# ANTICIPATED ACQUISITION BY

### **COCHLEAR LIMITED**

OF

# THE HEARING IMPLANTS DIVISION OF DEMANT A/S (KNOWN AS OTICON MEDICAL)

CASE ME/6999/22

**RESPONSE TO THE CMA NOTICE OF POSSIBLE REMEDIES** 

4 MAY 2023

#### **Response to the CMA Notice of Possible Remedies**

#### 1. Introduction and executive summary

- 1.1 This response, submitted on behalf of Demant A/S ("**Demant**"), relates to the proposed acquisition by Cochlear Limited ("**Cochlear**") of Demant's hearing implants division ("**Oticon Medical**") (the "**Transaction**") and responds to the CMA's Notice of Possible Remedies dated 20 April 2023 (the "**Remedies Notice**"). Cochlear and Demant are together referred to as the **Parties**.
- 1.2 In its Provisional Findings Report dated 20 April 2023 (the "**Provisional Findings**"), the CMA provisionally concluded that the Transaction may be expected to result in a substantial lessening of competition ("**SLC**") in the supply of bone conduction solutions ("**BCS**") in the UK.<sup>1</sup> In the Remedies Notice, the CMA has identified prohibition as likely to be the only effective remedy to the SLC, consisting of either (1) prohibition of the sale of Oticon Medical to Cochlear ("**Full Prohibition**") or (2) prohibition of the sale of the BCS business of Oticon Medical to Cochlear ("**Partial Prohibition**").
- 1.3 The SLC identified by the CMA only relates to the BCS market in the UK.<sup>2</sup> Accordingly, the CMA has accepted that the SLC may, in principle, be remedied effectively and comprehensively by Partial Prohibition.<sup>3</sup> [ $\gg$ ].
- 1.4 The Enterprise Act 2002 requires the CMA to remedy any SLC that it has identified by taking action to achieve "*as comprehensive a solution as is <u>reasonable and practicable</u>" (emphasis added).<sup>4</sup> Partial Prohibition is an effective remedy that is more reasonable and proportionate, and less costly, than Full Prohibition. In particular:* 
  - (a) **Partial Prohibition would comprehensively address the CMA's provisional competition concern**. The SLC identified by the CMA only relates to the supply of BCS products in the UK. In its Phase 1 Decision, the CMA found that the Transaction would not result in a realistic prospect of an SLC in relation to the supply of CI in the UK.<sup>5</sup> Therefore, Partial Prohibition would remove the concern identified in the Provisional Findings by prohibiting the sale of the BCS business to Cochlear.
  - (b) Partial Prohibition would substantially reduce composition and asset risks. Partial Prohibition would result in the BCS business continuing to operate under Demant's ownership. Therefore, no divestment of the BCS business to a third party purchaser is required to comprehensively resolve the CMA's provisional concerns. Accordingly, there can be no purchaser risk and any composition or asset risks associated with Partial Prohibition are substantially reduced compared to a typical divestiture remedy. Further, as acknowledged by the CMA in its Provisional Findings, absent the Transaction Demant would not have

<sup>&</sup>lt;sup>1</sup> Provisional Findings, para. 6.2.

<sup>&</sup>lt;sup>2</sup> Remedies Notice, para. 19.

<sup>&</sup>lt;sup>3</sup> Remedies Notice, para. 19.

<sup>&</sup>lt;sup>4</sup> Enterprise Act, section 36(3).

<sup>&</sup>lt;sup>5</sup> CMA's Phase 1 Decision, para. 168.

an incentive to close the BCS business.<sup>6</sup> This would effectively mean that, if the BCS business were to remain within Demant, it would continue to benefit from (1) the size and financial performance of the Demant group and (2) integration with the Demant group which supports the BCS business in relation to administration, procurement, distribution and R&D functions.<sup>7</sup> In addition, as explained in Section 4 below, the loss of synergies between the BCS and CI businesses, if any, would not give rise to material composition or asset risks as such synergies are either minor or readily surmountable.

