

Cochlear Limited

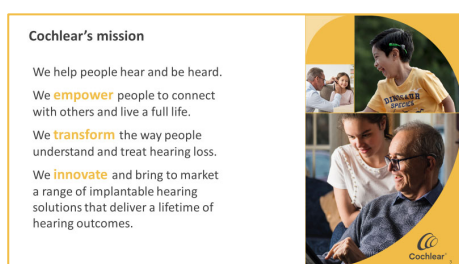
2020 Annual General Meeting

Chairman & CEO & President's Address

20 October 2020

Rick Holliday-Smith – Chairman

Ladies and gentlemen...



I will start today with **Cochlear's mission**. It is what drives the organisation and focuses the strategy. It has always been important, but never more so than now as we navigate COVID-19. I believe it kept us focused on our customers, on building awareness, and on our continued effort to strengthen our product portfolio.

The last year has been challenging for us. After a reasonable start to FY20, the impact of COVID-19 in the second half was substantial, involving the rapid deferral of cochlear implant surgeries across the world. As a result, underlying net profit declined by 42% for the full year. Then, after factoring in the patent litigation expenses, Cochlear recorded a net loss of \$238.3 million.

This **adverse litigation outcome** was the material driver of this loss. In March, the US Court of Appeals affirmed the US District Court award of patent infringement damages against Cochlear in this long-running lawsuit. Cochlear was ordered to pay US\$280 million in damages and post judgment interest.

The award related to one patent that has long expired. We believe the damages awarded were out of proportion with the limited application of the patented feature. While very disappointing, we acknowledge that inflated damages awards are a risk of patent disputes in the US. We have now lodged an appeal with the US Supreme Court against the Judgement, and we expect to know the outcome before the end of this financial year.

With the adverse litigation outcome occurring right as the global impact of COVID-19 was shutting down surgeries, we needed to respond quickly to ensure we remained strong. We **raised \$1.1 billion in capital** from shareholders in March and we expanded our debt facilities. These actions strengthened the balance sheet and our liquidity position, the goal being to ensure we could weather the expected extended business disruption caused by COVID-19.

Unlike so many other companies, we have a responsibility to be here for the next 100 years to support the children being implanted today with our devices and cannot put the financial security of our business at risk.

We raised this new capital at a time of extreme global market disruption and volatility, and we were one of the first to take decisive action. We saw this as a unique and dangerous market situation, and we adopted a conservative process that took as little risk as possible.

It was good that shareholders supported us, and we were pleased to see market conditions subsequently improve, although this was not clear at the time of our raise. In the months that followed we note that investors have been supportive of good companies with sound long term prospects.

Together with the capital raising we took the decision to preserve cash including the suspension of dividends until conditions improve. As a Board we are committed to paying dividends. We will resume them once we see a clear and sustained improvement in sales revenue and we are confident cash flow generation will be sufficient to support its resumption.

Cochlear is the global leader in implantable hearing solutions, and while COVID-19 has been incredibly disruptive, we have been clear from the outset that we want to emerge in a stronger competitive position. We are committed to supporting our recipients and the medical professionals we work with, and, just as importantly, to keeping our valuable workforce intact. At the same time, we committed to investing in our R&D programs as well as in our market growth activities.

I would like to take the opportunity to congratulate the Australian Government on its recent decision to revise the **R&D tax incentive**. The restructured incentive provides R&D intensive companies, like Cochlear, with a greater benefit from this tax incentive. This should be important in encouraging them to maintain, or increase, their Australian-based R&D activities.

These changes, combined with the recently announced Modern Manufacturing Initiative, have the potential to create the conditions needed in Australia to build, retain and attract medical innovation and advanced manufacturing.

Cochlear will reinvest any additional benefits from the R&D tax incentive into growing our business. In FY21 we will step up our R&D and market growth activities with the aim of emerging from COVID-19 in a stronger position. The CEO will provide more detail on our strategy and trading conditions shortly.



This last year has been important in achieving key milestones to deepen the penetration of cochlear implants in the adults and seniors segment of the global market. In August we saw the **publication of an independent global consensus on the use of a cochlear implant as the**

minimum standard of care for adults with bilateral severe, profound, or moderate sloping to profound hearing loss in a leading US medical journal (JAMA Otolaryngology).

