

Meeting Transcript

Annual General Meeting of Dimerix Limited

CEO Address

2.00pm, Thursday 28 November 2019 (Melbourne)

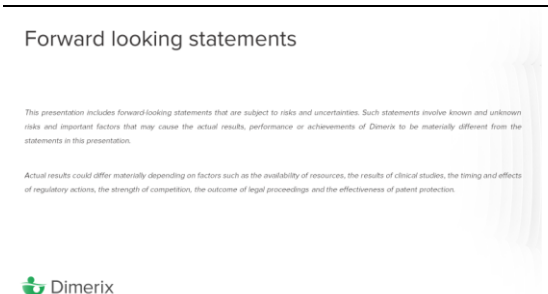
➤ **CEO & Managing Directors Address**



Thank you James, and good afternoon ladies and gentlemen. I hope that you all have had a chance to review the Company's Annual Report that we issued in September 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 the highlights of our 2019 financial outcomes and then a detailed review of our strategy. After the prepared remarks, I look forward to taking your questions.

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



Please turn to slide 2.

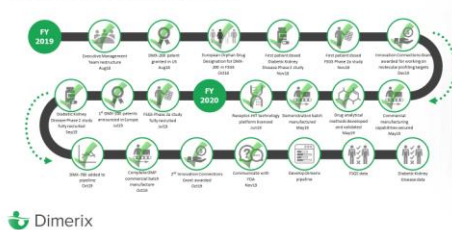
I would like to formally note our Forward-Looking Statement caveat by stating that...

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.

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

2018/2019 achievements



Please move to Slide 3.

As the CEO of an ASX listed biotech company, it is my responsibility to create a company that is competitive, resilient and innovative, allowing us to successfully navigate in a complex and constantly changing environment. One of Dimerix' greatest capabilities is the therapeutic science; we are a very small team but have attracted world-class scientists, clinical researchers and medical professionals to help develop new medicines in areas with high unmet needs. To this end, 2019 has been extremely busy as we made solid progress in addressing the near-term strategic priorities to deliver on DMX-200 in two different indications as well as diversifying risk through broadening our product portfolio, starting with DMX-700.

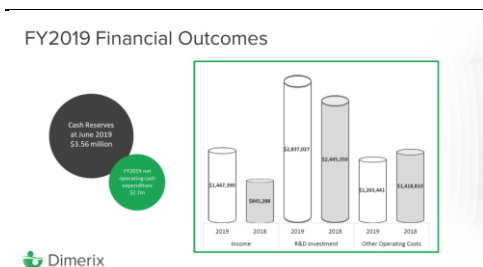
At the 2018 AGM, Dimerix committed to several key events to drive value for Dimerix during 2019. I am very pleased to report that since our last AGM, we executed on all of our planned operational goals, as you can see on this slide.

During the year, Dimerix has initiated and fully recruited two Phase 2 clinical studies, one in diabetic kidney disease and one in focal segmental glomerulosclerosis, or FSGS. This is a significant achievement, and I would like to thank the team for all their extraordinary efforts to meet these goals.

As you will appreciate, the current Phase 2 clinical studies play a large part in the Dimerix commercialisation plan but are by no means the only piece of the puzzle. To maximise the opportunity, the DMX-200 product development program requires integration of clinical development, patent strategy, commercial manufacturing supply, interaction with regulatory agencies in US and Europe, quality oversight, analytical development, pre-clinical activities and establishment of shelf-life. These are all R&D activities that Dimerix remains focussed on to achieve the best outcome for the patients and for our shareholders.

We have also made solid progress in addressing the near-term strategic priorities to broaden our product portfolio. Following work initiated at the end of 2018, we were pleased to announce the addition of DMX-700 for Chronic Obstructive Pulmonary Disease, known as COPD, to our pipeline recently.

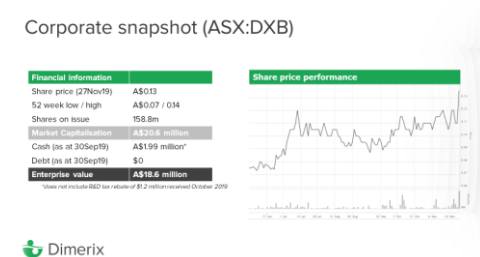
➤ **Slide 4 – FY2019 Financial Outcomes**



Turning to Slide 4.