- (c) *Partial Prohibition would create a stronger BCS business*. In its Provisional Findings, the CMA has provisionally concluded that whilst Oticon Medical has been loss-making overall, this has largely been caused by the performance of the CI business and not the BCS business, which has been "growing and profitable"<sup>8</sup> and has positive earnings before interest and taxes ("EBIT").<sup>9</sup> An assessment of the effectiveness of Partial Prohibition must consider whether, in the round, the CMA's provisional counterfactual conclusions in relation to the BCS business would change if the CI business were transferred to Cochlear. As explained below, the sale of the CI business would only serve to make the retained BCS business more financially robust.
- (d) Full Prohibition would not be "reasonable" and would be disproportionate to the SLC identified in relation to BCS. The CMA has provisionally identified an SLC in the BCS market and has not identified any concerns in the CI market. Accordingly, a remedy prohibiting the entire Transaction (*i.e.*, Full Prohibition) would not be reasonable and would be disproportionate to the SLC that has been provisionally identified. In addition, Full Prohibition would result in Demant having to close down its significantly loss-making CI business. Whilst Demant would take measures to minimise the impact of such closure on its existing customer base, they would be worse-off than in the scenario in which the business is sold to Cochlear. For example, [ $\gg$ ]. Demant's CI patients would be potentially [ $\gg$ ], as compared with Partial Prohibition. In the long term, such CI patients may [ $\gg$ ].
- 1.5 This response considers the CMA's conclusions on the relevant counterfactual in its Provisional Findings (Section 2), sets out how the BCS and CI businesses would be separated under a Partial Prohibition scenario (Section 3), and explains that Partial Prohibition does not alter the CMA's provisional conclusions regarding Demant's ability and incentive to support the BCS business (Section 4).

# 2. The CMA's provisional conclusions on the relevant counterfactual

2.1 Any assessment of the effectiveness of a Partial Prohibition remedy must be undertaken by reference to the CMA's provisional conclusions in relation to the counterfactual. The CMA has provisionally concluded that, absent the Transaction, Oticon Medical would most likely have continued to operate in the market for the supply of BCS

<sup>&</sup>lt;sup>6</sup> Provisional Findings, para. 4.46.

<sup>&</sup>lt;sup>7</sup> Provisional Findings, para. 4.44.

<sup>&</sup>lt;sup>8</sup> Provisional Findings, para. 4.67.

<sup>&</sup>lt;sup>9</sup> Provisional Findings, para. 4.40(d).

products in the UK (whether the BCS business continued to operate under Demant's ownership or under the ownership of an alternative purchaser).<sup>10</sup>

- 2.2 In reaching this provisional conclusion, the CMA recognised that the significant losses generated by Oticon Medical were driven by losses resulting from the CI business.<sup>11</sup> Specifically, the CMA noted as follows:
  - (a) The CI business has generated the majority of certain categories of operating costs, in particular R&D.<sup>12</sup> Administrative expenses for the CI business also increased [≫] in 2022.<sup>13</sup>
  - (b) The BCS business has consistently been profitable at an EBIT level over the period of the CMA's analysis. By contrast, the CI business saw an EBIT loss.<sup>14</sup>
  - (c) Between 2019 and 2022, the CI business' revenue declined by [≫] % (at an average annual rate of [≫] %), and by [≫] % in the last financial year. During this same period, the CI business' losses increased [≫]: at an annual average of [≫] % (in total by [≫] %). By 2022, the CI business' EBIT losses had increased to DKK [≫].<sup>15</sup>
  - (d) The evidence provided to the CMA implies that the Oticon Medical business would have been profitable without the CI business.<sup>16</sup>
- 2.3 Given that the CI business is responsible for Oticon Medical being loss-making, divesting the CI business to Cochlear does not change the CMA's provisional counterfactual conclusions concerning Demant's ability and incentive to operate the BCS business in the UK. In fact, disposing of the CI business would only increase Demant's ability and incentive to continue operating the BCS business, which means that the CMA's counterfactual findings remain unchanged.
  - (a) The CMA provisionally concluded that Demant had, and is likely to continue to have, the ability and incentive to support the activities of Oticon Medical (including the BCS business) as a result of (1) the size and financial performance of the Demant group and (2) the integration of Oticon Medical (and the BCS business) within the Demant group.<sup>17</sup> Both these factors are unaffected by a disposal of the CI business only.
  - (b) The CMA sees no incentive for Demant to close down the BCS business as (1) Demant has a responsibility to its BCS patients to continue to provide vital technology and (2) the BCS business has a leading market position in the UK

<sup>&</sup>lt;sup>10</sup> Provisional Findings, para. 4.121.

