affiliates or their respective licensee or sublicensee with respect to rights to develop or commercialize the Product (the “**Oral Milestone**”), and
- (iii) Parent will be obligated to pay an aggregate amount equal to \$50 million upon the first occurrence of the achievement of cumulative Product sales (gross amount invoiced for sales of the Product, less certain permitted deductions) in excess of \$500 million by Parent, its affiliates and their respective licensee or sublicensee with respect to rights to develop or commercialize the Product (but not a distributor of the Product acting solely in the capacity as a distributor), or any combination thereof (the “**Product Sales Milestone**”).

As previously described, the CVRs described in the Offer to Purchase have the same five essential characteristics the Staff has identified in the no-action letters cited above and we believe were present in the transactions described above:

- (i) the CVRs will be an integral part of the consideration to be received in the Offer and the Merger and will be granted pro rata;
- (ii) the CVRs will represent only the right to receive the contingent payments described above and will not represent any equity or ownership in Mallinckrodt, Parent or Purchaser, will not have any voting or dividend rights and will not bear a stated rate of interest;
- (iii) the CVRs will not be transferable except (1) upon death by will or intestacy; (2) by instrument to an inter vivos or testamentary trust in which the CVRs are to be passed to beneficiaries upon the death of the trustee; (3) pursuant to a court order; (4) by operation of law (including a consolidation or merger) or without consideration in connection with the dissolution, liquidation or termination of any corporation, limited liability company, partnership or other entity; or (5) in the case of CVRs held in book-entry or similar nominee form, from a nominee to a beneficial owner (and, if applicable, through an intermediary) or from such nominee to another nominee for the same beneficial owner, in each case as allowable by the Depository Trust Company;
- (iv) the CVRs will not be evidenced by any certificate or other instrument; and
- (v) any amounts ultimately paid to the CVR holders is not dependent on the operating results of the Filing Parties or Ocera, but rather is dependent upon the achievement of the IV Milestone, the Oral Milestone or the Product Sales Milestone, as applicable.

Based on the foregoing arguments presented, we respectfully submit that the CVRs do not qualify as “securities” required to be registered under the Securities Act.

- Please provide us with your analysis as to how the offer complies with the prompt payment provisions of Exchange Act Rule 14e-1(c) and the disclosure requirements of Item 1004 of Regulation M-A, given the deferred nature of any contingent consideration and the uncertainty of the total consideration to be paid to security holders, respectively. In your analysis, please address whether the rights that security holders receive would be considered enforceable as of the close of the offer under state law.**

***Prompt Payment Provisions of Rule 14e-1(c)***

We believe that the Offer complies with the prompt payment requirements of Rule 14e-1(c). Rule 14e-1(c) provides that “no person who makes a tender offer shall fail to pay the consideration offered or return the securities deposited by or on behalf of security holders promptly after the termination or withdrawal of a tender offer.” As set forth in the Offer to Purchase and related Letter of Transmittal, the merger consideration consists of the right to receive \$1.52 per Share in cash (the “**Closing Amount**”) plus one CVR per Share (together with the Closing Amount, or any higher amount per Share paid pursuant to the Offer, the “**Offer Price**”), which CVR represents the non-transferable contractual right to receive one or more payments in cash contingent upon the achievement of certain specified milestones. As described in the Offer to Purchase, Parent will accept for payment and promptly pay the Offer Price for all Shares validly tendered and not validly withdrawn prior to the Expiration Date, promptly after the Offer Acceptance Time.