You will have seen our annual report, as well as our recent quarterly financial release and noted that our financial position is healthy. When compared with 2018 financial year, I am pleased to note that our R&D expenditure is up, whilst our operating expenditure is down. I am pleased with the progression and continued investment in the research and development that Dimerix has made, whilst also conserving spend and continuing to maintain a healthy balance sheet.

➤ **Slide 5 – FY2019 Financial Outcomes**

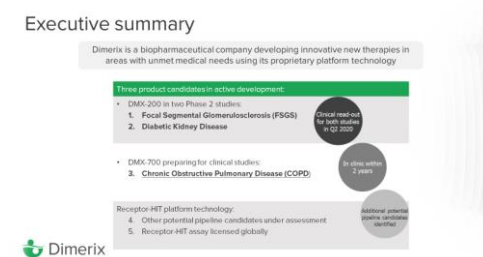


Turning to Slide 5.

The company is currently trading at 13 cents per share. With cash at 30 September 2019 totalling \$1.99 million. Note that this does not include the R&D Tax rebate of \$1.2 million we received in October 2019. This provides us with an enterprise value of over \$18 million compared with an enterprise value of \$12.9 million in 2018. Whilst I firmly believe that this still does not reflect the current opportunity value, it is heading in the right direction!

The current cash balance provides a solid base for the company to pursue the current clinical trials. 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 6 – Executive Summary**



Turning to slide 6.

At a high level we see the Dimerix business as having five distinct opportunities.

- Firstly, in DMX-200 for diabetic kidney disease, which is currently in a Phase 2b clinical trial. Over 20% of all diabetics suffer from kidney disease and diabetic kidney disease is the cause of 40% of all diagnosed kidney disease cases. With the incidence of type 2 diabetes growing so rapidly, so unfortunately too will the number of those with renal disease. There has been little innovation in the kidney disease space, and thus competition is low despite the growing need for new treatments. This provides Dimerix with a great opportunity to target a good portion of the addressable market, which is over \$1 billion US dollars.
- Secondly, DMX-200 for FSGS, which is currently in a Phase 2a clinical trial and has been granted Orphan Drug Designation in the US by the FDA and in Europe by the EMA. FSGS is a serious and rare kidney disease affecting approximately 120,000 people in the US. The disease progresses rapidly, with end stage renal failure typically occurring within 6 years. And again, despite the clear need of new drugs to help patients with this disease, there are no approved treatments for FSGS. This provides Dimerix with a real opportunity to target a significant portion of the addressable market, which is also over \$1 billion US dollars in the US alone.
- Thirdly, DMX-700 for COPD, which is currently in pre-clinical studies. COPD is a progressive & life-threatening lung disease that affects individuals of all ages. COPD can be caused by tobacco smoke, pollution, occupational dust and fumes and long-term

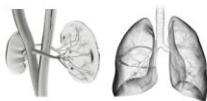
asthma, and there is currently no cure available, with existing treatments such as the asthma inhaler aimed only at relieving symptoms. COPD is the 4th leading cause of death globally and is the only disease in the top 5 causes of death that has increasing mortality rates – meaning more people are dying of COPD each year. This is another area that has had little innovation for over 15 years and has no new treatment candidates currently in late stage development, providing Dimerix with a great opportunity.


- Fourthly, by boosting the company's pipeline in the longer term and further diversifying both risk and future revenue stream. When assessing potential new pipeline opportunities that fit with the Dimerix corporate strategy and our core competencies, we use the information on patient need, technical experience, potential sales, competition and development complexity to select candidates that we believe will bring the greatest value to patients and our shareholders. A number of exciting new opportunities are under preliminary assessment, and we look forward to reporting on this progress in due course.
- Fifthly, by leveraging the Dimerix proprietary Receptor-HIT platform technology through our licensee, Excellerate Bioscience based in the UK.