<sup>&</sup>lt;sup>11</sup> Provisional Findings, para. 4.39.

<sup>&</sup>lt;sup>12</sup> Provisional Findings, para. 4.40(c).

<sup>&</sup>lt;sup>13</sup> Provisional Findings, Appendix E, para. 7.

<sup>&</sup>lt;sup>14</sup> Provisional Findings, para. 4.40(d).

<sup>&</sup>lt;sup>15</sup> Provisional Findings, Appendix E, paras. 7-10.

<sup>&</sup>lt;sup>16</sup> Provisional Findings, para. 4.41.

<sup>&</sup>lt;sup>17</sup> Provisional Findings, para. 4.44.

and a prominent position globally.<sup>18</sup> Both these factors are unaffected by a disposal of the CI business.

- (c) The CMA considered that Demant would have continued to develop Sentio, including with a view to its commercial release and this would likely have been the case irrespective of the position in relation to the CI business.<sup>19</sup> As discussed at paras. 4.13 to 4.17 below, the sale of the Nice manufacturing facility to Cochlear does not alter this conclusion.
- 2.4 The CMA's provisional conclusion that Oticon Medical would most likely have continued to operate in the market for the supply of BCS products in the UK absent the Transaction is therefore not altered by Partial Prohibition.

# 3. Separation of the CI business

- 3.1 Partial Prohibition would require the separation of Oticon Medical's BCS and CI businesses to allow Demant to retain the former whilst disposing of the latter to Cochlear. [≫], this would involve:
  - (a) The transfer of Neurelec SAS and Oticon Medical Maroc to Cochlear, including all employees, facilities, assets, intellectual property and liabilities;<sup>20</sup>
  - (b) The transfer of the contracts and permits relating to the CI business;<sup>21</sup> and
  - (c) The assets at the Nice manufacturing facility and all other assets that are otherwise related to the CI business, including all surgical support tools and software, fitting tools and software, implants, sound processors, accessories and customer software related to the CI business.
- 3.2 Demant would also need to enter into a supply agreement and a transitional services agreement as a part of the sale of the CI business to Cochlear. However, these relate to services that will be provided by Demant to Cochlear in relation to the CI business only and not *vice versa*. As such, these are not relevant to the CMA's assessment of the asset and composition risks relating to the BCS business.
- 3.3 With the exception of the Nice manufacturing facility and its role in the development of Sentio, tangible assets are not shared between the BCS and CI businesses. As further described below, some intangible assets are shared between the two businesses.
- 3.4 As the BCS business' synergies with the CI business (outside the development of Sentio) are limited to employees and certain assets addressed in Section 4 below Partial Prohibition would not require reciprocal supply or transitional services agreements for the BCS business. As a result, there are no significant composition or asset risks associated with Partial Prohibition.

<sup>&</sup>lt;sup>18</sup> Provisional Findings, paras. 4.45-4.46.

<sup>&</sup>lt;sup>19</sup> Provisional Findings, para. 4.95.

<sup>&</sup>lt;sup>20</sup> Merger Notice, Annex 201, Schedule 2.

<sup>&</sup>lt;sup>21</sup> Merger Notice, Annex 201, Schedule 2, Part 2.

