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6 June 2022

NSX Announcements

Pitt Street Research values COVIRIX Medical at US$5.46- US$8.45 per share

GoConnect Ltd ("GO8") is pleased to provide a copy of an investment research report on COVIRIX Medical Holdings Ltd prepared by Pitt Street Research ("PSR") and distributed by Martin Place Securities ("MPS").

MPS has been appointed as corporate advisor to COVIRIX Medical and a broker to the private placement of COVIRIX Medical shares to sophisticated and professional investors.

PSR has a strong reputation in health science and biotech investment research. PSR has performed a valuation on Covirix Medical in the preparation of this report.

PSR has arrived at a valuation range of US$5.46 to US$8.45 per COVIRIX Medical share equivalent to A$7.58 to A$11.74 per share at current exchange rate of about 72 cents USD to $1 AUD.

GO8 is a significant shareholder and co-founder of Go Green Holdings Ltd. GO8 holds 43.72% of Go Green Holdings Ltd. Go Green Holdings is a co-founder and significant shareholder in COVIRIX Medical. Go Green Holdings holds 24.07% of COVIRIX Medical.

The valuation range of A$7.58 to A$11.74 per COVIRIX Medical share represents a value of AUD 4.7 cents to AUD 7.3 cents per GO8 share for its indirect equity interest in COVIRIX Medical.

Attached is a copy of the Pitt Street Research report on COVIRIX Medical and the research summary report prepared by MPS distributed on 5 June 2022.

COVRIX MEDICAL HOLDINGS LTD (A$2.80)

Pre IPO opportunity in COVID-related antiviral product

Covirix seeking expressions of interest in raising A$14m pre-IPO through issue of 5m shares @ A$2.80 to fund Phase I & II clinical trials on repurposed antivirals for COVID

KEY POINTS

- **CVX20733 is an antiviral FDA- approved drug for another disease application**
- **Repurposing as inhalable small molecule broad spectrum drug for COVID-19**
- **Agreements in place to carry out Phase I & II Clinical trials in India and Nepal**
- **Repurposing will significantly reduce risk and timeline to market**
- **Revenue potential is large and no competitor yet identified**
- **Sole Aust/NZ distributor US supplier DiaCarta Inc's Rapid Antigen & PCR Tests**
- **Listing and secondary listing planned for Australia and Hong Kong**

SUMMARY

COVID-19 has been a major global pandemic that has caused widespread disruption to the world economy, personal health and national medical/health services.

National policy has focused almost entirely on inoculation and with experimental gene therapies as a total population strategy but very little has been done for an effective antiviral cure, exercise, diet and vitamin intake advice. Likewise, prophylactic approaches for processes of drugs or therapies have been largely ignored.

Covirix Medical has seen the opportunity to develop and promote antiviral COVID therapies for treatment of mild to acute infection as well as preventive using products that show highly effective results.

Its CVX-20733 compound is already FDA -approved for other infections but has demonstrated both antiviral and anti-inflammatory mechanisms in pre-clinical studies and has the ability to treat the virus, kill it and prevent it from spreading.

As an Australian-based clinical-stage pharmaceutical company with a highly experienced international team Covirix has a strategy to enter the market by supplying antiviral and anti-inflammatory treatments using drugs that already have safety confirmation and FDA Approval for other treatments.

By repurposing CVX-20733 to COVID, Covirix has a lower to-market timeline risk and cost.

CVX20733 will be delivered by inhalation to the respiratory tract where viruses congregate giving immediate and non-invasive application at lower application rates with low potential side effects risk.

Initial markets include the large population base of India and provisional patent covering 11 jurisdictions has been filed and published.

Covirix has a strategic partnership pending with US-based DiaCarta Inc to assist CVX20733 securing Investigational New Drug (IND) approval from the FDA as a Breakthrough Therapy. Covirix is also the sole Australian distributor of Diacarta's RAT and PCR products and a potential net income of A$70m from a single order is under negotiation.

Sophisticated investors are invited to request a confidential IM for Covirix.

NEAR TERM EARNINGS POTENTIAL

Year to June (US$m)	2023F	2024F	2025F	2026F	2027F
Sales (m)	11	14	18	35	71
EBITDA (m)	4	7	9	23	51
Net Profit (m)	3	5	6	16	35
EBITDA margin (%)	41%	47%	50%	63%	71%
RoA (%)	4%	6%	7%	16%	28%
RoE (%)	4%	6%	7%	16%	28%
EPS	4c	6c	8c	20c	44c

Source: Company, Pitt Street Research

3 June 2022

24 Month Price Target: (>A$10.00)

CAPITAL STRUCTURE

Share Price	A$2.80
Market Cap	$188m
Issued Shares including 5 million placement shares	67.3m

DIRECTORS

Kumud Dhital	Managing Director
Ian Nixon	Exec Director
Richard Li	Exec Director

TOP SHAREHOLDERS

Go Green Holdings	25%
Ian Nixon	25%
COVID Pharmaceuticals	25%
Somersham Super	24%
Small shareholders	~1%
Total	100%

This note has been prepared by Martin Place Securities Pty Ltd and is based on the attached report from Pitt Street Partners.

Data has been sourced from available public information and reflects the author's own assessments.

Martin Place Securities is a corporate adviser to Covirix

COVIRIX MEDICAL LTD

Covirix was set up in Melbourne in 2020 by experienced hospital and medical operators and administrators to provide non-inoculation products to sufferers of COVID viruses.

"Our mission is to develop effective therapeutics to treat both the acute and chronic phases of COVID-19, save lives, and lessen the misery affecting individuals, families, and society at large." - Kumud Dhital, COVIRIX Medical CEO

'Widespread and concurrent use of an effective and economically-priced inhaled drug would ease the safe return to normal life globally.'

Ian Nixon, COVIRIX Medical CMO

Valuation US$m	Base Case	Bull Case
Present Value of DCF	6,090	8723
PV of Terminal FCF	286	485
Enterprise Value	292	493
Cash on Listing	75	75
Equity Value	367	568
Shares outstanding	67.3	67.3
Implied Price US$	5.46	8.45
Implied Price A$	7.58	11.74

Milestones achieved in 2020

03 2020	COVIRIX Medical Pty Ltd incorporated (ACN 639 682 607)
	CVX 20733 Identified as ideal drug for repurposing. Approved drug for non-infective use with known action vs SARS-CoV-2
08 2020	MOU with COVID Pharmaceutical Pty Ltd for license to develop and repurpose CVX 20733 and related compounds for both anti-viral and anti-inflammatory therapies
	Provisional Patent filed for use of 20733 and related compounds as an anti-COVID-19 drug for delivery via inhalation, nebulization & intra-nasal routes
	Start of 1st Tranche Capital Raise
09 2020	Engagement of Prof Simon Tucker as Chief Virologist & Head of Clinical Development
	MOU with Deakin University, Melbourne for service engagement of Prof David Morton as Consultant Aerosol Scientist
11 2020	Antiviral Studies vs SARS C0V-2 at Southern Research (SR) Laboratories, USA.
12 2020	Market intelligence of preliminary antiviral efficacy for 20755 and 20788 in hand from SR Laboratories, USA
12 2020	Formulation work commenced for inhalational delivery

Milestones achieved in 2021

	Ongoing formulation work for inhalational and nebulizer delivery for CVX 20733
03 2021	Completed virology test data sharing agreement with Walter & Eliza Hall Institute on CVX 20733, CVX 20755
05 2021	Completion of satisfactory revalidation tests of CVX 20733 (+ 20755 & 20788) antiviral activity vs UK and South African variants of SARS-CoV-2 at ViroClinics, Netherlands
05 2021	Tranche 2 Capital Raise commenced
06 2021	NDA signed with major European API & pharmaceutical company with global production/distribution chain
06 2021	Identified GMP Facilities in India & Nepal for manufacture of CVX 20733 (Nebulised formulation) NDA with CRO in India and established communication with Government agencies in Zimbabwe and Nepal for accelerating Re-Phase I (Pharmacokinetic), Dose escalation Phase I, and II Studies
08 2021	MOU with Medical Ventures Pvt Ltd – CRO support for clinical trials in Nepal
09 2021	Asian Pharmaceuticals Pvt Ltd – GMP Manufacturer for clinical trials in Nepal

Milestones for 2022-23

Q1 2022	Expect waiver of further animal pulmonary toxicology and approval early Phase Clinical Trials of antiviral CVX 20733 in Nepal and India, Nepal
	Confirm DPI Manufacturer for CVX 20733
Q2-3 2022	Commence Pre-Phase1 Pharmacokinetic) studies of CVX 20733 in health volunteers (Nepal & India) Combined Phase I Dose escalation Study of CVX 20733 in Health Volunteers (Nepal and India)
Q4 2022	Commence Phase II Clinical Trial of Nebulised CVX 20733 in the following cohorts: non-isolated hospitalized COVID + individuals; hospitalized non-ventilated COVID +ve patients
Q3-4 2022	Explore formal listing on Australian, Asian or North-American Stock Exchange
Q1-2 2023	Phase III for CVX 20733 targeting: isolated non-hospitalised COVID + patients and hospitalised non-ventilated COVID+ patients

* The projected timelines are fluid and depend primarily on the initial validation studies of anti-viral activity being completed on time. While timeline delays are possible, the successful completion of these initial studies, together with commensurate investment, will permit many of the subsequent pre-clinical tests to be carried out concomitantly, so as to accelerate the necessary clinical trials.