We think this publication is an important step forward. It provides the foundation for the development of formal clinical practice guidelines. These guidelines will play an important role in building a clear and consistent referral path for those adults who would benefit more from cochlear implants than from hearing aids.

I'd now like to share a short video that captures the significance of this publication with the views of leading surgeons and clinicians in the field.

[International consensus paper video available at <https://adultheating.com/about/>]

The growing awareness of this need to treat severe age-related hearing loss with cochlear implants is supported by a better understanding of the **cost effectiveness of these implants for adults**. Payers are increasingly demanding cost-effectiveness data to support funding for health interventions. We believe Cochlear is well positioned with numerous studies demonstrating the cost related benefits of cochlear implants, for both children and adults.

The use of hearing aids and cochlear implants is clearly cost-effective and this has been proven in adults and seniors with an estimated return on investment of 10:1. Dementia and other cognitive decline diseases are some of the most expensive conditions to treat, costing an estimated US\$1 trillion globally in 2018, an estimate expected to double by 2030. Unfortunately, those with severe hearing loss are almost five times more likely to develop dementia than people without hearing loss.

Turning now to the important topic of **Board renewal**. Over recent years we have implemented a Board renewal process, adding several new directors with diverse backgrounds and relevant experience. We have sought to maintain a balance of continuity, and to introduce new skill sets. We are pleased with our recent appointments, with the new directors adding perspective and value to our Board discussions.

Two new directors join the Board this year, Michael Daniell, and Christine McLoughlin.

Michael was appointed in January and has worked in the medical device industry for over 40 years. He has extensive executive leadership experience and was Managing Director and CEO of Fisher & Paykel Healthcare from November 2001 to March 2016.

Christine will join in November and is a highly respected company director with domestic and international experience in financial and health services, and telecommunications. She is recognised for her achievements in driving continuous improvements in organisational culture and performance, and for her focus on creating value for shareholders by delivering for customers.

Long-serving director Donal O'Dwyer will retire from the Board at the end of this meeting. Donal has provided invaluable counsel during his 15 years on the Board. His extensive expertise in medical devices and healthcare, together with his significant global management experience, has contributed to Cochlear's performance and strategic direction. On behalf of the Board, I sincerely thank Donal for his service and contribution, and we all wish him well for the future.

Turning now to **diversity**. Our Diversity and Inclusion Framework was launched two years ago and is driving greater awareness across the organisation.

Achieving gender equality is one important element of this strategy. We strive for gender balance of 40:40:20, which means that 40-60 per cent of either gender is represented. While over 50% of Cochlear's employees are female, the representation of females reduces as the level of seniority increases.

We have set a target to achieve at least 40% female representation amongst our senior leaders within three years, up from 36% today. At Board level, we are targeting 30% female representation over the next two years, our board representation levels will be helped when Christine joins the Board in November.

Achievement of these targets is supported by focused activities in the areas of Talent Succession and Talent Acquisition, with the aim of increasing our pipeline of female talent. I think the current COVID-19 situation might increase the associated challenges we face, but we maintain our commitment.

Looking now to the future for Cochlear as we transition through the impact of COVID-19.

We need to consider the global environment and challenges carefully, and stay vigilant, but **we remain confident about our long-term opportunity**. There remains a significant unmet clinical need for cochlear and acoustic implants that should continue to underpin our long-term sustainable growth potential.

As we transition from the current health crisis to understanding the long-term economic impacts of the pandemic, we must focus on what may change in the hearing implant landscape. There will be opportunities and risks, so we need to be alert, fact driven and ready to adapt our strategy as is appropriate.

Front of mind is the debt burden that global economies will face particularly with increased competition for health funding. We expect payers to focus on health economics, including allocating spending to more cost-effective interventions, hopefully like cochlear implants.

The pandemic has driven the rapid adoption of tele-health and tele-medicine which should lead to faster structural changes in healthcare delivery.

We experienced this first-hand when the FDA fast-tracked the approval of our Remote Check solution in the US. Our professional partners have shown greater interest and demand for our connected care solutions, including Cochlear Link and Remote Programming.