Since the CVRs are not deferred cash payments to Ocera stockholders, but instead are non-transferable contractual rights to receive cash payments if and only if certain milestones are achieved (in accordance with terms of the CVR Agreement), they will be paid in compliance with the prompt payment rule. Once Parent pays the Offer Price, accepts the Shares validly tendered and not validly withdrawn in the Offer and enters into the CVR Agreement with Continental Stock Transfer & Trust Company, as rights agent (the “**Rights Agent**”), the rights of holders of CVRs will be fixed under the CVR Agreement. The CVRs represent the binding obligations of Parent under the CVR Agreement, and holders of CVRs will be entitled to enforce such obligations from and after the consummation of the Offer and pursuant to the terms of the CVR Agreement. Section 7.4 of the CVR Agreement states that the holders of CVRs are intended third party beneficiaries of the CVR Agreement, providing the following:

“Nothing in this CVR Agreement, express or implied, shall give to any Person (other than the parties hereto and their successors hereunder, and the Holders) any benefit or any legal or equitable right, remedy or claim under this CVR Agreement or under any covenant or provision herein contained, all such covenants and provisions being for sole benefit of the parties hereto and their successors, and of the Holders.”

Section 2.7 of the CVR Agreement states that holders of CVRs are entitled to bring actions to enforce the rights of such holders under the CVR Agreement, providing the following:

“Any actions seeking the enforcement of the rights of Holders hereunder may be brought either by the Rights Agent or the Acting Holders.”

Additionally, per Section 7.5 of the CVR Agreement, the CVRs are governed by Delaware law. Under Delaware law, determination of third party beneficiary standing is dependent upon intent to benefit the third party. Please see, e.g., *Global Energy Finance LLC v. Peabody Energy Corp.*, C.A. No. 08C-10-129 RRC, 2010 WL 4056164, at \*24-25 (Del. Super. October 14, 2010); see also *Insituform of North America, Inc. v. Chandler*, 534 A.2d 257, 268-70 (Del. Ch. 1987); *Amirsaleh v. Board of Trade of City of N.Y., Inc.*, C.A. No. 2822-CC, 2008 WL 4182998, at \*4-5 (Del. Ch. September 11, 2008). In *Global Energy*, the court stated “[a] third party beneficiary may recover on a contract made for that third party’s benefit. The creation of third party beneficiary rights requires that the contract confer an intended benefit on the third party, and the conferral of such benefit must be a material part of the contract’s purpose.” See *Global Energy Finance LLC*, supra, at \*25 (Del. Super. October 14, 2010). The Offer to Purchase, the CVR Agreement and the Merger Agreement evince a clear intent to make CVR holders intended beneficiaries of the CVR Agreement. The CVR Agreement satisfies the standard described in *Global Energy* and the other cases listed above.

The Staff has consistently granted no action relief or has not objected to payment of consideration in a tender offer where such consideration includes a contractual right to receive a contingent cash payment upon the achievement of specified milestones in an agreed upon time period. For example, in Boston Scientific’s acquisition of Rubicon Medical Corporation (which involved a tender offer to acquire all outstanding shares of common stock of the company), Boston Scientific proposed to pay, in addition to an upfront cash payment for shares of common stock, an “Additional Payment” to tendering security holders if certain milestones related to FDA approval of a medical device were achieved, with no further action required on the part of the holders. Boston Scientific received an SEC comment letter raising similar concerns raised by the Staff in Comment Number 2. In its May 17, 2005 response letter, Boston Scientific wrote, “The component of consideration represented by the Additional Payments will in fact be paid in compliance with the prompt payment rule, because the consideration is not the cash itself that might be paid in the future, but instead the right to receive the Additional Payments in cash if and only if certain milestones are achieved. Tendering security holders will obtain the right to receive the Additional Payments precisely at the same time as the cash component of the consideration is paid to the security holder in compliance with Rule 14e-1(c).” Boston Scientific thereafter accepted for payment, and paid for, shares of Rubicon in the tender offer, and the consideration paid included the contractual right to receive the Additional Payments upon the achievement of certain FDA approval related milestones.