Figure 2: Estimated Cost and Time savings through repurposed drug

Clinical Study	Estimated Timeframe	Estimated Completion Date	Estimated Cost (US$)
Expedited phase I/II entry without extensive inhaled toxicology	12-18 months	2Q23	8m
Complete phase I followed by phase II without extensive inhaled toxicology	18-24 months	4Q23 – 2Q24	10m
Complete phase I followed by phase II with a complete inhaled toxicology package	24-36 months	2Q24 – 2Q25	15m

Source: 'Expected Milestones', 'About us', COVIRIX Medical

GENERAL SECURITIES – ADVICE WARNING

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Before making an investment decision on the basis of this information, the reader needs to consider, with or without the assistance of an adviser, whether the advice is appropriate in light of their particular investment needs, objectives and financial circumstances.

ANALYST VERIFICATION

Barry Dawes, as the author of this note, and as Head of Resources of Martin Place Securities, hereby certifies that the views expressed in this research accurately reflect his personal views about the subject securities or issuers. No part of analyst compensation is directly or indirectly related to the inclusion of specific recommendations or views in this research. The analyst principally responsible for the preparation of this research has received compensation based on overall revenues, including investment banking revenues, of Martin Place Securities. The Analyst has taken reasonable care to achieve and maintain independence unbiased objectivity in making any recommendations.

The Analyst and his related entities hold no shares in Covirix at the date of this report.

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This views in this report are entirely those of the Analyst using publicly available information.

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PITT STREET RESEARCH

COVIRIX Medical

Tackling a global health concern

31 May 2022

COVIRIX Medical is an Australia-based clinical-stage pharmaceutical company which is repositioning an existing antiviral agent, CVX-20733, as a COVID-19 therapeutic. CVX-20733 has a proven dual-action mechanism and an established safety profile to be delivered in an inhalable form, to prevent and treat the COVID-19 virus irrespective of the variant. The antiviral and anti-inflammatory properties of the CVX-20733, would enable it to be administered as a prophylactic or treatment option to treat both acute and long COVID. The multiple applications of the drug facilitate access to four distinct potential market segments – active cases, primary/secondary contacts, other prophylactic users, and Long COVID cases. Together, the four segments present a likely patient population of ~1.5b patients by the end of 2023.

A faster, economical, but more promising approach

Drug development companies are faced with the task of finding an effective treatment for the COVID-19 virus - a pressing need with time constraints. Most companies have chosen to try and discover new compounds, but COVIRIX Medical has chosen to repurpose an existing, already approved drug to this task. This approach will enable the company to cut down the time to market (by 12-18 months) and the research and development (R&D) costs involved in the development of its lead candidate, which has a clinically proven action mechanism and tolerability.

Valuation range of US$5.46 – US$8.45 per share

We value COVIRIX Medical at US$5.46 per share base case and US$8.45 optimistic case using a DCF approach with an exit multiple. Risks include the rise of new, more resistant variants of COVID, as well as clinical trial risk and commercialisation risks. For more on the risks see the valuation section of this report

Year to June (US$m)	2023F	2024F	2025F	2026F	2027F
Sales (m)	11	14	18	35	71
EBITDA (m)	4	7	9	23	51
Net Profit (m)	3	5	6	16	35
EBITDA margin (%)	41%	47%	50%	63%	71%
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EPS	4c	6c	8c	20c	44c

Source: Company, Pitt Street Research

"Our mission is to develop effective therapeutics to treat both the acute and chronic phases of COVID-19, save lives, and lessen the misery affecting individuals, families, and society at large."
- Kumud Dhital, COVIRIX Medical CEO

Valuation metrics	
DCF fair valuation range (US$m)	5.46-8.45
WACC	19.3%
Assumed EV/EBITDA exit multiple	14x-19x

Source: Pitt Street Research

Subscribe to our research HERE

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The purpose of this report

Pitt Street Research has been commissioned by COVIRIX Medical to evaluate its technology and drug development plans, and to provide a valuation of the company. Pitt Street Research has used various sources made available by the company as well as public domain information in developing its view on COVIRIX.

We understand that COVIRIX Medical is planning a potential listing on the Stock Exchange of Hong Kong, Australia, or the US. Unless you are a professional or sophisticated investor as defined by Section 708 of the Corporations Act 2001, readers are encouraged to consult the formal Information Memorandum and/or Prospectus before making any investment in COVIRIX Medical. The company is making a placement of 5 million shares at A$2.80 per share to professional and sophisticated investors. **The raise of $14 million will be used to cover costs of phase 1+2 clinical trials in Nepal and India, expansion of executive and administrative support, and primary listing expenses.**

Introducing COVIRIX Medical

COVIRIX Medical is an Australia-based clinical-stage pharmaceutical and diagnostic marketing company focused on repurposing existing drugs for new indications. It was formed in 2020 to bridge the gap in treatment options for the COVID-19 virus, as recognised by the highly experienced founding team.

Vaccines are generally built to protect from specific variants of the virus. As the virus mutates, the vaccines lose their effectiveness.

While the importance of vaccines in containing and protecting from the COVID-19 virus cannot be underplayed, vaccines are generally built to protect from specific variants of the virus. As the virus mutates, the vaccines lose their effectiveness.

Out of the estimated 600 ongoing programmes, only one drug (Remdesivir) has received full approval by the FDA, while only eight others have received EUAs to fight the virus, suggesting a clear need to develop new treatment options to complement the use of vaccines.

However, developing a new antiviral compound takes a lot of time and investment, which is substantially limiting considering the urgency of the current global situation. There is also a need for treatments to address "Long COVID", the phenomenon whereby patients who no longer have the virus continue to suffer symptoms for weeks and months after infection. Various global studies have shown that Long COVID affects between 35% and 80% of recovered COVID patients.

CVX-20733 exhibits the ability to treat and kill the virus and prevent it from replicating.

CVX-20733, the company's lead compound, is a small molecule antiviral which has demonstrated both antiviral and anti-inflammatory mechanisms in the pre-clinical studies conducted by the company and external investigators. It exhibits the ability to treat and kill the virus and prevent it from replicating.

Importantly, CVX-20733 is a repurposed antiviral drug which will enable the company to reduce risk and save on the time to market, which will be crucial. It will also allow the company to save R&D costs and provide a proof-of-concept for the antiviral activity with a well-established safety profile.

The inhalable mode of delivery chosen by the company provides a clear and competitive advantage over the other drugs as it will allow the drug to be delivered to the site of infection. This will effectively lower the dose levels required and prevent side effects (common among drugs delivered intravenously or orally).

After a thorough evaluation of the registered trials, COVIRIX believes that no other company in the market is repurposing a comparable agent and medicine with a dual-action mechanism against the COVID-19 virus. To secure and further utilise this unique opportunity, the company has already a provisional patent covering 11 different jurisdictions - covering the compounds, their use against COVID-19 and mode of delivery.

COVIRIX Medical is targeting the Indian subcontinent, along with other countries, for clinical trials and fast track approval based on the company's established network and understanding of need.

At present, it is poised to raise ~US$ 85m through private placements and a public listing (possibly on an Australian, Asian or North American stock exchange) to fund its operating expenses during the development and commercialisation phase. It will also look to finalise its ongoing discussions with established development and manufacturing companies (such as Vectura, and Hovione Technology) and collaborate with suitable commercialisation partners. Having received positive results from virology tests, it plans to conduct Phase I and Phase II clinical studies, which are expected to be completed by 2Q23. The company is likely to apply for approval after the Phase II study under the fast-track designation offered by the Indian regulatory bodies.

The company has been appointed the distributor for DiaCarta's RAT & PCR COVID-19 test kits in Australia and New Zealand.

In addition to the drug development program, the company has been appointed the sole distributor for DiaCarta's RAT and PCR COVID-19 test kits in Australia and New Zealand. COVIRIX Medical has proposed to supply significant volume of RAT kits to the Australian Federal government in a deal which could bring in A$520m in revenue and A$72m in net profit from just one order.

Key reasons to look at COVIRIX Medical

~1.5b patient population for a lead candidate, CVX-20733

CVX-20733 exhibits antiviral and anti-inflammatory response, enabling it to be utilised as a treatment and prophylactic option, opening multiple patient population groups to the company. The company has identified four primary segments that it would like to target – active cases, primary or secondary contacts, front-line workers, and mass gatherings/travel. Whilst the company is focused on preventing Long COVID through the effective early primary treatment, it is also considering further developments including combination therapy to more specifically treat Long COVID, the symptoms of which are appearing in up to ~80% of the recovered patients. The four segments (plus Long COVID patients) are expected to enable access to a patient population of ~1.5b by the end of 2023.

Filling a gap in treatment options

Vaccines are important for containing and controlling the spread of viruses as well as treating them. However, vaccines are usually developed to treat specific variants and lose their effectiveness when exposed to newer variants. The spike proteins in the COVID-19 virus mutate to a newer variant, allowing the virus to escape the immunity provided by the vaccines and continue spreading and mutating. COVIRIX Medical recognised this gap in treatment and obtained the licence to develop an antiviral drug to treat and prevent the COVID-19 virus, irrespective of the variant.

Accelerated time-to-market with significant cost savings

Considering the urgency of the COVID-19 situation, the company adopted the strategy of repurposing an existing, approved compound to a new indication instead of developing a new compound. The strategy enables the company to

reduce its time-to-market and save substantial amounts of funds (otherwise spent on R&D) as the existing drug has a demonstrated antiviral and anti-inflammatory mechanism, plus a well-tolerated safety profile.