# 4. Partial Prohibition does not alter the CMA's provisional finding regarding Demant's ability and incentive to support the BCS business

- 4.1 In relation to Partial Prohibition, the Remedies Notice explains that there are existing interdependencies between the BCS business and the CI business and that third parties have indicated that, on its own, the BCS business may lose certain 'call point' market benefits.<sup>22</sup> It invites submissions on whether Partial Prohibition might adversely impact the BCS business as an effective competitor in the UK.
- 4.2 Partial Prohibition does not change the CMA's provisional counterfactual conclusions in relation to Demant's ability and incentive to operate the BCS business in the UK. In fact, Partial Prohibition would create a stronger BCS business.
- 4.3 As explained below, the assessment of the effectiveness of Partial Prohibition must consider whether, in the round, the CMA's provisional counterfactual conclusions in relation to the BCS business would be changed. The sale of the CI business would only serve to make the retained BCS business more financially robust. The loss of synergies the BCS business may have with the CI business can be readily overcome by the additional profitability generated by the disposal combined with the continued support of the Demant Group.

# Continued support of the Demant Group

- 4.4 The CMA has provisionally concluded that, absent the Transaction, Demant would most likely not have an incentive to close the BCS business.<sup>23</sup> Accordingly, within the Demant group, the BCS business would continue to benefit from the following:
  - (a) Demant's group level procurement and existing intra-group supply arrangements, particularly in relation to [<sup>∞</sup>];
  - (b) R&D at the group level in relation to [%] and [%];
  - (c) Non-cash benefits for Oticon Medical within the Demant organisation including brand association; and
  - (d) Shared intra-group services (*e.g.*, legal, facilities management and intellectual capital sharing).
- 4.5 As demonstrated in Annex 1, without the CI business, the BCS business would remain profitable within the Demant group going forward. In particular, Annex 1 presents the profitability of the BCS business during the FY23 FY25 period, if kept within Demant and in the event of a Partial Prohibition. This profitability assessment is presented under two scenarios, which differ on the basis of assumptions around FY23 revenues and expected revenue growth in the following years.
  - (a) **Scenario 1.** In this scenario, the FY23 revenue figure is in line with Oticon Medical's budget estimates as of February 2023 and are the figures reflected in the BCS business plan prepared by MW&L, Demant's financial advisers, as

<sup>&</sup>lt;sup>22</sup> Remedies Notice, para. 18.

<sup>&</sup>lt;sup>23</sup> Provisional Findings, para. 4.46.

submitted to the CMA on 23 March 2023.<sup>24</sup> Indeed, this scenario has been built by taking MW&L's model as a starting point and making two adjustments: (1) assuming a higher revenue growth for FY24-FY25 compared to the figures in the original MW&L model, thus addressing the criticisms raised by the CMA in its Provisional Findings,<sup>25</sup> and (2) removing the additional costs that MW&L estimated the BCS business would incur on a standalone basis if not kept within Demant.

- (b) Scenario 2. In this scenario, the FY23 revenue figure is in line with Oticon Medical's financial forecasts for the BCS business as of March 2022.<sup>26</sup> These are the latest forecasts available from the period before the ASPA was entered into, which the CMA has relied on in its own assessment of the Transaction.<sup>27</sup> Indeed, this scenario is largely equivalent to Oticon Medical's own forecasts for the BCS business, except for the additional costs that Demant estimates the BCS business would face if the CI business was sold to Cochlear.
- 4.6 In addition, for each of the two scenarios described above, two approaches have been implemented, which differ depending on whether or not the BCS business is expected to make any investments in a new Class III facility. The 'upper bound' approach assumes no additional costs associated with a Class III facility in the FY23 FY25 period,<sup>28</sup> whereas the 'lower bound' approach assumes that the BCS business invests in a new Class III facility within this period (and the costs of doing so are reflected in MW&L's model, as submitted to the CMA).<sup>29</sup>
- 4.7 This analysis shows that the BCS business would remain profitable even under very conservative assumptions regarding expected revenue growth and future expenses that the BCS business would incur when building and operating its own Class III facility. In particular, according to the most conservative estimate (*i.e.*, the 'lower bound' estimate in Scenario 1), the BCS business would generate annual profits in the range of DKK [≫] to DKK [≫] to DKK [≫] to £[≫]) in the FY23-FY25 period. Under less conservative assumptions, the BCS business could be expected to generate annual profits in the range of DKK [≫] to DKK [∞] to £[∞] to £[∞].
- 4.8 Demant's view is that the costs associated with a Class III facility and, accordingly, future profits of the BCS business in the event of a Partial Prohibition are likely to lie somewhere between the two scenarios described above.