The CVR portion of the Offer Price is substantially similar to the Additional Payments offered by Boston Scientific. Like the right to receive Additional Payments, the CVRs are the contractual right to receive cash if and only if certain milestones related to sales of the Product occur, with no further action required on the part of the holders. The CVRs will be granted at the same time the cash portion of the consideration is paid to tendering Ocera security holders. As a result, we espouse the same view expressed by Boston Scientific in its response letter to the Staff that the receipt by a tendering security holder, upon acceptance of his or her shares in a tender offer, of a contractual right to a contingent future payment is in compliance with the prompt payment standards of Rule 14e-1(c).

Furthermore, we maintain that structuring the total merger consideration into two components of an upfront cash payment and CVRs does not in any way contradict the objectives of Rule 14e-1(c), which was adopted to “protect investors by ensuring that deposited securities are not tied up for an unreasonable length of time and will not unduly burden either the offeror or its depository in their operations after the termination of a tender offer” (SEC Release No. 34-16384, Nov. 29, 1979). Since Parent will promptly pay the “consideration” by (a) paying the Offer Price and (b) entering into the CVR Agreement on or prior to the Offer Acceptance Time, securities tendered by Ocera security holders will not be “tied up” for an unreasonable length of time.

Bearing all of this in mind, we submit that the Offer satisfies the prompt payment requirements provided by Rule 14e-1(c).

***Item 1004(a) of Regulation M-A***

Regulation M-A Item 1004(a) requires that the bidder disclose the material terms of the transaction. Per Item 1(ii) of Regulation M-A Item 1004(a), such disclosure includes the amount and type of consideration being offered to security holders. This information is discussed at length throughout various sections of the Offer to Purchase. On the Cover Page, the Closing Amount and the existence of the CVRs are discussed. The CVRs are then described in further detail in the body of the Offer to Purchase. For example, on page 57 of the Offer to Purchase under the heading “CVR Agreement” in Section 11 – “The Merger Agreement; Other Agreements” we disclose the following information:

“At or prior to the Offer Acceptance Time, Parent and Mallinckrodt will enter into the CVR Agreement with the Rights Agent governing the terms of the CVRs. Each Share (other than excluded and dissenting shares), and each Share underlying an In the Money Company Stock Option, Company Warrant (other than Company Warrants cancelled in accordance with the Merger Agreement) and RSU immediately prior to the Effective Time, or the Offer Acceptance Time in the case of Shares validly tendered pursuant to the Offer, will be converted automatically into the right to receive, in addition to the Closing Amount, one CVR. The potential aggregate payments to the holders of all CVRs issuable under the Merger Agreement (which includes CVRs issuable to holders of certain stock options, warrants and restricted stock units of Ocera) and holders of certain Ocera stock options whose holders may be entitled to receive payments concurrently with the holders of CVRs

equals \$75 million, subject to reduction for Closing Shortfall or Measurement Date Shortfall, if any. See “— Merger Agreement — Transaction Expenses.” Each payment is conditioned upon the achievement of the applicable milestones on or before December 31, 2029, as follows:

- Parent will be obligated to pay an aggregate amount equal to \$10 million upon the enrollment of the first patient in a Phase 3 clinical trial of an intravenous formulation of the Product by Parent, any of its affiliates or their respective licensee or sublicensee with respect to rights to develop or commercialize the Product (the “**IV Milestone**”).
- Parent will be obligated to pay an aggregate amount equal to \$15 million upon the enrollment of the first patient in a Phase 3 clinical trial of an oral formulation of the Product by Parent, any of its affiliates or their respective licensee or sublicensee with respect to rights to develop or commercialize the Product (the “**Oral Milestone**”).
- Parent will be obligated to pay an aggregate amount equal to \$50 million upon the first occurrence of the achievement of cumulative Product sales (gross amount invoiced for sales of the Product, less certain permitted deductions) in excess of \$500 million, by Parent, any of its affiliates, or their respective licensee or sublicensee with respect to rights to develop or commercialize the Product (but not a distributor of the Product acting solely in the capacity as a distributor), or any combination thereof (the “**Product Sales Milestone**”).