The more appropriate mode of delivery through inhalation

The approved vaccines and antivirals have an oral or intramuscular mode of delivery. With COVID-19 being a pulmonary disease, oral/intramuscular delivery leads to dilution before the intended target is reached, leading to necessary administration of higher doses, wider tissue distribution and delay. Higher dose levels of drugs that take a longer pathway to reach the respiratory tract increase the risk of potential side effects. COVIRIX Medical plans to administer CVX-20733 in an inhalable form directly to the site of infection, therefore eliminating the need for excess dosage levels from oral administration and the risk of side effects in unnecessarily exposed tissues.

Management team with an eclectic mix of experience

The company's Chief Virologist (and head of Clinical Development) has previously led the development of Relenza, the first neuraminidase inhibitor for Influenza, and the first point-of-care diagnostic test for Influenza A and B. The other senior members of the management team include a medicinal and drug development chemist, two cardiovascular physicians, an investment banker and a pharmaceutical industry aerosol expert consultant who has formulated and designed aerosol inhalers for countless products. This diverse mix of experience in developing and commercialising drugs, formulating complicated solutions, raising and managing funds positions the company well to take advantage of the massive market opportunity for repurposed antiviral drugs. COVIRIX has also recently appointed two new members to its Scientific Technical Advisory Board including Professors Tim Block and Yanming Du. Professor Block is President of the Hepatitis B Foundation and the Baruch S. Blumberg Institute and Pennsylvania Biotechnology Centre, as well as one of leading experts in the world on the class of drugs COVIRIX is repurposing. Professor Du also hails from the Baruch S. Blumberg Institute, where he is a director and professor of medicinal chemistry, and has over eighteen years of expertise in medicinal chemistry and drug discovery.

The case for antivirals in conjunction with vaccines

Virus mutation causing recurring waves of primary infections

Sars-CoV-2, the virus family responsible for the COVID-19 pandemic, had infected nearly 300m people and caused 5.5m deaths worldwide by the end of 2021. Coronaviruses undergo frequent mutation, and while most of them may not pose any danger, certain variants may adapt to the human population and become more transmissible and/ or be highly infectious. These new variants may also have a survival advantage resulting in a greater threat, such as the variants from the UK, South Africa, Brazil, California and India.

The available vaccines for COVID prevention such as m-RNA (Pfizer and Moderna) and adenoviral vector vaccines (Oxford AstraZeneca, Sputnik, and J&J) are specific to the viral spike protein. These standard vaccines are built specifically to protect against entry of the original Alpha virus (first identified in Wuhan, China) into the human lung cell. The mRNA vaccines are designed to induce the human lung cell to produce its own non-infective copy of the spike protein thereby allowing the body to raise sufficient antibodies to counter any SARS-CoV-2 viral infection. However, the continuous virus mutation and selection leads to the evolution of the spike glycoprotein, which

causes vaccine-induced antibodies to have limited capability in providing protection against new variants of the virus.

Consequently, the threat of a high rate of primary infections continuously looms, with a magnitude like the waves caused by the highly infectious variants Delta and Omicron even in patients that have been triple vaccinated further emphasise that vaccines do not act as rescue medicines for immediate therapy. Indeed, Australia is currently leading the world in infections on a per-capita basis. Although vaccines seem to protect against hospitalisation and death the available evidence is that they offer little protection from acute infection and cannot, of course, treat the disease once established. Acute, mild to moderate COVID is by far the greatest burden of disease worldwide.

Long COVID – an emerging global health crisis

Long COVID is a condition where recovered COVID patients continue to suffer from a range of medical conditions such as anxiety, depression, sleep difficulties, fatigue, lung damage, heart and neurological issues and organ failures and could have continuing symptoms even after six months of recovery subject to the severity of the initial infective phase.

During the typical 'second wave', the hospitals were operating at full capacity and asymptomatic or mildly symptomatic COVID infected patients were advised to self-isolate in their homes to avoid overload on the healthcare systems. Patients, after recovery from COVID, may subsequently develop other health issues, which could be symptoms of Long COVID, and medical practitioners struggle to identify the root cause. This raises a need for robust post-COVID surveillance programmes and specific therapies for the rising tide of Long COVID patients, estimated at 189m counts.

The incidence of long COVID also reinforces the need for treatments for the virus itself. When infected people are not being treated, it allows the virus to continue to cause damage. The best way to minimise the risk of Long COVID is to treat the virus quickly after infection with an effective antiviral so it kills the virus early.

COVIRIX – a budding player on the block

COVIRIX, an Australia-based clinical-stage pharmaceutical company with primary focus on repurposing existing drugs (with approved indications) to new indications, was incorporated in March 2020 to combat the COVID-19 virus.

COVIRIX has a management and medical team who have rich experience in their relevant fields

The management and medical team at COVIRIX include accomplished professionals with a combined experience of more than 200 years in the fields of healthcare and biotechnology, drug development, drug synthesis, oral and inhalable forms of drug delivery and investment banking, enabling the company to cover all bases required to achieve success with its clinical pipeline.

Differentiated positioning in the COVID drug space

The emergence of cross-variants continues to be an existential threat and raises concerns about potentially more dangerous future mutations, regardless of vaccine-induced or naturally acquired variant-specific immunity. Vaccines provide protection from specific variants for a limited duration. An effective antiviral drug, which could kill the virus by blocking its reproduction and ending the continued mutations, can end the repeated waves. Antivirals

act differently to vaccines, as they are not specific to variants and provide a universal solution to the virus.

COVIRIX's broad-spectrum antiviral would be analogous to an antibiotic for bacterial disease

COVIRIX has selected a series of existing compounds with antiviral properties to develop them for acute and Long COVID indications. The company is working on developing a broad-spectrum antiviral, which is analogous to an antibiotic for bacterial disease. The company has set out to identify and repurpose small antiviral molecules that kill all the currently relevant strains of the virus such that clinical illness, as well as transmission, are stopped. This prevention of viral replication will limit the potential of further harmful mutations. The company states that a broad-spectrum antiviral will complement vaccines and stop the chain of transmission.

There could be various options for repurposed drugs and combination drugs, but each has associated impacts such as clinical side effects, efficacy limited by patient groups, mode of action, limitations of cost, effective use, safety and efficacy. However, repurposing existing compounds, the safety for human usage of which has already been proved, will allow COVIRIX to gain a quick entry to the market along with saving costs, factors which are crucial in the current time of need.

Repurposing drug CVX – 20733 for combat against COVID

COVIRIX is currently focused on repurposing CVX-20733, its primary drug candidate, which has a proven efficacy and safety profile, as a comprehensive antiviral drug for the treatment and prevention of the COVID-19 virus. The company has recently completed virology tests for the drug against several variants of the COVID-19 virus and is looking to move to the next phase of development with pre-clinical and Phase I clinical studies.

COVIRIX plans to repurpose its drugs for direct delivery through inhalation such that there is minimal side effect

The company believes that, while there are many antivirals being developed for the market, it offers a superior medical solution. Traditional oral delivery requires an increased dose level and can cause side effects in exposed tissues. However, COVIRIX is repurposing its drugs from oral usage to a smart inhaled aerosol dose form, which is a strategy established across other respiratory conditions including infections, and so should prove to be highly clinically effective against coronavirus. By inhalation, the safe and effective dose can be delivered straight to the target cells at the site of infection. As the drugs would be active at a fundamental level of viral replication, which differs from the vaccine targets, they cannot be rendered ineffective by vaccine escape variants.

Intellectual Property Provisional Patent filed covering 11 different jurisdictions

COVIRIX Medical has filed 11 provisional patents for the antiviral drug.

COVIRIX Medical has licensed the right to repurpose key antiviral compounds used in its drug candidates. The original patents for the licensed compounds, some of which have already been approved for specific indications, have expired, enabling COVIRIX Medical to use and patent them. The originators retain no rights to the compounds. COVIRIX Medical has filed a provisional patent covering 11 different jurisdictions for the antiviral drug, covering the unique inhalational form of delivery, dose design and formulations for the compounds developed by the company.

The patent filed by the company on 25 August 2021 was published on 03 March 2022 (**Publication Number: WO2022/040741**). The patent covers the following:

- **Use of compound for indications:** It covers the use of alpha-glucosidase inhibitors to treat or prevent viral respiratory tract infections, including coronavirus infections (preferably SARS-CoV-2 virus).
- **Modes of delivery**: It covers the forms of administration, including oral inhalation, dry powder formulation (including as an aerosol) and spray-dried formulation.
- **Use as mono or combination therapy:** It covers the use of the said alpha-glucosidase inhibitor in combination with one or more additional therapeutic agents, including an anti-bacterial agent, an antiviral agent, an anti-retroviral agent, an immunomodulator, an immunostimulant, an antibiotic and an anti-inflammatory agent.

CVX-20733 – A repositioned compound with dual action mechanism

CVX-20733, the primary drug compound and its related compounds demonstrate a dual-action mechanism as both an antiviral and anti-inflammatory. It belongs to a class which has previously showcased 10x potency in human respiratory cells. Also known as Miglustat (and marketed as Zavesca), it has a proven record of antiviral activity against a plethora of viruses. It has been approved to treat Type 1 Gaucher disease (in the US and EU) and Niemann-Pick disease type C (NP-C) (in Japan, EU and Canada).

In 2020, COVIRIX recognised the potential of the small molecule in treating the ongoing COVID-19 virus – a potential which has since been confirmed and validated in an external study (conducted by Rajasekharan et al.) and virology tests against different strains in different countries (including Netherlands, the US and Australia) conducted by the company itself.

