Statement of Issues

1 December 2022

Cochlear Limited – proposed acquisition of Oticon Medical A/S

Purpose

1. Cochlear Limited (**Cochlear**) proposes to acquire 100% of the shares in, and certain assets of, Demant A/S's (**Demant**) hearing implant division, Oticon Medical A/S (**Oticon Medical**) from Demant (the **proposed acquisition**).

2. This Statement of Issues:

   - gives the Australian Competition and Consumer Commission's (**ACCC**) preliminary views on competition issues arising from the proposed acquisition
   - identifies areas of further inquiry, and
   - invites interested parties to submit comments and information to assist our assessment of the issues.

3. Statements of Issues do not refer to confidential information provided by the parties or other market participants and therefore may not fully articulate the ACCC's preliminary position.

Overview of ACCC's preliminary views

4. In considering the proposed acquisition, the ACCC applies the legal test set out in section 50 of the *Competition and Consumer Act 2010* (the **CCA**). In general terms, section 50 prohibits acquisitions that would have the effect, or be likely to have the effect, of substantially lessening competition in any market.

5. The ACCC divides its preliminary views into three categories, 'issues of concern', 'issues that may raise concerns' and 'issues unlikely to raise concerns'. In this Statement of Issues there are three 'issues of concern' and one 'issue that may raise concerns'.

Issues of concern

Non-surgical bone conduction devices

6. The ACCC's preliminary view is that the proposed acquisition is likely to substantially lessen competition in the supply of non-surgical bone conduction devices in Australia. The ACCC is concerned that the acquisition would lead to higher prices, lower quality or service levels, and/or less innovation, research and development in the relevant market.

7. The proposed acquisition would remove Cochlear's closest competitor for the supply of non-surgical bone conduction devices. Med-El would be the only remaining competitor for the supply of non-surgical bone conduction devices. The ACCC's preliminary view is that Med-El is unlikely to provide a sufficient competitive constraint on a combined Cochlear-Oticon Medical. The ACCC also considers there are high barriers to entry and expansion and a low likelihood of new entry.

Surgical bone anchored devices

8. The ACCC's preliminary view is that the proposed acquisition is likely to substantially lessen competition in the supply of surgical bone anchored devices in Australia.

9. The proposed acquisition would result in a reduction in the number of suppliers of surgical bone anchored devices from three to two. The proposed acquisition would remove Oticon Medical as the only other supplier of percutaneous surgical bone anchored devices and as a potential competitor to Cochlear and Med-El in the supply of transcutaneous surgical bone anchored devices. The ACCC is concerned this would lead to lower quality or service levels, and/or less innovation, research and development in the relevant market and may lead to higher prices.

Reduced innovation in hearing loss technology

10. The ACCC's preliminary view is that the proposed acquisition is likely to reduce competition with the effect of lessening innovation, research and development in hearing loss technology and devices. A reduction in innovation would significantly impact the timeliness, choice and/or quality of devices and technologies available to those with hearing loss in the future.

Issue that may raise concerns

Cochlear implants

11. The ACCC's preliminary view is that the proposed acquisition may substantially lessen competition in the supply of cochlear implants in Australia. The proposed acquisition would further increase Cochlear's large presence in the already highly concentrated market for the supply of cochlear implants. The ACCC is concerned that the proposed acquisition may increase Cochlear's ability to profitably decrease quality or service levels and/or reduce incentives to innovate or invest in research and development for cochlear implants. The ACCC is also considering whether the proposed acquisition may lead to higher prices for cochlear implants in the long term.

Making a submission

12. The ACCC invites submissions from interested parties.

13. Interested parties should provide submissions by 5pm on 22 December 2022. Responses may be emailed to mergers@accc.gov.au with the title: Submission re: Cochlear/Oticon Medical – attention Annabel Garrard / Marisa Kuhlewein. If you would like to discuss the matter with ACCC staff or have any questions about this Statement of Issues, please contact Annabel Garrard on (02) 9102 4028 or Marisa Kuhlewein on (07) 3835 4668.

14. The ACCC anticipates making a final decision on 16 March 2023, however, this timeline can change. To keep up with possible timing changes and to find relevant documents, interested parties should visit the Mergers Register on the ACCC's website at https://www.accc.gov.au/public-registers/mergers-registers/public-informal-merger-reviews.