➤ **Slide 7 – Dimerix Strategy**

A pipeline of drugs identified using Receptor-HIT

Programs based on the critical scientific rationale that GPCRs act as a complex with other GPCRs and have novel pharmacology when in complex



 Dimerix

Strategic Fit

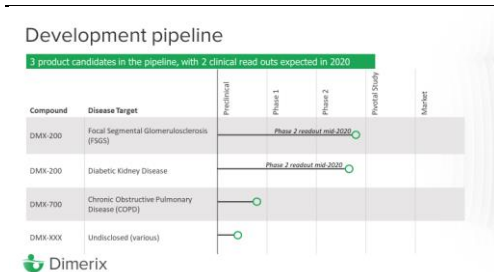
- Dimerix is developing a **commercial pipeline** of drugs for G Protein-Coupled Receptors (GPCR) largely targeting chemokine pathway diseases with a **clear unmet need**
- Dimerix can utilise its current core **competencies** and **capabilities** to execute on the disclosed opportunities
- Dimerix has identified **new uses** for existing drugs to drive the **discovery** of new drugs and research programs
- Dimerix has **multiple products** in its pipeline, at different development stages, **diversifying** risk and increasing potential future sources of revenue

Turning to slide 7.

I now turn to our growth strategy. Dimerix has a strong background in G Protein-Coupled Receptors, or GPCRs, on the back of its proprietary Receptor-HIT assay. We believe that we can leverage and utilise our core competencies in understanding the complexities of how this class of receptors signals to generate intellectual property and knowhow on a number of new

product development candidates in commercially attractive market segments. By focussing on our core competencies and capabilities, we believe it is an effective way to utilise our cash and manage the development risks that are inherent in the biotech industry, whilst simultaneously diversifying potential future sources of revenue.

➤ Slide 8 – Development Pipeline



Turning now to slide 8.

This slide shows the progression of our pipeline of drug candidates. Our DMX-200 for FSGS program leads the portfolio as a result of it receiving orphan drug designation in the US and Europe, and thus following a much faster path to market.

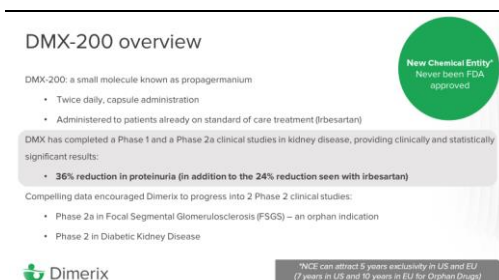
Our goals are to move our development projects through clinical trials and over time to develop a portfolio with multiple products in various stages of development, leading to partnerships and licensing deals and ultimately commercial success through milestones and royalties. With two assets that have Phase 2 clinical readouts anticipated in 2020, and a further asset heading towards the clinical, we are well positioned to deliver a growing product portfolio with a relatively low development risk and all with material commercial potential.

➤ **Slide 9 – DMX-200 overview**



Turning to our lead candidate DMX-200.

➤ **Slide 10 – DMX-200 overview**



DMX-200 overview

DMX-200: a small molecule known as propagermanium

- Twice daily, capsule administration
- Administered to patients already on standard of care treatment (irbesartan)

DMX has completed a Phase 1 and a Phase 2a clinical studies in kidney disease, providing clinically and statistically significant results:


- **36% reduction in proteinuria (in addition to the 24% reduction seen with irbesartan)**

Compelling data encouraged Dimerix to progress into 2 Phase 2 clinical studies:

- Phase 2a in Focal Segmental Glomerulosclerosis (FSGS) – an orphan indication
- Phase 2 in Diabetic Kidney Disease

New Chemical Entity*
Never been FDA approved

*NCE can attract 5 years exclusivity in US and EU (7 years in US and 10 years in EU for Orphan Drugs)

 Dimerix

Turning to slide 10.

As previously mentioned, our lead candidate is currently in two different Phase 2 clinical studies: a Phase 2 study in diabetic kidney disease, and a Phase 2a study in FSGS.

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 has never been approved in the United States and thus is considered a New Chemical Entity, which can attract a minimum 5-year exclusivity period during which time no generic competitors may challenge the product.

The current studies are being run on the back of some very compelling data seen in our previous Phase 2a study conducted in 2017. Both of the current DMX-200 Phase 2 studies are fully recruited and are expected to conclude mid-2020.

➤ **Slide 11 – DMX-200 regulatory strategy**



Turning to slide 10.