To harness this potential, COVIRIX Medical has adopted a unique approach of repositioning the existing compound, now known as CVX-20733, and the related compounds, to deliver an antiviral drug (as opposed to vaccines) in an inhalable form (as opposed to oral delivery).

This novel approach to treating the COVID-19 virus lends the company several specific advantages and can be explained as below.

The drug could have uses both preventive and active

COVIRIX's approach of repurposing an antiviral drug allows it to destroy the virus and prevent it from proliferating (spreading), irrespective of the strain.

COVIRIX's approach of repurposing an antiviral drug allows it to destroy the virus and prevent it from proliferating (spreading), irrespective of the strain. The dual-action mechanism (antiviral and anti-inflammatory) enables the company to target patients during different periods of recovery.

- At the time of infection, the antiviral properties can effectively kill the virus, allowing the company to serve the needs of the active cases of COVID-19.
- Various studies have estimated that between 35% and 80% of COVID-19 survivors could suffer from Long COVID. Moreover, the threat of a repeated infection from the virus continues. The antiviral and the anti-inflammatory response of the drug helps to deal with the virus and the associated secondary conditions/inflammations.

The above mechanism of actions enables COVIRIX to utilise it for therapeutic and prophylactic uses and target different segments of the population, which include:

- Active cases of infections
- Primary and Secondary contacts of the active cases
- Front-line workers
- Preventive use before mass gatherings/events

Improved time to market and cost-saving due to repositioning

Drug repositioning enables the company to significantly cut down on the R&D expenditure and the time to market associated with the development of a new drug.

Drug repositioning is the process of using an existing compound/drug for new indications/uses. The need for an immediate solution in the current scenario makes developing a new drug/compound a tricky choice. The company's use of an existing drug, repurposed against the COVID-19 virus, enables it to significantly cut down on the R&D expenditure and the time-to-market associated with the development of a new drug and provides a proven drug with an established safety profile.

The repositioned drug can undergo a fast-tracked development, with the company planning to complete the Phase II study by 2Q23 at the cost of US$ 8m in comparison to the regular pathway, which could delay it to 2Q24-2Q25 and cost an extra US$7m.

The more appropriate mode of delivery

While the many other drugs designed for the COVID-19 virus are delivered orally, the company decided to pursue an inhalable delivery platform as:

- COVID-19 is a pulmonary disease, and inhalation of the compound can allow the compound to directly and rapidly target the site of infection.
- Oral/intramuscular delivery will take a longer time to reach the intended site of infection, potentially leading to diluted and subdued efficacy.
- Inhalational delivery to the respiratory tract eliminates the need for excess dosage of the drug, as opposed to other forms. The excess drug dosage increases the chances of side effects in the exposed tissues. For example, the dose limiting GI side effects noted in earlier clinical trials in HIV patients, involving a high oral dose of miglustat are much less likely to be seen following inhalation.

A defined plan of commercialisation along with an established need for investment

COVIRIX aims to establish itself as an established treatment/prophylactic option for COVID-19 across geographies. To achieve that, it has identified the Indian subcontinent as the first target point of entry into the market, owing to:

- The rate of infections in the market.
- The encouraging regulatory guidelines (issued in 2021) which provide a fast-tracked pathway for repurposed drugs.
- The strong network of the company's India-based CEO being likely to help in gaining regulatory approvals and assimilating resources needed to conduct trials.

COVIRIX has identified the Indian subcontinent as the first target point of entry into the market.

The company has already established an in-principle partnership with a leading European drug manufacturer with adequate capacity to produce the required amount of API as and when required. The future agreement will also provide COVIRIX with access to the appropriate inhalable devices, which, when combined with the medical team's expertise in aerosol drug delivery, would allow the company to formulate an otherwise exacting solution.

Additionally, the company is in discussions with multiple other parties to pursue its commercial strategy and secure its supply chain for the development and commercialisation stage:

- A Portugal-based pharmaceutical company, Hovione Technology, and UK based Vectura to formulate and produce the DPI inhaler solutions required to deliver drug candidates.
- Parexel International and an MOU with Medical Venture Pvt Ltd to aid in planning and conducting trials as CROs in India and Nepal, respectively.
- Asian Pharmaceuticals Pvt Ltd to produce drug formulations needed to conduct clinical trials in Nepal.
- BioIntellect, Melbourne, Australia, in September 2020 to evaluate CRO capabilities for pre-clinical studies.
- Representatives in Nepal, Sri Lanka and Brunei to explore the possibility of finalising a pre-order commitment.

Valuable connections with the Blumberg Institute

In early May 2022, COVIRIX welcomed Professor Tim Block, president of the Blumberg Institute and Hepatitis B Foundation, to its Advisory Board along with Professor Yanming Du, who is director of medicinal chemistry at the Blumberg. At first glance people might think Hepatitis B has no relevance to COVID-19 but it is also a virus that can affect the liver. We also note that the Blumberg Institute is running research projects into COVID-19 including investigations into direct-acting antivirals that target SARS-COV-2 and 'minibodies' that can prevent the virus from binding to and attacking cell targets. Furthermore, there have been a number of hepatitis infections recently occurring among children in several countries with some early evidence linking their infections possibly to prior COVID infections.

Professor Block and Professor Du can bring a wide array of experience to the company and with their links to the broader medicinal community. We think CORIVIX and CVX-20733 can support the Institute's efforts. We also believe this partnership is validation of COVIRIX's ambitions and provides confidence that it can find further partnerships to help advance CVX-20733.

Expected milestones on the pathway of development

With focus and resources concentrated on CVX-20733, COVIRIX Medical has a clear pathway (as elaborated in Figure 1) that it is required to follow to progress through the different stages of clinical and commercial development of its drug candidates.

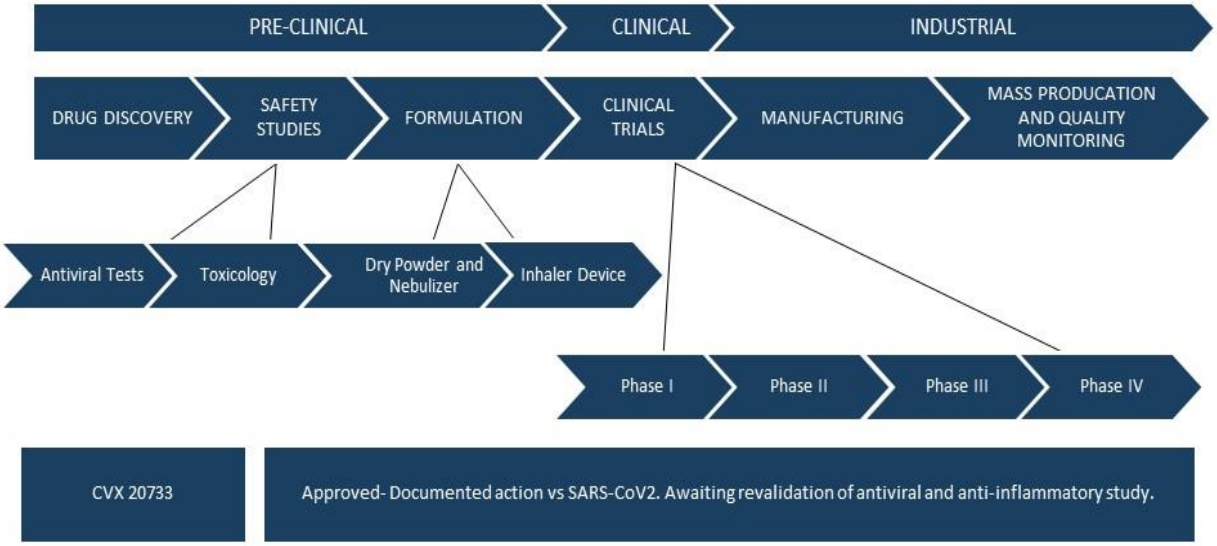
The company has already completed the pre-clinical phase of development, having received positive results from the virology tests for the antiviral efficacy conducted against the UK, South African and Delta variants of COVID-19. It is now gearing up to move to the clinical trials phase of development.

It is expecting to receive a waiver from conducting further animal studies and is looking to commence the pre-Phase I Pharmacokinetic and Phase I dose-

escalation in-human trials in healthcare volunteers and front-line workers in Nepal and India in 2Q–3Q22.

It will then proceed to the Phase II cohort-based study of the nebulised form of CVX-20733 in non-isolated hospitalised COVID-19 patients and hospitalised non-ventilated COVID-19 patients in 4Q22. It will look to complete it by 2Q23.

Figure 1: Development pathway for CVX-20733



Source: 'Critical Path', 'About us', COVIRIX Medical Website

The company's strategy to repurpose an existing drug is expected to hand it a significant advantage in two key metrics: R&D expenses and time-to-market (Figure 2). Repurposing an existing drug approved for other diseases indicates that the drug has a well-established and well-tolerated safety profile, enabling the company to accelerate the drug development process.

Finally, the company will look to commence the Phase III in-human clinical trial focusing on the same cohorts in 2Q23. Between Phase I and Phase II of trials in 3Q–4Q22, the company will look to become a listed company on an Australian, Asian or North American stock exchange.

Figure 2: Estimated Cost and Time savings through repurposed drug

Clinical Study	Estimated Timeframe	Estimated Completion Date	Estimated Cost (US$)
Expedited phase I/II entry without extensive inhaled toxicology	12-18 months	2Q23	8m
Complete phase I followed by phase II without extensive inhaled toxicology	18-24 months	4Q23 – 2Q24	10m
Complete phase I followed by phase II with a complete inhaled toxicology package	24-36 months	2Q24 – 2Q25	15m

Source: 'Expected Milestones', 'About us', COVIRIX Medical

Aiming to secure funds necessary for the commercial strategy

The company will look to public investors with plans to explore the possibility of listing on an Australian, Asian or North American stock exchange in 3Q-4Q22.