The amount payable per CVR is calculated by taking into account the exercise prices of certain Ocera stock options and the number of shares underlying such options, whose holders may be entitled to receive payments concurrently with the holders of CVRs. Based on the current capitalization information of Ocera provided to Parent by Ocera, the maximum aggregate payment per CVR is currently estimated to be \$2.58. Except as expressly set forth in the CVR Agreement, under no circumstances will interest be paid on the Offer Price, regardless of any extension of the Offer or any delay in making payment for Shares. Payment to holders with respect to a Milestone Payment in connection with the IV Milestone and Oral Milestone will be made no later than sixty (60) days following the date of the achievement of the corresponding milestone, and payment with respect to the Milestone Payment in connection with the Product Sales Milestone will be made no later than sixty (60) days following the final determination of the Product Sales statement reporting achievement of the milestone (the date that a Milestone Payment is made being the “**Milestone Payment Date**”).

It is anticipated that for each \$1,000,000 of Closing Shortfall or Measurement Date Shortfall, if any and as applicable, the per CVR amount payable upon satisfaction of the first Milestone set forth above, if any, will be reduced by approximately \$0.04.”

These disclosures specify the amounts that may be payable to the holders of CVRs and the circumstances under which such amounts would be paid. For the reasons described above, the Filing Parties believe that the Offer to Purchase describes all the material terms of the consideration offered to the holders of Shares and therefore complies with Item 1004(a) of Regulation M-A.

**3. We note the disclosure on page 4 indicating that holders of CVRs are intended third party beneficiaries of the CVR Agreement. Disclose the contractual rights the holders have against the Surviving Corporation, Parent, Mallinckrodt and/or the Rights Agent with respect to those parties’ respective obligations owed to holders pursuant to the agreements. Disclose for example, any limitations imposed on the enforcement of rights by holders.**

We acknowledge this comment by the Staff, and we have accordingly revised the Offer to Purchase, to add details about the contractual rights of the holders to the existing disclosures about such rights.

The disclosure in the last paragraph starting on page 4 of the Offer to Purchase under the heading “What is a CVR and how does it work?” in the Summary Term Sheet has been revised as follows (the language that has been added to the existing disclosures is underlined):

“Under the CVR Agreement, holders of CVRs are intended third party beneficiaries of the agreement. Furthermore, the CVR Agreement provides that holders of not less than thirty-four percent (34%) of CVRs have the right to (i) bring an action seeking the enforcement of the rights of the CVR holders under the CVR Agreement and (ii) request an audit of Parent’s records for purposes of verifying the accuracy of the statements made in the Product sales statements and determining whether the Product Sales Milestone has been met. If an independent accountant conducting such audit concludes that a payment with respect to the Product Sales Milestone should have been made but was not made when due, then Parent will be required to make payment of such payment amount plus interest. However, the enforcement of the rights of the CVR holders is limited for certain purposes. For example, nothing in the CVR Agreement provides that if Parent does not make payments upon reaching of the applicable milestones, holders of CVRs would be accorded greater rights against Parent or Mallinckrodt than general unsecured creditors of Parent and Mallinckrodt, as applicable, under applicable law. Additionally, the CVR Agreement grants Parent the right to amend, without the consent of the CVR holders, the CVR Agreement in certain instances which include (i) to evidence succession of a successor rights agent, (ii) to add to the covenants of Parent such further covenants, restrictions, conditions or provisions as the Parent shall consider to be for the protection of the CVR holders;