<sup>&</sup>lt;sup>24</sup> Parties' response to the CMA's Annotated Issues Statement and Working Papers, Annex 432.

Provisional Findings, Appendix F, para. 4(a). Annex 1 assumes revenue growth of [%] % for FY24 and [%] % for FY25 (reflecting Oticon Medical's financial forecasts for the BCS business) instead of [%] % for both years as reflected in MW&L's original model.

<sup>&</sup>lt;sup>26</sup> Merger Notice, Annex 023 - [%].

<sup>&</sup>lt;sup>27</sup> Provisional Findings, Appendix F, para. 4.

<sup>&</sup>lt;sup>28</sup> Remedies Notice Response, Annex 1, row 12.

<sup>&</sup>lt;sup>29</sup> Remedies Notice Response, Annex 1, row 17.

<sup>&</sup>lt;sup>30</sup> Figures converted from DKK to GBP using the Bank of England's average exchange rate for 2022 (GBP 1:DKK 8.7281).

### No material asset or composition risks for the retained BCS business

4.9 As described in Section 3 above, the retention of the BCS business would involve transferring (to Cochlear) – as part of the CI business – certain shared employees, customer contracts, the Nice facility, other tangible assets and some limited IT systems. With the exception of the Nice manufacturing facility's role in the development of Sentio, tangible assets are generally not shared between the BCS and CI businesses. Whilst some intangible IP assets are shared between the two businesses, as explained below, these would remain with the BCS business and the CI business would benefit from a licensing arrangement, as necessary.

# Employees

- 4.10 In 2022, of the [≫] Oticon Medical employees that would transfer to Cochlear under a Partial Prohibition scenario, only [≫] employees shared their time between the CI and BCS businesses. This consisted of [≫] employees in the United States, [≫] employees in France and [≫] employees in Morocco none of these employees are located in or provide services to the CI or BCS businesses in the UK. The costs of these shared employees are distributed between the CI and BCS businesses based on the time they spent in the different activities.
- 4.11 In the event of Partial Prohibition, [≫] of these shared employees in France and Morocco would transfer to Cochlear. Employees in the United States and all other employees of Oticon Medical would remain with the BCS business.<sup>31</sup>
- 4.12 Whilst some sales teams, clinicians and Key Opinion Leaders may work across both BCS and CI, this does not result in any material revenue synergies in the UK. As the CMA noted in its Phase 1 Decision, the strength of Oticon Medical's CI business as a competitor, both currently and going forward, is weak and reflected in its trivial share of supply, even pre-recall.<sup>32</sup> Oticon Medical has not sold any CI products in the UK since the product recall.<sup>33</sup> The loss of any CI-specific 'call points' cannot therefore have any material impact on the sales of the BCS business, nor adversely impact the effectiveness of a Partial Prohibition remedy.

# Assets and Facilities

- 4.13 As described in Section 3 above, Partial Prohibition would result in the sale and transfer of Oticon Medical's manufacturing facility in Nice to Cochlear. Whilst this manufacturing facility largely relates to the CI business, the facility is currently a subsupplier to the BCS business for the development of Sentio.
- 4.14 If ultimately launched by Oticon Medical, the legal manufacturer of Sentio would be Oticon Medical AB. Oticon Medical AB is certified to design, manufacture and market Class III medical devices. Accordingly, Oticon Medical AB would continue to be the

<sup>&</sup>lt;sup>31</sup> For completeness, the employees in the sales team responsible for Oticon Medical's UK sales are employed by Demant, rather than Oticon Medical.

<sup>&</sup>lt;sup>32</sup> CMA's Phase 1 Decision, para. 168.

<sup>&</sup>lt;sup>33</sup> Given the overlap in clinicians and key opinion leaders for CI and BCS, the recall also had the potential to damage Oticon Medical's reputation in BCS.

legally-certified manufacturer of the Class III device whether those activities are carried out in-house or outsourced to a third party.