While all the focus and existing resources are concentrated on CVX-20733, the company also recognises the need to secure necessary investments to successfully implement the commercial strategy. In addition to private sources, the company will look to public investors with plans to explore the possibility of a listing on an Australian, Asian or North American stock exchange in 3Q-4Q22.

The availability of the required funds can be crucial to adhering to development and commercialisation timelines and will be essential for certain key elements of the development process:

Collect additional data: Access to the required funds will enable COVIRIX Medical to conduct efficacy studies for the antiviral and anti-inflammatory mechanisms of CVX-20733 against newer variants of the COVID-19 virus. Gathering and analysing this data will help direct future efforts and gain further credibility by proving the effectiveness of the drug.

Maintaining sufficient inventory: Considering the sizeable target population and the urgency of the situation, the company could purchase the required drug from GMP manufacturers, arrange and formulate the doses and build up inventory in anticipation of future demand.

Manufacturing/Distribution Partners: COVIRIX Medical is looking to engage in discussions with potential partners (manufacturers, distributors) to help secure the supply chain for its lead candidate. The company has already made significant progress on this front, having signed NDAs/MOU with multiple companies for CRO support, drug formulation for the clinical studies in India and Nepal, and large-scale drug manufacturing.

Securing orders: Signing agreements with governments, hospitals and other early adopters to book orders for its lead candidate and build strong relationships with potential customers is a key focus area for the company.

Developing other candidates: While focusing on the lead candidate, the company could eventually look to develop another drug candidate, CVX 30100 (a non-steroidal anti-inflammatory drug), that can play a crucial role in the treatment of Long Covid- and non-COVID-related respiratory conditions. The company has opted terminate a license it had for this compound and concentrate on taking CVX 20733 to market, but may return at a later stage once CVX 20733 has reached commercialisation.

Sole distribution of COVID-19 test kits potentially worth A$72m in revenue

In addition to the company's drug development activities which are its primary area of concern, it has also signed on to act as the distribution agent in Australia and New Zealand for RAT and PCR test kits, produced by US company DiaCarta Inc.

DiaCarta Inc is a translational genomics and personalised diagnostics company that develops technologies that could contribute significantly to the fields of precision medicine and molecular diagnostics.

The RAT test kits manufactured by the company have already received the CE mark certification in the EU, with EUA approval pending from the FDA. Its PCR test is rated among the top 3 in FDA SARS-CoV-2 Reference Panel Tests and is the benchmark product in the market. DiaCarta Inc. can supply up to 30 million RAT tests a week with its current capacity.

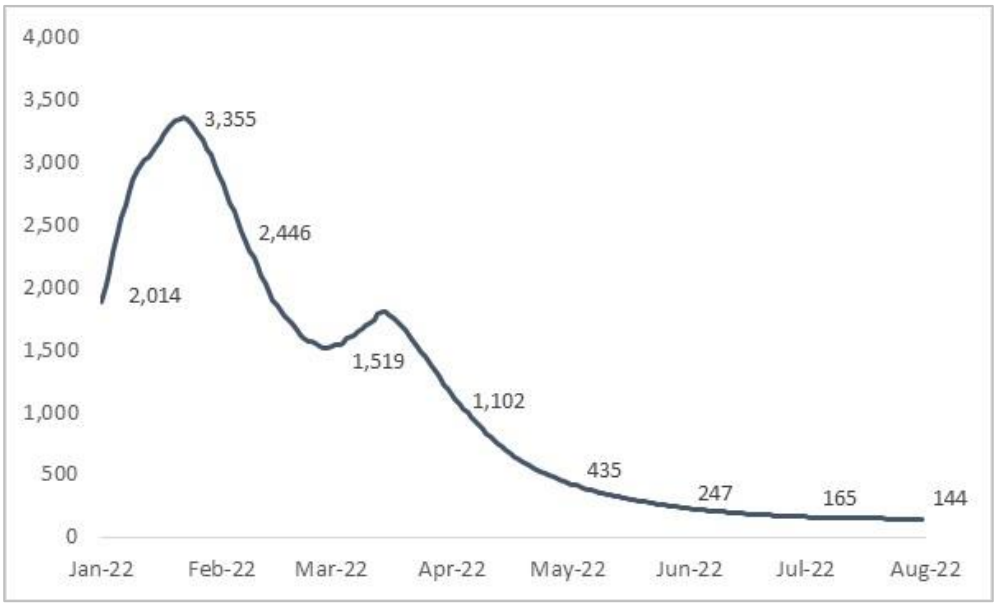
The DiaCarta supply deal could generate a revenue of A$520m and a net profit of A$72m.

COVIRIX Medical has applied to the TGA to register for the sale of the kits and proposed an offer to the federal government to supply significant volume of RATs FOB at the rate of 30 million units a week. If accepted, the supply deal could generate a revenue of A$520m and net profit of A$72m from a single order. These prospective revenue and profit are not currently included in our projections or in the valuation but if the government accepts the offer, it represents a further source of revenue for the company.

We also believe distributing test kits could give COVIRIX a competitive edge for initiatives such as the US government's recently announced Test to Treat program. This initiative aims to set up a 'one stop shop' for COVID treatment providing testing and treatments in the same location – primarily at pharmacies - and conducted on a walk-in basis.

Targeting ~1.5b potential patient population

Figure 3: COVID-19 daily cases trend – Actual (Jan-Apr) and Forecast (Apr-Aug) (in 000's)



Source: Infections and Testing, 'COVID-19 projections', healthdata.org

After over 2 years, over 500m cases have been reported globally but the real number of infections is expected to be 2x-4x that of the reported figures.

The first case of the COVID-19 virus was reported on 31 December 2019. Since then, over 500m cases of the COVID-19 virus have been reported globally, but the real number of infections is expected to be 2x-4x that of the reported figures. Yet after over two years, the COVID-19 virus has shown no signs of disappearing. The global daily caseload is expected to mellow down in the short term (Figure 3). However, it is likely the scenario could change quickly when new variants arise (as was witnessed in January 2022).

While long-term forecasts are difficult to make accurately, due to the pandemic's dynamic nature, a prediction system developed by a Lanzhou-based team expects the pandemic to subside by 2023 after reaching 750m cases worldwide. COVIRIX Medical believes that this total could further reach approximately 1.6b cases (equalling 20% of the world's population) by the time it disappears/weakens significantly. These claims have been validated to some extent by many scientists who believe that the virus will eventually

evolve into an endemic (with a seasonal pattern). However, a drop in vaccination rates, as WHO has warned, can lead to widespread epidemics at any point in the future until herd immunity is attained.

Herd immunity itself is a largely dismissed concept for COVID given its propensity to mutate with diminished efficacy very quickly after vaccinations. And with decreasing testing numbers, unreliable RATs, most of the world seeking to put the pandemic in the rear-view mirror and the rise of Long COVID, it is arguable that case numbers, hospitalisations and deaths have become unreliable in understanding the true state of the pandemic. The true picture could eventually be worse than official figures depict.

It is arguably case numbers, hospitalisations and deaths have become unreliable in understanding the true state of the pandemic.

Indeed, the World Health Organisation estimated earlier this month that the true number of lives lost due to the pandemic was close to 18 million – far outstripping the 5.9 million deaths recorded in that same period. In India, which will be one of the key markets for COVIRIX, it is estimated that COVID-related deaths have been underestimated by 10 times.

COVIRIX Medical, through its drug candidates, aims to offer a treatment and prophylactic antiviral drug options to cater to four primary target segments:

- Active cases: With the number of infections expected to reach **at least** 750m from 505m by the end of 2023, the company is likely to have a target population of **at least** 245m patients by 2023. The patient population could further grow depending on how the pandemic evolves through 2023 and beyond.
- Primary and Secondary Contacts: With the average patient infecting 4.3 contacts, this could present a potential target market of another 1.1b prophylactic users for the company.
- Front-line workers/mass gatherings/the travel industry: Offering a prophylactic option to the front-line workers, vulnerable and immunocompromised populations, people attending mass gatherings and related and high-risk events, and travellers, are additional sizeable market segments that the company can target.
- Long COVID: With 35-80% of COVID-19 survivors expected to experience Long COVID symptoms, the company's ability to cater to this segment of the patient population can enable it to access a potentially lucrative market (~189m patients) by 2023 that can grow as the number of active cases grows.