provided that, in each case, such provisions shall not adversely affect the interests of the CVR holders, (iii) to cure any ambiguities, correcting or supplementing any provisions of the CVR Agreement that may be defective or inconsistent therein, making any provisions with respect to matters or questions arising under the CVR Agreement; provided that such provisions do not materially adversely affect the interests of the CVR holders, (iv) as may be necessary or appropriate to ensure that the CVRs are not subject to registration under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), or any applicable state securities or “blue sky” laws; provided that, such provisions shall not adversely affect the interests of the CVR holders, (v) to reduce the number of CVRs, in the event any CVR holder agrees to renounce such CVR holder’s rights under this CVR Agreement in accordance with the terms of the CVR Agreement, (vi) to evidence the succession of another person to Parent and the assumption by any such successor of the covenants of Parent contained in the CVR Agreement, (vii) to evidence the assignment of the CVR Agreement by Parent, and (viii) any other amendment that would provide any additional rights or benefits to the CVR holders or that does not adversely affect the legal rights under the CVR Agreement of any CVR holder. Parent may also amend the CVR Agreement in certain other limited circumstances if it obtains the written consent of the holders of not less than thirty-four percent (34%) of the outstanding CVRs.”

The disclosure in the last paragraph starting on page 58 of the Offer to Purchase under the heading “CVR Agreement” in Section 11 – “The Merger Agreement; Other Agreements” has been revised as follows:

“The CVR Agreement provides that the CVR holders are intended third-party beneficiaries of the CVR Agreement. ~~Moreover, pursuant to~~Furthermore, the CVR Agreement, ~~provides that~~ holders of not less than thirty-four percent (34%) of CVRs ~~will~~ have the right to (i) bring an action seeking the enforcement of the rights of the CVR holders under the CVR Agreement and (ii) request an audit ~~by an independent accounting firm~~ of Parent’s records for purposes of verifying the accuracy of the statements made in the Product sales statements and determining whether the Product Sales Milestone has been met. If ~~such an~~ independent accountant conducting such audit concludes that ~~the Milestone Payment~~ a payment with respect to the Product Sales Milestone should have been ~~paid~~made but was not ~~paid~~made when due, then Parent will be required to make payment of such payment amount plus interest. However, the enforcement of the rights of the CVR holders is limited for certain purposes. For example, nothing in the CVR Agreement provides that if Parent does not make payments upon reaching of the applicable milestones, holders of CVRs would be accorded greater rights against Parent or Mallinckrodt than general unsecured creditors of Parent and Mallinckrodt, as applicable, under applicable law. Additionally, Parent is entitled to amend, without the consent of the CVR holders or the Rights Agent, the CVR Agreement in certain instances which include (i) to evidence succession of a successor rights agent, (ii) to add to the covenants of Parent such further

covenants, restrictions, conditions or provisions as the Parent shall consider to be for the protection of the CVR holders; provided that, in each case, such provisions shall not adversely affect the interests of the CVR holders, (iii) to cure any ambiguities, correcting or supplementing any provisions of the CVR Agreement that may be defective or inconsistent therein, making any provisions with respect to matters or questions arising under the CVR Agreement; provided that such provisions do not materially adversely affect the interests of the CVR holders, (iv) as may be necessary or appropriate to ensure that the CVRs are not subject to registration under the Securities Act of 1933, as amended (the “**Securities Act**”), the Exchange Act or any applicable state securities or “blue sky” laws; provided that, such provisions shall not adversely affect the interests of the CVR holders, (v) to reduce the number of CVRs, in the event any CVR holder agrees to renounce such CVR holder’s rights under this CVR Agreement in accordance with the terms of the CVR Agreement, (vi) to evidence the succession of another person to Parent and the assumption by any such successor of the covenants of Parent contained in the CVR Agreement, (vii) to evidence the assignment of the CVR Agreement by Parent, and (viii) any other amendment that would provide any additional rights or benefits to the CVR holders or that does not adversely affect the legal rights under the CVR Agreement of any CVR holder. Parent may also amend the CVR Agreement in certain other limited circumstances if it obtains the written consent of the holders of not less than thirty-four percent (34%) of the outstanding CVRs.”

