

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

30 September 2020

**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**

## Meeting Transcript

### Annual General Meeting of Dimerix Limited

#### CEO Address

11.00am, Wednesday 30 September 2020 (Melbourne)

#### ➤ CEO & Managing Directors Address

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##### Company Review

Dr Nina Webster  
CEO & Managing Director



Thank you James, and good morning ladies and gentlemen. I hope that you all have had a chance to review the Company's Annual Report that we issued at the end of August and I would encourage 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 then the highlights of our 2020 financial outcomes.

#### ➤ Slide 2 – Forward-Looking Statement

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##### 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.



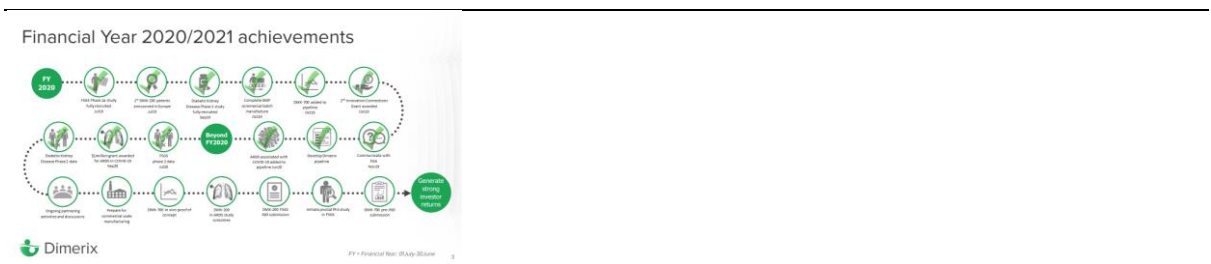
Please turn to slide 2.

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

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➤ **Slide 3 – 2018/2019 Financial Year Achievements**



Please move to Slide 3.

At the start of the 2020 financial year, we announced that we had been focusing on creating a company that is competitive, resilient and innovative, to allow us to successfully navigate in a complex and constantly changing environment. As you are all acutely aware, we have certainly been severely tested across all of these areas as a result of the global pandemic during the second half of the financial year, and we were extremely pleased to see our systems and processes successfully adapt to this evolving and challenging environment. Despite the global crisis, we have continued to make solid progress against all of our near-term strategic priorities that we believe will enable us to achieve our corporate objective.

Through the financial year, we continued to devote a large part of our development resources and expenditure to the two Phase 2 program: DMX-200 for Diabetic Kidney Disease and DMX-200 for Focal Segmental Glomerulosclerosis, or FSGS. We were very pleased to report that all of the primary and secondary endpoints were met in the FSGS study Phase 2a study, and the encouraging data that supports the ongoing development of DMX-200 for

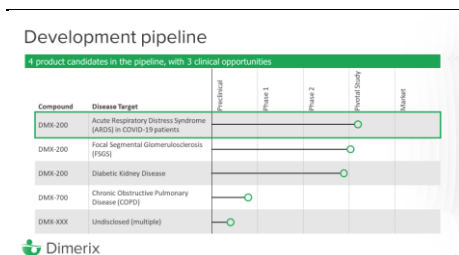
**Dimerix Limited**  
**30 September 2020 Annual General Meeting**  
**CEO Address**

FSGS in parallel to our program for patients with diabetic kidney disease. We have since also reported positive outcomes on the larger diabetic kidney disease Phase 2 study, which was consistent with the data seen in both our FSGS as well as our prior chronic kidney disease studies, and assists us in the planning of our next phase of development. I will comment on these results further in a moment.

As planned, we also continued to expand and diversify our pipeline through both internal and external efforts. We added two potential new medicines to our portfolio, DMX-700 for chronic obstructive pulmonary disease (COPD) in October 2019, which is in pre-clinical development; and DMX-200 in Acute Respiratory Distress Syndrome, or ARDS, associated with COVID-19 in June 2020. As and when we have sufficient resources, we also have a number of other commercially attractive opportunities identified, which will boost the company's pipeline in the longer term.

Suffice to say, the 2020 financial year has been extremely busy delivering on DMX-200 in two different indications, as well as diversifying risk through broadening our product portfolio and thereby providing an exciting platform for growth in the coming years.