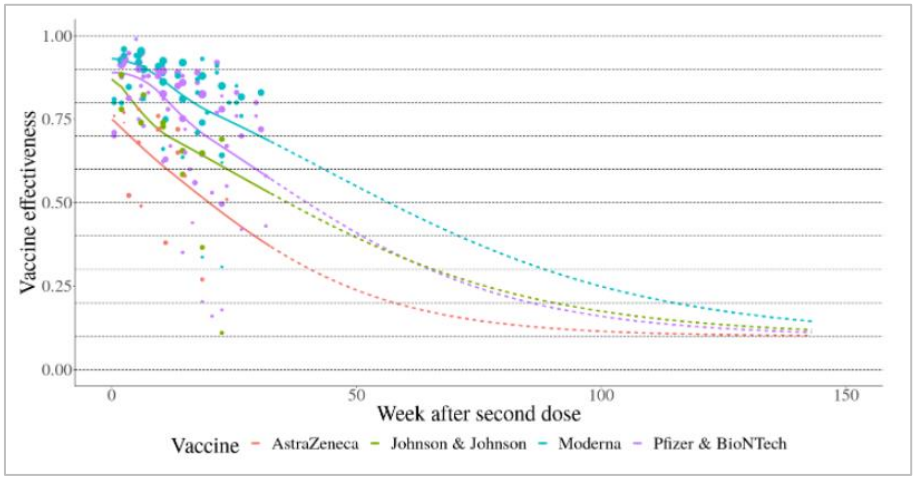
Adopting antivirals to chase a moving target

Ever since the COVID-19 virus was declared a pandemic by the WHO in March 2020, the market for the treatment options for the virus has continuously evolved. With the world waiting in despair, drug makers were able to develop drugs quicker than usual and carried out multiple drug development steps simultaneously (and not sequentially as is the case usually).

Among the different types of drugs being studied, including immunomodulators, and cell & gene therapies, vaccines took priority as several companies strived to bring their vaccines to market.

While there are plenty of vaccines to choose from, they are usually built to prevent and counter specific variants of the COVID-19 virus for a limited period of time before vaccine-induced immunity wanes (Figure 4).

Figure 4: Effectiveness of vaccine after the second dose



Source: 'COVID-19 model update: Omicron and waning immunity', IHME website

The virus tends to mutate into newer variants which can escape the antibodies developed by a previous infection/vaccination (as seen in the case of the recent Omicron variant). These variants may be more lethal or spread faster, rendering an overreliance on vaccines inadequate, as seen in the previous variants (Figure 5).

Figure 5: Effectiveness of approved/EUA vaccines against different variants

Vaccine	Ancestral		Alpha		Beta		Gamma		Delta		Omicron	
	Severe Disease	Infection	Severe Disease	Infection	Severe Disease	Infection	Severe Disease	Infection	Severe Disease	Infection	Severe Disease	Infection
AstraZeneca	94%	63%	94%	63%	94%	69%	94%	69%	94%	69%	71%	36%
CanSino	66%	62%	66%	62%	64%	61%	64%	61%	64%	61%	48%	32%
CoronaVac	50%	47%	50%	47%	49%	46%	49%	46%	49%	46%	37%	24%
Covaxin	78%	73%	78%	73%	76%	72%	76%	72%	76%	72%	57%	38%
Johnson & Johnson	86%	72%	86%	72%	76%	64%	76%	64%	76%	64%	57%	33%
Moderna	97%	92%	97%	92%	97%	91%	97%	91%	97%	91%	73%	48%
Novavax	89%	83%	89%	83%	86%	82%	86%	82%	86%	82%	65%	43%
Pfizer	95%	86%	95%	86%	95%	84%	95%	84%	95%	84%	72%	44%
Sinopharm	73%	68%	73%	68%	71%	67%	71%	67%	71%	67%	53%	35%
Sputnik-V	92%	86%	92%	86%	89%	85%	89%	85%	89%	85%	67%	44%
Other Vaccines	75%	70%	75%	70%	73%	69%	73%	69%	73%	69%	55%	36%
Other Vaccines (mRNA)	91%	86%	91%	86%	88%	85%	88%	85%	88%	85%	67%	45%

Source: 'COVID-19 model update: Omicron and waning immunity', IHME website

As the pandemic has progressed further, the need to use antivirals to prevent and treat COVID-19 is becoming increasingly clear.

This has led to the emergence of other potential drug types, including antivirals. Unlike vaccines, antivirals usually prevent viral replication across variants. As the pandemic has progressed further, with multiple new COVID-19 variants (all with distinct characteristics) being discovered, the need to use antivirals to prevent and treat COVID-19, in conjunction with vaccines, is becoming increasingly clearer.

Competitive Environment

COVIRIX Medical faces competition from well-known companies (such as Merck, Pfizer) with a significant resource advantage and newer players with potential breakthrough drugs – all vying to become one of the go-to drugs in the market. With competition expected to increase as companies' progress through to the later stages of development, COVIRIX Medical's ability to capture market share will depend on numerous factors (including superior clinical results, fund-raising activities, partnering with suitable companies, implementing of commercialisation strategies).

Only one antiviral drug has been approved for use. In contrast, several others have received EUAs, with plenty of opportunities available for new antivirals to enter the market and strengthen their position.

COVIRIX recommends usage of its antiviral drug in conjunction to the vaccines

In addition to antivirals, the company also faces a threat from pan COVID-19 vaccines/universal vaccines, which remain potent irrespective of the variant. While the number of pan COVID-19 vaccines under development at present might be few and far between, the successful development of pan COVID-19 vaccines can limit or eradicate the need for antivirals.

Companies comparable to COVIRIX Medical

We have listed a few peers who are either:

- Developing antiviral drugs against the COVID-19 virus using new or existing compounds (similar to COVIRIX), delivered orally or in an inhalable form (similar to COVIRIX) and are at different stages of development
- Developing a pan COVID-19 vaccine

Approved/EUA antivirals

- **Gilead Sciences:** It is a US-based, NASDAQ-listed biopharmaceutical company which develops medicines for a plethora of viral, inflammatory and oncology indications. It has developed Remdesivir (marketed under the name of Veklury), the first and only approved antiviral drug for the treatment of COVID-19 in hospitalised patients and patients with mild to moderate COVID-19. Remdesivir was originally tested unsuccessfully for Ebola and Hepatitis C before showing promising results in COVID-19 cell cultures and retained antiviral activity against all the major variants of the COVID-19 virus. The company generated US$5.6b from sales of Remdesivir in FY21 and has provided guidance of ~US$2b for FY22.
- **Ridgeback Therapeutics**: It is a US-based biotechnology company which develops medicines for pandemic and epidemic diseases. It is one of the two companies to have an approved drug for Ebola. In collaboration with Merck, it has also developed Molnupiravir, an oral antiviral drug for the treatment of COVID-19, which demonstrated the ability to reduce hospitalisations by 30% in the Phase III study. In December 2021, it received an EUA to treat mild to moderate COVID-19 adult patients at risk of progression to severe COVID-19. It is priced at US$712 for a 5-day course taken as 4 tablets twice per day. The company produced 10m courses of Molnupiravir in 2021 and is expected to produce at least double that in 2022.
- **Pfizer:** It is an NYSE-listed leading biopharmaceutical company which has developed eight approved drugs and has a pipeline of 89 candidates. It has 39 manufacturing sites and a distribution network

spanning 125 countries. It developed Paxlovid, a protease inhibitor which has received an EUA from the FDA to treat high-risk COVID-19 patients 12 years and older, exhibiting the ability to reduce hospitalisations by 89% within three days of onset as compared to the placebo. Paxlovid was initially developed to treat the SARS virus in the early 2000s and was later repurposed as an oral pill for the COVID-19 virus. Even before receiving the authorisation, Pfizer had signed a US$5.8b contract to supply 10m doses of the drug to the US government. It has 35 sublicensing agreements in 14 countries to distribute the drug.

- **Celltrion**: It is a leading Korean pharmaceutical company with a revenue of US$153b generated through its network across more than 90 countries. Regkirona (regdanvimab), a monoclonal antibody developed to fight against the COVID-19 virus, received EUA from the EC in November 2021 after a successful Phase III study. The drug is indicated for the treatment of adults with COVID-19 who do not require supplemental oxygen and who are at an increased risk of progression to severe disease. It demonstrated the ability to reduce the incidence of severe cases among the high-risk group by 72% and reduced time to symptom improvement by 4.9 days. The company is also developing an inhaled form of regdanvimab in collaboration with Inhalon Biopharma.

Under-development antivirals

- **TTF Pharmaceuticals**: Based in the US, it is a NASDAQ-listed pharmaceuticals company which utilises its proprietary Thin Film Freezing (TTF) technology platform to develop dry powder, inhalable forms of drugs. It has a pipeline of eight early-stage candidates, including two for COVID-19 – an inhaled antiviral and an inhaled monoclonal antibody. The inhaled antiviral drug, Niclosamide, demonstrated the ability to inhibit the Delta and Omicron variants in a preclinical study and is undergoing a Phase I study. It has signed an agreement with UNION Therapeutics, providing it with the option to exclusively licence Niclosamide.
- **BetterLife**: It is a Canada-based, listed clinical-stage biotechnology company focused on developing drugs and treatments for mental disorders. Its lead product, BETR-001, is a second-generation LSD compound with non-psychedelic properties. It is also developing AP-003, an inhaled antiviral therapy against COVID-19, through its subsidiary, Altum Pharmaceuticals. After the Phase I study confirmed the safety profile, it initiated a larger Phase II study to assess the safety of twice-daily inhaled doses of AP-003 taken in 10 days.
- **Shionogi**: Based in Japan, it is a listed pharmaceutical company that develops drugs and diagnostics reagents and produces medical devices. It is currently developing S-217622, an antiviral drug which acts as a protease inhibitor, in collaboration with Hokkaido University. In the Phase II study, the drug demonstrated an ability to rapidly decrease viral RNA on the fourth day of administration (in comparison with the placebo). It is seeking early authorisation based on the Phase II study results in Japan and has received approval from the US FDA to conduct a Phase III study to gain authorisation in the US.
- **Molecular Partners:** Based in Switzerland, it is a NASDAQ-listed developer of drugs which utilises its proprietary class of therapeutics to cater to oncology, infectious disease and ophthalmology indications. At present, it is developing Ensovibep, an antiviral therapeutic drug which works to

inactivate the COVID-19 virus, including the newer variants. The Phase II study for Ensovibep showed a 78% reduction in the combined risk of hospitalisation. Novartis, a leading pharmaceutical company, has exercised an option to carry out late-stage development of the drug and licence it. Novartis also applied for an EUA from the US FDA based on these results in February 2022.

