



Demant A/S: Notification of voluntary field corrective action by the cochlear implants business

14.10.2021 08:24:05 CEST | Demant A/S | Inside information

Company announcement no 2021-13

14 October 2021

Notification of voluntary field corrective action by the cochlear implants business

Oticon Medical, which constitutes the Hearing Implants business in the Demant Group, has decided to take voluntary field corrective action by recalling non-implanted Oticon Medical Neuro Zti implants and to temporarily halt sales of new implants. The recall is entirely related to the identification of performance issues in a small subset of implants, and there have been no reported safety events with the implants.

Oticon Medical's quality system has recently identified an increase in the number of Neuro Zti implant explantations and in the number of implants under surveillance to be explanted because of a loss of hermeticity whereby electronic components in the implants over time get exposed to moisture, causing the electronics to shut down and stop working. Investigations have shown that the potential performance issues relate to a manufacturing deviation, affecting up to 3,976 Neuro Zti implants. As of 13 October, a total of 28 implants had either been explanted or were under surveillance to be explanted. There are no safety concerns for existing users, and most users are unlikely to experience any issues.

As a consequence of the voluntary field corrective action, the Group expects no further sales of new cochlear implants in 2021, and the temporary halt in sales is likely to extend into 2022. Until implant sales recommence, revenue for Hearing Implants will comprise sales of external cochlear implant sound processors to existing users and of bone anchored hearing systems, which are expected to remain unaffected. In recent months, such continued sales have accounted for around 65% of total revenue for Hearing Implants.

In addition to lost revenue, the voluntary field corrective action will also result in certain one-off costs, which are expected to amount to DKK 70-100 million in 2021. These one-off costs are likely to include certain returns for credit of implants already sold, write-down of inventory related to affected implants, certain provisions etc. Most of these costs are not likely to affect the cash flow this year.

Excluding the one-off costs mentioned above, the Group's outlook for 2021 remains unchanged.

At this point, we lack clarity on the duration of the temporary halt in sales of new cochlear implants, but we expect the halt to extend into next year and thus to have a material negative impact on revenue for Hearing Implants in 2022. Until the issue is resolved, we will work diligently to mitigate the financial impact, and we will provide further information as needed.

"In spite of a low prevalence of performance issues in our cochlear implants, we are undertaking this voluntary action to stay true to our commitment of delivering products of the highest quality in all aspects. Fortunately, the issue does not entail any safety concerns for existing users, but we are of course truly sorry for any disruption and inconvenience that this may cause for our patients and customers and are committed to supporting them in resolving any issues they may experience," says Søren Nielsen, President & CEO of Demant.

Please reach out to the contact persons listed below with any questions. As per our financial calendar, our Interim Management Statement is scheduled for release on 2 November 2021.

<i>Further information:</i> Søren Nielsen, President & CEO Phone +45 3917 7300 www.demant.com	<i>Other contacts:</i> René Schneider, CFO Mathias Holten Møller, Head of Investor Relations Trine Kromann-Mikkelsen, VP Corporate Communication and Relations
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About Demant A/S

Demant is a world-leading hearing healthcare group that offers solutions and services to help people with hearing loss connect with the world around them. In every aspect, from hearing devices, hearing implants, diagnostics to audio and video solutions and hearing care all over the world, Demant is active and engaged. Our innovative technologies and know-how help improve people's health and hearing. We create life-changing differences through hearing health.

Attachments

- [2021-13 Notification of voluntary field corrective action by cochlear implants business.pdf](#)