➤ **Slide 4 – Development Pipeline**



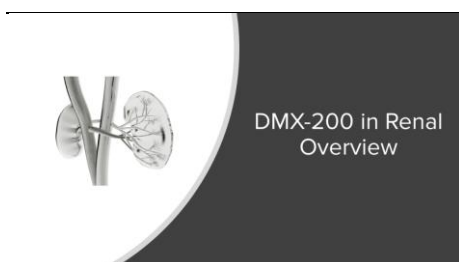
Turning to slide 4.

Using our proprietary platform technology, Dimerix identified a number of high unmet need and commercially attractive opportunities – DMX-200 in ARDS associated with COVID-19 which has parachuted into a large global clinical study, DMX-200 for focal segmental glomerulosclerosis, or FSGS, which has recently reported positive Phase 2a results, DMX-200 for diabetic kidney disease, which has also reported positive outcomes from the Phase 2 study, and DMX-700 for chronic obstructive pulmonary disease which is in pre-clinical.

Our goals are to move our development projects through clinical trials and over time to develop a portfolio with multiple products in various stages of development, leading to partnerships and licensing deals and ultimately commercial success through milestones and royalties. With three assets in late stage clinical development, and a further asset heading towards the clinical, we are well positioned to deliver a growing product portfolio and all with material commercial potential.

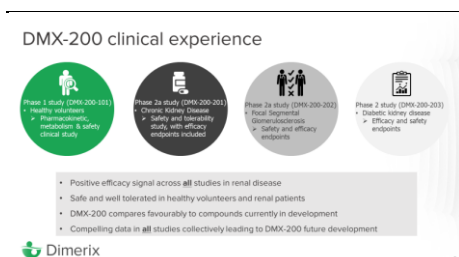
I will now jump straight into the question on everyone's mind – DMX-200.

➤ **Slide 5 – DMX-200 in renal overview**



Looking now to our lead candidate DMX-200.

➤ **Slide 6 – DMX-200 clinical experience**



Turning now to slide 6.

As a reminder, DMX-200 is a small molecule, given by oral administration to patients already receiving the current standard of care, an angiotensin receptor blocker, or ARB. DMX-200 is a New Chemical Entity, which can attract a minimum 5-year exclusivity period during which time no generic competitors may challenge the product.

The recent renal studies were run on the back of some very compelling data seen in our previous Phase 2a study conducted in 2017, and we were very pleased to report study results

from both the FSGS study and the diabetic kidney disease study that were consistent with our prior studies and that continue to support the development of DMX-200 in these kidney diseases.

I have since received questions or comments that have suggested a study failure in the diabetic kidney disease program. To be clear, based on our analysis and that of our specialist advisors, this is just not the case. Specifically, as was announced previously, in those diabetic kidney disease patients with a recognised marginally higher level of starting proteinuria, we observed a statistically and clinically significant reduction in the Albumin Creatinine Ratio, or ACR, the accepted measure of proteinuria in diabetic kidney disease patients.

As was also announced, all studies delivered positive data that is consistent with all prior data, and which adds to the growing body of evidence to support development of DMX-200 in both renal disease and in ARDS. Even more so, the data supports the mechanism of action of DMX-200 being effective in diseases where active inflammatory processes are driving disease progression.

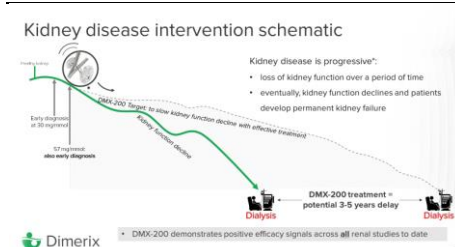
Importantly, the most recently announced diabetic kidney disease study was a Phase 2, and by its very nature is designed to be exploratory and informative. This is why a crossover study design was chosen to obtain maximum information from a relatively small study. As such, this study has provided extensive data on the effect of DMX-200 in patients with a broad range of proteinuria. This kind of qualitative data is essential to understand how DMX-200 works to assist in the planning of the longer and more costly pivotal studies.