Confidentiality of submissions

15. The ACCC will not publish submissions regarding the proposed acquisition. We will not disclose submissions to third parties (except our advisors/consultants) unless compelled by law (for example, under freedom of information legislation or during court proceedings) or in accordance with s155AAA of the CCA. Where the ACCC is required to disclose confidential information, the ACCC will notify you in advance where possible so that you may have an opportunity to be heard. Therefore, please identify any confidential information that is provided to the ACCC. Our *Informal Merger Review Process Guidelines* contain more information on confidentiality.

About ACCC 'Statements of Issues'

16. A Statement of Issues is not a final decision about a proposed acquisition. A Statement of Issues outlines the ACCC's preliminary views and identifies further lines of inquiry.

17. A Statement of Issues provides an opportunity for all interested parties (including customers, competitors, shareholders and other stakeholders) to ascertain and consider the primary issues identified by the ACCC. It is also intended to provide the merger parties and other interested parties with the basis for making further submissions should they consider it necessary.

Industry background

18. Hearing aids, non-surgical bone conduction devices, surgical bone anchored devices and cochlear implants are all used to treat varying degrees of hearing loss. Less severe hearing loss can be treated with hearing aids, while patients with more severe conductive hearing loss, or damage to the outer or middle ear, typically use non-surgical bone conduction devices or surgical bone anchored devices. Cochlear implants are typically used by patients with severe or profound sensorineural hearing loss.

Non-surgical bone conduction devices

19. Non-surgical bone conduction devices consist of an external sound processor (with a transducer) attached to an adjustable head band or fixed to a patient's skin behind the

ear. Sound vibrations can be transferred through the skin to the skull and then the cochlea without an implant. These devices are primarily used by children who are not old enough for a surgically implanted bone anchored device, or for adults or children who have fluctuating degrees of hearing loss.

20. The ACCC estimates that approximately 1,500 non-surgical bone conduction devices are supplied to patients in Australia each year.

Surgical bone anchored devices

21. Surgical bone anchored devices have an external sound processor and a surgically implanted fixture placed in the mastoid bone behind the ear. The ACCC understands that there are two key types of surgically implanted bone anchored devices:

    - Percutaneous: this device has an abutment protruding the skin, to which a sound processor is attached. These solutions are classified as 'passive' because the transducer is located outside the skin.

    - Transcutaneous: this device typically features magnets rather than a skin-penetrating abutment. These solutions may be 'passive' (transducer is held outside the body) or 'active' (transducer is under the skin).

22. The ACCC estimates that fewer than 500 surgical bone anchored devices are supplied to patients in Australia each year. Surgical bone anchored devices are listed on the Australian Government Department of Health and Aged Care Prostheses List (the **Prostheses List**). The ACCC understands that these devices typically cost in the order of AUD$10,000 per implant system.

Cochlear implants

23. Cochlear implants[1] feature an external portion that sits behind the ear consisting of a microphone and sound processor, and an internal portion that is surgically implanted and consists of a transmitter and receiver/stimulator. The transmitter receives signals from the sound processor and sends them to electrodes implanted inside the inner ear (the cochlea). The ACCC estimates that approximately 1,500 cochlear implants are supplied to patients in Australia each year. Cochlear implants are listed on the Prostheses List. The ACCC understands that these devices typically cost in the order of $AUD25,000 per implant system.

Prostheses List

24. The Prostheses List[2] is a Schedule to the *Private Health Insurance (Prostheses) Rules* (**Prostheses Rules**). The Prostheses Rules is a legislative instrument made under the *Private Health Insurance Act 2007* (Cth) The Prostheses List establishes the minimum benefit that private health insurers are required to pay (typically to a hospital) when a policyholder receives a listed device as part of hospital or substitute treatment and has the relevant private insurance coverage. The Prostheses List is administered by the Australian Government Department of Health and Aged Care on behalf of the Minister for Health and Aged Care. The Department, acting on the advice of the Prostheses List Advisory Committee, assesses applications for the listing of devices, decides

[1] The ACCC understands that Cochlear first developed and was granted a patent for the 'Cochlear Implant Device', which ended in 2012. The term 'cochlear device' is now used to describe the devices used to treat severe hearing loss, affecting the cochlea (part of the inner ear).
[2] https://www.health.gov.au/resources/publications/prostheses-list.

whether a device falls within an existing category or should be separately listed, and sets the benefit amount payable.