– **Anixa Biosciences:** It is a US-based, NASDAQ-listed biotechnology company which develops treatments for oncology and infectious disease indications. In collaboration with MolGenie GmbH, it has synthesised a new compound which acts as a protease inhibitor. Head-to-head *in-vitro* studies have suggested that the company's compound is more potent than the currently authorised protease inhibitors (Paxlovid by Pfizer). As the compound does not target spike proteins which mutate, it expects the compound to be effective against all the known variants. The company plans to conduct cellular assays and animal studies for the compound.

Pan-COVID-19 Vaccines

- **VBI Vaccines:** Headquartered in the US, it is a biopharmaceutical company with a pipeline of prophylactic and therapeutic drugs targeting multiple indications. The company has a COVID-19 programme in which it is utilising its proprietary enveloped virus-like particle (eVLP) technology platform to develop three drug candidates. One of the candidates (VBI-2901) is a pan COVID-19 vaccine which has generated positive results in pre-clinical studies against the Omicron variant and another variant found only in animals. The company will move to in-human clinical studies in the summer of 2022.

Base valuation of US$5.46 per share

Our basic valuation approach for COVIRIX Medical is as follows:

- We have built a DCF for COVIRIX Medical, incorporating its development and commercialisation plans of CVX-20733 (lead candidate) over a period of six years. At this stage we have not included the potential DiaCarta distribution deal or other treatments COVIRIX may bring to market over the next few years.
- Rather than assuming terminal growth, we have assumed an exit model at the end of FY27.
- The firm's value is the sum of present value of free cashflows for the period FY22 to FY27 and the present value of COVIRIX Medical's exit multiple-based terminal value.
- Our base case uses a WACC of 19.3% and an EV/EBITDA-based exit multiple of 14x. Our bull case uses a WACC of 14.3% and an EV/EBITDA-based exit multiple of 19x.
- In calculating the WACC we have used a risk-free rate of Return of 3.3%, the current rate of the 10-year Australian government bond, and a Beta of 1.0 accounting for the company's unlisted status. In our base case we use an Equity premium of 15.9%, while in our bull case we use 10.9%.
- We have used the company's shares on issue assuming completion of the current placement of 5 million shares– 67.315m shares. We have not accounted for future capital raises nor for the conversion of

options. There are only 200,000 options issued to date. The company has no debt other than normal trade creditors.

Commercial assumptions

Our revenue and earnings estimates can be found on page 21. The revenue has been forecast from FY23 onwards as the company will conduct studies in FY22 and will look to commercialise in FY23 under a fast-track designation. We have assumed:

- The company will gain a 1.7% market share in FY23 in India alone. This increases by 0.2% in FY24 and FY25 but in FY26 it rises by 1.5% to 3.6% and by 3.0% in FY27 to 6.5%.
- We have assumed roughly 213m COVID cases and that India accounts for 8.4% of the global total. For COVIRIX, this equates to 304,000 patients treated in FY23, 401,000 in FY24, 503,000 in FY25 and subsequently 995,000 in FY26 and 2.0m in FY27.
- In estimating COVIRIX's revenues, we have assumed pricing of US$250 per course of treatment, a 19% probability of success rate and that the company takes a 75% share of revenue.
- In FY23, we have assumed an EBIT margin of ~41%, gradually rising to ~70.8% by FY27. We have assumed cost of sales as 20.0% of revenues from FY23 to FY27.
- We have forecasted R&D expenses to rise by $1m a year as the company forecasted in its recent Information Memorandum. We have also assumed it can claim a rebate of 43.5% of the previous year's expense under the Australian R&D tax incentive.
- We assumed a one-off listing expense of $5m in FY22 and General & Administrative Expenses of $1m annually from FY23-FY27. Its expenses are 59.6% of revenues in FY23 but this drops over time – reaching 29.2% by FY27.
- We have assumed an average corporate tax rate of 30%.

Valuation per share of US$5.42 base case and US$8.39 bull case

Figure 6: DCF valuation for COVIRIX Medical

Valuation (US$)	Base case	Bull case
Present value of FCF	6,090,249	8,723,805
Present value of Terminal FCF	286,496,463	485,069,014.67
Enterprise Value	**292,586,712**	**493,792,820**
Net debt (cash)	(75,000,000)	(75,000,000)
Equity value (US$)	**367,586,712**	**568,792,820**
Shares outstanding	67,315,000	67,315,000
Implied price (US$)	**5.46**	**8.45**
Current price (US$)	-	-
Upside (%)	NM	NM

Source: Pitt Street Research

Figure 7: DCF value in US$ using various WACCs

Sensitivity Analysis									
WACC	**19.33%**								
Exit Multiple	**14x**	**Change in WACC**							
Implied Price (US$)	**5.46**	*17.83%*	*18.33%*	*18.83%*	*19.33%*	*19.83%*	*20.33%*	*20.83%*	*21.33%*
Change in Exit Multiple	*11x*	4.78	4.70	4.62	4.55	4.47	4.40	4.33	4.26
	12x	5.11	5.02	4.94	4.85	4.77	4.69	4.62	4.54
	13x	5.43	5.34	5.25	5.16	5.07	4.98	4.90	4.82
	14x	5.76	5.65	5.56	**5.46**	5.37	5.28	5.19	5.10
	15x	6.08	5.97	5.87	5.76	5.66	5.57	5.47	5.38
	16x	6.40	6.29	6.18	6.07	5.96	5.86	5.76	5.66
	17x	6.73	6.61	6.49	6.37	6.26	6.15	6.04	5.94

Source: Pitt Street Research

Helping COVIRIX Medical create shareholder value

We believe the following factors can be crucial for the company's valuation trajectory:

- The continued existence of the COVID-19 virus as a pandemic, epidemic or endemic in the coming years, along with long COVID, will ensure that the company has a sizeable target population.
- The emergence of new vaccine-resistant variants could further push the adoption of antivirals as a complementary treatment option.
- A waiver from animal studies in the Indian subcontinent (target market) and approval to accelerate clinical programmes without conducting inhaled toxicology studies would enable the company to reach the market faster and significantly save the R&D expenses.
- The ability to raise adequate funds required to implement the development and commercialisation strategy of the company.
- Forging partnerships with well-established players with a global presence to secure the supply chain will be key to the successful commercialisation of the company's drugs.

Financial Statements

Profit & Loss (US$m)	2023E	2024E	2025E	2026E	2027E
Sales Revenue	**11**	**14**	**18**	**35**	**71**
Operating expenses	(6)	(8)	(9)	(13)	(21)
Profit before tax (before exceptionals)	4	7	9	22	50
Tax expense	(1)	(2)	(3)	(7)	(15)

Cash Flow (US$m)	2023E	2024E	2025E	2026E	2027E
Profit after tax	3	5	6	16	35
Depreciation	0	0	0	0	0
Change in trade and other receivables	(2)	(1)	(1)	(4)	(7)
Change in trade payables	0	0	0	1	1
Change in inventories	(4)	(1)	(1)	(6)	(13)
Operating cashflow	(3)	3	4	6	17
Capex (- asset sales)	(1)	-	-	-	-
Investing cashflow	(1)	-	-	-	-
Dividends (ords & pref)	-	-	-	-	-
Equity raised (repurchased)	-	-	-	-	-
Debt drawdown (repaid)	-	-	-	-	-
Net change in cash	(4)	3	4	6	17
Cash at End Period	71	74	78	85	101

Balance Sheet (US$m)	2023E	2024E	2025E	2026E	2027E
Cash	71	74	78	85	101
Total Assets	79	83	90	106	142
Total Debt	-	-	-	-	-
Total Liabilities	0	1	1	1	3
Shareholders' Funds	78	83	89	105	140

Ratios (US$m)	2023E	2024E	2025E	2026E	2027E
Return on Equity (%)	4.0%	5.7%	7.3%	16.2%	28.9%

The risks

Changing trend of cases: The COVID-19 pandemic has been defined by a series of waves marked by a surge in the caseload which is followed by a period of decline before the cases plateau. Unfortunately, it is not possible to accurately predict if and when the next wave will occur. With COVIRIX Medical's drug candidates targeting the COVID-19 virus, the company's patient population and, in turn, the top line is highly dependent on the presence and timing of another such pattern of cases in the target markets.

Risk of a new, more resistant variant: The company is focused on the development of antiviral drugs which can be used irrespective of the variant. Another drug which exhibited similar characteristics was Sotrovimab, a popular competitor antiviral drug developed by the well-known GSK and Vir Biotechnology, which received EUAs in various countries and complete approval in Australia. However, results from new research have shown that the COVID-19 virus can build resistance against the drug within days of

administration and reduce its efficacy by more than 100 times, while another research showed that it proved to be ineffective against the Omicron variant. Similarly, there remains a possibility of the emergence of a new variant which could show resistance to CVX-20733 which could halt or hinder its development process.

Clinical trial risk: The prospects of all pharmaceutical companies are reliant on the success of the clinical studies conducted for their drugs. Failure to meet the primary and secondary end-points in any phase of the studies, as witnessed with Synairgen's inhalable antiviral drug (SNG001), could lead to an immediate adverse impact on the company's standing (Synairgen's stock price fell by 85% after the announcement) and pose an existential threat on the company's operations.