As such, Dimerix continues to undertake planning for its proposed Phase 3 pivotal program in FSGS, a rare kidney disorder without an approved pharmacologic treatment that often leads to end-stage kidney failure and for which Dimerix announced positive clinical study results in July 2020, as well as determine the next stages of development for diabetic kidney disease.

In parallel, as with all clinical studies, our Medical Advisory Board are further exploring and interpreting the relationship between the treatment effect seen in this study and other

patient factors, such as other medications, prognostic biomarkers or legacy effect. These data will be published in due course, once the Medical Advisory Board have had sufficient time to analyse and interpret the large volume of data.

➤ **Slide 7 – DMX-200 market opportunity**



Turning to slide 7, and to remind you of what potential market opportunity exists for DMX-200 in kidney disease, I would like to highlight that kidney disease is progressive, with patients ultimately requiring dialysis or transplant. As you have probably heard me say many times before, if you can imagine as you progress down the hill of kidney disease, you cannot climb back up. Without intervention, that slope can be relatively steep, such as in FSGS, and in many cases result in the need for renal dialysis.

Protein is present in the blood, and healthy kidneys should only allow tiny amounts to enter the urine as most protein molecules are too large for the kidney's filters, the glomeruli. Therefore, the presence of protein in the urine, or proteinuria, acts as a warning signal that not all is well with the kidneys, and it is therefore widely accepted as the best clinical marker of the rate of progression of kidney failure. Put another way, the higher levels of proteinuria are reflective of more active disease and an expectation of a faster decline in kidney function. If you can reduce the amount of protein in the urine, it demonstrates the progression of kidney failure as been slowed.

All studies conducted by Dimerix to date have demonstrated a reduction in proteinuria in many patients, with the Phase 2a FSGS study meeting all primary and secondary endpoints, demonstrating 89% of patients seeing a reduction against placebo, and the more recent Phase 2 diabetic kidney disease study demonstrating over 60% of patients with a starting baseline over 57mg/mmol also seeing reduction against placebo. The overall percent mean reduction of protein in the urine in those diabetic kidney disease patients on DMX-200 versus

placebo was both statistically and clinically significant and is in addition to the current standard of care treatment. As was stated during our recent investor call by both Professor Roger and Professor Packham, both nephrologists and investigators on the studies, this should translate to a slowing of disease progression, which is a great outcome for these patients and very compelling. Importantly, as illustrated on this slide, the difference between 30 mg/mmol and 57 mg/mmol is quite small on the scale of predicted kidney decline, and thus has no impact on the potential market for FSGS and very little impact on the potential market for diabetic kidney disease.

Looking at FSGS specifically, as a reminder FSGS is an orphan indication, meaning it is a rare disease, that attacks the kidney's filtering units, causing irreversible scarring which leads to permanent kidney damage and eventually failure requiring dialysis or transplantation. For those diagnosed with FSGS the prognosis is not good. The average time from diagnosis, at the top of the slope on this slide, to complete kidney failure, at the bottom of this green slope, is 5 years and sadly it affects both adults and children as young as 2 years old. 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. At this time, there are no drugs approved for FSGS anywhere in the world, so the treatment options and prognosis are poor.

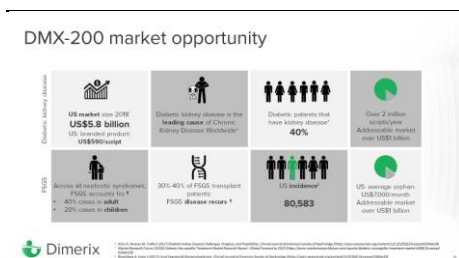
So the next question is, "where to from here?"

As Dr Wong, a member of our Medical Advisory Board and investigator on the study, stated in July - treatment with DMX-200 may result in clinically meaningful improvements in kidney outcomes when added to the standard of care in patients with FSGS, and this should be confirmed by a larger pivotal randomised controlled trial. The Medical Advisory Board's assessment at this time is that these data puts DMX-200 in a great position in the global development efforts for new treatments for FSGS. This is fantastic news for those patients diagnosed with FSGS, their families and their physicians.

It is anticipated that Dimerix will submit an IND for an FSGS study in Q1 2021 and initiate the study on clearance from the FDA.