We have invested in connected care solutions for many years. We believe they provide the opportunity to extend access to our products, and to optimise outcomes for our recipients, by transforming the care model, while at the same time delivering efficiencies to our associated clinical professionals.

We know there will be other risks that will confront us, so we need to stay alert. At the same time, we need to be carefully monitoring business performance and exercising sensible business judgment, especially in areas of long-term resource allocations, and in the shorter term by delivering fair executive remuneration outcomes.

Finally, I would like to acknowledge the **contribution of our 4,000 Cochlear employees**.

Their knowledge, expertise and passion are key to our future, and their continued focus on delivering excellence for our customers is important to our success, and to our market leadership position.

Our employees understand the importance of Cochlear being successful over the long-term so we can continue to support our customers, especially our recipients.

There are few companies that start a lifetime journey with each new recipient every day.

Our employees understood our recent actions, why we took the long term view we did, why we paid no incentives in 2020, and why we need to navigate to a more stable place as we better understand the impacts and challenges of COVID-19.

At the same time the Board understands the need to be fair with them as the current environment has seen many working much harder, and in unusual circumstances.

On behalf of the Board, I congratulate and thank all Cochlear employees for their outstanding efforts and contributions this past year.

In closing, the whole Cochlear team shares its sympathy with all those communities impacted by COVID-19. As the world responds to this pandemic, we remain committed to supporting our customers, employees, and communities to ensure that the important global work of delivering our hearing solutions continues.

Thank you and I will now hand over to our CEO & President, Dig Howitt.

Dig Howitt – CEO & President

Thank you Chairman and good morning...

I will touch on a few important topics today... our strategy, an update on trading since August and how we are stepping up some of our investments in FY21 to strengthen our competitive position.



Despite the difficult year, **our strategy remains unchanged**. We aim to *retain market leadership* with a strong product portfolio, supported by great field teams around the world whose presence with our professional partners and recipients, particularly over the last few months, has been noteworthy.

Cochlear's teams have remained focused on providing support to recipients, while continuing their outreach programs with candidates through the Company's direct-to-consumer marketing efforts. The rapid adoption of online and video conferencing tools with our professional partners, candidates and recipients is to be commended and has ensured that we can continue to provide valuable education and support throughout the pandemic

We know that to be successful over the longer-term, we need to invest to *grow the hearing implant market*. We invest in building awareness with candidates and professionals, in market access to broaden indications and funding, and in clinical evidence to support expanding access for hearing implants for people right around the world.

And while FY20 was financially challenging, we continue to aim – over the longer run – to *deliver consistent revenue and earnings growth*. We are a growth company that has, until FY20, been able to fund all of its investing activities, dividends, capital expenditure and acquisitions from cash flows, utilising only modest levels of debt. We are certainly targeting to return to that funding model.



The investment in R&D continues to strengthen our leadership position through the development of market-leading technology.

We have a wide range of fully-featured products and a broad patent portfolio that protects the Company’s intellectual property. Over \$2bn has been invested in R&D since listing with 14% of sales revenue invested in R&D in FY20.

Our implant portfolio is led by the Nucleus Profile Plus implant. Launched 15 months ago, it sets the benchmark in terms of size and reliability and is supported by a range of electrode options. It has been a key driver of market share gains made during FY20.

The Slim Modiolar Electrode has been in the market for a few years and there’s a growing body of data showing consistency of placement and improvements in hearing outcomes for recipients. We do believe that the future lies in getting electrodes closer to the auditory nerve to deliver better hearing outcomes, with perimodiolar electrodes now representing around 60% of our implant mix in markets where it is available.

The sound processors are a very important part of the portfolio and we lead in terms of size, connectivity and hearing performance.



The portfolio has been strengthened this year with seven important product approvals. You may recall me saying 18 months ago that we had a strong product pipeline. What you see here are the results of some of those products in that pipeline getting approval and coming to market.

The Osia 2 system has had a very strong reception from both patients and surgeons in the US over the last few months. The Slim 20 Electrode is rolling out now and is being well-received.

