

ASX Market Announcements Office
ASX Limited
Level 4, North Tower, Rialto
525 Collins Street
Melbourne VIC 3000

27 September 2021

ANNUAL GENERAL MEETING ADDRESS BY THE MANAGING DIRECTOR AND CEO

Attached is a copy of the address to be given by the Managing Director and CEO at Dimerix Limited's Annual General Meeting today.

This announcement is authorised for release by the Board of the Company.



Hamish George
Company Secretary & CFO
Dimerix Limited

For personal use only

Meeting Transcript

Annual General Meeting of Dimerix Limited

CEO Address

2.00pm, Monday 27 September 2021 (Melbourne)

➤ **CEO & Managing Directors Address**



Thank you James, and good afternoon ladies and gentlemen. I trust that you all have had a chance to review the Company's Annual Report for 2021 and I would encourage all investors and shareholders to review this for full details of our Company's operational results and activities.

I will start with the review of our recent accomplishments and will follow that with a review of our current programs and strategy and finish with the highlights of our 2021 financial outcomes.

We have allowed some time for questions at the end of this presentation. You may submit questions at any time in writing via the Q&A function at the bottom of your screen, which may be moderated or amalgamated, and I will address them at the end of the presentation.

➤ **Slide 2 – Forward-looking statement**

Forward looking statements

This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Dimerix to be materially different from the statements in this presentation.

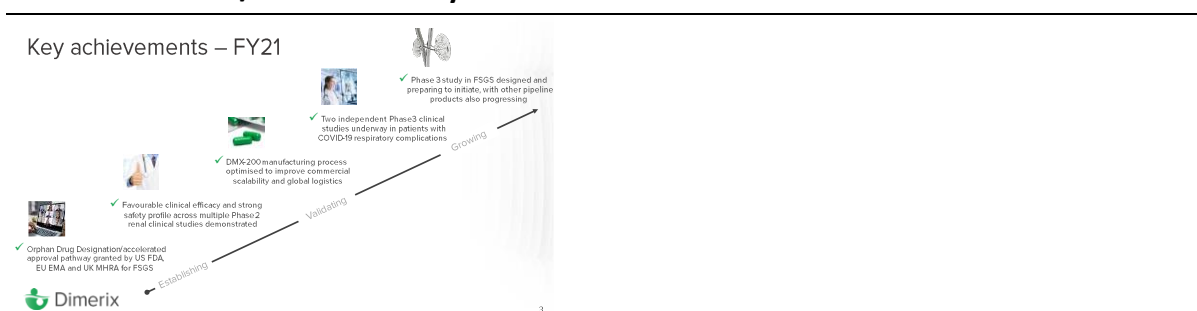
Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and effects of regulatory actions, the strength of competition, the outcome of legal proceedings and the effectiveness of patent protection.

I would like to formally note our Forward-Looking Statement caveat by stating that...

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➤ **Slide 3 – 2020/2021 financial year achievements**



Last year was pivotal for the future of Dimerix, as despite immense challenges to healthcare systems and society during the pandemic, we continued to deliver on our strategic goals. We are now extremely pleased to be entering a new chapter in the Dimerix story, as we progress, fully funded, to the final stages of development towards commercialisation.

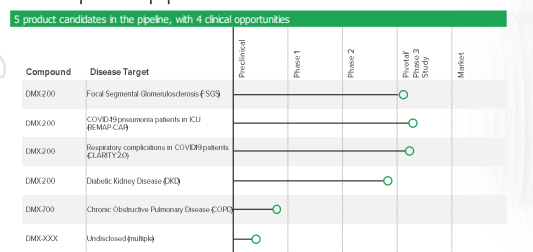
Whilst we expanded our programs to include supporting two global Phase 3 clinical studies, in an effort to develop a product that may help in the treatment of COVID-19 patients, we also remained focused on our renal portfolio, continuing to deliver on the two Phase 2 programs in 2020, and prepare for initiation of the Phase 3 study in patients with focal segmental glomerulosclerosis (FSGS) in 2021.

In addition to the two renal clinical studies that completed in 2020, we made significant progress in the broader development plans, including intellectual property strategy, commercial manufacturing supply, interaction with regulatory agencies in the US and Europe, quality oversight, analytical development and establishment of shelf-life for our lead product.