➤ Slide 8 – DMX-200 market opportunity



Turning to slide 8.

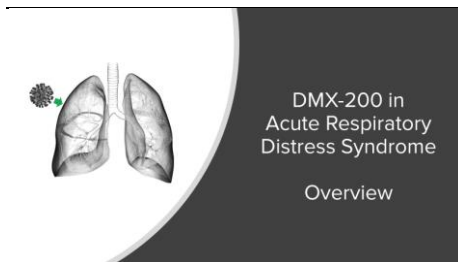
As I mentioned a moment ago, the recent study results in both FSGS and diabetic kidney disease are extremely encouraging for our market potential.

Looking first at FSGS, Dimerix has secured Orphan Drug Designation in both the US and Europe, which qualifies us for various development incentives by the FDA, likely to include: seven years of market exclusivity upon regulatory approval, exemption from certain FDA application fees, and an abbreviated regulatory pathway to approval, which Dimerix confirmed at its recent meeting with the FDA. It also potentially qualifies DMX-200 to attract orphan drug pricing, which allows the developer to recoup development costs despite the small number of patients. Note that the average orphan drug in the US retails for approximately \$7,000 per month, and there are over 80,000 FSGS patients in the US alone, making it a commercially attractive proposition.

If we turn to diabetic kidney disease first on slide 7, it is estimated that 40% of people with diabetes have kidney disease and many may not know it yet. With the incidence of diabetes growing so rapidly globally, so too will the incidence of kidney disease. This is a rapidly growing market, with few treatment options at this time.

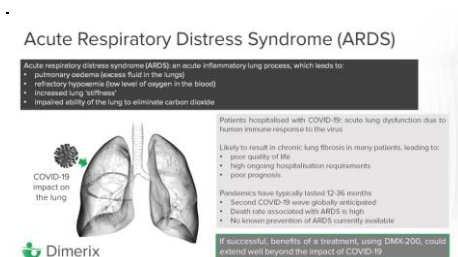
As such, the addressable market for DMX-200 has not changed and is expected to be over \$1 billion per annum. When I say addressable market, I should be clear that this means the size of the pie that Dimerix can go after, and that the size of the pie we are chasing has not changed as a result of the recent data.

➤ Slide 9 – DMX-200 in ARDS overview



Turning now to DMX-200 in Acute Respiratory Distress Syndrome, or ARDS.

➤ Slide 10 – ARDS



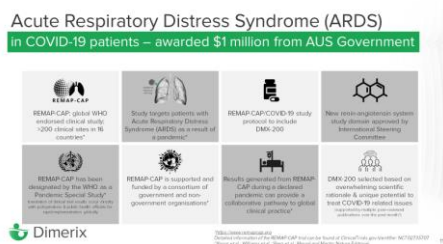
Turning to slide 10.

So what is it about DMX-200, which is Dimerix’s lead product candidate, that has led to its potential to treat COVID-19 patients?

We understand that DMX-200 works in these kidney diseases by reducing damage caused by inflammatory cells, and this is supported by all clinical data to date. We believe it does this by blocking the “signalling” process by which inflammatory cells move to the kidney, and prevents subsequent onset of fibrosis. The relevance of this to COVID-19 is that one of the hallmarks of severe cases is ARDS. This is a rapid, widespread inflammation of the lungs that often leads to respiratory failure and death.

We know that ARDS is caused by the human immune response to the virus. Based on the known effects in the lung of COVID-19, it is anticipated that DMX-200 could benefit ARDS patients with COVID-19 by reducing the recruitment of inflammatory cells to the lungs, and thus reducing inflammation and fibrosis.

➤ Slide 11 –ARDS and REMAP-CAP



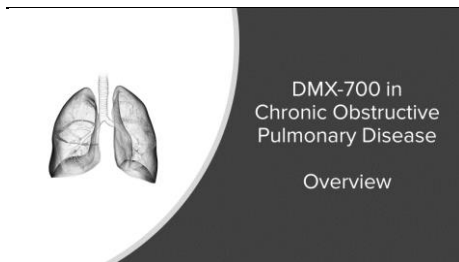
Looking at slide 11.