25. Surgical bone anchored devices and cochlear implants are listed on Part A of the Prostheses List while non-surgical bone conduction devices are not listed on the Prostheses List. The ACCC is considering how the Prostheses List impacts competition, including price competition, for surgical bone anchored devices and cochlear implants supplied to patients with and without private health insurance.

26. The ACCC's preliminary view is that the benefits listed on the Prostheses List:

    - set the minimum benefit payable by private insurers for their members that undergo surgery to receive a bone anchored device or cochlear implant in a private hospital or clinic, and

    - may be used as a reference price in negotiations between manufacturers and public hospitals for the supply of non-surgical bone conduction devices, surgical bone anchored devices and cochlear implants.

The parties

Cochlear

27. Cochlear is a public company listed on the ASX (ASX:COH), with global headquarters at Macquarie University, Sydney. In Australia, Cochlear designs, manufactures and supplies cochlear implants, non-surgical bone conduction devices and surgical bone anchored devices.

Oticon Medical

28. Oticon Medical is a subsidiary of Demant, a publicly listed company on the Danish stock exchange (CPH:DEMANT) and global manufacturer and supplier of various hearing solutions. Oticon Medical is a manufacturer and supplier of cochlear implants, non-surgical bone conduction devices and surgical bone anchored devices globally, including in Australia.

Other industry participants

Med-El

29. Med-El is an Austrian-based, privately-owned medical technology company. Med-El manufactures and supplies cochlear implants, non-surgical bone conduction devices and surgical bone anchored devices globally, including in Australia.

Sonova

30. Sonova Holding AG (**Sonova**) is a Swiss-headquartered global hearing care solutions provider. In Australia, Sonova supplies cochlear implants under the brand Advanced Bionics Australia (**Advanced Bionics**). Sonova does not currently manufacture or supply non-surgical bone conduction devices or surgical bone anchored devices globally, or in Australia.

Relevant hearing devices

31. Cochlear and Oticon Medical directly overlap in the manufacture and supply of cochlear implants, non-surgical bone conduction devices, and surgical bone anchored devices. **Table 1** below provides an overview of devices offered by the only suppliers of these devices and implants in Australia.

Table 1: Overview of relevant Cochlear, Oticon Medical, Med-El and Sonova devices

	Cochlear	Oticon Medical	Med-El	Sonova (Advanced Bionics)
Non-surgical bone conduction devices *(not on the Prostheses List)*	Baha Softband: adjustable latex-free band worn around the head with a Baha brand of sound processor attached. Baha SoundArc: behind-the-head band with a Baha brand of sound processor attached to connector disc	Ponto Softband: adjustable latex-free band worn around the head with a Ponto brand of sound processor attached.	ADHEAR: adhesive sticker used to keep the sound processor in place	N/A
Surgical bone anchored devices *(on the Prostheses List)*	Baha Attract: a passive transcutaneous system Baha Connect: a passive percutaneous system Osia: an active transcutaneous system	Ponto: a passive percutaneous system	Bonebridge: an active transcutaneous system	N/A
Cochlear implants *(on the Prostheses List)*	Implants and sound processors under the 'Nucleus' brand including the 'Nucleus Profile Plus' implant and Nucleus 7 and Nucleus Kanso sound processors.	Implants under the 'Neuro Zti' brand and sound processors under the 'Neuro' brand.	Implants under the 'Synchrony' brand and sound processors under the 'Rondo' and 'Sonnet' brands	Implants under the 'HiRes' brand and sound processors under the 'Nadia' and 'Marvel' brands

The proposed transaction

32. On 27 April 2022, Cochlear announced its intention to acquire 100% of the shares in and certain assets of Demant's hearing implant division, Oticon Medical, for consideration of approximately AUD$170 million. This is a global transaction and is being considered by competition authorities in other jurisdictions.

Future with and without the acquisition

33. In assessing a proposed acquisition under section 50 of the CCA, the ACCC considers the effects of the proposed acquisition by comparing the likely future state of competition if the proposed acquisition proceeds (the 'with' position) to the likely future state of competition if the proposed acquisition does not proceed (the 'without' position) to determine whether the proposed acquisition is likely to substantially lessen competition in any relevant market.