We faced a year of challenges and opportunities through the 2021 financial year. I am enormously proud of how adaptive and resilient our team was in the face of a global pandemic and am grateful for their unwavering commitment to deliver on strategy and further strengthen the pipeline.

➤ **Slide 4 – Development pipeline**

Development pipeline



Dimerix has continued to make solid progress against all of our near-term strategic priorities that we believe will enable us to achieve our corporate objectives.

Firstly, the Phase 3 study in patients with FSGS completed the first ethics submission in August, kicking off the formal activities that are required before recruitment can begin.

The REMAP-CAP COVID study is actively recruiting patients across Europe, and assuming recruitment rates continue to increase at the expected rate, it remains the target to recruit the final patients in Q4 2021.

I am pleased to report that, as announced on Friday 24th September, the CLARITY 2.0 study has now received the Indian regulatory approval recommendation, and having completed ethics approvals and site initiation, recruitment can begin imminently.

In addition to those near-term propositions, Dimerix also has 2 longer-term opportunities in diabetic kidney disease and chronic obstructive pulmonary disease (COPD).

Overall, we are well positioned to deliver a growing product portfolio and all with material commercial potential. Our development pipeline provides a solid basis, diversifying risk and of course potential sources of future revenue.

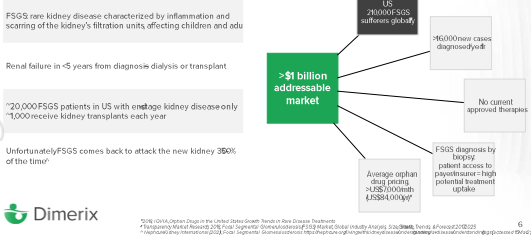
➤ **Slide 5 – Renal development overview**



Looking now to our renal program.

➤ **Slide 6 – FSGS market opportunity**

Why FSGS: unmet need and market potential



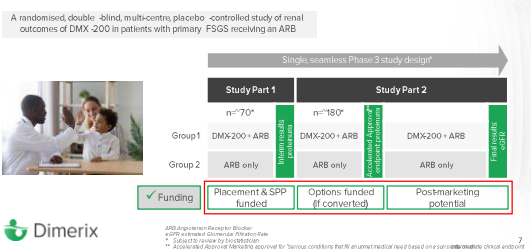
Our first renal candidate in Phase 3 development is for Focal Segmental Glomerulosclerosis, or FSGS. FSGS is an orphan indication, meaning it is a rare disease, that attacks the kidney's filtering units. It causes irreversible scarring which leads to permanent kidney damage, and eventually kidney failure, requiring dialysis or transplantation. Now, for those diagnosed with FSGS the prognosis is not good. The time from diagnosis to complete kidney failure is as short as 5 years, and sadly it affects children as young as 2 years old as well as adults. For those who are lucky enough to receive a kidney transplant, approximately 40% will get reoccurring FSGS in the transplanted kidney. The cause is unknown, but it does mean that these patients will ultimately end up on dialysis once again.

At this time, there are no drugs specifically approved for FSGS anywhere in the world, and the treatment options and prognosis remain poor. There are few other drugs in development for FSGS, with only a single (and potentially complimentary) molecule ahead of DMX-200 in its clinical trial. Thus, DMX-200 has the potential to be one of the first approved drug for FSGS.

With DMX-200 being a new chemical entity, and having secured orphan drug designation in key territories, the drug candidate may attract higher orphan drug pricing, which allows the developer to recoup development costs given the smaller number of patients. As an example, the average orphan drug in the US retails for approximately US\$7,000 per month. With over 80,000 patients diagnosed with FSGS in the US alone, the market is commercially attractive.

➤ Slide 7 – FSGS phase 3 study

FSGS phase 3 study primary endpoint



Following the successful Phase 2 data announced in 2020, we are now in the process of initiating the Phase 3 program in FSGS. The proposed single Phase 3 study has integrated 2 separate interim analysis points that measure protein in the urine (proteinuria), a surrogate

marker of kidney function, with the second analysis being the anticipated accelerated approval endpoint – at which time DMX-200 could potentially go to market.