**4. Please prominently disclose, if true, that payment of the CVR Portion is ultimately within the control of Purchaser.**

The CVR Agreement will be entered into by Parent, Rights Agent, and for limited purposes, Mallinckrodt, on or prior to the Offer Acceptance Time and will provide that the tendering security holders that become entitled to receive the milestone payments will be entitled to the benefit of and to enforce the CVR Agreement. The requirement to pay the milestone payments will constitute the enforceable contractual obligation of Parent, guaranteed by Mallinckrodt. If the applicable milestones are met, Parent will be contractually obligated to make the payments under the CVR Agreement and will not have any discretion over the timing or amount of the payments to be made thereunder. Pursuant to the CVR Agreement, the holders of not less than 34% of the outstanding CVRs will be able to enforce Parent’s payment obligations if Parent does not deliver the funds required to pay the milestone payments to the Rights Agent within 60 days following the attainment of a milestone (or, with respect to the Product Sales Milestone, within 60 days following the final determination of the statement reporting achievement of such milestone), or if any portion of the milestone payment has not been paid following the applicable payment date. Furthermore, pursuant to the audit rights in Section 4.3 of the CVR Agreement, holders of not less than 34% of the outstanding CVRs will have the right to request an audit by an independent accounting firm of Parent’s records in order to determine whether the payments relating to the Product Sales Milestone have been accurately made. Further, as disclosed on page 5 of the Offer to Purchase, Section 4.5 of the CVR Agreement provides that Parent shall use diligent efforts (as defined therein) to achieve the applicable milestones.

As disclosed in the Offer to Purchase on page 5, Parent's obligation to use "diligent efforts" does not mean that Parent guarantees that it will actually achieve any milestone, whether at all or by a specific date. Further, page 58 of the Offer to Purchase clarifies that there can be no assurance that any of the milestones set forth in the Offer to Purchase will be achieved or that any holders of CVRs will receive payments with respect thereto.

These disclosures suggest that there could be many reasons why any of the milestones are not met, some of which could arguably be within Parent's or Purchaser's control, but others would be entirely outside the control of Parent and Purchaser.

In response to the Staff's comment, the text under the heading "What is a CVR and how does it work?" in the Summary Term Sheet of the Offer to Purchase as well as the text under the heading "CVR Agreement" in Section 11 – "The Merger Agreement; Other Agreements" of the Offer to Purchase has been amended and supplemented to insert the following new paragraph after the current last paragraph under such headings:

"Under the terms of the CVR Agreement, Parent will have discretion with respect to the Product. Whether the applicable milestones are met will depend on many factors, some within the control of Parent and Purchaser and others outside the control of Parent and Purchaser."

5. **Please provide your analysis as to the materiality of bidder financial statements under Item 1010(a)-(b) of Regulation M-A. If you believe such disclosures are not required by Item 10 of Schedule TO and Item 1010(a) and (b) of Regulation M-A, please revise to disclose that (i) the bidders' financial condition could deteriorate such that it would not have the necessary cash or cash equivalents to make the required payments; (ii) holders of the rights to receive payments have no greater rights than those accorded to general unsecured creditors under applicable law; (iii) the rights would be effectively subordinated in right of payment to all of the bidders' secured obligations to the extent of the collateral securing such obligations; and (iv) the rights would be effectively subordinated in right of payment to all existing and future indebtedness, claims of holders of capital stock and other liabilities, including trade payables, of the parent's subsidiaries. Please also disclose the possible effects of a bankruptcy filing on your payment obligations.**

Pursuant to Item 10 of Schedule TO and Item 1010(a)-(b) of Regulation M-A, bidder financial information is required to be disclosed when such information is material. Given the manner in which the Offer is structured, we do not believe that the Filing Parties' financial statements are material to the decision of Ocera security holders to participate in the Offer and therefore, such financial statements do not need to be disclosed in the Schedule TO.