34. On 27 April 2022 (updated 15 November 2022), Demant announced it had decided to discontinue its hearing implants business and intended to sell Oticon Medical to Cochlear. Demant has stated that Oticon Medical is continuing its bone anchored hearing systems operations as normal while for cochlear implants it will put its efforts into supporting existing patients.[3]

35. The ACCC is considering the likely future absent the proposed acquisition, including:

    - whether Oticon Medical would continue to independently compete against Cochlear or whether Demant would sell the business (or part thereof) to an alternative purchaser, and

    - if Oticon Medical were to exit what would be likely to happen to Oticon Medical's assets (including its intellectual property and manufacturing and research and development facilities).

36. The ACCC has heard concerns Oticon Medical's existing customers may not receive ongoing support for their devices if the transaction does not proceed. The ACCC's preliminary view is that such concerns, while important, are unlikely to form part of the competition assessment as required by the Act.

Market definition

37. As stated in the ACCC's *Merger Guidelines*, the ACCC's starting point for defining relevant markets to assess the competitive effects of the proposed acquisition involves identifying the products actually or potentially supplied by the merger parties.[4] The ACCC then considers what other products constitute sufficiently close substitutes to provide a significant source of constraint on the combined Cochlear-Oticon Medical.

38. The ACCC's preliminary view is that the markets below are appropriate for considering the effect of the proposed acquisition on competition in Australia. There are a broad range of treatment options available to consumers with hearing loss, including various devices and reconstructive surgery. Consumer choices will depend on a range of factors, including the nature and extent of their hearing loss.

39. The supply or potential supply of cochlear implants, non-surgical bone conduction devices and surgical bone anchored devices is the area of overlap between the parties and therefore the starting point for the ACCC's analysis. Other hearing loss treatments, including hearing aids, while options available to customers and potential substitutes for some consumers, are unlikely to be relevant to identifying the relevant markets for assessing this transaction.

40. The ACCC understands that Cochlear and Oticon Medical are also both active in researching and developing future technologies and therefore the loss of rivalry may impact future competition for the supply of hearing loss technologies and devices more broadly.

[3] https://www.oticonmedical.com/au/about-oticon-medical/latest-news/corporate-news-articles/2022/disinvest-oticon-medical
[4] ACCC, *Merger Guidelines 2008* (updated 2017), paragraph 5.17.

41. The ACCC's preliminary view is that the relevant markets are likely to be:

    - a national market for the supply of non-surgical bone conduction devices
    - a national market for the supply of surgical bone anchored devices (noting that the ACCC is also further considering whether there are two separate markets in this category, one for *transcutaneous* surgical bone anchored devices and one for *percutaneous* surgical bone anchored devices), and
    - a national market for the supply of cochlear implants

Non-surgical bone conduction devices

42. The ACCC's preliminary view is that it is appropriate to consider non-surgical bone conduction devices in a distinct market from surgical bone conduction devices.

43. The ACCC understands non-surgical bone conduction devices are typically only used for patients where a surgical bone anchored device is not suitable due to factors such as the patient's age or anatomy. Cochlear implants are also not considered suitable to treat the type of hearing loss treated by non-surgical bone conduction devices.

44. The ACCC is considering whether there may be asymmetric supply-side substitution between surgical bone anchored devices and non-surgical bone conduction devices. The ACCC understands these devices may share a common sound processor.

Surgical bone anchored devices

45. Market feedback indicates that patients suitable for surgical bone anchored devices typically do not view non-surgical bone conduction devices as viable substitutes. Market participants consider non-surgical bone conduction devices less effective at correcting hearing loss than surgical bone anchored devices. Cochlear implants are also not typically suitable to treat the type of hearing loss treated by surgical bone anchored devices.

46. Within surgical bone anchored devices, the ACCC is considering the degree of substitutability between transcutaneous and percutaneous devices. It may be appropriate to consider these devices in distinct markets. For example, the ACCC will consider whether there are certain patients for whom only a percutaneous or only a transcutaneous device is suitable. Some market participants submitted that percutaneous devices treat a larger range of hearing loss.

Cochlear implants

47. Market feedback indicates there is very limited demand side substitution between cochlear implants and non-surgical bone conduction devices or surgical bone anchored devices.

48. Cochlear implants treat the most severe forms of sensorineural hearing loss, which non-surgical bone conduction and surgical bone anchored devices cannot.