With the KANSO 2, both our behind-the-ear and off-the-ear processors have a full range of connectivity with Apple and Android devices, and that connectivity is an enabler of our growing connected care solutions.

The Remote Check Solution was approved this year and is rolling out around the world, making care easier and simpler and more convenient for our professional partners and recipients. And connected care solutions like Remote Check have the ability to lower the overall cost of care for payers and consumers.

We're also adding clinical and surgical tools for audiologists and surgeons to make their jobs easier with Nucleus SmartNav being able to provide the surgeon with more information on the electrode insertion. We know that there is a clear link between the electrode insertion and hearing outcomes.

A key strength of our market leadership is that we are able to innovate across all areas of the portfolio with meaningful benefits for our recipients and our professional partners, and that builds our relative competitive position.

You may recall that in August we advised that we will not be providing earnings guidance due to the difficulty in forecasting revenues with so much uncertainty surrounding the timing of a global recovery from the pandemic. Until we regain that confidence, we have committed to providing more regular trading updates to investors.

So how are we seeing **market conditions during the first quarter of FY21...**

For the first quarter (Q1) of FY21, cochlear implant revenue in constant currency (CC) was 94% of Q1 last year.

For the developed markets, cochlear implant unit volumes experienced low single-digit growth which we believe reflects a return to surgery, including new and rescheduled surgeries, and market share gains. Trading activity continues to be mixed with the US, Germany and Korea showing good growth on last year, while many European markets, including the UK, Italy and Spain, have been regaining momentum more recently as clinics re-open and surgical throughput grows.

The new candidate pipeline is rebuilding quickly with clinical assessments close to pre-COVID-19 levels in many markets and solid lead generation from Cochlear's direct-to-consumer activities.

While current developed market surgery momentum is positive, we caution that there is still risk, noting that second waves of COVID-19 cases are likely to remain a reality for some time and may result in new restrictions to elective surgery, complicating recovery plans and timing.

For the emerging markets, unit volumes for Q1 were down around 40% on Q1 last year. Surgeries in China are growing but most other countries remain well behind last year. There continues to be uncertainty over the time it will take for some emerging markets to recover.

Services revenue continues to recover with Q1 CC revenue at around 86% of Q1 last year. The launch of the Kanso 2 Sound Processor, the growing recipient base and the adoption of remote care tools are expected to underpin demand for upgrades.

Acoustic revenue run rates have also been improving since May with Q1 CC revenue at around 89% of Q1 last year. Acoustics revenue is largely generated from the US and the UK. Surgery volumes have been recovering in the US since May with strong demand for the Osia 2 System while acoustic implant surgeries only recommenced in the UK during the quarter.

Overall, we continue to be pleased with the pace of recovery across our developed markets. We have a suite of new products that are just starting to be launched and are generating excitement and great feedback.

One of the important deliberations for our leadership team and the Board has been **how much to invest in FY21** to drive future growth opportunities given the uncertainty we still see around near-term revenue generation.

We have taken the decision to invest this year to strengthen our competitive position and stimulate growth to set ourselves up for FY22 and beyond.

So we will continue to invest in R&D. We very clearly have a strong portfolio and continue to have a strong pipeline of products and services coming through that pipeline. With the rapid changes in the operating landscape during March to May, including clinic closures and access to telemedicine in some markets, we are scaling up our connected care efforts even more.

We will also continue investing in awareness and referral channels in developed markets. There are significant numbers of people with hearing loss that meet the indications for our products, but the awareness is still low, and the referral channels are not clear and consistent, so investing in both of these areas will continue. With the consensus paper now published, we have the platform to work with industry to drive the development of clinical practice guidelines. It makes sense to drive these investments while professional engagement is heightened.

We will continue to invest in our direct-to-consumer marketing programs around the world to build grass roots awareness with consumers.

In emerging markets our growth depends on building awareness and deepening our presence. We continued to expand our presence in emerging markets through FY20 and we will continue to do that in selected markets into FY21 and beyond because we know that putting people on the ground, building relationships, driving awareness, getting governments on board with supporting implants for children is a very, very important part of our growth.

Thank you, and I will pass back to the Chairman.