Instruction 1 to Item 10 explains “[f]inancial statements must be provided when the offeror’s financial condition is material to [a] security holder’s decision whether to sell, tender or hold the securities sought.” In the Regulation M-A adopting release (Release Nos. 33-7760, 34-42055; October 22, 1999) (the “**Adopting Release**”), the SEC stated that there are several factors that should be considered in determining whether bidder financial statements are material, including: (i) whether the purpose of the tender offer is for control of the subject company, and (ii) the ability of the bidder to pay for the securities sought in the tender offer. The Adopting Release further specified that “[f]inancial information can be material when a bidder seeks to acquire the entire equity interest of the target and the bidder’s ability to finance the transaction is uncertain.”

Since Mallinckrodt has, and the Purchaser through Mallinckrodt will have, sufficient financial resources to pay the Closing Amount and all amounts payable in respect of the CVRs if the milestones associated therewith are achieved, we respectfully submit that the financial condition of the Filing Parties is not material to the decision of security holders to tender their securities in the Offer for the following reasons:

- as noted on pages 6, 14 and 30, the Offer is not subject to any financing condition;
- none of the CVR milestones is tied to the financial condition, results or position of the Filing Parties;
- as noted on pages 6 and 30 of the Offer to Purchase, Purchaser estimates that the total amount of funds required to purchase all outstanding securities of Ocera is approximately \$42 million, plus related fees and expenses, and approximately an additional \$75 million is needed to pay the maximum aggregate amount that holders of the CVRs and certain stock options would be entitled to in the event that all milestones are timely achieved;
- with cash and cash equivalents of \$371.8 million as of September 29, 2017 (as disclosed in Mallinckrodt’s most recent Quarterly Report on Form 10-Q), and not taking into account other sources of liquidity accessible to Mallinckrodt under current or planned financing arrangements, Mallinckrodt has liquid current assets, net of liabilities, well in excess of the amount required to pay the Closing Amount and any amounts payable in respect of the CVRs if the milestones associated therewith are achieved; and
- the CVRs represent the only portion of the consideration payable under the Merger Agreement as to which the receipt of cash will not occur at closing.

Considering the foregoing, we respectfully submit that the financial condition of the Filing Parties is not material to a security holder's decision to tender its securities in the Offer.

In response to the Staff's comment, the following language is added both (i) at the end of the paragraph under the heading "Is your financial condition relevant to my decision to tender my Shares in the Offer?" in the Summary Term Sheet of the Offer to Purchase, and (ii) at the end of Section 9 – "Source and Amount of Funds" of the Offer to Purchase:

"While, for the reasons stated above, we do not believe our financial condition to be relevant to your decision to tender your Shares, you should consider the following in connection with your decision to tender your Shares:

- Mallinckrodt's financial condition could deteriorate such that it would not have the necessary cash or cash equivalents to provide to Parent and Purchaser to make the required payments under the Merger Agreement and the CVR Agreement;
- holders of CVRs will have no greater rights against Parent and Mallinckrodt than those accorded to general unsecured creditors under applicable law;
- the rights of holders of CVRs will be effectively subordinated in right of payment to all of Mallinckrodt's and Parent's secured obligations to the extent of the collateral securing such obligations;
- the CVRs will be effectively subordinated in right of payment to all existing and future indebtedness, claims of holders of capital stock and other liabilities, including trade payables, of Parent's and Mallinckrodt's other subsidiaries; and
- the filing of a bankruptcy petition by, or on behalf of, Parent or Mallinckrodt may prevent Parent or Mallinckrodt, as applicable, from making some or all payments that become payable with respect to the CVRs."