The ACCC invites comments from market participants on its preliminary views about the definition of the relevant market(s). In particular:

- Are hearing aids close substitutes for non-surgical bone conduction devices, surgical bone anchored devices and/or cochlear implants? Can hearing aids be used in place of

these devices and vice versa? Please explain the circumstances in which hearing aids might be used instead of these devices.

- Are surgical bone anchored devices and non-surgical bone conduction devices close substitutes? Can surgical bone anchored devices be used in place of non-surgical bone conduction devices and vice versa? Please explain how.
- What factors influence the choice of surgical bone anchored devices?
- Are percutaneous and transcutaneous surgical bone anchored devices close substitutes? Is there a subset of patients for whom only a percutaneous bone anchored device or only a transcutaneous bone anchored device is suitable? If so, please explain why.
- What are the costs (or ease to which) suppliers can switch between the manufacture and supply of surgical bone anchored devices and non-surgical bone conduction devices?
- What are the costs (or ease to which) suppliers can switch between the manufacture and supply of percutaneous and transcutaneous surgical bone anchored devices?
- What is innovation and research and development focused on in the hearing loss industry (such as a new device or a type of hearing loss) now and in future? How easy or difficult would it be for current or potential suppliers to invest in research and development for certain hearing loss technologies?

Barriers to entry and expansion

49. The ACCC is considering the height of barriers to entry and expansion and the likelihood of a potential entrant entering in a timely and sufficient way in the relevant market/s.

50. Market feedback indicates that barriers to entry and expansion in the supply of non-surgical bone conduction devices, surgical bone anchored devices and cochlear implants are likely high. Specifically:

    - there are significant costs for product research and development
    - there are complex regulatory approvals required to deliver a product to market
    - having a trusted brand, experience and reputation in the industry is important to customers, including surgeons that recommend these devices to patients
    - there are economies of scale and scope associated with developing, manufacturing, and supplying various hearing devices that may limit the viability of entry without an established position in a related market.

51. Market feedback indicates there has not been any recent new entry into the supply of non-surgical bone conduction devices, surgical bone anchored devices or cochlear implants in Australia.

52. Market participants noted that the most likely future suppliers of non-surgical bone conduction devices, surgical bone anchored devices and cochlear implants are those already present in the supply of other hearing devices. For example, Demant first supplied hearing aids before entering the supply of non-surgical bone conduction devices and surgical bone anchored devices under Oticon Medical.

53. The ACCC is also considering the extent to which there are other firms globally, that are not currently present in Australia, that could potentially enter the Australian market. This includes:

    - existing suppliers operating in other countries such as US-based manufacturer of bone conduction solutions, Medtronic and China-based manufacturer of cochlear implants Nurotron Biotechnology Co. Ltd, and

    - firms that have products in development such as Australia-based medical start-up, Hemideina and US-based Envoy Medical, both of which have announced they are developing cochlear implant systems.

54. The ACCC's preliminary view is that Cochlear would not be competitively constrained by the threat of new entry in any relevant market post-acquisition.

The ACCC invites comments from market participants on its preliminary views about the existence and height of barriers to entry and/or expansion. In particular:

- What are your views on the significance of, and the difficulty of overcoming, the abovementioned (or other) barriers to entry and expansion for the supply of non-surgical bone conduction devices, surgical bone anchored devices and cochlear implants?

- Do barriers to entry and expansion vary for the different product markets (including non-surgical bone conduction devices, surgical percutaneous and transcutaneous bone anchored devices, and cochlear implants)?

- Which companies not currently supplying non-surgical bone conduction devices, surgical bone anchored devices and/or cochlear implants in Australia could begin doing so and why? What steps would they need to take to be successful?

Issue of concern: non-surgical bone conduction devices

55. The proposed acquisition would remove Oticon Medical as Cochlear's only significant competitor for the supply of non-surgical bone conduction devices. It would significantly increase concentration, reducing the total number of suppliers of non-surgical bone conduction devices from three to two in Australia. Cochlear and Oticon Medical supply most of the non-surgical bone conduction devices in Australia.

56. The ACCC's preliminary view is that this is likely to substantially lessen competition in the supply of non-surgical bone conduction devices in Australia and is likely to lead to increased prices, lower service quality and/or reduced incentives to innovate.

57. Market feedback indicates that Cochlear and Oticon Medical's non-surgical bone conduction devices are very similar. Both devices use a processor affixed to headbands, use similar passive technology, and achieve similar audiological and patient outcomes.