You will have noted that we were recently awarded \$1 million from the Australian Government from the highly competitive Medical Research Future Fund towards our inclusion in the REMAP-CAP study, for which we are very pleased with as this funding and endorsement is a reflection on the strong scientific rationale for DMX-200 in this setting.

We continue to work with the REMAP-CAP project teams and regulatory teams, and the international trial steering committee have approved the renin-angiotensin domain, including DMX-200. We acknowledge that the new renin-angiotensin system domain protocol for the global study, which includes DMX-200, is not yet available on the REMAP-CAP website and we will update the market as soon as we can in this regard. Please note that this timing is very much driven by the REMAP-CAP team.

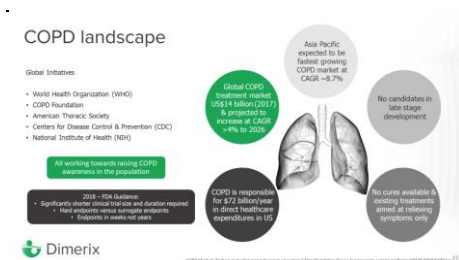
Our drug compound, DMX-200, is being prepared for the study at our FDA approved global contract manufacturer, and we have engaged with the relevant regulatory authorities accordingly. Historically, pandemics have lasted approximately 12-36 months, and we are unfortunately seeing some resurgences in the current pandemic right now. Whilst COVID-19 is likely to be around for a while yet, if DMX-200 does show some benefit in ARDS associated with COVID-19, it may also show benefit in ARDS associated with other infections too, such as pneumonia and influenza. Thus, this provides an opportunity that could extend well beyond the impact of COVID-19.

➤ Slide 12 – DMX-700 overview



Turning now to our new pipeline candidate DMX-700.

➤ Slide 13– DMX-700 landscape



Turning to slide 13.

In addition to the clinical advances we have made during the year, we have also continued to make progress on our candidate for chronic obstructive pulmonary disease, or COPD.

COPD is a global health issue, where in the United States alone it costs the health care system \$72 billion per year. With the global mortality rate increasing, no new treatment innovation for over 15 years and no candidates in late stage development, this provides Dimerix a significant opportunity to provide for an unmet need. Furthermore, whilst historical clinical studies in COPD have required long and arduous hard clinical endpoints, such as time to hospitalisation or death, in 2018 the FDA guidance was revised to provide for shorter and more manageable clinical studies using surrogate endpoints. A surrogate endpoint uses alternative measures, such as patient quality of life assessment as a representative measure of an expected outcome. As such, clinical outcomes can be achieved in months instead of years and are well within the Dimerix team capabilities.

➤ **Slide 14 – DMX-700 overview**

DMX-700 overview

DMX-700: oral administration candidate:

- Two molecules working together, each with an established safety profile
- Dimerix has completed initial studies on receptors involved in COPD
- Certain lung cells express multiple receptors, thus blocking only one receptor does not block signalling and results in only a partial response to treatment
- **DMX-700 blocks both receptors simultaneously to provide a complete response to treatment**
- Compelling data encouraged Dimerix to progress candidate towards clinical development

The diagram consists of two circular nodes connected by a horizontal arrow. The left node is dark grey and contains the text 'Formulation optimisation underway'. The right node is green and contains the text 'Entry into in vivo studies'. Below the diagram is the Dimerix logo.

Turning to slide 14.

DMX-700 for COPD is a very different candidate to DMX-200, targeting a different disease pathway. DMX-700 is built on the Dimerix core competency of understanding the complex pharmacology of chemokine G Protein-Coupled Receptors (or GPCR), and thus has a good strategic fit with current business model and corporate strategy. As such, Dimerix is utilising its current core competencies and capabilities to execute the development program.

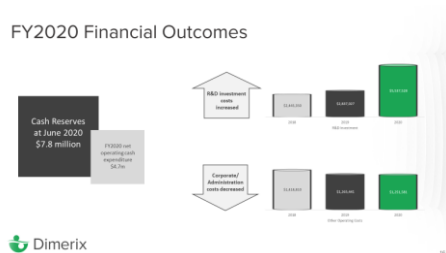
Further studies have been completed, and Dimerix has progressed its patent positioning by recently filing a PCT application. As was announced recently, the DMX-700 program has moved to the next stage of development being the optimisation of the DMX-700 drug product candidate to limit signalling of these receptors, as well as progressing towards the in-vivo dose ranging studies required prior to entering the clinical phase.