Dimerix has had consistent and aligned feedback from several regulatory authorities on the Phase 3 study endpoints, including the European EMA and the US FDA. The agencies confirmation of proteinuria as an appropriate surrogate endpoint for accelerated approval, along with its relationship to kidney function, has been unanimous and unequivocal, and provides us confidence that a single study with the accelerated proteinuria endpoint is approvable upon appropriate successful study data.

We are delighted to now be in the position to execute on this study, with a potential funding pathway right through to accelerated marketing approval.

➤ **Slide 8 – COVID-19 respiratory complications**



Turning now to respiratory complications associated with COVID-19.

➤ **Slide 9 – Vaccines and antivirals**

Vaccines very important
but may not be sufficient to meet the virus challenges

DMX-200

- Company's approach to approach is based on a clear scientific rationale, unique & potentially complementary to others being investigated globally
- If effective could be equally effective against any strain as well as other pneumonias
- Could well provide an opportunity well beyond COVID-19

Vaccines

Significant proportion of population may still be susceptible to COVID because they are:

- resistant to the vaccine
- cannot be vaccinated or
- choose not to be vaccinated

Still likely that many patients will get infected and will end up with COVID respiratory complications and potentially long COVID symptoms that extend long beyond recovery from the virus

Antivirals

May require characterisation of specific anti-viral target to be effective and may be specific to only one type of virus or strain

Potential for side effects
Must be initiated immediately after infection timing of which can be difficult if patient is asymptomatic



As we are all acutely aware, COVID-19 can cause lung complications such as pneumonia and, in the most severe cases, acute respiratory distress syndrome (ARDS). In COVID pneumonia, the lungs become inflamed with infiltrating cells and fill with fluid - limiting their ability to take in oxygen and causing breathing difficulties.

Vaccines are critically important to reduce the severity of symptoms and spread of the disease. However, even as vaccination rates increase, it is anticipated that a significant proportion of the population will still be susceptible to COVID-19 because they are either resistant to the vaccine, cannot be vaccinated or choose not to be vaccinated. Therefore, it is still likely that many patients will get infected and will end up with COVID respiratory

complications and potentially long-COVID, which refers to symptoms that extend long beyond recovery from the virus. As such, there remains a great need for treatments for patients with COVID.

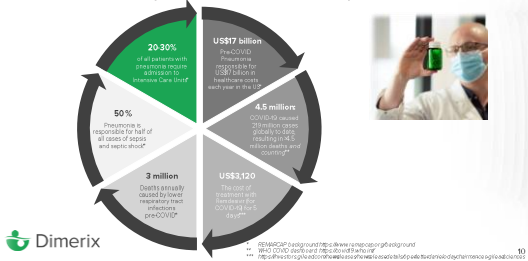
What is really important here is that the company's approach is based on a clear scientific rationale, is unique and potentially complementary to others being investigated globally.

DMX-200 may work by reducing the damage caused - by dialling down the immediate inflammatory response to the virus, and therefore preventing the cellular infiltration, flooding and lung damage. By limiting the inflammation and reducing the damage caused by the virus, DMX-200 may also reduce the severity and duration of those symptoms associated with COVID-19 disease, as well as potentially reducing the effect of long-COVID.

If DMX-200 is effective in these COVID-19 studies, it would likely be effective against other strains of the SARS-CoV2 virus as well as other causes of pneumonia with similar immune-mediated lung damage. Hence this could well provide an opportunity well beyond COVID-19.

➤ **Slide 10 – COVID and pneumonia market potential**

COVID-19 and pneumonia market potential



Turning now to the COVID and pneumonia market potential. Unfortunately, approximately ~15% of individuals with COVID-19 develop moderate to severe disease and require hospitalisation and oxygen support. Since early 2020, there have been more than 4.5 million deaths caused by respiratory complications associated with COVID-19. Even before COVID, there were 3 million deaths every year caused by non-COVID-19 pneumonias with 20-30% of all pneumonias requiring admission to an Intensive Care Unit.

There is still no specific antiviral treatment for COVID-19 infection, only supportive therapies including respiratory care for affected patients, especially in more severe cases. Interestingly, drug pricing of potential products in the ARDS and pneumonia field to date has been more in line with orphan drug pricing rather than typical branded product pricing. Needless to say, this is a commercially attractive market with a significant unmet need.