Commercialisation risk: After the successful clinical development of a drug candidate, it is imperative that a company has a well-rounded commercialisation strategy and the resources to implement it to gain market share in a competitive industry. Failure to plan for and execute a commercial strategy could prevent the company from realising the potential of its drugs and pose a risk to its forecast revenues.

Experienced Leadership Team

COVIRIX Medical's current leadership team has a vast array of complementary experience:

- **Founder & CEO Kumud Dhital** is a cardiothoracic surgeon and has held the position of programme director of Melbourne's Alfred-Heart and Lung and director of Lung Cardiothoracic Surgery and Transplantation at Alfred Hospital. He has served as a professor of Cardiothoracic Surgery at Monash University in Melbourne. Kumud has also held senior positions at St Vincent's Hospital in Sydney and Royal Papworth Hospital in Cambridge, UK.
- **Founder & CMO Ian Nixon** has practised as a cardiothoracic surgeon at St Vincent's Hospital in Melbourne, Australia, for more than 30 years. In collaboration with Dr. Peter Mossop, Ian evolved a new paradigm for the management of Aortic Dissection, which has helped significantly reduce the short-term and long-term mortality. He also served at the John Hopkins Hospital and Cleveland Clinic for four years after studying medicine at the University of Melbourne.
- **Founder & Head of Corporate Development Richard Li** has 40 years of extensive experience in investment banking, equity fund management, investment advisory service and stockbroking. He founded GoConnect Ltd and co-founded Go Green Holdings (a major shareholder of COVIRIX Medical), currently holding the position of Chairman at both companies. He has a network in Asia, built over four decades, and has previously led the listings of Chinese companies on the ASX.
- **Founder- Medicinal & Drug Discovery Chemist Seb Marcuccio** has garnered more than 30 years of valuable experience in drug discovery and development and organic chemistry-related projects. He worked at CSIRO, leading the development of an antiviral drug for Hepatitis B to Phase II trials and serving as the principal scientist behind the complex organoboron technology, which led to the filing of seven international patents. He founded Boron Molecular Pty Ltd, serving

as the R&D director and leading the development of more than 400 organoboron products.

- **Consultant David Morton** is an aerosol scientist who has led the development of an aerosol formulation for several marketed aerosol inhalers. He co-founded Vectura Group, pioneering its aerosol inhalation technology platform, including the PowderHale® technologies (used by Novartis, Chiesi Farmaceutici and GSK). He worked at Monash University, co-inventing the Monash Oxytocin dry powder inhaler technology, which won the 'Australian Innovation of the Year' award in 2013. Morton led the development of the Col2 with GSK and worked on Relenza and several other products. He has also authored more than 35 patent applications.
- **Chief Virologist & Head of Clinical Development Simon Tucker** is a well-known virologist who has extensive experience leading R&D projects in the pharmaceutical industry. He contributed to the discovery of amprenavir, an HIV protease inhibitor while working at GD Searle. He previously served as the Vice President of Research at Biota Pharmaceuticals, where he led R&D projects (including the discovery of Relenza for Influenza), forged partnerships with leading companies, and negotiated multiple licensing agreements.
- **CFO & Company Secretary Eric Pong** is the Company Secretary of GoConnect Ltd and CFO of Go Green Holdings, having gained valuable experience in accounting, finance and administration at ASX-listed companies in his career previously.
- **COVIRIX Scientific Technical Advisory Board Member Professor Tim Block** is the Co-Founder and President of the Baruch S. Blumberg Institute and the Hepatitis B Foundation which established the Institute in 2003 to advance its research mission. He was a tenured Professor at Thomas Jefferson University for 20 years and at Drexel University College of Medicine for 10 years.
- **COVIRIX Scientific Technical Advisory Board Member Professor Yanming Du** is director and professor of medicinal chemistry at the Baruch S. Blumberg Institute. He has more than eighteen years of expertise in medicinal chemistry and drug discovery. His current research focuses on the design and synthesis of novel compounds that can be effective against viral haemorrhagic fevers and diseases related to the liver.

Appendix I – Analyst certification

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research specialty at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and ResMed as well as numerous emerging companies. Stuart was a

Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.

- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.

Nick Sundich is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms.

Appendix II – Glossary

Anti-inflammatory drug: Anti-inflammatory drug is a drug or substance that reduces inflammation (redness, swelling, and pain) in the body.

Antibiotic: Antibiotics, also known as antibacterial, are medications that destroy or slow down the growth of bacterial infections in people and animals.

Antiviral: An agent that kills a virus or that suppresses its ability to replicate and, hence, inhibits its capability to multiply and reproduce.

API: It refers to Active Pharmaceutical Ingredient. API is the biologically active component of a drug product (tablet, capsule, cream, injectable) that produces the intended effects.

CE: It refers to a certification given to a medical device before it is launched in the European Economic Area which confirms that it meets standards.

CRO: It refers to Contract Research Organisation. A CRO is a company that provides clinical trial management services for the pharmaceutical, biotech, and medical device industries.

CSIRO: The Commonwealth Scientific and Industrial Research Organisation (CSIRO) is an Australian Government agency responsible for scientific research.

CVX-20733: CVX-20733 is a broad spectrum small molecule antiviral which exhibits the ability to treat and kill the virus and prevent it from replicating.

DPI: It refers to Dry-powder Inhaler. DPI is a device that delivers medication to the lungs in the form of a dry powder. DPIs are commonly used to treat respiratory diseases such as asthma, bronchitis, emphysema and COPD.

EUA: An Emergency Use Authorisation (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies.

FDA: It refers to Food and Drug Administration. FDA is an agency within the U.S. Department of Health and Human Services.

GMP: It refers to Good Manufacturing Practice. GMP is a system for ensuring that products are consistently produced and controlled according to quality standards.

Inhalable delivery: It refers to delivery of drug through inhalation from an inhaler/nebuliser to the respiratory tract

Intramuscular delivery: It refers to the delivery of drugs through an injection to the muscles

Intravenous delivery: It refers to delivery of drugs through an injection to the vein

LSD: It refers to Lysergic Acid Diethylamide.

Monoclonal antibody: It refers to a type of protein that can bind to certain targets on the surface of the viral cells.

MOU: A MOU is a document describing the broad outlines of an agreement that two or more parties have reached.

Mutation: A change in the DNA sequence of an organism.

Oral delivery: It refers to delivery of drug in the form of a tablet or capsule

Organoboron products: It refers to products made of organoboron compounds. Organoboron compounds are compounds of boron and carbon.

PCR: It refers to 'Polymerase Chain Reaction'. It is used to test genetic material from a specific organism, such as COVID-19 virus.

Pulmonary disease: It refers to a type of disease which affects a part of the respiratory system

Prophylactic: It refers to use of a drug to prevent disease

Protease Inhibitor: It refers to a compound that interferes with the ability of certain enzymes to break down proteins

RAT: It refers to 'Rapid Antigen Test'. It is a mass screening diagnostic test used to detect COVID-19 virus quickly.

Repurposed/Repositioned drug: It refers to the development of an existing drug for a new indication

Sars-CoV-2: 'Severe Acute Respiratory Syndrome Coronavirus 2' is the virus family responsible for the COVID-19 pandemic.

TGA: It refers 'Therapeutics Goods Administration'. It is regulatory body in Australia which regulates therapeutic goods, such as prescription medicines, vaccines, vitamins and minerals, sunscreens.

Virus RNA: It refers to a virus which is a virus which has ribonucleic acid (RNA) as its genetic material

WACC: It refers to the Weighted Average Cost of Capital. This is the rate that a company is expected to pay on average to all its security holders to finance its assets.

Appendix III – Major Shareholders

Investors	Ownership (%)
Ian Nixon Pty Ltd.	24.07%
Go Green Holdings Ltd	24.07%
COVID Pharmaceuticals Pty Ltd.	24.07%
Somersham Super Pty Ltd.	24.07%

Source: Company

Appendix IV – Established Active Relationships

Date	Type of Agreement	Company Name	Description
August 2020	MOU	COVID Pharmaceutical Pty Ltd Melbourne, Australia	Licence to develop and repurpose CVX 20733 and related compounds for anti-viral therapy
September 2020	MOU	Deakin University Melbourne, Australia	Service engagement of Prof David Morton
	CDA	Southern Research Institute Alabama, USA	Service partner for in vitro anti-viral studies
	NDA	BioIntellect, Melbourne, Australia	To scope pre-clinical CRO capability
December 2020	SAA	Metropolis Enterprises Group Ltd	Distribution of DiaCarta diagnostic solutions including PCR tests and RATs
May 2021	NDA	HOVIONE Technology Ltd, Lisbon, Portugal	To establish relationship for future DPI inhaler formulation and and manufacture
June 2021	NDA	Parexel International Pty Ltd, Sydney, AUS	Indian branch of PAREXEL (Australia) with global representation for CRO-assistance with clinical trials in India
August 2021	MOU	Medical Venture Pvt Ltd, Kathmandu, Nepal	CRO in Nepal to assist with planning Clinical Trials in Nepal
September 2021	MOU	Asian Pharmaceuticals Pvt Ltd, Rupandehi, Rupandehi, Nepal	Pharmaceutical company for local manufacturing of drug formulation for clinical trials in Nepal
	NDA	Vectura Ltd	UK company specialised in inhaled products
December 2021	NDA	Enochian Biosciences Inc	To explore synergy of separate therapeutic strategies

Source: 'Milestones Achieved', 'About us', COVIRIX Medical website

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