- 4.15 Any future Sentio implant would need to be manufactured in a facility that meets the requirements for a Class III device, including ISO 13485 and Medical Device Single Audit Program (MDSAP) certifications, as well as having the relevant equipment and manufacturing competencies (*e.g.*, laser welding, silicone over molding, cleaning and hermicity testing). Whilst the Nice manufacturing facility currently meets these requirements, Oticon Medical AB has a number of readily available manufacturing alternatives that include: (1) upgrading one of Demant's existing facilities to comply with the requirements for a Class III device; (2) outsourcing to one of multiple third party manufacturers that can manufacture the Sentio implant;<sup>34</sup> or (3) establishing or acquiring a new facility for this purpose at an estimated cost of approximately EUR [ $\gg$ ] (c. £[ $\gg$ ]).<sup>35</sup>
- 4.16 In fact, the Provisional Findings note that Demant's updated analysis exploring the potential costs of establishing a separate Class III facility to develop Sentio: (1) does not imply that such a plan would be unfeasible, and (2) envisages the BCS business establishing this facility absent the CI business, reducing the BCS business' ongoing reliance on the former.<sup>36</sup>
- 4.17 Finally, even accepting the CMA's counterfactual findings in relation to the launch of Sentio, the Sentio product would not be launched until [≫] at the earliest.

# Intellectual Property

- 4.18 Intellectual property rights ("**IPRs**") relating to the BCS business are registered to either Demant or Oticon Medical. Such IPRs are registered to the former if they also relate to the activities of the Demant group or the latter if they only relate to Oticon Medical's BCS and/or CI businesses.
- 4.19 Demant's IPRs would not transfer to Cochlear. The BCS business would therefore continue to enjoy the benefits of these IPRs in the event of Partial Prohibition.
- 4.20 Oticon Medical's IPRs can be categorised into three groups. IPRs that relate to (1) the BCS business only; (2) the CI business; and (3) both the BCS and the CI businesses.
- 4.21 The IPRs in group (1) would remain with the BCS business whilst IPRs in group (2) would transfer to Cochlear. The IPRs in group (3) would remain with the BCS business and therefore the disposal of the CI business would not impact the exploitation of shared IPRs by the BCS business.
- 4.22 For the sake of completeness, a licence agreement would be entered into between the Parties to ensure that the required IPRs, including Demant's IPRs, could also be exploited by the carved-out CI businesses, where required.

<sup>&</sup>lt;sup>34</sup> Whilst Oticon Medical has [&], potential contract manufacturers include [&] and [&].

<sup>&</sup>lt;sup>35</sup> Converted from EUR to £ using the Bank of England's average exchange rate for 2022 (GBP 1 = EUR 1.1732).

<sup>&</sup>lt;sup>36</sup> Provisional Findings, para. 4.94.

### IT systems

- 4.23 In general, the BCS and CI businesses have separate IT systems, infrastructures and applications. Certain internal systems for the CI business are currently also used by the BCS business (*e.g.*, the electronic document management system). As Cochlear would migrate all data relating to the CI business to its existing systems, these shared systems would not transfer to Cochlear and have no impact on the retained BCS business.
- 4.24 Notwithstanding the loss of the above synergies, the CMA has provisionally concluded that the size and financial performance of the Demant group means that it will continue to have the ability and incentive to support the BCS business, and these findings are not altered by a sale of the CI business to Cochlear under a Partial Prohibition scenario.<sup>37</sup>

# 5. Conclusion

5.1 For the reasons set out above, Partial Prohibition would comprehensively and effectively address the SLC identified, and does not give rise to any material composition or asset risks in relation to the retained BCS business. Additionally, Partial Prohibition would ensure Oticon Medical's CI patients have access to the necessary level of care and innovation from Cochlear, whilst creating a stronger more financially robust BCS business. In summary, Partial Prohibition is an effective remedy that is more proportionate and less costly than Full Prohibition, and should therefore be preferred by the CMA.

<sup>&</sup>lt;sup>37</sup> Provisional Findings, para. 4.44.