➤ Slide 11 –COVID-19 respiratory clinical studies

Two phase 3 studies in COVID-19 patients

REMAP-CAP

- >200 patients with COVID-19 pneumonia in ICU in Europe/UK
- WHO endorsed study
- Primary endpoint – 21 day mortality

CLARITY 2.0:

- >600 patients with COVID-19 respiratory complications in India
- Primary endpoint – 14 day WHO Clinical Health Score

Secondary endpoint: recovery and quality of life post hospitalisation (long-COVID assessment)



As a result of its mechanism of action, DMX-200 was invited into two different feasibility/Phase 3 studies in COVID-19 patients:

The first study, REMAP-CAP, is an investigator-led, global, WHO endorsed, study in patients with COVID-19 pneumonia, driven by a consortium of global trialists, clinicians and experts. The study has initiated a master protocol across over 300 clinical sites globally and has recruited over 7,000 patients with suspected or proven COVID-19 overall. The study domain which includes patients on DMX-200 as well as angiotensin receptor blockers and ACE inhibitors, is actively recruiting in both Europe and UK. Europe is bracing for an increase in case numbers and hospitalisations as winter and the colder weather approaches, which of course will influence recruitment rates. Recruitment milestones will be reported in due course.

REMAP-CAP is predominantly funded by the European Union through the H2020 European COVID-19 Emergency Research response. In addition, Dimerix was awarded \$1 million from the Australian Government’s Medical Research Future Fund to support inclusion of DMX-200 in this study.

In contrast to the REMAP-CAP study, which is in very sick patients in ICU, the second study, CLARITY 2.0 is another investigator-initiated study of DMX-200 but in patients with earlier stage COVID-19 complications. The primary endpoint is an 8-point clinical health score measured on treatment day 14. The clinical health score is adapted from the categorical scale recommended by the WHO for COVID-19 trials and ranks health states from being discharged, with no limitations, through to death. The CLARITY study is being run through the NHMRC Clinical Trials Centre at The University of Sydney and is currently active in India.

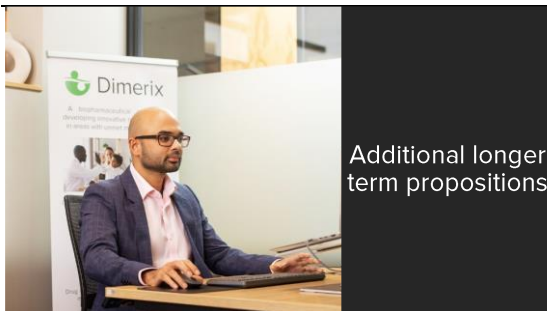
Whilst the initiation of this study was delayed significantly following the devastating impact of COVID-19 in India in April and May this year, we are very pleased to say that, as announced on Friday 24th September, the Indian regulatory agency, the Central Drugs Standard Control Organization (CDSCO), met on 2nd September 2021 to review the study protocol and has formally recommended that the DMX-200 clinical study in COVID-19 patients be approved.

Multiple clinical sites in India have been initiated and are ready to begin recruitment in the feasibility/Phase 3 clinical study of DMX-200 for the treatment of respiratory complications associated with COVID-19. A safety analysis will be conducted after the first 80 patients in the study, before seamlessly continuing to enrol the full 600 patients diagnosed with COVID-19.

In both studies, patients are also assessed at 26 weeks, to determine both the recovery and longer-term outcomes.

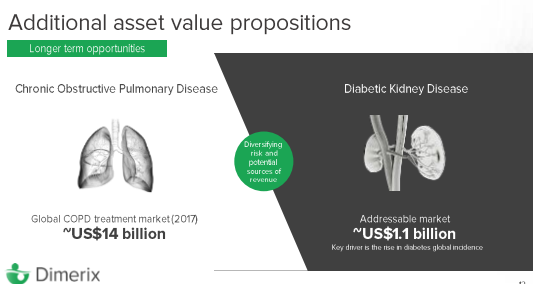
The scientific rationale for using DMX-200 in COVID related respiratory conditions is sound, and based on this rationale, we expect to see encouraging efficacy data in the two COVID studies. We recognise that, although we have completed four clinical studies in the renal space with promising efficacy outcomes, these are our first studies in any respiratory condition. Further, despite the similarities of the pathogenesis of the diseases, the two COVID studies are in very different cohorts of patients compared to renal disease. Even between the two COVID studies, we have two different cohorts, the REMAP-CAP study being in very sick patients in ICU, and the CLARITY study being in earlier stage complications. For these reasons, it is important to recognise that the data from one study will not necessarily be predictive of the outcome of the others.