58. Med-El is the only other supplier of non-surgical bone conduction devices in Australia. It launched its ADHEAR device in 2017 and accounts for a small proportion of the total sales of non-surgical bone conduction devices in Australia.

59. The Med-El ADHEAR uses an adhesive sticker to hold the processor in place (rather than a headband). Market feedback indicates that the ADHEAR corrects a smaller range of hearing loss than the Cochlear and Oticon Medical devices. Med-El alone is

unlikely to provide sufficient competitive constraint on the combined Cochlear-Oticon Medical to prevent a substantial lessening of competition.

60. The ACCC's preliminary view is that new entry or expansion is unlikely, given the abovementioned barriers to entry and expansion. The ACCC is unaware of any likely or potential entrants. Thus far, the ACCC has not seen indications of likely new entry or expansion in the near future. Market feedback also indicates the number of suppliers has decreased in recent years.

61. The ACCC is concerned that, irrespective of the precise market definition, the proposed acquisition would likely to lead to increased prices, decreased service quality and/or a reduced incentive to innovate and invest in research and development for non-surgical bone conduction devices in Australia.

The ACCC invites comments from market participants on its concerns in relation to non-surgical bone conduction devices. In particular:

- What type(s) of patient(s) use non-surgical bone conduction devices? How many patients are likely to require surgical bone anchored devices in future?
- What is the quality and price of Med-El's ADHEAR non-surgical bone conduction device compared to Cochlear and Oticon Medical's non-surgical bone conduction devices?
- How are prices determined for the acquisition of non-surgical bone conduction devices acquired from manufacturers? What are the ongoing associated costs?
- To what extent do non-surgical bone conduction devices rely on passive and/or percutaneous technology? Are non-surgical bone conduction devices likely to benefit from advances in active transcutaneous technology?

Issue of concern: surgical bone anchored devices

62. The proposed acquisition would result in a high degree of consolidation in the supply of surgical bone anchored devices, reducing the number of suppliers from three to two. Cochlear is the largest supplier of surgical bone anchored devices in Australia and the proposed acquisition would further increase its significant presence. The ACCC's preliminary view is that this consolidation is likely to substantially lessen competition in the supply of surgical bone anchored devices in Australia.

63. The ACCC estimates that the combined Cochlear-Oticon Medical would supply more than half of the surgical bone anchored devices in Australia.

64. Removing Oticon Medical as the only alternative supplier of percutaneous surgical bone anchored devices and as a potential supplier of transcutaneous surgical bone anchored devices, is likely to lead to decreased service quality and/or reduced incentives to innovate and may lead to increased prices.

65. Market feedback indicates that non-price factors, including reputation, service quality and innovation are important bases on which suppliers compete. As discussed at paragraph 71, the ACCC is particularly concerned about the potential chilling effect any consolidation may have on incentives to innovate and invest in research and development for hearing technology.

66. The ACCC is also investigating the impact of the Prostheses List on price competition, including the difference between pricing in public and private hospitals, and whether suppliers compete with respect to prices on the Prostheses List itself.

Cochlear and Oticon Medical are the only suppliers of percutaneous surgical bone anchored devices in Australia

67. Cochlear and Oticon Medical are the only suppliers of percutaneous surgical bone anchored devices in Australia. The ACCC is considering the extent of substitutability between transcutaneous and percutaneous surgical bone anchored devices and in particular, the extent to which Med-El (which only sells a transcutaneous surgical bone anchored device) would provide a competitive constraint on a combined Cochlear-Oticon Medical in the supply of surgical bone anchored devices.

68. Market feedback indicates that there may be a class of patients for whom only a percutaneous surgical bone anchored device is suitable. The ACCC is considering the size and scope of this patient class and the likely effect that removing Oticon Medical as the only alternative supplier of percutaneous surgical bone anchored devices may have on price and non-price outcomes.

Loss of potential competition for transcutaneous surgical bone anchored devices

69. Market feedback indicates transcutaneous devices are typically preferred where either a percutaneous or transcutaneous device may be suitable. This is due to the lower risk of infection and more discreet design.