Last week, I was in the US meeting face-to-face with the FDA to confirm our regulatory strategy and path forward for DMX-200. A pre-IND meeting for our orphan disease indication, FSGS, provided Dimerix with the opportunity to discuss with FDA the unique challenges of rare disease drug development and where regulatory flexibility can be justified. The guidance received by the FDA on program designed and presented by Dimerix provides us with clarity, acceptability and approvability of the remaining planned development.

Importantly, the meeting provided clarity on the remaining development of DMX-200 for FSGS through to market approval, including confirmation of endpoints for accelerated marketing approval, and the requirement for a single Phase 3 study. The agency also confirmed the proposed non-clinical package and proposed specifications for the pharmaceutical-grade drug manufactured by Dimerix are appropriate for registration of DMX-200.

In the meantime, Dimerix plans for the success of the current Phase 2 clinical trials and will engage in key preparations for the next steps.

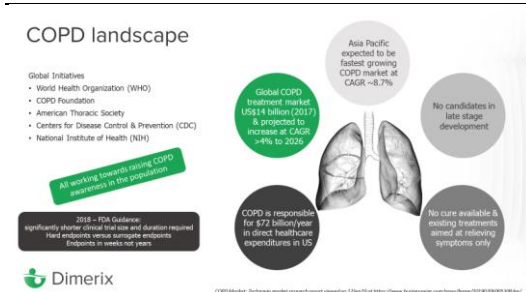
➤ **Slide 12 – DMX-700 overview**



DMX-700
Overview

Turning now to our new pipeline candidate DMX-700.

➤ **Slide 13 – DMX-700 landscape**



Turning to slide 13.

We are very excited to formally add DMX-700 to our active development pipeline. 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 historically 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**



Turning to slide 14.

DMX-700 for COPD, 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 can utilise its current core competencies and capabilities to execute the development program.

Our proprietary assay, Receptor-HIT, has identified a heteromer association between two receptors that have been independently implicated in the pathophysiology of COPD, however investigations into each individual receptor have provided disappointing results to date. Dimerix anticipates that this is due to the heteromer nature of the receptor and has discovered that simultaneous inhibition of both receptors may significantly improve efficacy. The receptor targets and DMX-700 will remain undisclosed pending additional data and patent positioning.

Initial studies have been completed, and Dimerix has completed a key step in securing ownership over what it believes is an important new drug discovery by lodging a provisional patent application for DMX-700.

Over the next 12 months Dimerix will conduct further proof of concept studies to perform the value added verification in support of a robust product development pathway and patent position. DMX-700 is a New Chemical Entity, however the safety profile is well understood. As such, it is anticipated that Dimerix would initiate human clinical studies in less than 2 years.

➤ **Slide 15 – Value driving events**



Turning now to our key value drivers

➤ **Slide 16 – Key Value Drivers**



Turning to slide 16.

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

In terms of DMX-200 clinical trials, we currently expect initial data from both trials in mid-2020. In parallel, Dimerix continues to plan for success in these studies, and is undertaking certain time critical activities to ensure effective and efficient progression in the next steps towards commercialisation, such as manufacturing supply and progress towards submitting an Investigational New Drug (or IND) application to the FDA. 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 with some further in vitro assessment required, prior to initiating the in vivo assessment in an appropriate COPD model to confirm target engagement, pharmacokinetics (or PK) and pharmacodynamics (or PD). Dimerix has engaged a clearly delineated stage-gate development approach to limit capital risk.

Of course, we will update the market should our expenditure profile change as a result of any of the above activities.

Before I conclude, I want to summarise and emphasise that Dimerix is a company with an experienced management team and Board, two strong Phase II assets and has a solid track

record of delivering on promise. Our goal is to develop commercially attractive products for unmet medical needs and to create further value for our shareholders. We are comfortable with our financial position at the end of the financial year, which provides a solid base to support our growth and diversification strategy as we near commercialisation milestones in relation to our lead candidates.

I would like to take the opportunity to thank our shareholders, both longstanding and new. Your ongoing support is appreciated as we look ahead to our clinical studies completion and value creation. And finally, I would like to extend my appreciation to the Dimerix team for their efforts and achievements during 2019 financial year. We look forward to sharing more milestone successes with you in the future. I thank you for listening.

➤ **Slide 17 – Close of Presentation**



We now invite you to join us for a coffee where we will be happy to take questions or have further discussion. We thank you for your time.

END