➤ **Slide 12 – Additional longer term propositions**



Turning now to our two longer-term opportunities.

➤ **Slide 13– Additional asset value propositions**



In addition to the significant clinical advances we have made during the year in our near-term opportunities, we have also continued to make progress on our longer-term opportunities in diabetic kidney disease and in chronic obstructive pulmonary disease, or COPD.

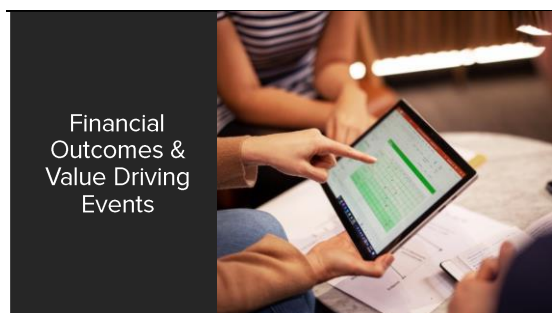
The results of our Phase 2 study in diabetic kidney disease were reported in the 2021 financial year, with 30% of all participants falling below the threshold for diabetic kidney disease diagnosis by the end of the study, and that number being 50% of those with a slightly lower starting baseline - which is a fantastic outcome for those patients! It was also noted that protein levels in the urine appeared to be continuing to trend downwards at the end of both DMX-200 treatment periods, which also indicated that a longer study treatment duration was warranted. We are assessing the next study design in diabetic kidney disease patients.

With regards to timing of such a study, it is worth noting two things: first, diabetic kidney disease is clearly not an orphan indication and not eligible for accelerated approval, thus the development pathway was always naturally 3 to 4 years behind FSGS; and second, despite data being consistent across all kidney studies we have conducted to date, FSGS patients are quite different from diabetic kidney disease patients, so, again, one is not necessarily predictive of the other.

Looking at chronic obstructive pulmonary disease, COPD is the third-leading cause of death in the world, and although treatments exist to improve the symptoms of COPD, there is currently no way to slow progression of the condition or cure it. In 2020, approximately 10% of the adult population were reported to suffer from COPD, and it was estimated that over 3 million deaths were caused by the disease in 2019, which equates to 6% of all deaths globally in that year.

During the 2021 financial year, we announced further in-vitro data on the DMX-700 program in COPD. The final pharmacological studies will lead to initiation of the pre-clinical model expected in the current financial year, which will help determine the dosing required for the clinical study. Again, we look forward to reporting on this in due course.

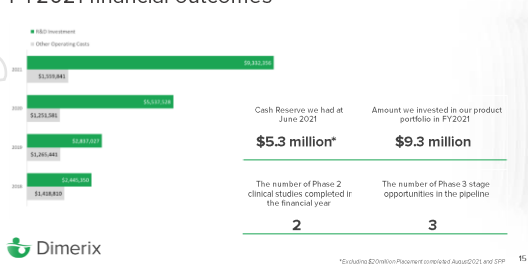
➤ **Slide 14 – Financial outcomes and value driving events**



Turning now to our 2021 financial outcomes and key value drivers

➤ **Slide 15 – Financial outcomes**

FY2021 financial outcomes



Over the past few years, Dimerix has consistently increased its R&D activities whilst simultaneously keeping overheads at a minimum, and the company finished the year under budget. Prudent cost management remains a key priority for the business, with the cost base being carefully managed to ensure delivery of a sustainable business beyond the current milestones.

In summary, the results for the financial year are as follows:

- Research and Development Investment costs of \$9.3 million, up 68% from 2020
- Corporate and administration expenses of \$1.6 million, maintained from 2020
- Net Loss After Tax of \$6.4 million driven by increased R&D costs
- Cash Reserves at the end of period was \$5.3 million down from \$7.8 million on 30 June 2020

I am really pleased to say that all three of our near-term opportunities are now funded.