➤ **Slide 15 – Financial Outcomes & Value Driving Events**

The slide header features the Dimerix logo on the left, which includes a stylized green figure. To the right of the logo, the text 'Dimerix' is written in a bold, sans-serif font. Below 'Dimerix', the text 'Financial Outcomes & Value Driving Events' is written in a smaller, lighter font. The background is a dark grey gradient.

Turning now to our 2020 financial outcomes and key value drivers

➤ **Slide 16 – FY2020 Financial Outcomes**



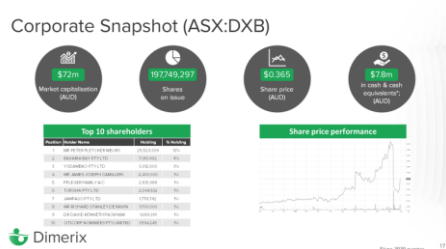
Turning to Slide 16.

You will have seen our annual report, as well as our most recent quarterly financial release and noted that our financial position is healthy. Over the past few years, Dimerix has consistently increased its R&D activities whilst simultaneously reducing overheads, and the company finished the year under budget. 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 \$5.5 million, up 95% from 2019
- Corporate and administration expenses of \$1.25 million, down 1% from 2019
- Net Loss After Tax of \$4.49 million driven by R&D, up 55% from 2019
- Cash Reserves at the end of period was \$7.8 million up from \$3.56 million on 30 June 2019

➤ **Slide 17 – FY2019 Financial Outcomes**



Turning to Slide 17.

The company is currently trading at 36.5 cents per share, up from 9 cents per share this time last year. With cash at 30 June 2020 totalling \$7.8 million, this provides us with an enterprise value of over \$64 million compared with an enterprise value of \$18 million in 2019.

The current cash balance provides a solid base for the company to pursue the current activities, which includes the planning for its proposed global Phase 3 pivotal program in FSGS as well as for the COVID-19 study in Acute Respiratory Distress Syndrome. We continue to assess the longer term strategy, including planning for the success of DMX-200 and progressing towards submitting an Investigational New Drug (or IND) application to the FDA, associated partnering activities, DMX-700 development plans and the impact on future cash flow and funding.

➤ **Slide 18 – Key Value Drivers**



Turning to slide 18.

Looking ahead, there are multiple key drivers of financial value for Dimerix.

In terms of DMX-200 in renal clinical trials, we currently expect to file an IND and initiate a study in FSGS in Q1 2021. In parallel, it is anticipated that efficacy data for DMX-200 in respiratory complications associated with COVID-19 will also be available within this financial year, as well as progressing the manufacturing scale up and regulatory activities. Dimerix continues to engage with potential licensing partners as we progress, with the aim to provide the best outcome for both the patients and our shareholders.

The DMX-700 development plan will continue to progress towards the clinical phase, with some further in vivo assessment in an appropriate COPD model to confirm target engagement, pharmacokinetics (or PK) and pharmacodynamics (or PD).

Our goal is 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.

Dimerix is a small and very dedicated team, who have been working extremely hard throughout the global pandemic to deliver on the two Phase 2 clinical studies in renal disease, as well as the ARDS opportunity in patients with COVID-19 and the COPD program. We have evolved significantly over the past couple of years, and now have multiple assets in commercially attractive and growing markets that all have a high unmet need and with little or no current marketed competition.

Thank you to the patients and their families who inspire us, to our employees for their dedication, to our investigators, partners and collaborators who facilitate us, and to our shareholders for their support. I am proud of the progress we continue to make and am confident that together we can achieve all we set out to do. I look forward to reporting on our progress throughout the 2021 financial year.

➤ **Slide 19 – Close of Presentation**



At this point, I would normally invite you to join us for a coffee where we would take questions or have further discussion. However, given this is not possible this year, I invite you to email me any questions or comments you may have to [investor@dimerix.com](mailto:investor@dimerix.com).

This concludes the call and I wish you all a pleasant day.

**END**