70. Oticon Medical does not currently supply a transcutaneous surgical bone anchored device globally or in Australia. However, the ACCC is considering whether, in the future, absent the proposed acquisition, Oticon Medical is likely to enter the manufacture and supply of these devices. Oticon Medical has recently conducted clinical trials of an active transcutaneous surgical bone anchored device, which may indicate that Oticon Medical could commence supply of these devices in the near future if the proposed acquisition does not proceed.

The ACCC invites comments from market participants on its concerns in relation to surgical bone conduction devices. In particular:

- How closely does Med-El compete with Cochlear and Oticon Medical in the supply of surgical bone anchored devices? Consider factors such as price, quality service levels, functionality, reputation, innovation and research and development.
- How important will Oticon Medical likely be as a future supplier of surgical bone anchored devices? How likely is Oticon Medical to launch an active transcutaneous bone anchored device in Australia, in the absence of the proposed acquisition?
- Is Med-El likely to provide sufficient incentives for a combined Cochlear-Oticon Medical to continue innovating and investing in research and development for surgical bone anchored devices? Would a combined Cochlear-Oticon Medical have sufficient incentives to continue to invest in and innovate its percutaneous technology?
- What role does the Prostheses List play in price competition for the acquisition of surgical bone anchored devices from manufacturers? Does this differ between private and public hospital systems, if so, how?

Issue of concern: reduced innovation in hearing loss technology

71. The ACCC has preliminary concerns that the proposed acquisition would reduce competition, with the effect of lessening innovation in hearing loss technology and devices. Market feedback indicates innovation is a significant basis on which suppliers compete for market share. The ACCC is concerned the proposed acquisition would remove Oticon Medical as a global innovator and also reduce or delay incentives for firms to invest in improving, updating and launching new products. Over the long term, this could ultimately mean lower product quality and reduced choice for patients globally and in Australia.

72. Firms have incentives to engage in research and development to protect their market share and to win share at the expense of competitors in the future.

73. The ACCC is considering what impact the removal of Oticon Medical would have on innovation for hearing loss technology and devices. Importantly, the ACCC is considering whether the effect is likely to amount to a substantial lessening of competition. In doing so, the ACCC is considering both the number of innovators with and without the proposed acquisition. More competitors engaged in innovation leads to a higher probability of successful new innovations coming to market and stronger incentives to innovate.

74. The extent and quality of each firm's contribution to innovation is also a relevant factor and the levels of investment will be influenced by the extent of competition in the industry. Market feedback indicates that Oticon Medical may be particularly innovative in the development of bone conduction technology for both non-surgical and surgical applications. Oticon Medical currently has a smaller presence in the manufacture and supply of cochlear implants, and may also have a smaller impact with respect to innovation for cochlear implants than it does for bone conduction devices.

75. The ACCC understands decisions to invest in product innovation are made at the global level, taking into account the full range of competitors suppliers face, or may face, across the different markets in which they compete or are likely to compete. With this in mind, the ACCC is considering whether existing established firms (such as Med-El and Sonova), as well as emerging and/or potential future firms in the industry, are likely to provide a combined Cochlear-Oticon Medical with sufficient incentives to continue to innovate as would have occurred absent the proposed acquisition.

76. In addition to research and development activities undertaken "in house" by firms active in the manufacture and supply of hearing devices, the ACCC understands that there may be additional firms (and individuals) that undertake research and development in hearing loss technologies and innovation. The ACCC is considering the contribution these organisations make to innovation and how their innovations are commercialised.

77. Market feedback indicates there may be research and development occurring that is common or applicable across a broad range of devices in the hearing loss industry. This appears more likely the case with respect to processors than with respect to implants.

78. The ACCC will continue to investigate the likely effect of the proposed acquisition on global innovation in the development, manufacture and supply of hearing loss technologies and how this might affect patients in Australia.

The ACCC invites comments from market participants on its concerns in relation to a potential reduced innovation in hearing loss technology. In particular:

- Is Oticon Medical a particularly innovative provider of hearing loss technology and/or devices? Are there any examples of past or anticipated significant innovations from Oticon Medical?
- Describe the different types of intellectual property relied upon when developing cochlear implants and bone conduction devices. Are there any patents or other intellectual property that are particularly important to the development, manufacture and development of these devices?
- Will the presence of other firms such as Sonova and Med-El sufficiently drive innovation for hearing technology and devices? Are there particular devices or technologies that these firms are innovative in, or are likely to be in the future?
- To what extent do you consider Cochlear and Oticon Medical compete against each other to develop new technology to treat hearing loss? How does this compare to other companies involved in hearing loss research and development?
- What other companies could begin (or expand into) research and development for technologies and devices to treat hearing loss? Is there any benefit to already being in the hearing industry? For example, what is the likelihood a hearing aid company could invest further in research and development and compete with a combined Cochlear-Oticon Medical on innovation?
- What factors influence firms' decisions to invest in hearing loss research and development?
- If the acquisition proceeds, do you expect the rate at which new hearing loss technology is developed to change? Please explain how.
- Does the proposed acquisition raise any Australia-specific issues relevant to innovation in hearing loss technology?