Aside from the two COVID studies that were already funded as I previously mentioned, in August, we completed a two-tranche placement with institutional, and sophisticated investors raising a total of A\$20 million. A Share Purchase Plan was also launched for a further \$2 million under the same terms as the placement, which will close tomorrow, being 28th September 2021.








This is transformational for the company, as proceeds from the raise should fund the FSGS kidney Phase 3 program right through to first interim analysis point, or Part 1 of the study. And with the attaching options issued as part of the placement and SPP, which may expire approximately 4 weeks after that first interim data read-out, we anticipate that with positive data, we may have sufficient capital to fund the Phase 3 program through to potential accelerated marketing approval.

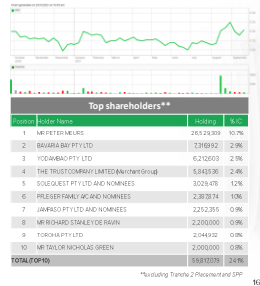
Needless to say, I think this is very exciting for Dimerix and its shareholders.

➤ **Slide 16 – Corporate overview**

Dimerix Limited
27 September 2021 Annual General Meeting
CEO Address

Corporate overview

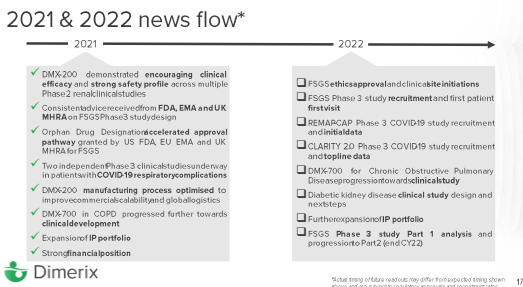
 Ticker Symbol	ASXDXB
 Share price	AS0.31
 Total ordinary shares on issue	248,499,122
 Market Capitalisation	AS77 million
 Average volume	934,479
 Cash Balance (30 Jun 21)	AS5.3 million*
 Top 20 Shareholders own	30.1%



As at the last market close, the company is trading at 31 cents per share. At the end of the June quarter, we had \$5.3 million in cash, and as I mentioned a moment ago, we announced the \$20 million Placement and \$2 million Share Purchase Plan in August. Assuming full subscription of the share purchase plan, this gives us a proforma balance of \$27.3 million, before costs.

There has been significant change in our share register as a result of the recent placement. The Top 10 listed on this slide do not include any shares to be issued in Tranche 2 of the placement or the share purchase plan, and thus is likely to change following issue of those shares.

➤ **Slide 17 – FY2022 news flow**



As you can imagine, with multiple Phase 3 studies, it is extremely busy within Dimerix at the moment, and I am very much looking forward to providing updates to the market in due course.

During the 2021/22 financial year, we anticipate providing guidance on all our near-term propositions, including the FSGS Phase 3 program site initiations and recruitment, as well as initial data on the two COVID-19 clinical studies. Further, we look forward to presenting additional data on the longer-term opportunities including progress on the DMX-700 program in COPD and the next steps in diabetic kidney disease program.

Dimerix remains actively engaged with potential licensing partners as we progress each of our programs, with the aim to provide the best outcome for both the patients and our shareholders. Dimerix continues to build strategic alliances across commercial, clinical and manufacturing areas at the appropriate stage of development. These collaborations will

enhance the potential for the success of Dimerix product candidates, which will mitigate capital obligations and commercial risk. However, it is important to note that it is our intention to partner the products for the right value and at the appropriate stage of development, which also provides the appropriate return on investment to shareholders.

Our goal remains to develop commercially attractive products for unmet medical needs and to create value for our shareholders. Dimerix has a solid financial base to support our growth and diversification strategy, as we now take the next steps towards commercialisation of our development candidates.

➤ **Slide 18 – Questions**

Questions?



"We are profoundly aware of the potential impact Dimerix may have in improving the lives of millions of people around the world with both respiratory and renal conditions"
The Dimerix Team



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I thank all of our existing shareholders and stakeholders for their patience and support, and I welcome all our new shareholders.

Our people and culture are vital to our success, and we continue to focus on the importance of a diverse and motivated team. I would like to thank the Dimerix team, as well as our Board, for their continued hard work and dedication as we look forward to continued success in the coming year.

Thank you for your attention. I now invite any questions you may have on the progress and strategy for the Company.

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