6. **We note the disclosure in the first full paragraph on page 62 indicating that the conditions "are for the sole benefit of Parent and Purchaser, may be asserted by Parent or Purchaser regardless of the circumstances giving rise to any such conditions (including any action or inaction by Parent or Purchaser)..." (emphasis added). The inclusion of offer conditions is not objectionable when the conditions are objectively determinable and outside the control of the bidders. Please revise to remove the implication that the conditions may be triggered at the election of the bidders.**



The Filing Parties acknowledge the Staff's comment and confirm their understanding that the conditions to the Offer should be objectively determinable and outside the control of the Filing Parties so as to avoid any implication that the Offer be considered impermissibly illusory or in contravention of the Exchange Act. We respectfully submit that the conditions to the Offer set forth in Section 15 – "Conditions of the Offer" are objectively determinable and do not reflect any circumstances in which the Filing Parties have the possibility, solely through their action or inaction, to trigger the offer conditions or the termination of the Offer.

The Merger Agreement, negotiated at arm's length, generally provides that the parties will use their respective reasonable best efforts to take, or cause to be taken, all actions, and to do, or cause to be done, all things necessary, proper or advisable in order to consummate the Merger and the other transactions contemplated by the Merger Agreement. See Section 11 – "The Merger Agreement; Other Agreements – Merger Agreement – Efforts to Consummate the Merger" starting on page 48 of the Offer to Purchase. This covenant represents contractual obligations of Parent and Purchaser, fully enforceable by Ocera. If Parent were to breach this covenant, such "inaction" would be the basis for a claim, as to which Ocera would be entitled to an award of specific performance to cause Parent and Purchaser to comply. See Section 11 – "The Merger Agreement; Other Agreements – Specific Performance" on page 55 of the Offer to Purchase.

Because these contractual obligations of Parent and Purchaser, and Ocera's right to seek a specific performance remedy, are fully described in the Offer to Purchase, we respectfully submit that there is no implication that the Offer could be considered illusory. Furthermore, any decision by any governmental entity to seek any enforcement action or to require any remedial measures in connection with the Offer is within the discretion of each such entity, and not a matter that the Parent and Purchaser can trigger at their convenience. We therefore respectfully submit that the conditions to the Offer do not make the Offer terminable at the convenience of Parent or Purchaser by means or circumstances under their control.

In light of the Staff's comment, and to avoid any confusion, the Offer to Purchase has been revised to delete the parenthetical "(including any action or inaction by Parent or Purchaser)" on page 62 in Section 15 – "Conditions of the Offer" of the Offer to Purchase.

7. **We further note the disclosure in the first full paragraph on page 62 relating to the bidders' failure to exercise any of the rights described in this section. This language suggests that if a condition is triggered and a bidder fails to assert the condition, it will not lose the right to assert the condition at a later time. Please note that when a condition is triggered and a bidder decides to proceed with the offer anyway, we believe that this decision is tantamount to a waiver of the triggered condition(s). Depending on the materiality of the waived condition and the number of days remaining in the offer,**

**the bidder may be required to extend the offer and recirculate new disclosure to security holders. In addition, when an offer condition is triggered by events that occur during the offer period and before the expiration of the offer, the bidder should inform holders how it intends to proceed promptly, rather than waiting until the end of the offer period, unless the condition is one where satisfaction of the condition may be determined only upon expiration. Please confirm the bidders' understanding on both points in your response letter.**

The Filing Parties confirm their understanding that: (1) if a condition of the Offer is triggered and the Filing Parties decide to proceed with the Offer anyway, this decision is considered a waiver of the triggered condition(s), and the Filing Parties may need to disclose such information to the security holders and extend the Offer depending on the number of the days remaining in the Offer, and (2) if a condition of the Offer is triggered by events that occur during the offer period and before the Expiration Date, the Filing Parties shall inform the security holders how it intends to proceed promptly and not wait until the end of the offer period, unless the condition is one where satisfaction of the condition may be determined only upon the Expiration Date.

\* \* \*

If you have any questions regarding the foregoing, please do not hesitate to call me at (314) 259-2797.

Very truly yours,

/s/ Stephanie M. Hosler  
Stephanie M. Hosler

cc: Mallinckrodt plc