Issue that may raise concerns: cochlear implants

79. Cochlear is by far the largest manufacturer and supplier of cochlear implants in Australia and globally. Oticon Medical, although much smaller, is one of only three competitors to Cochlear in Australia. The ACCC's preliminary view is that the proposed acquisition may substantially lessen competition in the supply of cochlear implants by removing one of the few constraints on Cochlear. This may lead to increased prices, decreased service quality and/or reduced incentives to innovate.

80. Cochlear commercialised the first multi-channel cochlear implant in 1985 and is the largest developer, manufacturer, and supplier of cochlear implants globally. Cochlear has a dominant position in cochlear implants and accounts for most cochlear implant sales in Australia.

81. As stated in the ACCC's *Merger Guidelines,* while some firms may be relatively small in terms of size and market share, they may nevertheless have a significant influence on the competitiveness of the market. Mergers involving such firms may result in

unilateral effects by impeding or removing significant aspects of competition, such as innovation or product development.[5]

82. Oticon Medical entered the supply of cochlear implants in 2013. Market feedback indicates that Oticon Medical is a smaller manufacturer and supplier of cochlear implants in Australia. Its sales may have been adversely affected by an October 2021 product recall and temporary halt in new sales of its Neuro Zti brand of cochlear implants.[6] Nevertheless, the ACCC is considering whether Oticon Medical may provide an important competitive constraint both now and in the future, including on innovation and research and development.

83. The ACCC is also considering the extent of the competitive constraint from the remaining suppliers, Med-El and Sonova. Both companies currently have low sales volumes in Australia, but are the second and third largest competitors to Cochlear globally.

84. The ACCC is considering the potential for either or both companies to expand Australian sales. To the extent Med-El and/or Sonova have a larger presence in overseas jurisdictions the ACCC will consider whether this may assist expansion in Australia given economies of scale and the global nature of research and development and production supply-chains for these devices.

The ACCC invites comments from market participants on its concerns in relation to cochlear implants. In particular:

- How important will Oticon Medical likely be in the future as a supplier of cochlear implants, if the proposed acquisition does not proceed?
- Has Oticon Medical demonstrated a greater degree of innovation and investment in research and development for cochlear implants (relative to other suppliers)?
- How closely do Med-El and Sonova (Advanced Bionics) compete with Cochlear in the supply of cochlear implants? Consider factors such as price, quality, service levels, functionality, innovation, and research and development.
- What role does the Prostheses List play in price competition for the supply of cochlear implants by manufacturers? Does this differ between private and public hospital systems or other channels of supply, if so, how?
- Has Oticon Medical's 2021 recall of its Neuro Zti cochlear devices impacted its ability to compete at present for sales of its cochlear implants? Has it had any impact of Oticon Medical's reputation? How common are recalls in the supply of cochlear implants, and other hearing technologies?

ACCC's future steps

85. As noted above, the ACCC invites submissions from market participants on each of the issues identified in this Statement of Issues and on any other issue that may be relevant to the ACCC's assessment of this matter. Submissions should be emailed to mergers@accc.gov.au by no later than 22 December 2022.

[5] ACCC, *Merger Guidelines 2008* (updated 2017), paragraph 5.11.
[6] https://www.productsafety.gov.au/recalls/oticon-medical-a-division-of-audmet-australia-pty-ltd-%E2%80%94-the-neuro-zti-evo-and-cla-cochlear-implants

86. The ACCC will finalise its view on this matter after it considers submissions invited by this Statement of Issues.

87. The ACCC intends to publicly announce its final view by 16 March 2023. However, the anticipated timeline may change in line with the *Informal Merger Review Process Guidelines*. A Public Competition Assessment explaining the ACCC's final view may be published following the ACCC's public announcement.